A pilot randomised controlled trial of a peer-based low-intensity psychosocial intervention for reducing depressive symptoms in pregnant women in rural Bangladesh

Rehenuma Tarannum

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ABSTRACT

Antepartum depression or depression during pregnancy is a significant public health concern because of its adverse impact on maternal and child health. Nearly 50% of pregnant women suffer from depressive symptoms and the rate is significantly higher in low- and middle-income countries (LMICs) than in high-income countries (HICs). Despite the high prevalence of antepartum depressive symptoms among pregnant women in LMICs, many women have limited or no access to mental health care facilities in these regions. In light of these problems, the aim of this pilot study was to examine whether participation in a peer-based low-intensity psychosocial intervention had any effect on mild-to-moderate depressive symptoms in pregnant women residing in a low-resource setting in rural Bangladesh. A mixed method approach was used in this early intervention study to evaluate the intervention, with a pilot randomised controlled trial (RCT) and a process evaluation. The study participants were 70 pregnant women and five peers from a rural sub-district of Bangladesh, randomised into control and intervention groups. The intervention group received the intervention delivered by the peers for five weeks. The intervention was the antenatal part of the Thinking Healthy Programme–Peer delivered. Data were collected at baseline, post-intervention and four weeks after completion of the intervention. In addition, intervention group participants and peers were interviewed as part of a process evaluation.

The findings of the study showed that at post-intervention, the intervention group had a significant decrease in depressive symptoms and a slight increase in self-esteem and perception of quality of life compared with the control group. The improvement in these parameters was more significant at post-intervention than at 4-week follow-up. The process evaluation indicated that the women perceived that taking part in the study was helpful in reducing their depressive symptoms and they were also satisfied with the peers delivering the programme. Peers were motivated to become involved in the project because they thought it was an excellent opportunity to learn new knowledge and skills, and because of their altruistic desire to help others.

While the effectiveness of the peer-based intervention needs to be established in a large RCT, the outcomes of this study provide preliminary evidence, context and direction for implementation of an effective, low-cost, feasible, evidence-based intervention in primary health care settings in LMICs like Bangladesh.

DOCTOR OF PHILOSOPHY DECLARATION

I, Rehenuma Tarannum, declare that the PhD thesis entitled '**A pilot randomised controlled trial to assess the feasibility of a peer-based low-intensity psychosocial intervention for reducing depressive symptoms in pregnant women in rural Bangladesh'** is no more than 100,000 words in length including quotes and exclusive of tables, figures, appendices, bibliography, references and footnotes. This thesis contains no material that has been submitted previously, in whole or in part, for the award of any other academic degree or diploma. Except where otherwise indicated, this thesis is my own work".

Signature: Rehenuma Tarannum Date: 15/11/2018

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CHAPTER ONE

Introduction

1.1 Introduction

In this chapter, an overview of the study is presented. The chapter commences with the background of the study, and is followed by a description of the research question, aims and definition of the most frequently used terms in the thesis. Then, a justification for the study is described. Finally, the structure of the thesis is presented.

1.2 Background

Depression, the most common mental health disorder and leading cause of disability worldwide, has a significant prevalence rate during pregnancy or the antepartum period. It is estimated that around 8.5–11% of pregnant women are diagnosed with major depressive disorder during the antepartum period (Verreault et al., 2014; Woody, Ferrari, Siskind, Whiteford, & Harris, 2017; World Health Organization, 2018a). Additionally, several studies have reported that as many as 41% of pregnant women suffer from mild-to-moderate depressive symptoms (Atif, Lovell, & Rahman, 2015; Fisher et al., 2012; Verreault et al., 2014). Although less severe than major depression, pregnant women suffering from mild-to-moderate depressive symptoms experience significant impairment in their daily lives (Atif et al., 2015). Depressive symptoms exert a negative impact on the health of the pregnant mother and her unborn baby, and there is a direct link between antepartum depressive symptoms and increased risk of postpartum depression (Atif et al., 2015; Kirkan et al., 2015; Redshaw & Henderson, 2013). For this reason, in recent years emphasis has been placed on the importance of screening for depressive symptoms during antenatal check-ups (Venkatesh, Kaimal, Castro, & Perlis, 2017). Screening is necessary because, if detected early, the progression and impact of these symptoms can be significantly reduced with evidence-based early interventions (Petri et al., 2017; Van Zoonen et al., 2014). In high-income countries (HICs) such as Australia, screening for depressive symptoms in pregnant women is highly recommended during antenatal care (Department of Health, 2018; O'Connor, Rossom, Henninger, Groom, & Burda, 2016). However, the practice is not yet established in the health systems of many low- and middle-income countries (LMICs) (Gelaye, Rondon, Araya, & Williams, 2016), where the primary foci of maternal healthcare are minimising obstetric complications and reducing maternal morbidity (Lassi, Middleton, Bhutta, & Crowther, 2016). Furthermore, LMICs often

lack effective mental health systems to provide mental health care to pregnant women suffering from depressive symptoms and other mental disorders (Dua et al., 2017; Fisher et al., 2012). In particular, the majority of pregnant women residing in rural LMICs have inadequate access to mental health care in primary care settings (Baingana, Al'Absi, Becker, & Pringle, 2015; Gureje et al., 2015; Patel, Simon, Chowdhary, Kaaya, & Araya, 2009). The principal barriers to help-seeking by pregnant women in these rural regions are social stigma, financial insufficiency, inadequate knowledge and awareness of depression in this cohort, lack of mental health care facilities in primary health care settings, and inadequate provision of health workers (Patel & Saxena, 2014). Therefore, finding a cost-effective, accessible and feasible intervention to extend mental health care to pregnant women in LMICs is a major concern and priority for health organisations like the World Health Organization (WHO) (Biesheuvel-Leliefeld et al., 2015; Bockting, Williams, Carswell, & Grech, 2016; Patel & Saxena, 2014; Rahman, Fisher, et al., 2013).

In 2008, the WHO introduced the *Mental Health Action Plan 2013–2020*, designed to increase access to mental health care services in low-resourced areas of the world. The four primary objectives of the programme were to: (1) aid in establishing effective leadership and governance for mental health care systems; (2) expand the scope of mental health care services in community-based settings; (3) implement policies for extending mental health care; and (4) strengthen research, evidence and information systems for mental health (Baingana et al., 2015; Bockting et al., 2016; World Health Organization, 2013). As a part of the action plan, the WHO developed guidelines for the assessment and management of the most common mental disorders to aid general practitioners, nurses, midwives and other health professionals practising in non-mental health settings. The WHO further extended the programme by developing a series of low-intensity psychological interventions to expand mental health care coverage in LMICs where health professionals were not readily available (Chowdhary et al., 2014). The first of these low-intensity psychosocial interventions was the Thinking Healthy Programme (THP), in which community health workers in LMICs would be trained to provide support to women suffering from depressive symptoms during and after childbirth. The results of the original RCT of the THP, conducted in rural settings in India and Pakistan, showed that intervention group participants had significant reduction in depressive symptoms and improved overall functioning (Maselko et al., 2015). Despite the positive outcome of the RCT, there were significant challenges in implementing the intervention in community health care settings because of the additional workload it placed on community health workers (Singla et al., 2014).

Hence, a simplified modified version of the THP was developed (Sikander et al., 2015), called the Thinking Healthy Programme–Peer delivered (THPP), which is delivered across the antepartum and postpartum periods. The intervention uses peer mothers to deliver the intervention to women experiencing mild-to-moderate depressive symptoms. This form of peer support programme aims to extend mental health care support to women during pregnancy and the postpartum period in areas lacking access to mental health care facilities (Atif et al., 2017; Sikander et al., 2015).

Peer support is a relatively new concept in health care systems in LMICs. Studies conducted in HICs such as the USA, UK and Australia, have reported the effectiveness and positive impact of peer support interventions on the mental health of individuals (Bellamy, Schmutte, & Davidson, 2017). Peer-based services are now used increasingly in mental health care settings in HICs for depression and other common mental health disorders (Bellamy et al., 2017; Ramchand et al., 2017; Rogers, 2017; Tse et al., 2017; Vayshenker et al., 2016). However, no studies have been located in existing literature examining peer support interventions as an aid to extending mental health care to people living in rural low-resourced areas in Bangladesh. One study was located in which peer counsellors were used to promote exclusive breastfeeding by mothers in Bangladesh. The intervention was successful in encouraging the majority of the participants to practice exclusive breastfeed for up to five months after birth (Haider, Kabir, Huttly, & Ashworth, 2002).

In her practice, the present researcher, a general practitioner experienced in providing primary health care in rural Bangladesh, encountered numerous occasions where large numbers of pregnant women needed mental health care for their depressive symptoms. Even when referred to mental health care facilities, most could not access them because of financial and other problems (Rahman, Surkan, Cayetano, Rwagatare, & Dickson, 2013). Another problem was that health professionals in primary health care settings in LMICs like Bangladesh are often not trained to provide adequate mental health care (Bruckner et al., 2011). Bangladesh adopted a mental health care policy in 2006 with the aim of promoting and addressing mental health issues and providing comprehensive mental health services in primary health care (Islam & Biswas, 2015). However, the final *Mental Health Act* needed to implement the policy is still in draft version and awaiting approval by the responsible authorities (Hossain, Ahmed, Chowdhury, Niessen, & Alam, 2014; Islam & Biswas, 2015). As a consequence, there are still very few mental health care services available in primary health care settings in the country.

From this researcher's perspective, women residing in rural areas need greater access to mental health services in their communities, and a peer-supported mental health programme may provide that platform to extend mental health care into these communities.

The present study is unique because it aims to evaluate a peer-based intervention to reduce antepartum depressive symptoms in pregnant women in rural Bangladesh, where the scope of peer support interventions in providing mental health care is yet to be established. The study may provide primary evidence in planning and designing a large-scale study of the tested intervention and provide insight into the potential of using such a low-intensity intervention in community-based settings in rural Bangladesh and in other LMICs.

1.3 Research question

What effect has a peer-based low-intensity psychosocial intervention in reducing depressive symptoms in pregnant women in rural Bangladesh?

1.4 Aims

The primary aim of the study was to pilot test the effect of a peer-based low-intensity psychosocial intervention in reducing mild-to-moderate depressive symptoms in pregnant women residing in a low-resource setting in rural Bangladesh.

The secondary aims of the study were to:
(1) Test the effect of the programme in improving pregnant women's self-esteem and quality of life (QoL),
and
(2) Evaluate pregnant women's and peers' perspectives about the usefulness of the programme.

1.5 Definition of terms

Terms frequently used in the thesis are briefly described in this section.

- **Depressive symptoms:**

"In typical depressive episodes of all three varieties (mild, moderate, severe), the individual usually suffers from depressed mood, loss of interest and enjoyment, and reduced energy leading to increased fatigability and diminished activity. Marked tiredness after only slight effort is common. Other common symptoms are:

(a) reduced concentration and attention;
(b) reduced self-esteem and self-confidence:
(c) ideas of guilt and unworthiness (even in a mild type of episode);
(d) bleak and pessimistic views of the future;
(e) ideas or acts of self-harm or suicide;
(f) disturbed sleep;
(g) diminished appetite" (World Health Organization, 2018b, p. 100)[1].

- **Antepartum period:** The antepartum period is defined as the period of pregnancy (from conception to active labour).

- **Peer:** In this study, peers are mothers who share similar characteristics with the pregnant women participants, such as geographic location, age, religion, ethnicity or socioeconomic status.

- **Low-intensity psychosocial intervention:** Low-intensity psychosocial interventions are modified, evidence-based psychological interventions that use less intense levels of human resources to deliver and are often provided by individuals without formal qualifications in mental health care who are given basic training to deliver such interventions.

1.6 Justification for the study

Justification for the study is premised on the high prevalence of antepartum depression and the need for low-cost, effective interventions in low-resource settings**.** Existing literature provides ample evidence of the adverse impact of antepartum depression on maternal and child health (Atif et al., 2015; Gentile, 2017; Pearlstein, 2015; Staneva, Bogossian, Pritchard, & Wittkowski, 2015). However, for a considerable period, the primary focus of research into depression related to pregnancy and childbirth has been on the postnatal period (Davalos, Yadon, & Tregellas, 2012; Falah-Hassani, Shiri, & Dennis, 2017). This focus may have been attributable, in part, to a misconception that pregnancy is protective against depression (Payne, 2012). In fact, pregnant women have the same risk of experiencing depressive symptoms as non-pregnant women and those suffering from depression in the postnatal period (Biaggi, Conroy, Pawlby, & Pariante, 2016; Payne, 2012). Moreover, studies from LMICs show that women residing in adverse socioeconomic conditions are at higher risk of developing depression than those in high-income countries (Atif et al., 2015;

[1] The diagnostic criteria of major depressive disorder are discussed in Chapter Two, Section 2.2.2 in detail.

Fisher et al., 2012; Marcus, Yasamy, van Ommeren, Chisholm, & Saxena, 2012). Hence, women need considerable psychosocial support for depressive symptoms during pregnancy. In light of the lack of interventions that focus specifically on antenatal depressive symptoms (Chowdhary et al., 2014), there is a need for research to develop effective, low-cost, practical interventions to provide mental health care in low-resource settings for this period.

A large gap in knowledge exists about peer-based interventions in health systems in LMICs (Singla et al., 2014). The aim of the proposed research is to evaluate the potential of this additional human resource—peers—that remains unexplored in LMICs, particularly in Bangladesh. The peers in the current study were selected from a local community and were trained to deliver the selected intervention. The low-intensity intervention used in the study is the antenatal part of the THPP programme. The findings may inform the planning and implementation of a larger RCT to evaluate the potential of the antenatal part of the THPP as a stand-alone intervention for reducing antepartum depressive symptoms. It may also generate evidence about the development of early peer-based intervention strategies in low-resource settings for depressive disorder during pregnancy. Furthermore, the findings may provide recommendations to health planners about designing and implementing evidence-based, cost-effective alternative ways of extending effective mental health care through peer support programs in low-resource settings.

1.7 Structure of the thesis

This thesis is presented in eight chapters. In Chapter Two, literature regarding depression and pregnancy is examined. In Chapter Three, literature pertaining to peer support is explored. In Chapter Four, the design and methods of the study are outlined, and the results of the pilot RCT are presented in Chapter Five. Then the results of the process evaluation of the pregnant women and peers are presented in Chapters Six and Seven, respectively. Finally, in Chapter Eight, the findings are discussed, and implications and conclusions of the study are presented.

CHAPTER TWO

Depression and pregnancy

2.1 Introduction

In this chapter, an overview of literature on depression or major depressive disorder and its relation to pregnancy is presented. The chapter is divided into three sections. The first section contains an overview of major depressive disorder, its clinical symptoms and diagnostic criteria. A description of the aetiology and the disability, morbidity and mortality associated with the disorder then follows. Next, the treatment for the condition according to its severity, based on the clinical practice guidelines of the Royal Australian and New Zealand College of Psychiatrists, is described. In the second section, a review of literature on antepartum depression or depression during pregnancy is presented. It starts with a discussion of the prevalence and risk factors for antepartum depressive symptoms, and the impact of antepartum depression on maternal and child health. An overview of literature on psychosocial interventions that focus on depression and depressive symptoms during pregnancy is then presented. Finally, the third section presents an overview of the mental health and antenatal health care systems in Bangladesh.

2.2 Depression

2.2.1 Overview of depression

Depression or major depressive disorder is one of the most common mental disorders around the world (Murtagh, 2015). It is a serious mental disorder characterised by persistent presence of sad, empty and irritable mood along with several psychological and physical symptoms (American Psychiatric Association, 2013; Colledge, Walker, Ralston, & Davidson, 2014). Psychological symptoms include loss of interest or enjoyment in previously enjoyable activities, reduced self-esteem, feelings of worthlessness, pessimism, guilt, social isolation, diminished ability to concentrate and recurrent thoughts of death or suicidal ideation. Physical symptoms include reduced appetite, weight change, disturbed sleep, fatigue, loss of libido, bowel disturbance, and slowing of activities or motor retardation[2] (Table 2.1). Low self-esteem, or negative beliefs about oneself, is a common symptom of depression (Sowislo & Orth, 2013).

[2] Psychomotor retardation is a central feature of depression characterised by motor and cognitive impairments, affecting speech, motility, and ideation. The symptoms include slowing of speech, disturbance in facial expressions, disturbance in fine motor behaviour, gross locomotor activity and impaired thinking (Bennabi, Vandel, Papaxanthis, Pozzo, & Haffen, 2013).

Low self-esteem may influence the progression and further worsening of low mood, feelings of loneliness, and detachment from regular social activities. Collectively, these symptoms hamper the individual's day-to-day activities markedly and exert disabling effects on mental and physical health (Colledge et al., 2014; Murtagh, 2015).

Table 2.1: Symptoms of depression

Core symptoms	**Other psychological symptoms**
1. Depressed mood 2. Loss of interest 3. Decreased energy or increased fatigability	1. Reduced self-esteem and confidence 2. Pessimism 3. Guilt 4. Loss of enjoyment 5. Diminished ability to think or concentrate 6. Recurrent thoughts of death or recurrent suicidal ideation
Somatic or physiological symptoms 1. Weight change 2. Fatigue 3. Loss of libido 4. Reduced appetite 5. Insomnia or hypersomnia 6. Bowel disturbance 7. Motor retardation or slowing of activities	

(Source: Diagnostic and Statistical Manual (5th ed.). Washington DC: American Psychiatric Association, 2013).

Depression can potentially affect all individuals, irrespective of their age, sex, religion or geographic location. It causes great suffering to affected individuals and leads to poor functioning in daily living activities at work, home and in the community. Twice as many women suffer from the disorder as men, and people living in communities affected by adversities are more susceptible to developing depressive symptoms (Malhi et al., 2015; World Health Organization, 2017a). It is a serious mental disorder and its incidence has been increasing markedly in recent years. For instance, in the past decade there has been an 18% increase in the incidence of depression. Globally, around 322 million people (4.4% of world's population) suffer from depression, but less than half of those affected receive appropriate treatment for the condition (World Health Organization, 2017a).

The WHO predicted that depression would be the second highest cause of disability by 2020 and the leading cause of disability by 2030 (World Federation for Mental Health, 2012). However, current evidence shows that the significant increases in incidence and prevalence of depression have made it the leading cause of disability more than ten years sooner than

predicted by WHO, making it the major contributor to the global burden of disease[3] in the world (World Health Organization, 2017a). In *Global Health Estimates*, WHO reports that depression contributed to 7.5% of all years lived with disability and more than 50 million years lived with disability[4] in 2015 (World Health Organization, 2017a). The majority (over 80%) of the disease burden occurred in LMICs.

