NIHR Global Health Research Group – Developing Psychosocial Interventions Pakistan – Proposal
In collaboration with Interactive Research and Development

Aims and Objectives:
The National Institute for Health Research Group for developing psychosocial interventions aims to explore the feasibility, acceptability and effectiveness of the following two resource-oriented approaches: i) DIALOG+, ii) family involvement using Trialogues. DIALOG+ is an app-based intervention designed to make routine meetings between patients and mental health professionals therapeutically effective. Family involvement helps family members or friends to provide support and effective care to patients within the community. In this project, we aim to refine each of these low-cost interventions to the local context, and then test their acceptability, feasibility and effectiveness.
The research study will address the following research questions:
1) How can each intervention be used to support community mental health care in the regional context?
2) How is each intervention experienced by participants (patients, family members/friends and mental health professionals)?
3) How do patient outcomes change when each intervention is used?

Background
Depression is the leading cause of disability with more than 300 million people living with depression globally (WHO, 2017). Depression significantly impairs the individuals quality of life, social relationships, community and economic participation and physical health (Whiteford et.al., 2015). Psychological intervention is recommended as the first-line treatment has been found to be an effective first-line treatment for depression and is recommended by the WHO Mental Health Gap Action Programme (WHO, 2008). Despite the high prevalence and associated morbidity, in low resource settings almost 90% of people suffering from depression do not receive the treatment and support they need (Patel et.al., 2010). A growing body of evidence indicates that first-line psychological counselling intervention delivered by trained and supervised lay counsellors using a stepped care approach healthcare facility and community settings is effective for symptom alleviation

In Pakistan, prevalence studies of depression and anxiety range between 22% and 60% in any given population and there is only 1 psychiatrist for 500,000 people (WHO, 2009). Most of this treatment gap is attributed to lack of mental health services and resources, particularly in rural and low-income regions. Global mental health practitioners have supported a task-shifting approach to address the high burden in LMICs. Through task-shifting, lay counsellors are trained to become the primary providers of mental health services for common mental disorders (CMDs). Referral mechanisms to specialists (trained psychiatrists and psychologists) are set up for patients with severe disorders and unresponsive patients.

Working to address this treatment gap, Interactive Research Development, a public health research and service delivery organization launched its mental health program, ‘Pursukoon Zindagi’ (Peaceful Life) in 2014, based on the concept of task-shifting. Using an integrated approach, community health workers were trained to provide basic counselling for symptoms of

anxiety and depression in low-income communities and situated in community primary care clinics and other healthcare facilities. Community members unable to visit the clinic are provided the option of home-visits. A referral mechanism has been built in so that patients with severe mental health issues and unresponsive patients are referred to trained psychologists. The trained psychologist also provides supervision to the lay counselling practice in the field.
Since its initiation, the program has trained over 80 community health workers and has screened over 50,000 community members for depression and anxiety using a validated screening tool and offered councelling sessions. 3,365 participants have completed counselling sessions and symptom alieviation was noted after 3 - 4 counseling sessions.

We would now like to explore the use of resource-oriented interventions within such a program to further improve patient outcomes. Resource-oriented approaches support patients to draw from existing resources within themselves and within relationships with their families, and wider social networks to reduce distress. The approaches developed are low cost and can be utilised in different settings, without the need for specialist staff or training. Identification and testing of psychologica interventions which can be delivered by lay counsellors is a priority for the global mental health field (Collins, et.al., 2011).

DIALOG+ is a brief, inexpensive, flexible, technology assisted intervention that stuctures basic communication between patients and mental health profeesionals during routine consultations. It's been found to be effective in improving patient outcome and satisfaction within patients with severe mental disorders in high income settings(Priebe et al. 2015, 2017; Omer, Golden, and Priebe 2016).

Using a guided intervention like DIALOG+ will add further structure to the counselling sessions and build capacity in the lay counsellors. It will improve their ability to provide more complex treatment support and care to their clients as well as include the patient in the treatment process. This will also streamline the process in high burden settings ensuring that patients receive quality care and important areas of concern are not missed due to fatigue.

The structured communication will serve as a quality control measure and standardize the program's ability to evaluate. While clinical outcomes of lay counselling are monitored by the program using the Aga Khan University Anxiety and Depression Scale (AKUADs)- a validated depression and anxiety scale, there has been no systematic research into assessing the quality of interaction and its impact on the overall quality of life of the patients and treatment satisfaction in Pakistan.

