

## A PROTOCOL OF A CROSS SECTIONAL STUDY TO ASSESS DEPRESSION IN ANTENATAL MOTHERS

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### ABSTRACT:

**Background:** Maternal depression is associated with a number of adverse maternal outcomes such as preterm birth, maternal dysfunction, maternal suicide and perinatal outcomes such as low birth weight, lower rates of breastfeeding, increase in diarrheal disease, hospitalisations, poor emotional, social development, lower academic achievements in adolescence and future mental health problems for the children of the mothers. Maternal depression has rightly been identified as a priority mental health condition and large scale community interventions in low and middle income countries (including India) have been shown in RCTs to be effective in not only improving maternal depression but also improve the perinatal outcomes. Given the scale, severity of the problem and strength of evidence available for effective interventions in the Indian context, there is a great opportunity for implementation research in this area. As a first step there is a need to understand the prevalence of the problem and associated risk factors in our context.

**Aim:** Aim of this study to understand the prevalence of maternal depression and associated risk factors among antenatal mothers attending Sri Ramachandra Medical College (SRMC) Obstetrics outpatient department.

**Methods:** A cross-sectional design will be employed for determining the prevalence, while a case control framework will be used for the risk factor analysis. Antenatal mothers will be stratified according to the trimester of the pregnancy. Semi-structured socio demographic proforma; Patient Health Questionnaire (PHQ-9 Tamil version), Generalised Anxiety Scale (Tamil Version) and Brief COPE (Tamil version) questionnaire will be administered for antenatal mothers who offer informed consent. Those who score above 10 points on the PHQ scale will be interviewed using the MINI diagnostic interview schedule for clarifying diagnosis. Those who are diagnosed with depression will be referred to the SRMC psychiatry department for treatment & follow up.

**Analysis:** Statistical analysis is to be done using computer software, to assess the prevalence of antenatal depression and the associated risk factors. Descriptive statistics will be used to describe the sample. Mean, standard deviation and range will be employed to describe continuous variables, while frequency distributions will be obtained for categorical variables. The chi square and fisher's exact tests will be used to assess the significance of associations between categorical variables. Multivariate analysis will be performed using stepwise backward logistic regression models

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## **Introduction:**

Maternal wellbeing has been defined as a state in which a mother realizes her abilities, is able to cope with the common stresses of life and can offer meaningful contribution to her community (1). Maternal depression is a key impediment to this worthy goal and is largely neglected in most maternal and child wellbeing programs around the world (2). A systematic review of studies (3) has shown that it is common in low and middle-income countries with a prevalence of 15.6 % (95% confidence interval, CI: 15.4 to 15.9). In a study by George et al (4) the prevalence of maternal depression in semi urban Tamil Nadu was 16.3%.

Multiple risk factors have been shown to be associated, which vary depending on the local and cultural factors. Financial difficulties, non-arranged marriage, marital conflict, preference for male child, previous miscarriage, still birth, child with special needs, domestic violence, partner with alcohol dependence (4-7) were some of the common risk factors identified in studies conducted in India. Good social support, high satisfaction with pregnancy and multiparity were protective factors (5, 6).

Depression in mothers is associated with poor quality of life (WHO report 2007), increase in suicidal behavior (8) pre term birth (9) LBW (10) and poor nutrition in the child (11, 12). Further, antenatal depression increases the risk of post natal depression which is associated with increase in diarrheal diseases, early cessation of breastfeeding, increased the risk of antisocial behavior, ADHD symptoms, emotional difficulties and cognitive development in the child (13). A recent study has indicated that maternal depression is associated with poor academic achievement in adolescence (14).

High quality studies in low and middle-income countries have shown that it is possible to successfully target maternal depression through lay workers (15) trained in psychosocial interventions and some have been integrated in existing maternal and child health programs (16-18). Successful treatment of maternal depression has correlated with improvement in mother child interaction, better rates for breastfeeding and vaccination (16-18). WHO has called for integration of mental health in maternal and child health programs with a

focus on recognition, prevention, early intervention and treatment of maternal depression (19).

Yet, services for screening and treatment of maternal depression have not been organized even in most tertiary care settings in India. There are few studies on antenatal depression from India.

## **Objectives:**

The aim of this study is to evaluate the prevalence of antenatal depression and the associated risk factors in a tertiary care maternity hospital as a first step towards organizing treatment services for effective intervention.

## **Methodology**

### ***Setting***

This study will be conducted in Obstetrics & Gynaecology department (O&G) of the Sri Ramachandra Medical College & Research Institute (SRMC & RI) in Chennai. The antenatal clinic is a busy unit with an average of about 60 outpatients assessed every day.

### ***Design***

A cross-sectional design will be employed for determining the prevalence, while a case control framework will be used for the risk factor analysis.