Depression profoundly impacts adversely on individuals' QoL; in particular, engagement in regular social activities and performance of activities of daily living (Gulinello, Chang, Yao, Hu, & Wang, 2015). The disorder is also significantly associated with decreased productivity and concentration at, as well as absenteeism from, work; and concentration in educational studies (Lepine & Briley, 2011). In fact, evidence suggests that the overall loss of workdays is greater with depression than with other common chronic medical disorders, like heart disease, arthritis, asthma and diabetes (Gulinello et al., 2015; Hughes, Seemann, George, & Willis, 2018; Lepine & Briley, 2011). Diminished cognitive abilities, in addition to decreasing social functioning due to depression, may lead to reduced income and loss of employment. This, in turn, become a considerable burden for affected individuals, their families and the general community at large. Major depressive disorder, if left untreated, leads to significant disability and even death in individuals (Ferrari et al., 2014; Walker, McGee, & Druss, 2015; Whiteford, Ferrari, Degenhardt, Feigin, & Vos, 2015). Seventeen percent of people presenting to general practitioners in HICs like Australia have depression (Murtagh, 2015), and the lifetime risk of suffering from clinical depression is around 15%. In addition, around 26% of young adolescents have been reported to be suffering from sub-threshold depressive symptoms (Hill, Pettit, Lewinsohn, Seeley, & Klein, 2014; Peters, Shankman, Deckersbach, & West, 2015). Sub-threshold depressive symptoms can be defined as presence of depressive symptoms to a degree that does not meet the clinical diagnostic criteria for major depressive disorder but which is often associated with day-to-day functional impairment and with a high risk of developing major depressive disorder if left unattended (Hill et al., 2014). Forty percent of individuals experiencing depressive disorder have their first episode by 20 years of age (Malhi

[3] The WHO Global Burden of Disease (GBD) measures the burden of disease using disability adjusted-life-years (DALY). This time-based measure combines years of life lost due to premature mortality and years of life lost due to time lived in states of less than full health. One DALY can be thought of as one lost year of 'healthy' life.

[4] Years lived with disability are calculated by multiplying the prevalence of a disorder by the short- or long-term loss of health associated with that disability (the disability weight).

et al., 2015). Depression is also a major risk factor for ischemic heart disease. Major depressive disorder was responsible for around 3% of the total ischemic heart disease related Disease Adjusted Life Years (DALYs) in 2010 (Charlson et al., 2013). Depression is also an important risk factor for suicide (Ferrari et al., 2014). Mental and substance use disorders account for two-thirds of suicide deaths worldwide, and 46% of these deaths are in people with major depressive disorder (Ferrari et al., 2014). For these reasons, the WHO prioritised depression as the major theme of the 2017 World Health Day, and launched a one-year campaign named 'Depression: Let's Talk,' to increase global awareness and help-seeking in individuals with depression (World Health Organization, 2017b).

Depression is reported to be the most common mental disorder in Bangladesh, and women (17%) are at a higher risk of developing the disorder than men (12.9%) (Hossain et al., 2014; Islam & Biswas, 2015). Women residing in rural areas are particularly vulnerable to developing mental health disorders because of lack of proper health care, early marriage, illiteracy, stigmatisation and domestic violence (Hosain, Chatterjee, Ara, & Islam, 2007; Islam & Biswas, 2015).

2.2.2 Diagnostic criteria for depression

Currently, health professionals use one of two classifications for depression and psychiatric disorders: the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (American Psychiatric Association, 2013) and the World Health Organization's *International Classification of Disease Classification of Mental and Behavioural Disorders*, known as ICD-11 (World Health Organization, 2018b). Both classification systems are similar, and the ICD-11 classification is described in this thesis. The ICD-11 classification is the most commonly used classification and is considered the international standard for reporting health statistics by WHO member countries, including Bangladesh (First, Reed, Hyman, & Saxena, 2015).

In ICD-11, depressive disorder is classified as a single depressive episode or a recurrent depressive disorder. These are further categorised as mild, moderate or severe (World Health Organization, 2018b). This categorisation is based on the number and severity of symptoms, degree of daily functioning affected, absence or presence of somatic symptoms, and number of depressive episodes. The description of the diagnostic criteria of single depressive episode is outlined in Table 2.2.

According to ICD-11, for a definite diagnosis of recurrent depressive disorder, a person must have experienced at least two depressive episodes, either mild, moderate or severe, lasting for a minimum of two weeks and separated by several months without significant mood disturbance (World Health Organization, 2018b).

Table 2.2: ICD-11 classification of depressive episode

Main criteria:

1. The depressive episode should last for at least two weeks.
2. There has been no manic[5] or hypomanic episode[6] at any time before or during the episode.
3. The episode is not attributable to psychoactive substance or drug misuse or to any organic mental disorder.
4. These three main criteria must be present in all episodes (mild, moderate and severe) of depression.

Mild depressive episode:

1. Presence of two of the three core symptoms.
2. Presence of at least two of the other psychological and physiological symptoms to give a total of four symptoms.
3. None of the symptoms should be present to an intense degree.
4. The affected individual will have some difficulty in daily activities and social functioning but does not cease to function properly.

Moderate depressive episode:

1. Presence of two of the three core symptoms.
2. Presence of at least four of the other psychological and physiological symptoms to give a total of six symptoms.
3. The affected individual will experience considerable difficulty in performing social, work and domestic activities.

Severe depressive episode:

1. Presence of all three core symptoms.
2. Presence of at least four of the other psychological and physiological symptoms to give a total of eight symptoms.

[5] 'A mental state of elevated, expansive, or irritable mood and persistently increased level of activity or energy' (American Psychiatric Association, 2013, p. 824).

[6] 'An abnormality of mood resembling mania but of lesser intensity' (American Psychiatric Association, 2013, p. 823)

3. The affected individual will not be able to continue with social, work, or domestic activities, except to a very limited extent.

Source: ICD-11 classification of mental and behavioural disorder: clinical description and diagnostic guideline. Geneva: World Health Organization, 2018.

2.2.3 Aetiology of depression

A large body of research has been conducted to try to identify the exact cause of depression and other depressive disorders. A single cause has yet to be established (Durisko, Mulsant, & Andrews, 2015; Yim, Tanner Stapleton, Guardino, Hahn-Holbrook, & Dunkel Schetter, 2015), but researchers have identified several factors associated with the development of depression, broadly categorised into three categories: biological, psychological and social or environmental (Durisko, Mulsant, & Andrews, 2015; Yim, Tanner Stapleton, Guardino, Hahn-Holbrook, & Dunkel Schetter, 2015).

2.2.3.1 Biological factors

Biological factors for depression include abnormalities in the neuro-endocrine system, dysfunctional immune system and genetic factors. Although a particular pathology underlying major depressive disorder has not been identified, the disorder is linked with multiple brain abnormalities. One such brain abnormality is in the monoamine neurotransmitter system. Considerable evidence supports the hypothesis that insufficient monoamine activity (serotonin, dopamine and norepinephrine) is linked with depressive disorders (Goldman, Glei, Lin, & Weinstein, 2010; Leggio et al., 2013; Mahar, Bambico, Mechawar, & Nobrega, 2014; Moret & Briley, 2011). Monoamines are responsible for transmission and regulation of behavioural and cognitive processes in individuals, such as mood, sleep, attention, memory, motor activity, pain control and temperature regulation, through transmission and regulation of synaptic impulses within nerve cells (Barrett, Boitano, Barman, & Brooks, 2012). Serotonin plays a major role in mood and behaviour regulation and a considerable amount of research has established that there is link between lowered serotonin levels and increased risk of suffering from depression (Mahar, Bambico, Mechawar, & Nobrega, 2014). Most antidepressant medications currently available to treat depression act on the serotonin neurotransmitter system pathway to increase the level of serotonin in the body (Moret & Briley, 2011). The increased

level of serotonin improves mood and other cognitive functions, which, in turn, decrease depressive symptoms in the affected individual.

In addition to serotonin, dopamine and norepinephrine also play an important part in the pathogenesis of depression. Emerging evidence shows that a dysfunctional dopamine system is also associated with the pathophysiology of depression (Grace, 2016; Leggio et al., 2013). In his review of dysfunctions of the dopamine system associated with the pathophysiology of depression and schizophrenia, Grace (2016) found that some major symptoms of depression, such as anhedonia[7], amotivation and psychomotor retardation, are more persistently associated with an abnormal dopamine system than an abnormal serotonin system. Expressions of dopamine neurons are often diminished and down regulated in chronic stress and depressive disorder (Leggio et al., 2013).

Moret and Briley (2011) showed evidence that reduction of norepinephrine levels in individuals with depression currently in remission or no longer taking medication is associated with rapid reappearance of depressive symptoms. However, depletion of norepinephrine levels did not result in depressed mood in healthy individuals.

There is a strong genetic and familial predisposition to depression, especially in early onset depression. Findings from multiple twin and family studies suggest that depression has a 37% heritability with a two-to-fourfold increase in the risk of suffering from major depressive disorder among first degree relatives (Lohoff, 2010). Although the number and identity of the causative genes for the disorder are yet to be discovered, serotonin transporter gene is thought to have a link with the disorder (Colledge, Walker, Ralston, & Davidson, 2014; Risch et al., 2009).

2.2.3.2 Psychological and behavioural factors

Adversity in childhood, stressful life events, and emotional deprivation in early life often precipitate depressive episodes in individuals (Colledge et al., 2014; Murtagh, 2015; Risch et al., 2009). Evidence suggests that repetitive negative thinking and rumination contribute significantly to the development of major depressive disorder (Kertz, Koran, Stevens, & Bjorgvinsson, 2015; Wilkinson, Croudace, & Goodyer, 2013). Such thinking patterns are also associated with poorer treatment outcomes in depressed individuals. Children and adolescents

[7] Anhedonia: 'The loss of pleasure or lack of reactivity to pleasurable stimuli' (Pizzagalli, 2014, p. 394).

are more susceptible to develop depression due to negative thinking and rumination (Wilkinson et al., 2013). Individuals exposed to emotional abuse and deprivation in their early life are more susceptible to developing depression in later life (Calvete, 2014; Shapero et al., 2014). Individuals experiencing major life events, such as loss of intimate family members, loss of job and divorce, are also vulnerable to developing depressive symptoms at some stage in their life (Shapero et al., 2014; Wilhelm et al., 2006). Stressful life events like unemployment, relationship difficulties, financial difficulties, and chronic physical illness also contribute to the development of depression (Shapero et al., 2014). It is possible that stressful psychological factors cause stimulation of serotonin neurotransmission in the human brain, which in turn stimulates cascading of events that lead to low serotonin levels and influence the development of depression (Mahar et al., 2014).

2.2.3.3 Social factors

A lack of close intimate relationships, living alone, lack of social support and decreased physical activity increase an individual's risk of suffering from major depressive disorder (Colman et al., 2014; Santini et al., 2016; Santini et al., 2017; Santini, Koyanagi, Tyrovolas, Mason, & Haro, 2015). In a systematic review of 51 studies investigating the link between social relations, social networks and connectedness with depression in the general population, Santini et al. (2015) concluded that perceived emotional support and large social networks are strongly protective against depression (Santini et al., 2015). In another prospective community-based study conducted in Ireland, strong spousal support and support from friends and children were found to be negatively associated with the onset of depressive symptoms in older men and women (Santini et al., 2016). In adolescents, social support also plays important role in protecting against depression. Colman et al. (2014), in their review of findings from Canada's *National Population Health Survey,* reported that high levels of social support in adolescence, increased physical activity, high levels of education and skills were negatively associated with the risk of suffering from depression in later life. Increased participation in social or recreational activities was also found to be associated with decreased risk of depression in adults (Santini et al., 2017). All studies cited in this section reported interpersonal stress, social isolation and rejection, and decreased physical activity as strong predictors for the onset of depression. *The social signal transaction theory of depression* may offer an explanation for this response. The theory hypothesises that biological responses activated in times of actual physical threat and injury are also activated by social and psychological stresses (Slavich & Irwin, 2014). The biological response in such conditions includes activation of inflammatory

processes that, in turn, cause increased amounts of pro-inflammatory cytokines[8] in the body. These pro-inflammatory cytokines can cause profound behavioural changes that initiate depressive symptoms such as low mood, anhedonia, fatigue, psychomotor retardation and social withdrawal (Slavich & Irwin, 2014).

2.2.4 Treatment of depression

The Royal Australian and New Zealand College of Psychiatrists has developed comprehensive evidence-based clinical practice guidelines for treatment of depression (Malhi et al., 2015). These are summarised in Table 2.3. The guidelines recommend a step-up[9] approach to treatment of depression to prevent further episodes of depression following treatment. According to the recommendation, psychosocial treatments alone are adequate for mild-to-moderate episodes of depression. More severe episodes may require treatment with antidepressant medication or a combination of psychological and pharmacological treatment. Pharmacotherapy is essential in severe episodes of depression. In high-risk cases, like severely depressed individuals with suicidal ideation or refusal to eat, urgent intervention with electro-convulsive therapy is recommended (Malhi et al., 2015).

Use of antidepressant medication has changed over time. First generation antidepressants, such as tricyclic antidepressants (commonly referred to as tricyclics) and monoamine oxidase inhibitors (commonly referred to as MAOIs), were used as the first line of treatment for major depression (Berton & Nestler, 2006). Currently, second-generation antidepressants, such as selective serotonin receptor inhibitors (commonly referred to as SSRIs) and serotonin norepinephrine reuptake inhibitors (commonly referred to as SNRIs) are the first choice of treatment for depression because of their increased tolerability and safety profile (Leggio et al., 2013). The mechanism of action of these medication groups involves inhibition of reuptake of serotonin or norepinephrine, antagonism of inhibitory pre-synaptic serotonin or norepinephrine receptors, or inhibition of monoamine oxidase. All these mechanisms cause enhanced activity of these neurotransmitters and improve depressive symptoms in individuals (Leggio et al., 2013; Moret & Briley, 2011). These antidepressants are used as a single type of medication, one or another according to the patient's response to treatment (Leggio et al., 2013). In one

[8] Tumour Necrosis Factors (TNF –α), Interleukin 1 (IL-1) and Interleukin-6 (IL-6) are the pro-inflammatory cytokines of the body. These are considered as the main mediators of the inflammatory process and together co-ordinate to enhance and stimulate inflammation in human body (Slavich & Irwin, 2014).

[9] A Step-up care is defined as the supportive and rehabilitative healthcare given to a patent with slowly progressing condition requiring increased (stepped-up) levels of care over time.

exception, a combination of MAOIs and one other antidepressant is sometimes prescribed to achieve maximum efficacy for the management of treatment resistant depressive disorder not responding to single antidepressant therapy (Thomas, Shin, McInnis, & Bostwick, 2015).

Table 2.3: Management of depression or major depressive disorder

Goal: The goal of the treatment is complete remission of depression with full functional recovery and development of resilience.

Step 0:

- Taper and cease any agents that can essentially lower mood.
- Institute sleep hygiene.
- Implement appropriate lifestyle changes e.g. smoking cessation, adopt regular exercise and achieve a healthy diet.
- Address substance misuse if relevant**.**

If step 0 is insufficient, follow step 1:

STEP: 1

General psychosocial interventions

1. Psychoeducation (family, friends, caregivers)
2. Low intensity psychosocial intervention (internet-based education, low-intensity CBT)
3. Family support groups, community group.
4. Employment, housing

Formulation based interventions

Psychological therapies:

1. Cognitive behavioural therapy (CBT)
2. Interpersonal therapy
3. Acceptance and commitment therapy
4. Mindfulness based cognitive therapy

Pharmacotherapy

- **First line**

Selective Serotonin Receptor Inhibitors (SSRI), Serotonin Norepinephrine Reuptake Inhibitors (SNRIs), Noradrenergic and Specific Serotonergic Antidepressants (NSSAs), Norepinephrine Dopamine Reuptake inhibitors (NDRIs), Noradrenaline Reuptake Inhibitor (NaRIs)

- **Second line**

  Tricyclic Antidepressant (TCAs), Monoamine Oxidase Inhibitors (MAOIs)

If Step 1 is insufficient, follow Step 2.

Step 2:

- Combine pharmacotherapy and psychotherapy.
- Increase dose of antidepressant medication.
- Augment antidepressant medication with lithium or antipsychotic medication.
- Combine antidepressants.
- Repetitive Transcranial Magnetic Stimulation (rTMS)[10]- if available

If step 2 is insufficient, Step 3.

Step 3: Electroconvulsive therapy (ECT)

Source: Royal Australian and New Zealand College of Psychiatrists clinical practice guidelines for mood disorders

[10] 'Repetitive Transcranial Magnetic Stimulation (rTMS) is a non-invasive technique for modulating cortical and sub-cortical function with the use of rapidly changing electro-magnetic fields generated by a coil placed over the scalp' (Berlim, Van den Eynde, & Jeff Daskalakis, 2013, p. 543).

However, a significant number of individuals with depression fail to show improvement in their symptoms or complete remission even after multiple antidepressant medications (Leggio et al., 2013). Leggio et al. (2013) report that around 37% of people with depression show resistance to antidepressant therapy after treatment with at least two antidepressant medications, and only 37% shows complete remission after treatment. The cause of treatment resistant depression is unclear, but some evidence suggests that the lack of exact aetiology may play a part (Leggio et al., 2013).

Use of antidepressants can have significant side effects and individuals must follow specific precautions while taking these medications (Bet, Hugtenburg, Penninx, & Hoogendijk, 2013; Correll, Detraux, De Lepeleire, & De Hert, 2015). In addition, most antidepressant medications are relatively contraindicated during pregnancy because they can exert a harmful effect on the foetus (Ray & Stowe, 2014). Use of antidepressants during pregnancy is often determined by a risk–benefit analysis. Even those antidepressants that are safer for use during pregnancy are reported to increase the risk of children developing autism spectrum disorder in later childhood (Boukhris, Sheehy, Mottron, & Berard, 2016). Hence, more emphasis is now being placed on the use of psychosocial therapies for treatment of perinatal or antepartum depression.

2.2.4.1 Psychosocial interventions for depression

Psychotherapies or psychosocial interventions are considered the first line of treatment for mental disorders such as depression and anxiety (Abbass et al., 2014). Psychosocial interventions may range from simple psychoeducation, guided self-help and increased social and family support to more advanced psychotherapies like cognitive behavioural therapy (CBT), interpersonal therapy (IP), problem solving therapy and mindfulness-based cognitive therapy (Patel et al., 2007). In a meta-analysis of 25 RCTs examining the effect of psychological therapies on preventing depressive episodes in individuals diagnosed with major depressive disorder, Biesheuvel-Leliefeld et al. (2015) showed that psychological treatments were effective in preventing recurrence or relapse of major depressive episodes. Individuals receiving psychological treatment showed significant improvement compared with those not receiving psychological treatment for over two years. Biesheuvel-Leliefeld et al. (2015) also provided evidence that psychological treatments were more effective than treatment with antidepressant medication in preventing relapse or recurrence in individuals suffering major depressive disorder. The preventive actions of the psychological interventions were also

increased in individuals with major depressive disorder, particularly individuals who received therapy during the acute phase of the disorder. Hetrick, Cox, Witt, Bir, and Merry (2016), in their systematic review of the effectiveness of psychological treatments such as CBT and IP in reducing the risk of onset of depressive disorders in children and adolescents, indicated that psychological therapies exerted small yet significant effects on reducing the risk of onset of depression. However, the review provided inconclusive findings about the effectiveness of psychological treatments and the authors believed further large-scale research was warranted to establish the importance of psychological therapies in preventing depression in children and adolescents.