Families of patients with mental disorders often have various psychological and social resources that can be strengthened and utilised in mental health care. This may help to improve experiences of all family members and lead to better health and social outcomes of the patients.

Extensive research has explored different models for involving families in mental health care of patients with severe mental disorders, often focusing on psycho-education and various methods of family therapy. Research evidence suggests that different approaches can be effective in improving patient outcomes and reducing the burden on families.

A particular approach for involving families is the 'trialogue', a form of open communication in groups with professionals, patients and their families. The family intervention in the NIHR Global Health Research Group follows the principles of 'trialogue' and takes components of a specific form of 'trialogue', called psychosis-seminars. It emphasises the civil rights and strengths of both patients and their families, require mutual respect of all groups and promote the sharing of experiences and learning within and across families and groups(Kaselionyte et al. 2016; MacGabhann et al. 2018). As part of the NIHR Global Health Research Group on Developing Psychosocial Intervetions for Mental Illness, these interventions are simultaneously being tested in a multi-design, multi-LMIC study with patients with severe mental disorders in Bosnia, Uganda, Colombia, Peru and Argentina.

The use of evidence based resource –oriented approaches like DIALOG+ and Family involvement using trialogues could result in tremendous strides in improving the awareness about mental disorders, reduce the treatment gap and improve the care of patients. However, there have been no known studies have been done in the regional context to investigate the effectiveness of these approaches, specifically within people suffering from CMD.

METHODOLOGY

Operational Definitions

- **DIALOG+ Intervention**: The DIALOG+ intervention is designed to be implemented within routine meetings between mental health service providers and patients. DIALOG + is a technology mediated intervention, which involves a structured patient assessment covering satisfaction with eight life domains and three treatment domains (DIALOG) and a four-step solution focused therapy approach to address patient concerns (+). Intervention duration 6 months
- **Family Involvement Intervention:** The intervention will be trialogue, bringing together 5 patients, their family members or friends and mental health professionals in monthly meetings, allowing attendees to share experiences on pre-agreed topics to learn from one another. The content of each session will be co-produced but each session will include psychoeducation, mutual learning and support. At each meeting there will be 5 families (5 patients and up to 10 family members) and 1 mental health counsellor. Intervention duration: 6 months
- **Manchester Short Assessment of Quality of Life (MANSA);** it has been developed as a condensed and slightly modified instrument for assessing quality of life. It has been tested in a sample of community care patients. It is a sixteen item scale assesses quality of life in different life domains.
- **Aga Khan University Anxiety & Depression Scale (AKUADS):** Locally developed and validated 25-point questionnaire with Likert scale rating 0-3 for each question. Score > 20 considered normal. 20 -40 mild, and 40-60 moderate and > 60 severe.
- **Self-Reporting Questionnaire (SRQ-10):** 10-point questionnaire about symptoms of depression with Yes/No response. Score > 6 indicate symptomatic for depression.
- **Objective social outcome index (SIX);** is a method which summarizes objective indicators of social outcome in mental health. It provides meaningful results and can be used in research and clinical practice. It captures relevant changes over time.

Study Design

Non-clinical, non-randomized trial

Study Setting

- Dialog+: Indus Health Primary Care Clinic in North Nazimabad, Delhi Medical Center (DMC) (facility-based) and home-based counselling in community near IHN Korangi Campus primary care clinic.

- Family Involvement Intervention: Community/health center within 10 km of Indus Hospital Korangi Campus.

Study Duration: February 2019 – October 2019 (9 months)

DIALOG+

DIALOG+ consists of a patient-centered assessment whereby a mental health professional invites the patient to rate their satisfaction with different life domains and treatment aspects. This is followed by a four-step solution-focused approach to identify the patient's resources and develop solutions to deal with the patient's concerns. The intervention is available as an app and makes use of a tablet computer (e.g. iPad or android device) within routine clinical meetings.

Study Procedure Dialog+:

Research Methods, Procedures and Tools:

Four counsellors serving two catchment populations in Karachi, Pakistan will be trained to use the DIALOG+ app. Two counsellors will be based at the Indus Health network primary care clinics (Korangi, North Nazimabad) and two counsellors will be community-based counsellors who make home-visits for home-based counselling of patients identified at the IHN primary care facility. In a non controlled trial, patients visiting the two clinics who meet the eligibility criteria of age 18-65 years and are fluent in Urdu will be screened using the SRQ-10 (Self-Reporting Questionnaire). Those who score 6 or above on the scale will then be further screened using the longer AKUADs. Those who score within the mild to moderate range (21-60) on the AKUADs are eligible to take part in the Pursukoon Zindagi program and will be offered counseling sessions. Consecutive patients visiting the study sites will be screened for eligibility untill enrollment is complete.