### ***Participants: Inclusion & Exclusion criteria***

In this study all patients attending the antenatal clinic who are above the age of 18 and are able to provide informed consent will be eligible to participate. Patients with mental subnormality and those who refuse consent will be excluded.

*Estimated time period:* We estimate that the study will be conducted from January to March 2019.

### **Sample size calculation and sampling**

The sample size calculated was 207 using the following assumptions: prevalence of antenatal depression to be 16% (4) precision of 5% with an alpha error of 5%. The population will be stratified based on the trimester of the pregnancy.

### ***Procedure:***

The participants will be screened for depression and evaluated for associated risk factors. Those who screen positive will be interviewed further for

diagnostic evaluation. Patients who qualify for a diagnosis of depression will be referred to the psychiatry department of the SRMC hospital for further management

#### **Assessment and Diagnosis of depression:**

**1. The Patient Health Questionnaire (PHQ)** (validated Tamil version) (20) is a self-administered version of the PRIME-MD diagnostic instrument for common mental disorders. The PHQ-9 is the depression module, which scores each of the 9 DSM-IV criteria as “0” (not at all) to “3” (nearly every day). Construct validity was assessed using the 20-item Short-Form General Health Survey, self-reported sick days and clinic visits, and symptom-related difficulty. Criterion validity was assessed against an independent structured mental health professional (MHP) interview in a sample of 580 patients. In this study those who score above cut score of 10 will be interviewed using the Mini International Neuropsychiatric Interview- Plus Version 5.0.0 (MINI).

#### **2. Mini International Neuropsychiatric Interview-Plus Version 5.0.0 (MINI)**

The MINI-Plus 5.0.0 is an internationally validated brief structured interview that is used extensively as a diagnostic tool for psychiatric disorders from the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition and the International Classification of Diseases-10. The reliability and validity of this instrument is well established (21)

#### **3.Generalized Anxiety Disorder-7 (GAD-7)**

The GAD-7 was designed for use in primary care patients. It consists of a self-report questionnaire that allows for the rapid detection of generalised anxiety disorder. Subjects are asked if they were bothered by anxiety related problems over the past two weeks by answering seven items on a 4-point scale. The total scores ranged from 0 to 21. At a cut-off score of 9, the GAD-7 had a sensitivity of 89 % and a specificity of 82 % for detecting GAD compared with a structured psychiatric interview (22)

#### **4. Brief COPE**

The Brief COPE (Tamil version) is a well validated scale that has been used extensively to assess coping with cancer, depression, and HIV. This is a 28 item scale scored from 1-4 for each question

(23) An exploratory factor analysis (EFA) yielded a 16 item scale with 5 factors (active planning, social support, avoidant emotions, substance use, religion). A second CFA demonstrated good model fit and acceptable reliability ( $\alpha=0.61$ ) of the adapted scale.

#### **5. Socio-demographic proforma**

A semistructured proforma with the following content will be used to get information about some key associated factors. (*Prepared from Systematic review.Fisher 2012*)

a) *Socio economic status*: Age (<20); educational status (<year 10 school); Religion (minority); unmarried; slum dwelling; employment status b) *Relationship with partner*: Physical violence; unsupportive; alcohol related problems; unemployed partner c) *Family factors*: Poor support from in laws; nuclear family; poor relationship with mother; more than 3 children; pressure to have male child d) *Reproductive health*: unwanted pregnancy; past abortion; past still birth e) *Mental health*: Past or family history of mental illness

#### **STATISTICAL ANALYSIS:**

Statistical analysis is to be done using computer software, to assess the prevalence of antenatal depression and the associated risk factors. Descriptive statistics will be used to describe the sample. Mean, standard deviation and range will be employed to describe continuous variables, while frequency distributions will be obtained for categorical variables. The chi squared and fisher's exact tests will be used to assess the significance of associations between categorical variables. Multivariate analysis will be performed using stepwise backward logistic regression models.

**Ethics and dissemination:** This study is approved by the Institutional Ethics Committee, Sri Ramachandra Medical College & Research Institute. Results will be published in a relevant scientific journal.

**Discussion:** Antenatal depression can have potentially long-lasting effects on the child mother and the family. Early identification and treatment can go a long way in mitigating this. Evaluating the prevalence and associated risk factors for antenatal depression will enable provision of maternal mental

health services. Such an approach will foster a positive relationship between Obstetrics and Psychiatry departments, lessen the stigma and pave a way for holistic care in general hospital setting. There is huge variability in prevalence of depression, based on study setting, trimester of pregnancy. Our study will help to understand the nature and prevalence of risk factors for depression and anxiety in antenatal mothers, their coping abilities and help us to plan for an intervention addressing those risk factors, there by promoting the well-being of mother and the child.

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