In another meta-analysis, Cuijpers et al. (2014) examined the effectiveness of psychotherapies in reducing sub-clinical depressive symptoms and examined whether the effects were comparable with the effects of psychological treatments for major depression. It was found that psychotherapies exert small-to-moderate, statistically significant effects on sub-threshold depression compared with as-usual care and they were able to reduce significantly the onset of depression at 6- and 12-month follow-up. However, the effects were found to be much less than the effects of conventional psychological treatment of major depression. The therapies used in the studies included in the meta-analysis were mostly based on CBT.

Psychological therapies involve a variety of treatment strategies and aim to develop a relationship with the client through structured and purposeful engagement. The common aim is to increase awareness and modification of maladaptive thoughts and behaviour to positive, meaningful action to improve the overall mental health well-being of the individual (Cox et al., 2014).

2.3 Overview of depression in pregnancy

During the childbearing years, particularly during pregnancy and the year following childbirth, women are more vulnerable to depression than at any other period of life (BeyondBlue, 2015; Kessler & Bromet, 2013). According to DSM-5, perinatal depression is defined as the onset of a major depressive episode during pregnancy or within four weeks after delivery of the baby (American Psychiatric Association, 2013). Antepartum depression is the term for depression during pregnancy and postnatal depression is the term for depression that occurs within one year of childbirth (Robertson, Celasun, & Stewart, 2008). Globally, perinatal, antepartum and postpartum depression are common in women, but, unfortunately, most affected women do not seek help during this period. In addition, and until recently, most literature has focused only on

postpartum depression (Davalos, Yadon, & Tregellas, 2012). However, current evidence suggests that antepartum depression is as common as postpartum depression and may exert similar long-term adverse effects on the mother and the baby during and after pregnancy. Furthermore, around half of the major postnatal depressive episodes actually begin in the antenatal period (American Psychiatric Association, 2013). For these reasons, it is important to screen for depressive symptoms in the antenatal period and to intervene as early as possible to reduce the progression of this mental disorder.

2.3.1 Prevalence of antepartum depression

Depression is the most common mental disorder that affects women during pregnancy (Fisher et al., 2012a). At least 15% of pregnant women worldwide suffer from mild-to-moderate depression during pregnancy (Atif et al., 2015; Fisher et al., 2012; Zafar et al., 2014). In a meta-analysis of 66 studies investigating the prevalence of antenatal and postnatal co-morbid anxiety and depression conducted across 30 HICs, such as USA, Australia, Canada and Brazil, Falah-Hassani et al. (2017) reported that the overall prevalence of co-morbid anxiety and mild-to-severe depressive symptoms across the pregnancy was 9.5%. Women residing in LMICs are more vulnerable to developing depressive symptoms during their pregnancy and they also have inadequate access to appropriate health care (Fisher et al., 2013), yet there is limited evidence from LMICs regarding the prevalence of antepartum depression. Furthermore, most studies on the prevalence of perinatal depression from LMICs have been based on participants presenting to health centres or antenatal clinics (Fisher et al., 2013). Some community-based studies reported a much higher prevalence of perinatal depression in women residing in rural low-resource areas of LMICs (Atif et al., 2015). The prevalence of antepartum depression reported by these studies was 22% in Vietnam (Fisher et al., 2013), 25% in Pakistan (Rahman, Iqbal, & Harrington, 2003), 46% in South Africa (Hartley et al., 2011; Rochat, Tomlinson, Bärnighausen, Newell, & Stein, 2011) and 59.5% in Ethiopia (Hanlon et al., 2008). In Sri Lanka, the prevalence of depression among first-time pregnant women was reported to be 10.4%, while another study conducted in Sri Lanka reported a prevalence of 16.2% (Herath, Balasuriya, & Sivayogan, 2017). In another study conducted to identify the presence of depressive symptoms among Asian women living in the UK, Dhillon and MacArthur (2010) found the prevalence of antepartum depressive symptoms was 30.7% (Dhillon & Macarthur, 2010), which was greater than the prevalence found in Pakistan (25%) and Vietnam (22%) (Atif et al., 2015). The study did not examine the reasons for the high prevalence of antepartum depression among Asian women living in UK. It searched for a possible link between male

gender preference for babies and increased risk of antepartum depression but did not find any connection.

To date, few studies have been conducted on women with antepartum depression in Bangladesh. Just two studies on depressive symptoms in pregnant women in rural areas of the country were located in the literature, both reporting the prevalence of sub-threshold depressive symptoms as measured by the Edinburgh Postnatal Depression Scale (EPDS). Gausia, Fisher, Ali, and Oosthuizen (2009) examined the prevalence and contributory factors for depressive symptoms among pregnant women in rural Bangladesh. The community-based study included 361 pregnant women residing in the Matlab sub-district of Chandpur district of Eastern region of the country. The findings showed that 33% of participants suffered from depressive symptoms during pregnancy and 14% of these had thoughts of self-harm during their pregnancy. In a similar population-based cohort study conducted in two rural sub-districts of Mymensingh district, Nasreen, Kabir, Forsell, and Edhborg (2011) explored the prevalence and associated factors for depressive symptoms and anxiety among rural pregnant women. In comparison to the previous study by Gausia et al. (2009), this study had a larger sample size of 720 randomly selected pregnant women in the third trimester of pregnancy. The results showed that 18.3% of the women suffered from depressive symptoms, 29.4% had symptoms of anxiety, and 3.4% had depressive and anxiety symptoms. Overall, both studies examined the prevalence of depressive symptoms among pregnant women rather than clinical depression. The contributory factors that were identified in both studies were domestic violence, including intimate partner violence, poor relationships with their husband and other family members, financial difficulties, previous history of depressive symptoms, and lack of social and family support (Gausia et al., 2009; Nasreen et al., 2011).

2.3.2 Risk factors for antepartum depression

Atif et al. (2015) identified three key risk factors for antepartum depression in LMICs in their systematic review of the magnitude of antepartum depression, the impact of antepartum depression on maternal and child health and interventions for maternal mental health disorders. The first group of risk factors was socioeconomic vulnerability, including poverty, unemployment, illiteracy, and lack of empowerment in women. The second group of risk factors was negative life experiences, including unplanned pregnancy, previous history of stillbirth or current pregnancy complications, previous history of mental disorder, being single or divorced, and financial difficulties. The third group of risk factors included inter-relational

problems, intimate partner violence and verbal abuse, hostile in-laws, and inadequate family support during pregnancy. These risk factors, along with social stigma and delayed care-seeking behaviour, often led to adverse consequences for the health of the mother (Atif et al., 2015; Islam & Biswas, 2015). In a community-based observational study among rural pregnant Bangladeshi women examining the associations between different forms of domestic violence, emotional distress and cortisol levels, Ziaei, Frith, Ekstrom, and Naved (2016) found that 57% of participants had experienced at least one form of domestic violence in their lifetime. This included physical, sexual, and emotional violence and controlling behaviour. The most common forms of violence experienced by participants were controlling behaviour (36.8%) and emotional violence (27.5%). Women experiencing intimate partner violence were found to be at higher risk of developing emotional distress during their pregnancy. The findings also indicated a strong association between emotional violence and increased risk of suicidal ideation among participants (Ziaei et al., 2016).

In some countries, a cultural preference for newborn babies to be of male gender was found to be associated with a high risk of perinatal depression. Protective factors against depression that were identified were a high level of education, presence of practical social and emotional support, being from the ethnic majority, having permanent employment, and having a supportive partner (Atif et al., 2015). Studies included in the systematic review of Atif et al. (2015) were mostly conducted in low-resource settings in Bangladesh, Pakistan and India.

2.3.3 Impact of antepartum depression on mothers' and children's health

Several studies from LMICs have reported detrimental effects of antepartum depression on the health of mothers and their children (Atif et al., 2015). Depression is associated with poor pregnancy outcomes such as preterm birth and spontaneous abortions (Woods, Melville, Guo, Fan, & Gavin, 2010; Atif et al., 2015). In addition, antepartum depression is considered the main risk factor for developing postpartum depression and psychosis (Milgrom et al., 2008; Robertson, Grace, Wallington, & Stewart, 2004). Untreated antenatal depression puts mothers at greater risk of suffering postpartum depression with or without functional disability and suicidal ideation, and poor parenting problems, with growth and nutrition problems in children (Atif et al., 2015; Nasreen, Kabir, Forsell, & Edhborg, 2010). Suicide is an important cause of mortality in pregnant women from HICs and LMICs (Fisher et al., 2012; Lindahl, Pearson, & Colpe, 2005; Palladino, Singh, Campbell, Flynn, & Gold, 2011). In a study of suicide and homicide deaths during pregnancy and the perinatal period in the USA, Palladino et al. (2011)

found that the incidence of suicide and homicide related death during pregnancy was 2.0 to 2.9 per 100,000 live births. Lindahl et al. (2005), in their systematic review of the prevalence of suicidal ideation, deaths, attempts and thoughts of self-harm, reported that around 5–14% of pregnant women have suicidal or self-harm ideation during and after pregnancy. The study also reported that around 20% of deaths in the postpartum period were due to suicide (Lindahl et al., 2005). Thoughts of self-harm were found to be more common than suicidal attempts or ideation. Gausia et al. (2009), in their study on antepartum depression and suicidal ideation among pregnant women in rural Bangladesh, reported that around 17% of participants had thoughts of self-harm during their pregnancy.

Evidence from LMICs including Bangladesh suggests that antepartum depression is linked to poor growth *in utero* and babies with low birth weight (Joanna Maselko et al., 2014; Nasreen, 2011; Nasreen et al., 2010). Children of depressed mothers also suffered more from under-nutrition and illnesses like diarrhoea and respiratory infections than children of non-depressed mothers in the same region (Nguyen et al., 2014). A link between maternal depression and impaired cognitive development in children and delay in achieving other developmental milestones has been reported in a systematic review by Atif et al. (2015). Another study by Woods et al. (2010) suggested that children of depressed mothers are more likely to be at increased risk of developing social and behavioural problems in later life than children of non-depressed mothers.

2.3.4 Psychosocial interventions for perinatal depression

Until recently, the focus of depression associated with pregnancy has been mainly on postpartum depression. Hence, most interventions focus on postpartum depression, with only a few focusing solely on antepartum depression (Clarke, King, & Prost, 2013; Rahman, Surkan, et al., 2013). In addition, there is a shortage of low-intensity interventions focusing only on antepartum depression that are feasible for use in low-resource settings (Jesse, Kim, & Herndon, 2014). According to WHO, low-intensity psychological interventions are modified, evidence-based psychological treatments, such as brief, basic versions of existing evidence-based psychological treatments (e.g., cognitive-behavioural therapy, interpersonal therapy). delivered by paraprofessionals. The term ‘low intensity’ indicates a less intense level of specialist human resource use. It means that the intervention has been modified to use fewer resources than conventional psychological treatments by specialists (World Health Organization, 2014). Although researchers from LMICs have developed some psychosocial

interventions for low-resource settings, the main focus of these interventions has been on maternal mental health during the postnatal period (Chowdhary et al., 2014; Patel et al., 2011; Rahman, Fisher, et al., 2013).

Chowdhary et al. (2014) discussed the content and delivery of such interventions and their feasibility in their systematic review of non-specialist health worker based, low-intensity psychosocial interventions for perinatal depression in LMICs. The review included nine studies in which the interventions were delivered during the antenatal period and extending into the postnatal period. Four of nine studies used changes in perinatal depressive symptoms as the primary outcome. The primary outcomes in the other studies were the physical health of mother and infant, quality of mother–child interaction, infant weight and height, child development'. (Chowdhary et al., 2014, p. 116). Four studies adapted the intervention from evidence-based psychosocial treatment such as IP, CBT and problem-solving therapy. One study used an adaptation of a pre-existing preventive mother–infant intervention programme and another study adopted a psychoeducation programme. In the remaining studies the interventions were designed and developed particularly for the context of the study (Chowdhary et al., 2014). Evidence from the systematic review showed that it was feasible to carry out low-intensity, non-professional led interventions in low-resource settings in LMICs. However, adequate training and supervision for the non-specialist health workers who delivered the interventions was not always possible; hence, there was inconclusive evidence about the efficacy of the interventions.

To date, only one study could be located using a psychosocial intervention focusing solely on antepartum depressive symptoms. The intervention was developed for women with low incomes living in rural North Carolina, USA (Jesse et al., 2010; Jesse et al., 2015). In an RCT of the intervention, Jesse et al. (2015) evaluated the feasibility and efficacy of a culturally tailored modified CBT programme in reducing antepartum depressive symptoms in 147 pregnant mothers registered with a local health department. Only pregnant women experiencing depressive symptoms in their pregnancy were included. The study distinguished between pregnant women suffering from antepartum depressive symptoms and those suffering from clinical antepartum depression. Pregnant women with high scores on screening tools and who indicated having suicidal ideation or thoughts were referred to their respective pregnancy care manager or physician for further evaluation of their severe depressive symptoms. The participants were randomised into control and intervention groups. The intervention group

received a six-week intervention that included group and individual sessions delivered by non-mental health specialist social workers and nurses. The control group continued with their usual care during pregnancy. The outcomes showed a significant improvement in depressive symptoms among women in the intervention group compared with those in the control group. Taking part in the intervention significantly reduced depressive symptoms in women at high risk of developing depression. Women in the intervention group also perceived the intervention to be useful and continued to use the techniques learned even after the end of the intervention. However, the study had a high attrition rate of 35% because of participants' other commitments such as childcare, school schedules, work and inconvenience of attending the intervention's two-hour sessions. Nevertheless, the feasibility of implementing such a CBT-based intervention for antepartum depressive symptom in primary care settings was established in that study. The study also highlighted the need for further research on ways to promote greater participant engagement to prevent high attrition among rural low-income pregnant women.

2.4 Maternal and mental health care systems in Bangladesh

Maternal health service provision is an important indicator of the overall health system capability of any country. Improving maternal and child health care is a top priority in the health system in Bangladesh. In the last 20 years, the government of Bangladesh has taken extensive measures to improve maternal and reproductive health care in rural areas. According to the *Millennium Development Goals Progress Report 2015*, Bangladesh had achieved the goal of improving maternal health by 2015 (Anwar, Nababan, Mostari, Rahman, & Khan, 2015; Das, 2015; Pulok, Sabah, Uddin, & Enemark, 2016). Bangladesh achieved a 40% decrease in maternal mortality rate between 2001 and 2010, from 322 to 194 per 100,000 live births (General Economics Division, Bangladesh Planning Commission, & Government of the People's Republic of Bangladesh, 2015; Nguyen et al., 2012). These achievements may be attributable to the implementation of *National Health Care Policy 2010,* which included measures such as strengthening the primary health care system at village level, extending the use of information and communication technology, and improving government and non-government collaboration in extending women-focused health care to the low-resource settings of rural Bangladesh (Chowdhury et al., 2013). Hossain et al. (2014) showed evidence that Bangladesh achieved significant improvements in some health indicators, such as maternal mortality rate, infant and under-5 mortality rate, extended vaccination and oral dehydration programmes, compared with South Asian countries such as India, Pakistan, Nepal, Laos and Myanmar. Public health expenditure in Bangladesh is also greater than that of most of these

countries except Nepal and Laos. However, Bangladesh lags behind these neighbouring countries in some other health indicators, such as antenatal health care use, skilled birth attendants and institution-based delivery.

Although the country has achieved significant improvements in extending basic maternal health care services in rural low-resource settings, health-seeking behaviours among pregnant women is very low. The *Bangladesh Demographic and Health Survey 2014* found that only 50% of pregnant women attended at least one of the four recommended antenatal check-ups during their pregnancy (National Institute of Population Research and Training, Mitra and Associates, & ICF International, 2015) and only around 25% of pregnant women attended antenatal clinics for all four antenatal check-ups. Only 43.5% of live births were attended by skilled health professionals, trained birth attendants assisted in another 10% deliveries, untrained birth attendants assisted in more than one-third (38%) of live births, while experienced relatives or friends who had previously assisted at or attended deliveries were present at the remaining 7% of live births (National Institute of Population Research and Training et al., 2015). Factors such as birth order, maternal education, financial capabilities, and access to local health care play an important role in such help-seeking behaviour in the country. Until now, the focus of the antenatal heath care system in Bangladesh has been on reducing maternal mortality and ensuring universal access to health care. In these circumstances, mental health is often overlooked during antenatal care. The clinical practice guidelines for the country are yet to incorporate and adopt regular screening for depression and other common mental health disorders during routine antenatal visits (Hossain et al., 2014). Analysis of the Demographic and Health surveys of Bangladesh and other LMICs have indicated that the foci of antenatal care are mostly on advising women on regular healthy eating and ensuring regular oral vitamin intake, measurement of weight and blood pressure, routine laboratory investigations (Benova, Tuncalp, Moran, & Campbell, 2018; Islam & Masud,2018; National Institute of Population Research and Training et al., 2015).

Mental health is a neglected domain in the Bangladesh health system (Anwar et al., 2015; Hossain et al., 2014). Islam and Biswas (2015), in their situation analysis of the mental health care system in the country, reported that around 16% of the total population were estimated to be suffering from a mental disorder (Islam & Biswas, 2015). Another systematic review of mental disorders in Bangladesh reported the prevalence to range from 6.5% to 31% among adults and 13.4% to 22.9% in the population aged below 16 years (Hossain et al., 2014). These

numbers clearly identify mental disorders as a major public health problem in this LMIC (Islam & Biswas, 2015; World Bank, 2015). Nevertheless, only 0.5% of total health expenditure is allocated to mental health care in Bangladesh, and of the total budget allocation to mental health, 67% is spent on psychiatric hospitals (Islam & Biswas, 2015). Health expenditure for improving and extending mental health care services at primary and secondary health care level is minimal or non-existent (Hossain et al., 2014; Nguyen et al., 2012). Furthermore, Bangladesh currently has an acute shortage of skilled mental health professionals. There are only 0.49 professionals per 100,000 population who are trained and experienced in providing mental health care services. The number of psychiatrists per 100,000 population is just 0.073 and most of these are based around the capital city, Dhaka (Islam & Biswas, 2015). There are only 0.18 general physicians per 100,000 population who work in mental health facilities but do not specialise in psychiatry. Other mental health professionals include nurses, psychologists, social health workers, occupational therapists and other mental health workers. More than half (62%) of these professional's work in specialised government mental health care facilities, and the remainder are based in non-government and private mental health facilities. Facilities are based mainly in urban areas. As a result, there is a disproportionate distribution of mental care professionals between rural and urban areas. People residing in rural low-resource areas often do not have proper access to the necessary mental health services.

2.5 Summary

Globally, depression is a major and increasing public health problem. Although a number of biological, social and behavioural factors contribute to the development of depression, the exact cause of the disorder is yet to be established. The disorder can affect all individuals irrespective of age, sex, religion and geographical area. Women are up to three times more susceptible to developing the disorder than men. In particular, women of reproductive age are at increased risk of developing depression, with around 10–15% experiencing depressive symptoms during their pregnancy. Women residing in rural low-resource settings of LMICs are more vulnerable to developing depression. Factors such as intimate partner violence, illiteracy, lack of awareness, limited access to mental health services, fear of stigmatisation and pre-existing financial and social problems make women in these areas more susceptible to developing depressive symptoms during their pregnancy. Existing literature focuses mainly on postpartum depression, whereas antepartum depression is equally common and has similar negative effects on the health of pregnant women and their babies. It is important to address depressive symptoms during pregnancy to reduce their harmful effects on maternal and child

health. Psychotherapies are considered the most effective treatments for depression during pregnancy, because antidepressant medication can have negative effects on the unborn child. However, because of lack of adequate mental health professionals, traditional psychotherapies are often not suitable to be integrated in primary health care settings in low-resource areas. Hence, there is need for research to develop non-professional low-intensity psychotherapies which are particularly useful for low-resource settings like rural Bangladesh, where mental health is a substantially neglected sector in the country's health system.