Eligible participants at this point will be asked if they are interested in additionally taking part in the research study using DIALOG+ within their counselling sessions. All interested participants will be consented before completing another screening tool, the Manchester Short Assessment of Quality of Life (MANSA) which measures quality of life. Only those that score 5 or below on the scale will be eligible to take part in the research study. This level of screening will allow for inclusion of patients within whom a noticible change in score may be observed at the end of the study period. A total of 40 patients will be enrolled in the intervention. Patients who are

ineligible on the MANSA scale will continue with their counselling sessions as per routine care within the PSZ program.

After completing the informed consent and screening process, patients who are eligible will complete the sociodemographic questionnaire and other outcome measures at baseline. These measures include:
SIX
AKUADs
MANSA

Each participant will be enrolled for a total of 7 counselling sessions at: baseline, week 3, week 6, week 10, week 14, week 18, week 22. The AKUADs will be re-administered at week 6 and week 22 (general practice within PZ program), whereas the other measures (MANSA, SIX) will only be administered at baseline and at the end of the intervention period at 22 weeks. Each counselling session at baseline and follow up will be conducted using the DIALOG+ app. If consent is provided, at least one session from each group will be audio-recorded to measure adherence to the intervention.

DIALOG+ has been developed to turn routine meetings between a patient and mental health professional into a therapeutically effective intervention. It is based on quality of life research, concepts of patient-centered communication, developments in information technology, and components of solution-focused therapy. Supported by an App using a tablet computer, it delivers assessment, planning, intervention and evaluation in one procedure.

In the meeting with the mental health professional, patients rate their satisfaction with eight life domains, and three treatment aspects. The ratings are summarized on-screen, allowing for comparisons with ratings from any previous meeting. Patients can then decide which life domains and/or treatment aspects they would like to discuss in the current meeting. Each selected life domain or treatment aspect is addressed in a four-step approach. The four steps are: 1) understanding (Why is the patient dissatisfied? What went nevertheless well?); 2) looking forward (What is the best case scenario? What is the smallest step forward?); 3) exploring options (What can the patient, the mental health professional and others do?); and finally 4) agreeing on actions (What should be done until the next meeting?). The agreed actions are briefly documented and revisited at the beginning of the next meeting.

Family Involvement Intervention:
This intervention involves regular meetings of patients, their family members and mental health professionals to discuss pre-agreed, co-produced to allow learning through sharing experiences, mutual support and psychoeducation. Trialogues will be held once per month over 6 months at local community or health centers and will be chaired by attending mental health counsellor (to help with group facilitation). Each group will consist of five patients, one to two family members per patient, and a mental health counsellor. Mental health counsellors will attend training in group set-up and facilitation, and the trialogue intervention will adhere to adapted existing guidelines.

Study Procedure – Family Involvement Intervention:

A second study will be conducted with 30 patients (not included in the DIALOG+ intervention) All interested and eligible participants (aged 18-65 years, fluent in Urdu, AKUADs score mild to moderate range (21- 60) will be consented before completing another screening tool, the Manchester Short Assessment of Quality of Life (MANSA) which measures quality of life. Only those that score 5 or below on the scale will be eligible to take part in the research study. Patients who are ineligible on the MANSA scale will continue with their counselling sessions as per routine care within the PSZ program. Consecutive patients visiting the study sites starting from March 2019 will be screened for eligibility untill enrollment is complete. Eligible patients will go onto complete the baseline questionnaire and will be asked to identify 2 family members who may be willing and interested in taking part in the study. Family members will be approached and consented. Consenting family members will complete a short questionnaire including sociodemographic information as well as a short assessment on caregiver burden.

Patients enrolled in the Family Involvement intervention will be engaged in one interactive group trialogue session a month for 6 months which will include patients, their family/friends/neighbors along with a mental health professional. This will be in addition to the 6 counselling sessions (CAU) (one per week) that the patients receive at the facility.