CHAPTER THREE:
Peer support

3.1 Introduction

In this chapter, an overview of literature on peers and peer support programmes is presented. It starts with the definitions and characteristics of a peer, followed by a definition of peer support services. Then, the theoretical perspective for services and the five most commonly described theories underlying peer support programmes are summarised. Next, a discussion on the services in general health care settings is presented, followed by an overview of peer support in mental health care. Finally, literature on peer support for antenatal and postnatal depression is discussed.

3.2 Concept of peer support

Peer support, in general, can be described as a sharing of experiences and knowledge between two individuals and using that knowledge to overcome the common situation that both have experienced or are now experiencing. Researchers have defined peer support in various ways. Definitions in the literature focus mainly on the role and nature of the services peers provide. While there is no clear definition of peer support, most definitions are based on the peers' role in mental health care. Mead, Hilton, and Curtis (2001) defined peer support as, 'a system of giving and receiving help, founded on key principles of respect, shared responsibility and mutual agreement of what is helpful' (p. 6). Mead et al. (2001) described the concept of peer support as building up an inter-relational connection or affiliation between two individuals having a shared experience. This connection empowers the two individuals to share knowledge learned through the commonly lived experience and discuss possible ways of overcoming the situation, without having the constraints of traditional relationships like parent, spouse or sibling. Instead of being labelled as a 'patient' or 'disabled,' as in professional health care settings, peer support offers a non-judgmental and resourceful platform for affected individuals. This platform allows the person and the peer to work together independently to move beyond and overcome the illness through developing trust and building community support (Mead et al., 2001; Mead & MacNeil, 2006). Solomon (2004) describes peer support as a system of extending support and assistance through offering empathy and companionship, with a view to helping the affected individual with the symptoms of mental conditions. As Solomon (2004) defines, 'Peer support is social, emotional support, frequently coupled with

instrumental support, that is mutually offered or provided by persons having a mental health condition to others sharing a similar mental health condition to bring about a desired social and personal change' (p. 393). The support can be either in-group or individual face-to-face sessions or through Internet or telephone support. Repper and Carter (2011) further described peer support as an approach for promoting well-being in individuals, focusing on strengths and recovery through shared experienced and empathy.

The core concept of peer support is based on fostering positive attitudes and self-confidence in being able to function efficiently and independently. As opposed to an illness model that focuses on an individual's symptoms or problems, peer support focuses more on the person's ability for self-improvement and motivation for overcoming the stressful situation (Repper and Carter (2011). The American Academy of Family Physicians described four key functions of peer support services for general and mental health settings (Fisher et al., 2015). The Academy defined the concept of peer support service based on the functions the service provides rather than focusing on the individuals that deliver the support service or the implementation process of the service. The functions are to provide: (1) support in day-to-day management to pursue specific treatment-related goals developed with the clinical team, (2) social and emotional support to cope with negative emotions and encourage helpful behavioural actions, (3) a platform to link clinical care with community resources, and (4) ongoing support for prevention and management of chronic diseases that reflects the lifelong characteristics of such conditions.

Within the context of peer support, it is important to discuss and understand the characteristics of the delivery agent, the peer, in a peer support programme. A 'peer' means 'a person of the same age, status or ability as another specified person' (Oxford English Dictionary, 2017). In healthcare settings, a peer is a person who shares similar characteristics or an illness with the target group and agrees to help another individual in the target group either voluntarily or on a paid basis. Solomon (2004) and Tse et al. (2017), in their discussion of peer support for mental health care services, included two more comprehensive definitions of a peer for mental health care. Solomon defined a peer as 'an individual with severe mental illness who is or was receiving mental health services and who self-identifies as such' (p. 393). Tse et al. (2017) defined peer workers as 'individuals recovering from mental illnesses who identify themselves positively as such and have a strong desire to use their lived experiences to help others with similar conditions' (p. 27). Simoni, Franks, Lehavot and Yard (2011), in their conceptual analysis of peer interventions to promote health, proposed four characteristics of peers. First,

peers do not necessarily have to share the same health condition or illness as the target population to provide peer support (Simoni et al., 2011). The shared characteristics may include being in the same group category (such as gender, ethnicity, education), occupying a similar role (being a mother), having a similar experience (history of abuse), and a having a history of going through a similar stressful life situation such as divorce or loss of a close relative. Second, the benefit of peer support derives primarily from shared experience and knowledge of a commonly experienced situation between two individuals rather than the advantages of the support they provide. Third, peers do not have professional training or qualifications for the support they provide; they are trained specifically for the intervention as part of a peer support programme. Finally, the peer's role does not signify the naturally occurring social network and interactions of a family member, friends or community. Peers are selected or volunteer specifically for their particular role. They are then trained for a particular support programme (Simoni et al., 2011).

3.3 Theoretical framework for peer support

Most existing literature on peer support interventions lacks discussion of the theoretical perspective of peer-based interventions (Simoni, Franks, Lehavot, & Yard, 2011). As far as can be established, few researchers have attempted to explain the concept of peer support services while describing the peer-based intervention (Rogers, 2017; Simoni et al., 2011). Simoni et al. (2011) and Solomon (2004) are among the few researchers who have offered a comprehensive theoretical analysis of peer support services and discussed possible theories that support the underlying processes for peer support services**.** These researchers have described five conventional theories that underlie peer delivered services: social support theory, social comparison theory, social cognitive or learning theory, helper therapy principle, and experiential theory. Furthermore, Simoni et al. (2011) included two additional theories for peer support services: dynamic social impact theory and social network theory.

Social support theory

Social support theory is the most popular and comprehensive theory that researchers use to describe how peer support services can help improve health outcomes (Chinman et al., 2014; Simoni et al., 2011). Social support is defined as the availability of support and perception from others that individuals are cared for, loved and valued, and are part of a community that they can rely on to meet their psychological needs (Kim, Sherman, & Taylor, 2008; Solomon, 2004). Numerous studies have demonstrated that social support can have a positive influence on

individuals' mental and physical health (Chronister, Chou, & Liao, 2013; Kim et al., 2008; Mead et al., 2001; Santini et al., 2016; Simoni et al., 2011). Simoni et al. (2011) described some possible physiological and behavioural mechanisms by which social support exerts positive effects on individuals. The first physiological mechanism is that the presence of close relatives creates a state of calmness in an individual and helps the person to relax during stressful situations. The other physiological effect is that perceived social support enhances and boosts an individual's immune system, which, in turn, helps reduce anxiety and depressive symptoms. The behavioural mechanisms included are decreased threat perception, increased adherence to healthier activities, and increased coping with stressors. Solomon (2004) discussed three types of social support: emotional, instrumental (practical) and informational. Emotional support provides empathy, reassurance and attachment. Instrumental support is provided through materials, goods and services, whereas informational support provides guidance, directions and reviews. In this perspective, peer support helps in building a group of individuals which one can rely on for assistance and who share their ideas and experiences of their illnesses. People with mental illnesses often experience isolation from social groups and their community. They often perceive themselves as separate from their community and believe that their community cannot understand them or the experiences they are going through (Mead et al., 2001; Repper & Carter, 2011). Peer support, therefore, offers a platform that is built on empathy and companionship. It gives individuals the perception that they are not the only one to go through stressful situations in life. It also offers a sense of optimism and helps individuals in need to go through the journey of recovery from the illness through providing emotional and instrumental support (Repper & Carter, 2011; Solomon, 2004). Such support services differ from the naturally occurring support systems of families, friends and relatives. Peers are purposefully selected and specifically trained to match the needs of the individual receiving the peer support. (Simoni et al., 2011). These characteristics, along with the non-reciprocal nature of peer support services, make it more effective and advantageous for individuals compared to the naturally occurring support networks in the community. Nevertheless, as Simoni et al. (2011) highlighted, peer support services based on social support theories also has some disadvantages, which might adversely affect the effectiveness of these services. Peer workers, in general, come in contact with the affected individuals with depression only for the duration of the intervention. This time-limited duration of involvement does not allow the peers to learn about the individual's past experience and learning capabilities to adopt new behaviours. In addition, in contrast to the naturally occurring support systems,

peer involvement in individuals' social networks are less strong. For this reason, the initial effect of peer support services may diminish over time.

Social comparison theory

Social comparison theory revolves around two types of social comparison, upward comparison and downward comparison (Simoni et al., 2011; Solomon, 2004). Upward comparison denotes that people's sense of self-perception and self-evaluation increases on seeing other peers doing better in similar stressful events. It gives them hope and inspires them to strive forward. In peer support services, individuals are given an opportunity to compare themselves with a peer who has done better in coping with the condition. Thus, the individual is motivated towards self-improvement to overcome the illness. In peer support services the peers get a sense of being in a better position than the service recipients. This gives the peers a sense of optimism and motivation for continuous development of their skill to help others to deal with the stressful condition. In contrast, downward comparison puts the individual in a perspective of an individual who is less accomplished in a similar situation.

Simoni et al. (2011) discussed the concept of social comparison theory within the context of the three main 'purposes' (or reasons) for which individuals use knowledge and information derived from other individuals. First, the self-evaluation purpose by which individuals use the received information to verify their opinions and abilities for action in addition to clarifying their emotional state. Second, the self-enhancement or self-protection purpose by which people compare themselves with others who are less privileged (downward comparison) in order to improve their self-esteem. Finally, the self-improvement purpose by which individuals may gain inspiration and hope from others doing well and adopt new knowledge from them in order to overcome difficulties. Peer support services that incorporate all three components of this social comparison process might be maximally beneficial to the service recipients' health and wellbeing. However, it is noteworthy that in some circumstances (e.g., delivering complex and highly technical information) peers might not be the appropriate delivery agent for conveying information. The creditability of a message is sometimes strengthened by the authority of expert health professionals. Furthermore, sometimes biased attitudes and internalised repression may influence the individuals for whom the support is intended to reject peers as less valuable than health professionals.

Social learning theory

The social learning theory of Bandura (1971) hypothesised that individuals learn from direct experience or by observing others. The learning process through direct experience is guided by the successful and unsuccessful consequences of any given action. Individuals often encounter challenging circumstances where they must choose ways to deal with the situation. Some ways may turn out to be successful and some may be unsuccessful. While learning from direct experiences, individuals learn to adhere to the successful ways This, in turn, helps build adaptive thoughts and behaviours that might be helpful in providing guidance for future actions in similar circumstances. In peer support, peers learn from their direct experience of commonly lived situations and develop confidence in dealing with similar situations in the future. Thus, they become capable of providing realistic and unique knowledge that professional service providers cannot offer. Simoni et al. (2011) and Solomon (2004) considered this learning process as a way to improve self-efficacy, where peers become more confident in helping others to cope with their illness.

Helper therapy principle

Helper therapy principle is another therapy that researchers use to describe the underlying process of peer support services. The therapy, originally introduced by Riessman (1965), focuses on peers' perspectives and motivation for providing the service to another individual going through a similar experience. According to Salzer and Shear (2002), the helper therapy principle is based on four benefits that peers gain by fulfilling their role in providing peer support: (1) peers develop an increased sense of self-competency by making an impact on an individual's life through the peer support service; (2) peers perceive the service as an equal opportunity for giving and taking between themselves and others; (3) the helper peer gets the opportunity to gain more 'personalised learning' and skills to handle stressful situations while helping others; (4) the helper peer gets more social approval from those helped and develops an increased sense of 'self' for better engagement with the community**.** Overall, these benefits inspire peers and better position them to help others in need.

Experiential theory

'*Experiential knowledge* is specialised information and perspectives that people obtain from living through the experience of having a severe psychiatric disorder' (Solomon, 2004, p. 394). Solomon (2004) and Simoni et al. (2011) described this knowledge as 'unique', 'pragmatic' and 'specific' to one's circumstances. When the knowledge and information is shared with

someone in a similar situation, the commonalities of the problem emerge and both individuals have an opportunity to use their resources to overcome the situation. Solomon (2004) regarded the process of experiential learning as a more active approach to coping with illness, by promoting self-determination and self-empowerment. Jordi (2010) defined experiential learning as an interactive process between the human concsiousness and mind. The process involves reflections of cognitive process of the human brain through which individual gather knowledge from their experiences.

3.4 Peer support in general health care

Peer support services were first introduced as a way of expanding mental health care in health settings. However, the scope and potential of the services have also been evaluated in general health care settings. At present, peer support services are being implemented in diverse health settings worldwide. Below are examples of some general health conditions where peer support services are being used as part of the total health care regime.

3.4.1 Peer support services for individuals with cardiovascular disease

Cardiovascular disease is one of the major causes of illness and disability worldwide. It exerts chronic disabling effects on individuals' health and well-being (Parry & Watt-Watson, 2010). Currently, peer support services are increasingly being used in cardiovascular health settings (Simoni et al., 2011). In most cases, the services focus on increasing medication adherence and providing social and emotional support to those suffering from chronic disabling heart diseases (Simoni et al., 2011). Parry and Watt-Watson (2010), in their systematic review of peer-based interventions for individuals with heart disease, discussed the effects of peer support services on improving health and well-being of individuals suffering from this condition. The study included six RCTs that evaluated evidence-based interventions to improve health outcomes of individuals with heart disease. Four of the trials were conducted in the USA and one each in Canada and Australia. The outcomes assessed were improvement in symptoms like pain, fatigue and anxiety, and improvement in physical and/or social functioning and self-care. Six trials included in the review reported that the peer support services resulted in significantly improved health status and health behaviours, improved self-efficacy and reduced visits to hospital emergency departments (Carroll & Rankin, 2006; Heller, 1995; Lorig, Ritter, & Gonzalez, 2003; Parent & Fortin, 2000; Riegel & Carlson, 2004; Thoits, Hohmann, Harvey, & Fletcher, 2000). However, given the small sample size of the trials, the usefulness of their results to support the effectiveness of peer support was limited. The systematic review reported

some benefits of peer support in the health care of individuals with heart disease. It was found that peer support interventions had the potential to improve health and well-being in individuals with heart disease. However, the authors also indicated that there was a large gap in research on peer support services in cardiovascular health care settings. Studies included in the review did not discuss mechanisms of how peer support services benefited individuals with heart disease. In addition, there was lack of theoretical basis for the peer-based interventions selected in the studies.

3.4.2 Peer support for individuals with diabetes mellitus

The treatment of diabetes is long term and requires multidisciplinary management from multiple resources. Peer support services are popular for improving health outcomes in individuals suffering from diabetes (Johansson et al., 2016). The American Academy of Family Physicians, in collaboration with an associated pharmaceutical company, established the Peer for Progress project in 2006 for individuals with diabetes and other health problems worldwide (E. B. Fisher et al., 2015). The aim of the project was to promote peer support programmes and establish and integrate evidence-based peer support services in general health care settings, particularly for the management of diabetes. In an evaluation of the contribution of peer support programme in health care, E. B. Fisher et al. (2015) found that peer support programmes were feasible for use across a broad range of settings, including high- and low-resource settings. The review also provided evidence that the peer support programme had led to significant improvements in clinical outcomes, specifically reduction in HbA1c, enhanced medication adherence and improvement in self-management. Fisher et al. (2015) reported that after the conclusion of funding from the Peer for Progress programme, multiple health care settings in Thailand, China and UK decided to continue with the programme.

In a systematic review, Dale, Williams, and Bowyer (2012) discussed the effects of peer support services on health outcomes of individuals with diabetes. The review included 25 studies, of which 17 were conducted in the USA, four in the UK, and one each in Ireland, Canada, Australia and the Netherlands. The designs, settings and outcome measures differed considerably between studies. The outcomes included clinical outcomes (e.g., changes in levels of HbA1c, cholesterol, blood pressure, symptoms of hypoglycaemia and body mass index), health and behavioural outcomes (e.g., self-activity, diet, visits to health centres) and psychosocial outcomes (e.g., self-efficacy, depression and perceived social support). The review authors reported inconsistent findings on the effectiveness of peer support services.

Several studies included in the reviews reported positive outcomes, but nearly half the studies reported no effect of peer support services on individuals with depression. The review authors concluded that well-designed, large-scale studies were needed to confirm the effectiveness of peer support services for individuals with diabetes before integrating such services in diabetes management programs.

In a more recent study, Johansson et al. (2016) conducted one of the largest cluster-randomised trials to evaluate the effectiveness of peer support services in the management of people with diabetes mellitus. The study included 1,327 participants recruited from general health care settings in the Salzburg province of Austria. The intervention was delivered over a two-year period and a process evaluation was carried out to monitor the implementation of the intervention. The primary outcome of the study was a reduction in HbA1c level. The study found that integration of peer support services, in addition to the traditional management of diabetes, was feasible in health settings. However, the study did not find any significant difference in clinical outcomes between the control and intervention groups.

3.4.3 Peer support services for individuals with HIV infection

Peer support services are popular in the care of people with HIV/AIDS in HICs and LMICs (Chang et al., 2015b). Chang et al. (2015b) conducted an RCT to evaluate a peer intervention programme on HIV care engagement and adherence to prevention care utilisation among HIV-infected individuals on pre-antiretroviral therapy. The RCT was conducted in a rural province of the Rakai District of Uganda. A total of 442 participants were randomised to intervention or control groups. The intervention group received monthly supervision and assistance from peer workers for a period of one year. The peers were trained to provide three-level assistance to the participants. First, peers monitored participants' clinical status, treatment adherence, number of outpatient visits and sexual behaviours. Second, peers provided psychological support and encouragement, counselling, reminders and information on clinic appointments, support available for HIV care, and reducing risky sexual behaviours. Third, peers referred participants needing a further level of care to health care centres. The control group received the standard package for HIV care provided by the Rakai Health Science programme. At one-year follow-up, the results showed that intervention group participants were more likely to adhere to the treatment regimen than those in the control group. Among intervention group participants, the effectiveness of the programme was only evident among participants not enrolled in a HIV care regimen before the RCT. Intervention group participants who were

previously enrolled in a standard HIV care regimen did not show any effects of the peer-based interventions. Chang et al. (2015a) concluded that the peer support service was most effective for HIV-infected individuals who had not received any initial standard care for their condition.

3.4.4 Peer support services to promote smoking cessation

Ford, Clifford, Gussy, and Gartner (2013) conducted a systematic review of peer support programs for promoting smoking cessation in disadvantaged groups such as those who were homeless, prisoners, people with low socioeconomic status, and Indigenous people. The review included eight studies. Among the selected studies, three showed no significant effects of peer-led interventions on smoking cessation, two showed immediate post-intervention effects of the services, and three showed mid-term effects. However, studies reporting positive effects of the peer support services reported that the effects of peer support did not last for more than six months. Ford et al. (2013) concluded that there was a substantial gap in evidence-based peer support services to promote smoking cessation. The reviewed studies also did not provide sufficient evidence for monitoring the treatment fidelity of the interventions.