One group session will comprise of 5 patients along with one or two family/friends per patient and one trained counsellor as a facilitator at a local community or health center. The purpose of this session would be to discuss topics relating to mental health chosen by all participants and will involve caregivers and patients sharing experiences and learning within and across families and professionals. The aim is to build a supportive environment for patients as well as their family members. A member of the research team will support the mental health professionals in setting up the first meeting, and groups will be encouraged to meet once per month over six months. The topics discussed at each Family Intervention session will be co-produced. Each session is likely to last 1-1.5 hours with a break, and may take place during the evenings to accommodate participants who might be working during the day. The groups will be closed to new participants joining once the intervention has begun, but recruited participants who miss meetings will still be able to attend future meetings. At least one session from each group will be audio-recorded to measure adherence to the intervention.

Each patient/family unit will be reimbursed PKR 600 for travel to each session.

At the end of the DIALOG+ and Family Involvement intervention sessions (6 months), qualitative interviews will be conducted with a subset of participants, who initially consented to be interviewed and audio recorded. Participants (patients, family members/friends and mental health counsellors) will be purposively recruited to ensure that all types of experiences are included. The interviews will focus on i) the experience of the intervention, ii) barriers and facilitators attending intervention sessions, iii) suggested adaptations and iv) the practical delivery of the intervention including frequency of sessions. Within the interviews, participants will be asked to focus on examples of their experience of the intervention, instead of giving general opinions regarding the intervention. The interviews will be audio-recorded and

conducted by a researcher. Each interview will last approximately 45-60 minutes. Each participant will be reimbursed PKR 500 for the qualitative interview. The audio recorded sessions will be further transcribed and analyzed to assess feasibility and acceptability.

Outcome meaures:

Self-Reporting Questionnaire (SRQ-10): 10 point questionnaire about symptoms of depression with Yes/No response. Score > 6 indicate symptomatic for depression**.**

The **AKUADs** is a 25 point questionnaire with 0-4 rating (Never, Sometime, Most of the time, Always). Score of > 20 indicates symptoms of depression and/or anxiety.

The **MANSA**(Priebe et al. 1999) is a quality of life assessment with 16 questions. 12 questions response is rated on a 1-7 scale, and four are Yes/No responses. Score of 5 or less the patient will be considered eligible for the study.

Objective social outcome index (SIX)(Priebe et al. 2008)**;** is a method which summarizes objective indicators of social outcome in mental health. It provides meaningful results and can be used in research and clinical practice. It captures relevant changes over time.

Burden Assessment Scale (BAS) (Reinhardt et.al., 1994) 19 item questionnaire to assess objective and subjective caregiver burden.

Ethical considerations

IRB approval for the study will be requested from the Review Board at Indus Hospital Research Center and Queen Mary Ethics of Research Committee before it starts as it involves human participants. This will be a minimal risk study as it consists of interviews only. Written informed consent will be obtained from all participants. Ethical issues regarding confidentiality will be addressed. Participants will have the freedom to refuse to participate or to not answer any particular question(s), or refuse to audio-recording of their sessions, all information provided by them will be confidential and known only by the research team.

ANALYSIS OF RESULTS

Data Analysis

Quantitative data analysis:

For both studies, the number of screened participants, eligible participants and of those who refused participation or were not approached will be recorded. The analysis will assess the number of intervention sessions received by patients, and will collect data on drop-out (including reasons for drop-out if available) from treatment, which will inform the assessment of acceptability of the interventions. The intervention topics discussed in meetings (DIALOG+ and Family Involvement Intervention) will be tabulated.

Descriptive statistics will be reported for socio-demographic data for all participants. To assess for effectiveness of the different approaches, mean and standard deviations before and end of six month) will be calculated, and the analysis will test the significance of the differences between the means of outcomes measured. For Study 1 – DIALOG+ and Study 2 – Family Involvement, the primary outcome the change in MANSA score at baseline and 6 months. Change in

AKUADs score at baseline, midpoint and end of intervention will also be calculated and compared.

Qualitative Analysis:

Qualitative data will be analyzed using thematic analysis following the guidance of Miles & Huberman (1994) and will be conducted using NVivo (version 11) qualitative analysis software. All interviews will be audio-recorded and transcribed verbatim. A researcher will remove all identifying information from the transcripts, including any references to patients, mental health professionals or local services.
An inductive approach will be used to provide new insights and richer understanding of the data without using preconceived categories. Two members of the research team will first familiarize themselves with the transcripts. Open coding will be used (making notes and headings in the text to describe the content). Similar codes will be grouped under themes, and the identified themes and sub-themes will then be checked and refined. Inter-rater reliability in applying second level codes (or categories) will be calculated for 20% of the data.

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