3.5 Peer support services in mental health care

Peer support services were introduced as self-help programmes in health settings in the USA over 30 years ago (Repper & Carter, 2011; Tse et al., 2017). Since then, the concept has evolved, and such support services are increasingly gaining recognition in mental health care settings worldwide (Gillard, Gibson, Holley, & Lucock, 2015; Tse et al., 2017). Health policies in several HICs, such as the USA, UK, Australia and New Zealand, also recommend integration of peer support programmes within mental health services to help achieve better treatment outcomes for people with mental disorder (Gillard et al., 2015).

Recent systematic reviews and meta-analyses have provided evidence about the usefulness of peer support programmes for achieving better treatment outcomes in individuals with mental disorders, including depression, schizophrenia and bipolar disorder (Cabassa, Camacho, Velez-Grau, & Stefancic, 2017; Chinman et al., 2014; Gillard, Edwards, Gibson, Holley, & Owen, 2014). Boardman, McCann and Kerr (2014) reported that a peer support programme helped people with schizophrenia to improve their overall adherence to antipsychotic medications. In a meta-analysis of 26 studies on peer-administered interventions for depression, Bryan (2013) reported that the interventions significantly reduced depressive symptoms in individuals with depression, with a median effect size of 0.45 that was comparable to professionally-administered interventions. However, there is lack of empirical evidence on the effectiveness

of peer support services in existing literature. The mechanism by which peer support benefits individuals, and the best structure and implementation process for support services, remains unclear (Rogers, 2017).

Rogers (2017), in his review of peer support services in the USA, included evidence that discussed the effectiveness of peer support services in that country. The review showed that although findings were not conclusive, peer support exerted some positive effects for better treatment outcomes in mental healthcare. Positive effects highlighted in the review were enhanced social functioning and better community involvement. Other benefits were reduced stigma, increased hopefulness, reduced dependency on professional services, and self-empowerment. Lloyd-Evans et al. (2014), in their systematic review and meta-analysis of peer support for people with severe mental disorder, included 18 RCTs conducted in the USA, UK and Australia. There were differences in the type of peer support services included in the review and the mental health conditions (e.g., schizophrenia, bipolar disorder and major depressive disorder) included in each trial. The findings from the systematic review and meta-analysis showed that peer support services were more common in voluntary settings and in regional mental health care facilities. Nevertheless, Lloyd-Evans et al. (2014) found very limited evidence to support the effectiveness of peer support in health care settings. Consistent with the finding of Rogers (2017) and Lloyd-Evans et al. (2014), Cabassa et al. (2017) also reported similar inconclusive findings in respect to the effectiveness of peer support programmes and believed these were due to several methodological limitations in the included studies. The limitations were associated with pilot study designs, lack of diversity in terms of ethnicity, regions and race in study settings. Studies included in the Cabassa et al. (2017) review were mostly pilot studies, which examined the feasibility and acceptability of peer-based interventions. Hence, evidence from large scale RCTs was very limited in this review. The 18 studies included in this review were conducted across the USA (n=12) and Australia (n=6). Hence, the generalisability of the findings to other settings, such as non-English speaking countries and low-resource settings, is limited.

Mahlke, Kramer, Becker and Bock (2014), in their review of peer support in mental health services, discussed the benefits and challenges for integration of peer support services in mental health care settings. Consistent with the findings from the above-mentioned studies, the authors could not find sufficient evidence about the effectiveness of peer support services for individuals with severe mental disorder. Because of the diverse nature of peer support services,

along with differences in the conditions for which services were provided, it was difficult to draw conclusions about the efficacy and effectiveness of the reviewed peer support programmes. The positive features reported in most reviews were a sense of increased social support, increased self-confidence and hope, empowerment, and reduction in stigmatisation of mental illness. Tse et al. (2017), in their longitudinal qualitative study of peer support services, discussed findings from a health setting in Hong Kong. The study included the views of peer support service users about the support programme. The findings indicated that, as a newly introduced concept in health care settings in Hong Kong, the role of peers was unclear. However, the findings also highlighted similar positive findings to that of studies conducted in Western settings such as increased motivation and positive thinking.

Repper and Carter (2011), in their review of peer support services for mental health care, discussed the effects, development and challenges of implementing peer support services in mental health care settings. They also identified inconsistent findings resulting from differences in primary outcome measures and in peers' role in studies. No significant improvement was found in some RCTs comparing peer support services with as usual care for hospitalisation admission rates and the length of stay for different health conditions. However, in a broader sense, the review found some positive findings about the effectiveness of peer support services Several studies included in the review reported lower re-hospitalisation rates and longer participation periods in peer support programmes. The review found little evidence that peer support services increased empowerment for consumers and peer support workers. Some evidence showed that participants receiving peer support services showed enhanced social functioning and better community involvement compared with others not receiving peer support. Repper and Carter (2011) summarised several challenges in the peer support role, including maintaining professional boundaries, peer accountability, power issues and job stress for peers, which may put them at risk of relapse of their own mental disorder.

Pfeiffer, Heisler, Piette, Rogers, and Valenstein (2011), in their systematic review, examined the effectiveness of peer-based interventions in reducing depressive symptoms. In seven RCTs included in the review, peer support interventions were compared with usual care of individuals with depression. In another seven RCTs, peer support interventions were compared with group cognitive behavioural therapy (CBT). The review found that peer support significantly improved depressive symptoms compared with usual care of people with depression. However, no statistically significant differences were found between outcomes for participants receiving

peer-based interventions and those receiving group CBT. Pfeiffer et al. (2011) concluded that peer support interventions exerted positive effects in reducing depressive symptoms in individuals and the effect was comparable to that of group CBT.

Overall, the above-mentioned studies indicate that there is lack of empirical investigations to establish the effectiveness of peer support programmes in mental health services. More research is warranted to understand the concept of peer support programmes and better implementation processes are needed to achieve the best outcomes from peer support (Cabassa et al., 2017; Tse et al., 2017). Furthermore, there is a lack of research conducted on peer-based interventions in low-income countries (Lloyd-Evans et al., 2014; Mahlke et al., 2014; Repper & Carter, 2011).

3.6 Peer support for antepartum and postpartum depression and other perinatal mental illness

Few researchers have evaluated peer support for reducing depressive symptoms during pregnancy. Existing peer support programmes have focused on reducing postnatal depression rather than antepartum or postnatal depressive symptoms. To date, only one study was located in the literature in which the peer support programme focused solely on antenatal or prenatal depression. In that study, by Field, Diego, Delgado and Medina (2013), the authors compared the effects of a peer support programme with those of structured interpersonal psychotherapy. Forty-four prenatally depressed women were assigned randomly to peer support and interpersonal therapy groups. Trained psychotherapists delivered the interpersonal therapy. In both interventions, participants took part in weekly group sessions for 21 weeks. The sessions lasted for 20 minutes in the peer support group and one hour in the interpersonal therapy group. The outcomes of the trial were assessed as decreased depressive symptoms, decreased anxiety and decreased cortisol levels among the participants. Notably, the result of the trial showed that both groups experienced significant reductions in depression and anxiety levels and lowered cortisol after taking part in the interventions. The effects in the peer support group were comparable with those in the interpersonal psychotherapy group. Moreover, participants in the peer support group experienced greater decrease in cortisol levels than those in the interpersonal therapy group. The findings of the study suggest that peer support programmes may be more cost-effective and less time consuming than structured interpersonal psychotherapy. However, the effect of the intervention did not last long after the delivery of

the intervention. Field et al. (2013) concluded that longer, more extensive interventions should be designed and evaluated for reducing antepartum depression.

Phipps (2014) conducted a pilot RCT to explore the feasibility of peer support for mothers in the postnatal period in England. The study included 30 mothers in their postnatal period, equally divided into control and intervention groups, and eight peers. The intervention group received weekly one-to-one peer support for six weeks and was followed up at the end of the intervention, while the control group received as-usual care. The intervention group showed significant improvement in their depressive symptoms after receiving peer support. There was also a significant improvement in self-esteem and self-confidence in the parenting role in these women. In a larger scale RCT, Dennis et al. (2009) examined the effects of telephone-based peer support on the prevention of postnatal depression in mothers at high risk of developing postnatal depression. The trial included 701 women at their first week postpartum who were at risk of developing postnatal depression, as assessed by the EPDS. The participants received at least eight telephone calls from the peer volunteer until 12 weeks postpartum. The peer volunteers were selected on the basis of their self-reported history of and recovery from postnatal depression and English language proficiency. The findings of the trial showed that participants in the intervention group were less likely to report symptoms of postnatal depression at 12 weeks postpartum than those in the control group. Dennis et al. (2009) reported that, compared with the control group, intervention group participants had half the risk of developing postpartum depression. One limitation of the study was that during the first follow-up at 12 weeks postpartum, women with severe depression or a score of more than 20 in EPDS were immediately referred to health care centres for treatment. Hence, at second follow-up at 24 weeks, no significant group difference was found between control and intervention groups. For this reason, the efficacy of such peer support programmes in long run could not be evaluated from the study. Despite these weaknesses, 80% of intervention group participants provided positive reviews of their experience of the intervention. The participants were satisfied with their peers and would recommend such programmes to other women in their postpartum period (Dennis, 2010; Dennis et al., 2009).

McLeish and Redshaw (2015), in their qualitative study, examined a variety of models of volunteer peer-based services provided to vulnerable groups of women during pregnancy and early parenthood in England. Forty-two mothers and 47 peer volunteers from nine peer support projects were interviewed to reflect on their experiences of receiving and delivering peer

support. The participants were from a diverse range of cultural and ethnic backgrounds, including some from extremely vulnerable circumstances, like women suffering from depression and anxiety, single mothers and from low socioeconomic backgrounds. The study findings indicated that peer support services had the potential to create a platform where socially meaningful relationships of trust could occur. Peer volunteers were found to be advantageous in connecting with, and providing support to, these vulnerable and marginalised groups of pregnant women and mothers. The forming of this unique relationship and bond between peers and mothers was based on trust and mutual understanding, where the peers were identified as non-judgemental, caring individuals focused only on the mothers' well-being. The mothers also indicated that they felt respected and cared for during peer support as the interaction with peers was more flexible and personal in contrast to interactions with health and social care professionals. Furthermore, the findings highlighted that the shared characteristics between peers and mothers enabled the peers to be non-judgmental and provide empathetic support to mothers dealing with challenging issues and stigma. Overall, the findings suggested that peer support services have the potential to improve emotional outcomes in mothers in regard to reducing feelings of loneliness and stress.

The findings of the McLeish and Redshaw (2015) study were also supported by another qualitative and meta-ethnographical study by Jones, Jomeen, and Hayter (2014), on the impact of peer support on mothers suffering from perinatal mental illness. Similar to the McLeish and Redshaw (2015) study, 95 pregnant women and mothers from 5 peer support projects in England, Canada and Finland were interviewed for this meta-ethnography. Participants were asked to reflect on their experiences of perinatal mental illness, their experiences of the peer support service, and the effect of the service on their perinatal mental health. The study findings suggested that engaging with other peer mothers through shared experiences can accelerate the transition from depression and reduce the burden of distress on pregnant women and new mothers. The findings highlighted that peer support services can play a pivotal role in reducing feelings of isolation and loneliness, which often give rise to depression during the perinatal period. The findings also emphasised the importance of developing the right peer support service specific to the mothers' needs to ensure that maximum benefit from the service are achieved. Peer support services which were not focused on mothers' specific needs were not helpful for recipients. Hence, it is important to design and implement the right services focused on the target group's needs, and to improve access to services (Jones et al., 2014).

The Jones et al. (2014) and McLeish and Redshaw (2015) studies identified some challenges in interpreting their findings in supporting peer support services for pregnant women and new mothers. AS qualitative studies, the findings were limited to the context in which they were undertaken. In addition, in the McLeish and Redshaw (2015) study, some participants were unable to reflect on the whole experience of their respective peer support services because of the timing of the interview. Some mothers were interviewed in the middle of ongoing peer support services rather than at the end of the intervention. Furthermore, the authors of both studies acknowledged that, to date, there has been a little agreement on a precise definition of peer support services and the exact operational model of such services for pregnant women and mothers.

In addition to these studies, Sikander et al. (2015) examined the effectiveness and cost-effectiveness of the THPP to pregnant women and mothers at high risk of developing postpartum depression. The current study is based on the antenatal part of the THPP programme and details are described in methodology chapter.

3.7 Summary

Peer support is the system of giving and receiving help between two individuals based on shared experience and mutual understanding. The conceptual framework for peer support is based on affiliation or connection between two individuals sharing similar experiences or characteristics. Social support theory, social comparison theory, helper therapy principle, experiential theory and social learning are some of the major theories that researchers use to describe the underlying process of peer support. Emerging evidence shows that peer-based interventions are increasingly used in general and mental health care settings worldwide. Although there is inconclusive evidence on the effectiveness of peer support, systematic reviews of peer support programmes report that participation in such interventions increases social functioning, community involvement and empowerment, and reduces stigmatisation in individuals with mental illness. More research is warranted to understand the mechanism of peer support and to establish the effectiveness of the peer support programme to be implemented in the health settings worldwide. Few researchers have examined the effects of peer support programme in reducing depressive symptoms during and after pregnancy. However, the few studies in the literature report positive findings for peer support in reducing depressive symptoms during and after pregnancy.

CHAPTER FOUR

Design and methods of the study

4.1 Introduction

In this chapter, the design and methods of the study are presented. A mixed methods design, incorporating a pilot RCT and a process evaluation were used to evaluate the programme. The chapter commences with an overview of the conceptual framework and design rationale for the study. Next, the methods of the study, including selection and recruitment of participants and sample size, are discussed. This is followed by a summary of the data collection instruments, procedures, and data analysis methods. Finally, the chapter concludes with a discussion of ethical considerations and rigour of the study**.**

4.2 Conceptual framework for the study

The conceptual framework for the study is based on Beck's (1979) cognitive theory of depression (Figure 4.1). According to this theory, three main dysfunctional elements of a person's belief system are present in depressive and other related mental disorders. These are (1) cognitive triad, (2) schemas, and (3) cognitive errors (Beck, Rush, Shaw, & Emery, 1979). The cognitive triad consists of three distinctive patterns that form Beck's cognitive triad of depression (Figure 4.1) (Beck & Haigh, 2014; Beck et al., 1979). Depression or depressive symptoms lead to a feeling of inadequacy or incompetency in the individual (negative views of oneself), which leads to pessimistic interpretations of present circumstances.

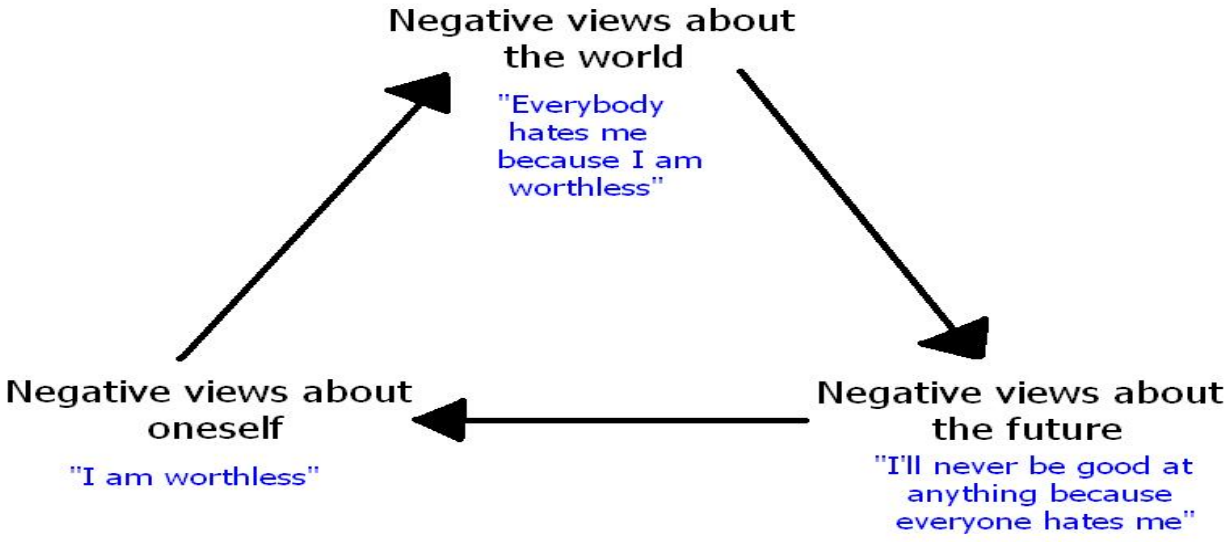

Figure 4.1: Beck's Cognitive triad of depression (Gerrig, Zimbardo, Campbell, Cumming, & Wilkes, 2011, p. 399).

Consequently, this leads to feelings of hopelessness about the future (negative views about the future) and the individual becomes less motivated to pursue any life goals. All these experiences give rise to certain complex cognitive structures or processes in the brain and affect the overall cognitive processes in individual. These are known as the cognitive schemas (the second element) that are activated in specific situations and determine the behaviour of the affected individual. The American Psychological Association defines cognition or cognitive process as the 'Processes of knowing, including attending, remembering, and reasoning; also, the content of the processes, such as concepts and memories' (Gerrig et al., 2011, p. 207). This higher brain function is responsible for processes like judgement, problem solving, planning, imagination and perception. Beck and Haigh (2014) indicated that cognitive schemas are generally responsible for biased-beliefs and related behaviours in normal life, but when this built-in biased response in the brain become maladaptive, it increases the individual's likelihood of developing subclinical or clinical mental disorders. The third element of the theory includes faulty information processing (cognitive errors) which affects individuals' thinking capabilities and the content of meanings and interpretation (Beck & Haigh, 2014). Mental disorders, like depression, lead to an exaggeration of the normal adaptive system in the brain for which affected individuals hold on to negative beliefs despite contrary evidence. Subsequently, these errors in the information processing system lead to other cognitive biases and maladaptive behaviours. For this reason, it is generally accepted by cognitive and behaviour therapists that conscious cognition of the mind has the ability to influence individuals' conception of reality, which, in turn, may impact their behaviour (Brewin, 1996). On this basis, Beck (1976) and other leading researchers of depression and mood disorders pioneered the concept of CBT.

CBT is an umbrella term that refers to therapies or interventions that incorporate cognitive and behavioural elements that aim to improve mental health (Brewin, 1996). The elements are specifically designed on the basis of the concept that change of maladaptive belief or thinking can change the related behaviour, actions and emotions (Beck & Haigh, 2014). CBT includes techniques and strategies directed to alter individuals' thinking patterns and correct misconceptions (Brewin, 1996; Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012) During the therapy, affected individuals are first guided to understand the relationship between their thoughts, moods and behaviours. Next, individuals' unhealthy negative thoughts are identified, and finally, specific behavioural actions are recommended to replace negative thoughts with helpful thoughts and practise of healthy behavours (Sudak, 2012). Since its early development,

various disorder-specific CBTs have been developed. The effectiveness of CBT for reducing depressive symptoms is well established and, currently, is considered as the first-line of treatment for mild-to-moderate depression (Nathan & Gorman, 2015; Sudak, 2012). The part of the THPP that is used in the present study is based on the principles of CBT and incorporates all three specific components of the CBT triad. However, unlike traditional CBT, the CBT in THPP is less intense in nature and does not require mental health specialists to deliver the therapy. THPP was designed as a low-intensity psychosocial programme for low-resource settings in LMICs and can be delivered by non-professionals (Sikander et al., 2015).

4.3 Design rationale

Given the aims of the current research — to evaluate a low-intensity peer delivered psychosocial intervention for antepartum depression — a mixed methods study was designed. Mixed methods research integrates quantitative and qualitative methods in a single project (Creswell, 2014). Such a combination of both types of data enhances the overall strength of the research design (Creswell, 2014; Tashakkori & Teddlie, 2010) and overcomes the weaknesses of using quantitative or qualitative methods alone. There are three basic models of mixed methods research: convergent parallel, explanatory sequential and exploratory sequential (Creswell, 2014). Convergent parallel mixed methods design is where quantitative and qualitative data are collected simultaneously (Creswell, 2014). In this method, qualitative and quantitative data are equally valued and the data are analysed independently. Finally, both types of data are integrated for interpretation of the overall research problem. This design can be used to develop new interventions such as health promotional interventions. For example, Classen et al. (2007) used a convergent parallel mixed methods design to evaluate causative factors influencing motor vehicle accidents in older adult drivers (aged 65 years or more) in order to develop a comprehensive health promotion plan to increase their safety.

In explanatory sequential mixed methods design, quantitative data are collected and analysed in the initial phase. Then, qualitative data are collected and analysed in the second phase. Here, quantitative data collection is prioritised over qualitative data and the latter data builds upon the result of quantitative data analysis. In this type of design, the aim is to explain quantitative results in more detail through qualitative data. For example, Sikander et al. (2015) used an explanatory sequential mixed methods design in evaluating the original THPP programme. They included an RCT of the THPP programme and at the end of the trial included qualitative interviews of intervention recipients to explore the trial outcomes in more detail. Together, the results of the

RCT and information gathered from qualitative interviews were helpful in understanding why and how the programme benefited the participant mothers with depressive symptoms.

In exploratory sequential mixed methods design, qualitative data are collected and analysed first. Then, information obtained from the initial qualitative data analysis is used to establish the second quantitative phase. This type of mixed methods design is used in developing research instruments or interventions. For example, Stoller et al. (2009) conducted an exploratory sequential mixed methods study to explore the factors that influenced alcohol consumption in non-abusive drinkers diagnosed with Hepatitis C. In addition to exploring the modifying factors, the findings suggested areas to modify existing instruments for use with non-abusing drinkers to advise them to reduce their alcohol consumption because of medical reasons.

In the present study, an explanatory sequential mixed methods design was used. Quantitative data included outcome measures of the pilot RCT in terms of reduced depressive symptoms, change in QoL and self-esteem (dependent variables). Data analysis of quantitative data was used to explain if any change in depressive symptoms (dependant variable) resulted from taking part in the intervention (independent variable). Then, in the second phase a qualitative and quantitative process evaluation was carried out. The process evaluation was included in the study to monitor and document the implementation of the intervention and also to outline the participants' views about the usefulness of the programme.

4.3.1 Justification for a pilot randomised control trial

A pilot RCT was designed to collect quantitative data in the present study. Pilot RCTs are usually undertaken to investigate new strategies or an intervention that has been tested in one sample population and is now being tested in another sample population (McGrath & Brandon, 2018). Shader (2015) defined pilot studies as "preliminary, exploratory, preparatory, small-sample effort undertaken to decide whether a larger study is warranted" (p. 1380). Such studies are often considered as the small-scale or miniature version of a larger RCT to investigate whether all the major components of the larger study can be put together (Abbott, 2014; Arain, Campbell, Cooper, & Lancaster, 2010; Eldridge, Chan, et al., 2016; Leon, Davis, & Kraemer, 2011). According the United Kingdom General Medical Research Council, pilot and feasibility studies are explicitly important to pinpoint or identify problems that may arise during a full-scale RCT of a complex intervention (Eldridge, Lancaster, et al., 2016). In this regard, Lancaster (2015) identified seven objectives of pilot studies. These are to (1) investigate the ethical aspect of a study protocol for the future trial; (2) obtain initial evaluation of sample size

calculation; (3) investigate data collection instruments and questionnaire in the defined population; (4) evaluate the randomisation procedure; (5) investigate the recruitment rate and consent procedure; (6) evaluate the acceptability of the intervention to the participants; and (7) to identify the most appropriate primary outcome measure.

The CONSORT 2010 statement on reporting randomised pilot and feasibility trials describes pilot studies as subsets of feasibility studies, with similar aims and objectives and with a particular design (Eldridge, Chan, et al., 2016). Both types of studies have similar components and are conducted before a large RCT to calculate important parameters needed to plan the main study (Eldridge, Chan, et al., 2016; Eldridge, Lancaster, et al., 2016). Hence, it is common for researchers to use the term 'feasibility studies' interchangeably with 'pilot studies' (Arain et al., 2010; Eldridge, Lancaster, et al., 2016; Leon et al., 2011). However, researchers like Arain et al. (2010), Eldridge, Lancaster, et al. (2016) and Abbott (2014) have distinguished between the two type of studies. In comparison with feasibility studies, pilot studies have more detailed methodological components like randomisation, inclusion of a control group, and sample size estimation. Important parameters of an RCT, such as inclusion of control group and randomisation, are often not included in feasibility studies (Arain et al., 2010). Arain et al. (2010) also highlighted that often feasibility studies do not include a primary objective to evaluate the possible outcome of the intervention. In a further note, Eldridge, Lancaster, et al. (2016) indicated that feasibility studies are conducted at a much earlier stage of a research process, whereas pilot studies are conducted as a miniature version of the main RCT to pilot test the effect of the intervention. Eldridge, Lancaster, et al. (2016) identified three distinct types of studies that are termed as pilot or feasibility studies in the research literature: (a) randomised pilot studies, (b) non-randomised pilot studies, and (c) feasibility studies that are not pilot studies. The design and procedures of the current study are more aligned with a pilot RCT as it included all three major components of an RCT, that is, randomisation, inclusion of a control group, and manipulation of the intervention group (LoBiondo-Wood, Haber, & Titler, 2018).

Pilot RCTs are underpowered and purposely have a small sample size because of the necessity to evaluate the intervention's safety, feasibility, efficacy and acceptability before proceeding to a full-scale study (Abbott, 2014; McGrath & Brandon, 2018). Data from a pilot trial also help with the effective management of limited research resources, including timeframe and budget, management of study population and data management problems, and assessment of

the intervention effect and variance of effect (Leon et al., 2011; Thabane et al., 2010). The findings of a pilot trial indicate the scope of the intervention being investigated and can be used as a guide to plan a full-scale study. The data provide potential preliminary evidence on the primary hypothesis of the intervention that needs to be confirmed in the full-scale study (McGrath & Brandon, 2018; Vogel & Draper-Rodi, 2017). The aim of the present study is to evaluate a section of the THPP as a sole intervention that has not been evaluated on its own in any other study. The pilot trial will help determine the potential of this part of the intervention as a stand-alone intervention for women with mild-to-moderate antepartum depressive symptoms living in rural low-resource settings of Bangladesh.

4.3.2 Process evaluation

Process evaluation is a method of exploring 'the implementation, receipt and settings' of an intervention (Oakley et al., 2006, p. 413). It strengthens the results of RCTs and gives an in-depth understanding of what makes an intervention a success or failure (Grant, Trewwek, Dreischulte, Foy, & Guthrie, 2013 Foy, & Guthrie, 2013; Oakley et al., 2006). It is also considered important in interpreting and further exploring a study's outcomes (Oakley et al., 2006). Furthermore, it helps validate the actual implementation and documentation of an intervention before planning and designing a larger effectiveness study of that intervention (Grant, Treweek, Dreischulte, Foy, & Guthrie, 2013; Saunders, Evans, & Joshi, 2005). Oakley et al. (2006) suggested that process evaluation of an intervention helps identify the reason for the failure of an intervention by distinguishing between an inherently faulty intervention and a badly implemented intervention. In designing a process evaluation, it is important to incorporate a combination of qualitative and quantitative research methods to appropriately investigate the primary research question (Moore et al., 2015). As Moore et al. (2015) further illustrated, use of quantitative methods identifies the key variable measure, like treatment fidelity, dose implemented and reach of the intervention; whereas use of qualitative methods help in capturing the experience and challenges faced by the participants and also indicate the changes required in future studies.

The process evaluation in the present study contained qualitative and quantitative methods and aimed to evaluate the participants' views of the shortened form of the THPP intervention and experience during the intervention delivery. The evaluation was also necessary because this was the first time the intervention was being tested in rural Bangladesh, which is situated in a different cultural and geographical region than the original study in India and Pakistan. The process

evaluation comprised participants taking part in individual semi-structured, audio-recorded qualitative interviews and answering a short questionnaire containing Likert-type responses. The interview included questions on participants' perceptions about the implementation, delivery and usefulness of the programme. Separate semi-structured interview schedules for peers and intervention group pregnant mothers were developed (Appendix E and F).

4.4 Methods of the study

4.4.1 Settings of the study

The study was carried out in three rural Unions[11], namely Shaharbil, Purbo Boro Bheola and Lokkhachor. These Unions are situated in the Chakaria sub-district of Cox's Bazar district in south-eastern Bangladesh. They are situated within a 10 km radius of each other and comprise a total of 25 wards and 47 villages. The population of Shaharbil Union is 30,288, Purbo Boro Bheola Union 36,269 and Lokkhachor Union 12,800. The average household size in these Unions is 5.4 persons. The main sources of livelihood of families residing there are farming, raw salt production, and fish cultivation. The literacy rate of the population is around 47.6% and the ratio of men to women is 104:100 (Bangladesh National Information Portal, 2016).

Recruitment and initial screening of participants took place in antenatal and outpatient clinics in Upazilla (sub-district) health complex (UHC), Chakaria and the outpatient clinic of each Union Health and Family Welfare Centre (UHFWC) of the unions. Chakaria UHC is a 50-bed public hospital, which provides inpatient and outpatient health services to a population of approximately 500,000 people in the sub-district (Ministry of Health and Family Welfare, 2015). It also has a Family Planning and Maternal and Child Health Care Unit, which provides a range of antenatal services, including emergency obstetric care. UHFWCs provide outpatient medical and health promotion care in rural areas.

[11] Unions (Union Councils or Union Parishad) are the smallest rural administrative units of local government in Bangladesh. Each Union comprises approximately nine Wards and each Ward comprises two or three villages. A chairperson and 12 elected members from the local area comprise the governing body of a Union. Currently, there are 4,554 Unions in Bangladesh. Union councils are responsible for maintenance of law and order and help in adopting and implementing development schemes and improving public welfare services in rural regions (Faizullah, 1985).

4.4.2 Selection and recruitment of participants

4.4.2.1 Recruitment of pregnant women

A probability sampling approach was used to recruit participants. In the antenatal clinic, health staff gave brief information about the study to potential participants presenting at the clinic. The researcher visited the antenatal clinics of UHC and UHFWC and health staff of the centres were notified of her presence on the day. Flyers and information sheets (Appendix A) containing the researcher's mobile telephone contact details were distributed in other health facilities, including community clinics and private health facilities. This approach meant that pregnant women not presenting in the recruitment areas had the option to contact the researcher directly by telephone and to take part in the study. Potential participants, who contacted the researcher by phone, were given a date to attend to the health complex or a community clinics to participate in the screening process.

When a pregnant woman expressed interest in participating in the study, the researcher approached her, provided detailed information about the study and answered her questions. After the project was explained to eligible participants, and they were provided with a copy of the Participant Information Sheet, they were given around 30 minutes to read this information and consider whether to participate in the study. Once the 30-minute period had elapsed, they were then given the opportunity to meet with and ask questions of the researcher about their involvement, prior to giving written consent to participate in the study. Immediately after giving consent, participants took part in the screening process. The informed consent was obtained before the screening process. Pregnant women who met the inclusion criteria of the study were asked to discuss their involvement with their families. This was necessary because the intervention encourages and promotes the participation of family members during the intervention delivery and the effectiveness of the intervention is related to co-operation from the family. After a few days, and with their families' informal consent, the researcher called participants again and confirmed their inclusion in the study. All families supported the pregnant women's participation in the study.

The following inclusion and exclusion criteria were used to recruit pregnant women in the study:

Inclusion criteria for pregnant women

1. Pregnant women between 12- and 30-weeks' gestation.
2. Aged 18 years or above.

3. Scoring 10–14 on the Patient Health Questionnaire (PHQ-9).

Exclusion criteria for pregnant women prior to and during the study

1. PHQ-9 score above 14.
2. Diagnosed with severe depression with or without suicidal ideation.
3. Diagnosed with any acute medical complication during pregnancy or developing complications during participation in the study.
4. Currently receiving treatment for an acute episode of mental disorder or develops an acute episode during participation in the study.

4.4.2.2 Recruitment of peers

Separate flyers and information sheets (Appendix C) to recruit peers were distributed in outpatient care at UHC, UHFWC and other health clinics. Prospective peers were asked to express their interest to the health staff of the facility. Their contact details, with their approval, were forwarded to the researcher by the health staff. Prospective peers could also contact the researcher directly to seek more information about the study. A mutually agreeable meeting time was then set and the researcher gave potential peers detailed information about the study. The peers were encouraged to ask questions and all their queries were answered to their satisfaction. Finally, eligible participants were asked to sign informed consent and were included in the study as peers.

Inclusion criteria for peers:

1. Local women sharing similar experiences, such as being a mother with similar characteristics like age, religion, ethnicity or socioeconomic status.
2. Having at least 10^{th} grade school level education.

4.4.3 Number and types of participants

4.4.3.1 Sample size

Pregnant women

A number of factors influenced the sample size for pregnant women in this study. Although the effectiveness of THPP has been established, the power analysis used in the original RCT was based on the complete THPP (Sikander et al., 2015). The current study used only the antenatal section of the THPP, which is one-third of the complete THPP. As this part of the THPP had not been examined solely in any previous RCTs, it was not possible to calculate the actual effect size of the selected part and do a power analysis for the current study. Furthermore,

several researchers, like Lancaster et al. (2004), Leon et al. (2011) and Thabane et al. (2010), have stated that pilot RCTs do not require a formal power analysis. Instead, they should be based on practicability and the importance of investigating the feasibility and acceptability of an intervention (Leon et al., 2011).

There are mixed views about the sample size of pilot studies. Lancaster, Dodd, and Williamson (2004) recommend including at 30 or more participants, whereas Cocks and Torgerson (2013) suggest including at least 50 participants. Considering these recommendations, the proposed study included 60 participants for the pilot RCT, plus an additional 10 participants to allow for attrition. Having 35 participants in each group meant that the pilot RCT was feasible for the researcher to conduct.

Peers

With 35 participants in the intervention group, 6 peers were selected to deliver the intervention. This allowed up to 6 pregnant women per peer for the duration of the study and allowed for potential attrition of peers.

4.4.3.2 Randomisation

Seventy participants (pregnant women) were randomised equally into control and intervention groups. The randomisation process was carried out by the Principal Supervisor to maintain 'allocation concealment'[12] and in accordance with the CONSORT guidelines for conducting RCTs (Doig & Simpson, 2005; Schulz, Altman, Moher, & Group, 2010). Participants were grouped initially into computer-generated random blocks of 4 to 6 persons. Then, from each block, equal numbers of participants were allocated to the control and intervention groups. This form of block randomisation reduces bias in allocating participants to control and intervention groups and is used commonly in RCTs with small sample sizes (Doig & Simpson, 2005; Efird, 2011). It also ensures that all participants have an equal chance of being in the intervention or control group.

[12] **Allocation concealment**
A technique of preventing selection bias by researcher responsible for assigning participants to intervention group by concealing the allocation sequence from them, until the assignment is complete. Allocation concealment prevents researchers from (unconsciously or otherwise) influencing which participants are assigned to a given intervention group' (Schulz, Altman, Moher, & Group, 2010).

4.5 Procedure

4.5.1 Background to the Thinking Healthy Programme–Peer delivered (THPP)

To bridge the gap between the high prevalence of mental health disorders, inadequate numbers of skilled health professionals and the need for mental health services in LMICs, the World Health Organization (WHO) adopted the *Mental Health Gap Action Programme* (Saxena, Funk, & Chisholm, 2013) to upscale mental health services in LMICs. The programme aims to publish a series of evidence-based interventions to extend mental health services to low-resource settings (Patel & Saxena, 2014). The WHO defines this evidence-based intervention as low-intensity psychosocial interventions that are less intense, use fewer resources and can be delivered by available primary or community health workers (Chowdhary et al., 2014; World Health Organization, 2014). The first intervention developed in the series was the THP programme for perinatal depression. The programme was developed by the Human Development Research Foundation in Pakistan and its evaluation in clinical trials showed significant improvement in mothers' depressive symptoms during the postnatal period (Atif et al., 2015; Chowdhary et al., 2014; Rahman et al., 2008; A. Rahman et al., 2013). THP uses basic CBT techniques and focuses on maternal depression during and after pregnancy (Gilmore & McAuliffe, 2013). Community or primary health workers are the intended delivery agents for the intervention (Sikander et al., 2015). However, because of additional workload associated with using the THP, it is often not possible to involve community or primary health workers in implementing such programmes in primary health care settings in LMICs (Singla et al., 2014). In this context, the simplified THPP version was developed which involved peer mothers from local communities to deliver the intervention (Sikander et al., 2015). It included a total of 10 face-to-face individual home-based sessions and four group sessions delivered across the antenatal and postnatal periods (Table 4.1). The effectiveness and cost-effectiveness of the programme has been evaluated through RCTs in two rural settings in Pakistan and India (Sikander et al., 2015). Pregnant women and mothers taking part in the intervention achieved significant improvements in their depressive symptoms. These RCTs also evaluated the potential use of peers to help overcome human resource shortages in mental health care systems in LMICs (Sikander et al., 2015).

Table 4.1: Content of Thinking Healthy Programme–Peer delivered

Sessions (Time of delivery)	**Objectives**
Individual session 1 (Antepartum period)	**Introduction and engagement**
Individual session 2 (Antepartum period)	**Mother's personal health**
Individual session 3 (Antepartum period)	**Mother's relationship with people around her**
Individual session 4 (Antepartum period)	**Mother's relationship with her child**
Individual session 5 (Postpartum period)	**Mother's personal health**
Individual session 6 (Postpartum period)	**Mother's relationship with people around her**
Individual session 7 (Postpartum period)	**Mother's relationship with her child**
Individual session 8 (Postpartum period)	**Mother's relationship people around her**
Individual session 9 (Postpartum period)	**Mother's relationship with her child**
Individual session 10 (postpartum period)	**Mother's relationship with her child**
Group session 1 (Antepartum period)	**Mother's and child's well-being**
Group session 2 (Postpartum period)	**Mother's and child's well-being**
Group session 3 (Postpartum period)	**Mother's and child's well-being**
Group session 4 (Postpartum period)	**Mother's and child's well-being**

Source: Reference manual for Thinking Healthy Programme–Peer delivered (THPP)

4.5.2: Intervention used in the current study

The intervention selected for the present study was the antenatal section of the THPP. This part of the THPP was selected given the focus of the study and lack of evidence for a suitable peer-based low-intensity intervention for antenatal depressive symptoms in women living in rural settings in LMICs. It comprised five sessions, four of which were individual face-to-face sessions and one a group session. The group session included groups of pregnant women in the intervention group. Peers delivered the individual sessions weekly in participants' homes or and the group sessions took place in convenient places decided by each group. Each session required around one hour to complete (Table 4.2).

Table 4.2: Intervention sessions in the current study

Sessions	Objectives
Individual session 1	**Introduction and engagement** Introduction to the peer delivered programme for the pregnant women
Individual session 2	**Pregnant women's personal health** Helping pregnant women to improve their mood by paying attention to their personal health
Individual session 3	**Pregnant women's relationships with people around them** Helping pregnant women to improve their mood by paying attention to their relationship with people around them
Individual session 4	**Pregnant women's relationships with their unborn child** Helping pregnant women to improve their mood by paying attention to mother–child relationship and preparing for the arrival of the baby
Group session 1	**Mother and child well-being** To promote rest To promote healthy eating

Permission to use the antenatal section of THPP was obtained from the original developer, Dr. Atif Rahman, on behalf of the THPP team (Appendix N). The team provided the researcher with the intervention and necessary peer training manuals. The researcher received two days' training through Skype videos from a master trainer of THPP and the original SHARE (South Asian Hub for Advocacy Research and Education) on mental health protocols. The training included discussion on the prevalence, causes and effects of perinatal depression; background

of THPP intervention; training procedures for peers, including development of communication skills; and discussion about confidentiality and other ethical aspects of the programme delivery. In addition, to ensure that the intervention was delivered properly and effectively, the researcher had a monthly Skype video meeting with the master trainer to follow up and discuss any questions she had about the delivery of the intervention, and the master trainer could be reached through emails for any additional queries.

4.5.3 Training of the peers

The peer training manual used in the study was a slightly modified version of the manual used in the original THPP programme. The modification, undertaken with permission of the developer, reflected the antenatal focus of the study and the cultural context of the data collection site. For example, only the training required for delivering antenatal sessions was included in the adjusted training manual. In addition, the term 'pregnant mothers' used in the original training manual was changed to 'pregnant women' in the training manual for the study because the original study included pregnant women and mothers in the postnatal period. In contrast, the current study only included pregnant women.

The six selected peers received four days' (24 hours) training from the researcher (Table 4.3). Each peer was provided with one training manual, one reference manual, one THPP manual and other materials, for example, health charts and calendars required for programme delivery. On the first day, the training included an overview of the complete study. The peers learned about the concept of peer support programmes and THPP. They also learned about antepartum depressive symptoms, its consequences and summary of available treatment. The second day of the training programme involved teaching peers about the concept of CBT and ways of improving their communication skills. The third day included role playing on different aspects of the intervention, such as introduction to the pregnant women, effectively engaging them in conversation and delivering different parts of the individual and group sessions. On the fourth day, the ethical aspects of the programme, including maintaining confidentiality and professional boundaries, and overcoming challenging situations during programme delivery were addressed.

In addition to the four-day training programme, peers received fortnightly face-to-face booster sessions or periodic meetings with the researcher to maintain their skills over time. The booster sessions gave peers the opportunity to share their experiences with each other and the

researcher and address any issues arising during the programme delivery. The researcher also telephoned peers individually each week to discuss any concerns or issues that arose during the delivery of the intervention. Peers had direct access to the researcher by telephone or face-to-face appointment, if required.

Table 4.3: Content of the preparatory workshop for peers

Day 1	1. Overview of the THPP programme 2. Overview of the current study 3. Concept of the peer support programme 4. Antepartum depression symptoms, consequence and treatment options
Day 2	1. Concept of CBT 2. Improving communication skills 3. Role play
Day 3	1. Role playing of the sessions of the intervention
Day 4	1. Ethical aspects of the study 2. Maintaining confidentiality and professional boundaries 3. Overcoming challenging situations during programme delivery

4.5.4 Programme delivery

Initially, each of the six peers was assigned to deliver the programme to a maximum of six pregnant women. However, after withdrawal of one peer, the six intervention group participants assigned to her were distributed among the other five peers according to their availability and expression of interest. However, care was taken to ensure that none of the five peers was overburdened with too many intervention group participants.

The researcher introduced each of the intervention group participants to their assigned peers in the first introductory session. Next, the peer set a mutually agreeable time to meet each week with participants to deliver the next three individual sessions. The final group session included groups of pregnant women assigned to the same peer. Each group selected a convenient place for its group session.

4.5.5 Control group

Control group participants continued with their usual antenatal support locally during their participation in the study. Those who had not attended an antenatal clinic at the time of recruitment were encouraged to attend the recommended antenatal check-ups at their nearest health facilities (e.g., UHC, UHFWC, community clinics etc.). In addition, they were provided with a brochure containing brief information about depression, including, for example, symptoms and treatment options. At the end of the data collection period, control group participants were provided with the printed materials that had been given to the intervention group (i.e., diet chart, exercise chart, rest chart).

4.6 Data collection

Data were collected on three occasions: at the beginning of the programme delivery (Week 0), the end of the programme (Week 6), and follow-up (Week 10). The process evaluation was undertaken at the end of the programme with the intervention group only. Interviews with the pregnant women took place either on the day of completion of the programme or shortly afterwards. The peers were interviewed on the day of the group session after completing the group session for their respective group of pregnant women (e.g., final day of the programme delivery).

4.6.1 Data collection instruments

Four data collection instruments and two interview schedules were used to collect data in the present study.

Sociodemographic questionnaire

Sociodemographic data included name, age, marital status, contact details, education level, occupation, number of pregnancies, place of receiving antenatal care, previous history of mental illness, and family history of mental illness. The demographic information was collected from eligible participants after recruitment.

Patient Health Questionnaire-9

The Patient Health Questionnaire 9 (PHQ-9) was used as the primary screening tool and to assess the outcomes of the RCT in the current study. PHQ-9 is the depression module of the instrument PHQ (Kroenke, Spitzer, & Williams, 2001). It uses the nine criteria listed in *Diagnostic and Statistical Manual* 4th edition (DSM-4) for diagnosing depressive episodes in individuals (Kroenke & Spitzer, 2002; Kroenke et al., 2001). It has been found equally useful

for establishing a provisional diagnosis of depression and for grading the severity of depressive symptoms. It is a 9-item questionnaire that uses a four-point Likert scale, ranging from '0' (not at all) to '3' (nearly every day) (Santos et al., 2016). The total score ranges from 0 to 27 and a cut-off score of 10 indicates the presence of mild-to-moderate depressive symptoms. A score of 14–19 indicates the presence of moderately severe depressive symptoms, and a score of 20 and over signifies the presence of very severe depressive symptoms requiring further evaluation. Validity and reliability of the PHQ-9 has been established in multiple studies (Martin, Rief, Klaiberg, & Braehler, 2006). It is comparable with the EPDS, one of the most commonly used instruments for screening perinatal depression in Australia, the UK and the USA (Martin et al., 2006; National Collaborating Centre for Mental Health, 2014; Santos et al., 2016; Zhong et al., 2015). Another reason for choosing the PHQ-9 scale over EPDS is that it was used as the primary screening tool in the original trial of the THPP study (Sikander et al., 2015). Although evidence for use of the PHQ-9 for screening antenatal depressive symptoms in Bangladesh could not be found, it has been used to assess depressive symptoms in patients with diabetes mellitus in the country (Roy, Lloyd, Parvin, Mohiuddin, & Rahman, 2012).

World Health Organization Quality of Life-BREF scale

The WHO Quality of Life-BREF (WHOQOL-BREF) scale is a 26-item questionnaire that measures individuals' perceptions of well-being (Skevington & McCrate, 2012). The scale is the shorter version of the original WHOQOL scale developed in 1991. Since its development, the WHOQOL-BREF scale has been translated into more than 20 languages (Tsutsumi et al., 2006). In addition, the validity and reliability of the instrument is well documented for use in Bangladesh (Tsutsumi et al. (2006). The WHOQOL-BREF is regarded as a high-quality instrument and was tested to assess the QoL in people suffering from more than 27 chronic diseases and mental disorders, including depression, in terms of the person's own perception of well-being (Skevington & McCrate, 2012). Furthermore, the instrument has been specifically tested for assessing QoL in pregnant women and mothers following childbirth (Vachkova, Jezek, Mares, & Moravcova, 2013; Webster, Nicholas, Velacott, Cridland, & Fawcett, 2010). The WHOQOL-BREF focuses on four broad domains of life: physical health, psychological health, social relationships, and the person's environment. The number of questions in each domain is 7, 6, 3 and 8 respectively. Each item is rated on a 5-point Likert scale. The response options in each section of the scale differ. They include responses like 'very dissatisfied' to 'very satisfied', 'not at all' to 'extremely' and 'very poor' to 'very good'

depending on the type of question asked. The final scores are then transformed and interpreted according to WHO guidelines for interpreting WHOQOL-BREF (Gholami, Jahromi, Zarei, & Dehghan, 2013).

Rosenberg's Self-Esteem Scale

Rosenberg's Self-Esteem Scale is one of the most widely used instruments to measure individuals' confidence in self-abilities or self-worth (McKay, Boduszek, & Harvey, 2014). The scale has been translated into 28 languages worldwide and administered to participants in 53 countries, including Bangladesh (Schmitt & Allik, 2005). This 10-item Likert-type scale assesses global self-worth by measuring positive and negative feelings about oneself. It contains 5 positive and 5 negative items. Each item scores from '0' (strongly agree) to '3' (strongly disagree), and the total score ranges from 0 to 30. Scores ranging from 15 to 25 indicate normal self-esteem and scores below 15 indicate low self-esteem.

Interview schedules for process evaluation

Two separate interview schedules (Appendix E and F) — one for the pregnant women and the other for the peers — were developed from Borrelli's (2011) framework for assessment, monitoring and enhancement of treatment fidelity in public health clinical trials and Lichstein, Reidel, and Grieve's (1994) treatment implementation model for evaluating RCTs. Both schedules contained items in a Likert scale ranging from 'strongly agree' to 'strongly disagree' and qualitative questions to explore participants' views further on the intervention, delivery and usefulness and peer's role. The semi-structured schedules contained items to explore participants' understanding of the skills and knowledge provided during the programme delivery and their confidence on using these skills in future. All interviews during the process evaluation were audiotaped and transcribed verbatim for qualitative data analysis.

4.7 Ethical considerations

Ethical approval to conduct the study was obtained from the Victoria University Human Ethics Research Committee (HRE 16-180) (Appendix J) and Bangladesh Medical Research Council (RN-05519062017) (Appendix K). All ethical aspects of the study were considered and adhered to according to the guidelines of the National Health and Medical Research Council, Australia (NHMRC) and complied with the World Medical Association's (WMA's) Declaration of Helsinki (National Health and Medical Research Council, 2018; National Statement on Ethical Conduct in Human Research, 2007, (updated 2018); World Medical

Association, 2013). According to the NHMRC guidelines, human research is conducted on the grounds of the relationship between the participants and the researchers (National Statement on Ethical Conduct in Human Research, 2007, (updated 2018)). This relationship is built upon on a set of four values; namely, research merit and integrity, justice, respect for the participants involved and beneficence (NHMRC, 2018). According to the Australian code for responsible conduct of research, it is the researcher's responsibility to "ensure that the ethics principles of research merit and integrity, justice, beneficence and respect are applied to human research" (National Health and Medical Research Council, 2018, p. 4).

A research study is considered to have merit and integrity when the proposed research has justifiable potential benefits including the contribution to knowledge and understanding to promote individual and social wellbeing. To uphold this merit and integrity, the research project must be based on extensive literature review and designed using appropriate methods suitable to achieve the proposed aims.

To ensure that the proposed research is just, it is important to consider the scope and objectives of the project including fair and logical description of inclusion and exclusion criteria for participants. It is important to ensure that the recruitment of participants is fair and there is no unjust burden on or exploitation of participants regarding involvement in the study.

The value and principle of beneficence in research implies that the possible benefits of the research must outweigh the risk of harm to participants. Minimising the risk of harm or discomfort should be the top priority in designing a research project. In this account, it is the researcher's responsibility to safeguard the welfare of participants during data collection and every participant should have clear knowledge of the potential risks of participation in the research.

Concerning the value of respect to the individuals involved in the research, it is essential to abide by ethical principles for ensuring research merit and integrity, justice and beneficence. In addition to the recognition of the intrinsic values in individual human beings, respect for their welfare, beliefs, perception, tradition, customs and cultural heritage is also vital for upholding the value of respect in research studies.

Considering these ethical principles and the need to abide by the set of values describes above, the main ethical aspects for the present study identified were informed consent; participant

withdrawal; privacy, confidentiality and anonymity; data storage, access and disposal; and minimising the risk of harm.

4.7.1 Informed consent

Informed consent is an essential ethical aspect for any research study. It is an absolute necessity to uphold the value of respect to participants in terms of giving scope to the participants' power to make their own decisions. According to NHMRC guidelines, the main criteria for obtaining informed consent from participants are as follows:

1. The individual's decision to participate in a study should be voluntary. The decision should be based on adequate information and understanding of the research project including its purpose, methods, demands, potential benefits and risks.

2. The information must be presented in a way so that it is understandable to the participant.

3. The process of communicating information to and asking consent from the person should be based on mutual understanding between the researcher and the person rather than a matter of performing a formal procedure. To achieve this mutual understanding, participants must have the opportunity to ask any questions and have their queries clarified regarding participation.

4. Information given to participants must include:

- methods used to protect the privacy and confidentiality of participants,
- contact details for the researcher and details of the persons or institutions designated to receive complaints,
- statement of the participant's right to withdraw from the study,
- source of funding of the research and any payment to participants, and
- the expected benefit for the individual and wider community.

5. The consent can be verbal or written depending on the type and level of risk in the research study and participants' personal and social circumstances.

6. Participants can be reimbursed for costs incurred because of participation including travel cost, accommodation and child care, and for the time involved in participation. However, the research project will be ethically unacceptable if the reimbursement is disproportionate to the time involved and acts as an encouragement for participants to participate in the study.

7. Participants should never feel pressured or coerced to participate in the study because of someone else's wish or perceived position of power of the researcher. A participant must be included after ensuring that the consent is voluntarily and is not influenced by other factors.

8. In some studies, it is sometimes necessary to involve others in consent procedures. The NHMRC (2018) guidelines state that in some communities the decision to participate in a study depends not only on individual consent but also requires the consent of families and community elders. Hence, it is the responsibility of the researcher to include all the interested parties in designing and planning of the study.

In the present study, the researcher provided a printed Participant Information and Consent form (Appendices A, B, C, D) written in plain language in Bengali to all potential participants. With the help of the available health staff in the clinics, verbal explanations were also given to those unable to read. Communication were also conducted in local dialect whenever necessary. Potential participants were encouraged to ask question about any aspects of the study they did not understand, and all queries were answered to their satisfaction. Considering the traditional and cultural values of the data collection site and the safety of the peers delivering the intervention, all the potential participants were also asked to obtain verbal consent from their families before giving their final written informed consent.

4.7.2 Withdrawal from the study

Another important ethical aspect of a research study is the participant's right to withdraw from the research at any stage (National Statement on Ethical Conduct in Human Research, 2007, (updated 2018)). The NHMRC guidelines state that all participants should be informed of this right before participation. Participants also have the right to withdraw their data from the study and know about the implications of such withdrawals.

In the present study, all participants were informed of their right to withdraw from the study at any time during data collection. They were advised to contact the researcher if they wanted to withdraw from the study. In the event, none of pregnant women withdrew from the study and only one peer discontinued before beginning the intervention delivery.

4.7.3 Privacy and confidentiality and anonymity

Privacy and confidentiality are two crucial components of a research study that researchers must address during the development of the study. Privacy refers to participants' right over the

personal information shared during the course of the research project with the researchers or other authorised personnel involved in it. Confidentiality refers to specific steps undertaken by the researcher to keep participants' information secure and anonymous to the greatest possible extent.

Participants' privacy, confidentiality and anonymity was maintained throughout the present study. During the intervention delivery, peers were given specific instructions to maintain confidentiality to keep participants' shared information secure and were strictly instructed not to discuss the women's information with anyone. During data collection, all participants were given numeric codes, which were stored separately from data files. Only the supervisors (Professor Terence McCann and Professor Mary Carolan-Olah) and the researcher had access to the file containing participants' names and contact details. Audio recordings were stored with a unique code number for each participant. Hence, no identifiable information was disclosed during the transcription process.

4.7.4 Data storage, access and disposal

At the end of data collection, all hard copies were brought back to Australia and stored in a locked filing cabinet in the College of Health & Biomedicine, Victoria University. Electronic data were stored in a password-protected file in the Principal Supervisor's and the researcher's computers and in the Student R-drive account. All data will be stored for five years after the completion of the study and destroyed according to the ethical guidelines of the University. Hard copies will be shredded, and soft copies will be deleted from computers and R-drive account.

4.7.5 Minimising the risk of harm

4.7.5.1 Psychological risks

There were some psychological risks to the pregnant women in participating in the study. The risks were identification of pregnant women with high depression scores (15 or more in PHQ-9) during the screening process, and participants becoming emotionally distressed while participating in the study. In both instances, a systematic referral process was put in in place to manage these risks. High-risk participants (3) who scored more than 14 on the PHQ-9 scale were excluded from participation in the study and referred to an appointment with the antenatal clinic in Chakaria Health Complex as a first step. In the second step, where necessary the

researcher made appointments for these women with a consultant psychiatrist at the nearest mental health care facility. The External Investigator, Professor Mottalib, who was a consultant psychiatrist and Head of the Psychiatry Department of the nearest psychiatry facility, agreed to help with any high-risk participants referred from the antenatal clinic for further evaluation. None of the three high-risk pregnant women who scored more than 14 during screening in PHQ-9 needed this referral to the psychiatry facility.

4.7.5.2 Social risk

There were minor social risks associated with participation in the study. Participants may have been subjected to stigmatisation from the community during the data collection period because they were perceived to have depression or a mental illness. The participants did not have mental illness because they did not meet the DSM-5 or the ICD-10 diagnostic criteria for depression. Furthermore, the words 'depression' and 'depressive symptoms' were avoided at all times during programme delivery in this study. It was also explained to participants' families that the study was to examine whether the intervention could help pregnant women relieve their day-to-day stress and worries about achieving a healthy outcome from their pregnancy. The same approach was followed in the original THPP trial to minimise the stigmatisation of participants.

4.8 Data analysis

4.8.1 Quantitative data analysis

Quantitative data were analysed using SPSS Version 25 (IBM Corp., 2017). Data screening was conducted before data analysis. All variables were examined for data entry, normality, missing values, distributions and the assumptions of appropriate analyses. Descriptive statistics were conducted to detect errors in data entry and out-of-range values. The data were also evaluated for skewness, kurtosis, stem-and-leaf plots, histograms and outliers.

Cronbach's alpha was used to evaluate the reliability of each scale used in data collection. The Cronbach's alpha co-efficient score showed that each scale had satisfactory reliability for the study (PHQ-9= 0.81 WHOQOL= 0.89, RSS= 0.70). Demographic data were analysed using descriptive statistics. Independent samples *t*-tests were conducted to calculate mean scores in intervention and control groups at baseline, post-intervention and follow-up time-points. A series of logistic regression analyses were conducted to identify characteristics of participants from whom data were collected at follow-up and to identify characteristics of participants lost post-intervention or at follow-up. The characteristics or predictors were entered into separate

logistic regression analyses, with regression coefficients, standard errors (SE), odds ratios (OR), 95% confidence intervals and significance levels reported for each variable.

Intent-to-treat (ITT) principles were used for the main data analyses; all cases were analysed according to their assigned treatment group, and analysis was confined to participants who had completed baseline data collection**.** Differences in total scores on PHQ-9, RSS and WHOQOL-Bref scales were examined using mixed models repeated measures (MMRM) analysis of variance. In line with ITT principles, this method allows researchers to include participants with missing data under certain assumptions and hence was considered appropriate for the current study. The residuals from the models were evaluated for substantial non-normality. *A priori* contrast analyses were used to compare changes in intervention and control groups from baseline to post-intervention and baseline to follow-up time-point. The calculation of between group effect sizes[13] (Cohen's *d*) was done by dividing the difference between the observed group means by their pooled standard deviation.

4.8.2 Qualitative analysis

Thematic analysis was used to analyse qualitative data. This allows the commonalities and differences between pieces of data to be recognised, with a focus on the relationships between different parts, and then allows researchers to draw conclusions that appear around clustered themes (Braun & Clarke, 2006; Gale, Heath, Cameron, Rashid, & Redwood, 2013). Braun and Clarke's (2006) six-step process of analysing qualitative data was used to develop themes. (i) To acquire a broader understanding of participants' views, interview transcripts were repeatedly read and examined closely to identify meanings and re-appearing patterns and ideas. Initial notes were obtained, and ideas were marked for coding of data. (ii) After generating a list of ideas, data were organised into meaningful groups and codes were inserted. (iii) Codes were then collected and combined to develop provisional themes. (iv) Themes were reviewed and refined multiple times to generate a thematic 'map' of the data analysis. (v) The next step involved appropriately naming and defining each theme. (vi) Finally, interpretation of extract examples within and across the themes was done to produce a precise, coherent and logical account of the overall thematic analysis (Braun & Clarke, 2006).

[13] Effect size: 0.2=small, 0.5=medium, 0.8=large.

4.9 Study rigour

Pilot RCTs are considered a fundamental step in clinical research projects, especially RCTs of new pharmaceutical, educational, social, psychological or behavioural interventions (Arain et al., 2010; Leon et al., 2011). Thabane et al. (2010) suggest that the design for a pilot RCT should be as close as possible to that planned for the full RCT and should incorporate a control group. Inclusion of a control group in pilot trials, to make comparisons with an intervention group, is considered a more rigorous approach than a single arm quasi-experimental study (Arain et al., 2010). It was important in the present study to include a control group to determine the effect of the intervention on the intervention group. Comparison of baseline and follow-up data collected from control and intervention group participants helped determine whether any effect or changes in the outcome data were the result of taking part in the intervention and not for any other reason.

The pilot RCT and the process evaluation in the present study were based on the Borrelli (2011) framework for assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials and the Lichstein, Reidel, and Grieve (1994) treatment implementation model for evaluating RCTs. Treatment fidelity refers to the 'ongoing assessment, monitoring, and enhancement of the reliability and internal validity of a study' (Borrelli, 2011, p. 1). The overall study design and evaluation rigorously followed the five domains of Borrelli's (2011) framework, namely: study design, provider training, treatment delivery, treatment receipt, and treatment enactment.

During the qualitative part of the process evaluation all interviews were audiotaped and transcribed verbatim. Process evaluation is considered as a useful way to assess an intervention trial (Bellg et al., 2004; Borrelli, 2011). Participants in the process evaluation were asked to answer a list of open- and closed-ended questions relating to provider training standards, treatment delivery, treatment receipt, and treatment enactment (Appendices E, F).

4.9.1 Treatment fidelity of the intervention

A pilot study needs a rational theoretical basis for the intervention and appropriate methodology (Leon et al., 2011). The effectiveness of an intervention depends on the effectiveness of its delivery, in other words, treatment fidelity. Although there are no hard and fast rules to ensure treatment fidelity for an intervention, a comprehensive plan must be implemented to ensure effective delivery of the intervention (Borrelli, 2011).

Treatment fidelity needs to be ensured in five domains delivery during the data collection period (Bellg et al., 2004; Borrelli, 2011): study design, treatment providers' training, treatment delivery, treatment receipt, and treatment enactment. The first domain is the study design and it has been described in previous section. The latter four domains are described in the following section. All the strategies described accord with the treatment fidelity framework recommended by the U.S. National Institute of Health Behavioural Change Consortium (Bellg et al., 2004; Borrelli, 2011).

Provider training and preparation of peers

In the study, the treatment providers were the peers. After recruitment, all six peers had undergone a minimum of four days' (24 hours) preparatory training. Training included educating them about the different aspects of depression and antepartum depression, treatment options for antepartum depression and the role of cognitive behavioural therapy, concepts and contents of the Thinking Healthy Programme–Peer delivered, role and responsibilities of peers, and effective communication skills. Training also included role play exercises using actual sessions of the intervention. The researcher had established communication with the team behind the THPP through emails and they could be approached any time regarding any queries about the training for the intervention.

All peers were provided with a take-home booklet containing detailed information about depression, the THPP, communication skills and peers' role in the study. To ensure that the peers were adequately trained the researcher asked them to answer questions about antepartum depression and the THPP approach. This ensured that all peers had acquired sufficient knowledge about the content of the training sessions. To maintain peers' skills over time, face-to-face booster sessions or periodic meetings were conducted fortnightly. In addition, the researcher had regular contact with the peers through telephone calls and peers were encouraged to contact her at any time if they had queries. These steps helped in preserving fidelity in provider training of the study (Bellg et al., 2004; Borrelli, 2011).

Treatment delivery

The researcher recorded the dates and times when the peers delivered intervention sessions to pregnant women participants, and she observed each peer delivering the first session of the intervention. In addition, the peers and the participants were asked a series of questions after the session. This was to ensure that all components of the session had been delivered according to the intervention manual and to confirm that the peers and participants were confident and

comfortable with the way the intervention was delivered. These strategies for monitoring and improving treatment delivery ensured treatment fidelity throughout the delivery of the intervention.

Treatment receipt

After each of the THPP sessions, the peer asked the pregnant women if they had understood all parts of the session and if they had any questions, to ensure that participants had understood all parts of the session. The THPP contained charts and checklists that were given to women after each session and they were asked to follow the charts and complete the checklists as part of their homework for next session. This ensured that the participants engaged with the content of the sessions and used the cognitive and behavioural skills taught in each session.

Treatment enactment

Intervention group participants were encouraged to use cognitive and behavioural skills taught during the intervention and after completion of the intervention. Qualitative interviews also provided information about participants' perspectives and level of understanding of the intervention. The interview also included questions about their use of the CBT skills taught during the intervention. After the intervention was delivered, the intervention group participants received weekly telephone calls for four weeks from their peers until follow-up data collection time. The aim of this support was to improve treatment enactment and answer any questions.

4.10 Summary

A pilot RCT of a CBT based intervention and a process evaluation was used in the study. This approach was chosen to find out the possible effects of the selected intervention on depressive symptoms in pregnant women. The selected intervention was part of the original THPP intervention. Data were collected from three rural areas of Bangladesh, and all ethical principles were adhered to throughout the study.

CHAPTER FIVE

Results of the pilot randomised controlled trial

5.1 Introduction

In this chapter, the findings of the RCT, evaluating the effect of the peer-based intervention, are presented. The chapter begins with a description of the participant flow in the study. Then, the sociodemographic characteristics of the participants are presented. The primary outcome of the study, a change in depressive symptoms in participants, is reported in the following section. Finally, the secondary outcomes of the study, changes in self-esteem and QoL scores, are described.

5.2 Participant flow

A total of 116 pregnant women (hereafter, the women) were screened to participate in the study (Figure 5.1). Seventy (60.3%) of the women met the inclusion criteria and consented to take part. They were assigned randomly to control and intervention groups. In the intervention group, three participants were lost to follow-up. They could not be reached by telephone or traced back to the home addresses provided at recruitment. Another three participants did not complete the five-week intervention. Among these, one participant had a premature delivery before the intervention commenced. Two were unable to complete the programme beyond the second session because they were visiting their maternal homes in other sub-districts. This meant that 29 participants finished the five-week programme with the peers and completed the post-intervention questionnaires. Before the final data collection, another participant's baby was delivered and, hence, this woman was excluded from the final data collection. As a result, 28 participants completed the questionnaires at follow-up.

In the control group, 33 participants completed the questionnaires at baseline (Figure 5.1). Two were lost after screening and could not be contacted. Another two were excluded at the post-intervention data collection time-point, one because of a miscarriage and the other whose baby was delivered prematurely before post-intervention data collection. Hence, post-intervention data were collected from 31 participants. Follow-up data were collected from 29 of these, with two participants giving birth before the final data collection. Overall, at post-intervention, data were collected from 60 participants and the attrition rate was 14.2%. At follow-up, data were collected from 57 participants and the attrition rate was 18.5%.

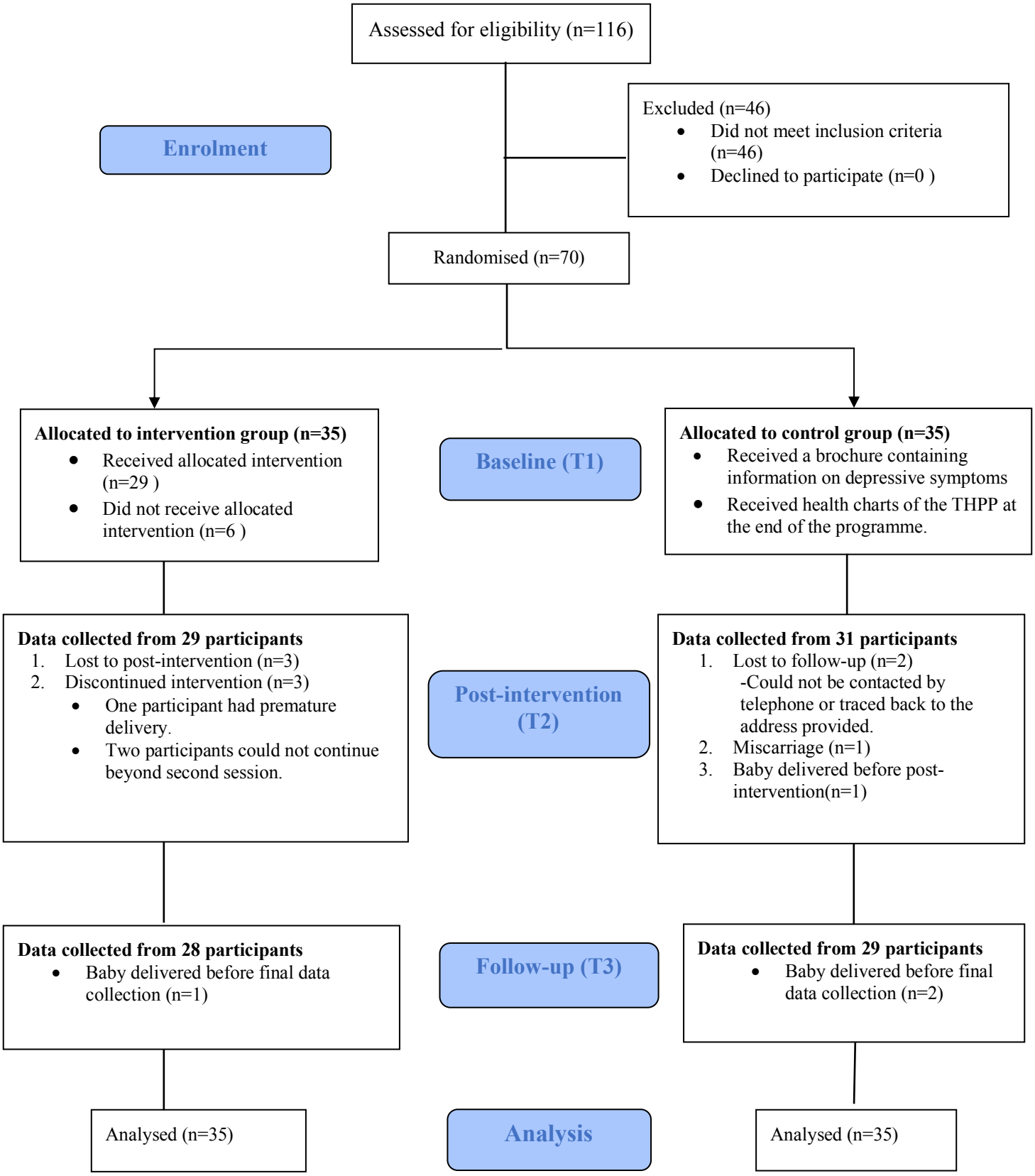

Figure 5.1: CONSORT flow diagram for participant flow in the study

A logistic regression analysis (Table 5.1) was undertaken to check for any relationship between missing data and different variables (i.e., age, education level, pregnancy trimester, place of antenatal care, previous history of mental illness and family history of mental illness and score of PHQ-9) at time-point baseline (T1). The findings showed that there were no statistically significant associations between the missing data and the variables in the analyses. This indicates that the likelihood of missing data was not dependent on any of the variables examined and, therefore, was random in nature.

Table 5.1: Results of simple logistic regression analyses predicting the presence of data at post-intervention or follow-up

	B	S. E.	Sig. (*p*)	Exp (B)	95% CI
1) Age	–.224	.143	.16	.819	0.620–1.08
2) Education level	.985	.567	.08	2.678	0.882–8.13
3)Number of pregnancies	.912	.466	.06	2.381	0.971–5.84
4) Pregnancy trimester	–.545	1.374	.63	.525	0.037–7.41
5) Place of antenatal care	–.526	.421	.18	.562	0.243–1.29
6) Previous history of mental illness	–.890	2.205	.74	.479	0.007–34.60
7) Family history of mental illness	–101	2.199	.87	.695	0.010–49.97
8) PH9 score	–.130	.229	.60	.888	0.566–1.393

1) **B** The set of coefficients estimated for the model.
2) **S.E.** Standard deviation of the sample distribution for a statistic.
3) **Sig. (*p*)** Statistical significance or *p* value
4) **Exp (B)** Exponentiations of the coefficients
5) **95% CI** 95% confidence interval

5.3 Sociodemographic characteristics

The sociodemographic characteristics of the women are summarised in Table 5.2. At the time of recruitment, the mean age of participants was 22.91 years, ranging from 18 to 32 years. Of the 70 women, four[14] (5.7%) did not have any formal education, having never attended any school. Twenty-six (37.1%) had primary school education, ranging from grades 1 to 5.

[14] Primary education (grades 1–5) in Bangladesh was not compulsory before 1990 (Hahna, Islama, Nuzhata, Smytha, & Yanga, 2015).

Table 5.2: Sociodemographic characteristics of participants

	Total n=70 n (%)	Intervention n=35	Control n=35	Test statistic	value	df	*p* value
Educational level				χ^2	2.855	3	.414
• **No education**	4 (5.7)	1 (2.9)	3 (8.6)				
• **Primary school (grade 1–5)**	26 (37.1)	16 (45.7)	10 (28.6)				
• **Secondary school (grades 6–10)**	34 (48.6)	15 (42.9)	19 (54.3)				
• **Senior school (grades 11 and 12)**	6 (8.6)	3 (8.6)	3 (8.6)				
Parity				χ^2	4.99	2	.288
• **1**	24 (34.3)	12 (34.3)	12 (34.3)				
• **2**	21 (30.0)	8 (22.9)	13 (37.1)				
• **3**	18 (25.7)	9 (25.7)	9 (25.7)				
• **4**	5 (7.1)	4 (11.4)	1 (2.7)				
• **5**	2 (2.9)	2 (5.7)	0 (0)				
Pregnancy trimester				χ^2	.500	2	.779
• **First trimester**	16 (22.9)	9 (25.7))	7 (20)				
• **Second trimester**	38 (54.3)	19 (54.3)	19 (54.3)				
• **Third trimester**	16 (22.9)	7 (20)	7 (25.7)				
Place of antenatal care				χ^2	1.065	3	.785
• **None**	37 (52.9)	17 (48.6)	20 (57.1)				
• **CHC/CC/Local midwife**	15 (21.4)	9 (25.7)	6 (17.1)				
• **UHFWC**							
• **Private**	9 (12.9)	5 (14.3)	4 (11.4)				
	9 (12.)9	4 (11.4)	5 (14.3)				
Previous history of mental illness				χ^2	1.061	1	.303
• **Yes**	4 (5.7)	3 (8.6)	1(2.9)				
• **No**	66 (94.3)	32 (91.4)	34 (97.1)				
Family history of mental illness				χ^2	.348	1	.555
• **Yes**	3 (4.3)	1 (2.9)	2 (5.7)				
• **No**	67 (95.7)	34 (97.1)	33 (94.3)				
Age in years				χ^2	9.31	14	.810
Mean	22.91	23.71	22.11				
Standard deviation	4.046	4.33	3.62				
Minimum	18	18	18				
Maximum	32	32	32				

Thirty-four women (48.6%) attended secondary school, ranging from grades 6 to 10. Of these, only one had completed the Secondary School Certificate examination but she did not continue beyond that level of education. Six participants (8.6%) had an education level equal to or above 11th grade. Of these six, one had completed the Higher Secondary School Certificate examination and one woman had graduate diploma-level education.

Regarding the participants' pregnancy, 16 (22.9%) were in the first trimester[15], 38 (54.3%) in the second trimester[16] and 16 (22.9%) in the third trimester[17]. The mode or modal number[18] of current pregnancies was 2 or 3, ranging from 1 to 5. At the time of recruitment, 37 (52.9%) participants had not yet attended any antenatal check-up. Fifteen (21.4%) had attended their local community clinic, community health centres or visited local midwives for antenatal care. Nine (12.9%) participants had visited the central sub-district government hospital, and 9 (12.9 %) had attended private clinics.

Most participants (n=66, 94.3%) reported no previous history of mental illness. Four (5.7%) reported a previous history of mental illness but could not name the actual illness. Three of these (8.6%) participants were in the intervention group and one (2.9%) in the control group. Only three participants (4.3%) reported a family history of mental illness, one in the intervention group and two in the control group.

5.4 Intervention outcomes

5.4.1 Depressive symptoms

The primary outcome of the study was measured using the Patient Health Questionnaire-9 (PHQ-9) scale. This nine-item scale measures the presence of depressive symptoms. The scores range from 0–27, with higher scores indicating a greater presence of depressive symptoms[19]. The mean scores on the PHQ-9 scale in the current study for two groups over the three time-points are illustrated in Table 5.3 and Figure 5.2. Both groups had similar low mean scores at baseline, with the mean and standard deviation for the intervention group being 11.51 (SD=1.541) and for the control group 12.31 (SD=1.530). The intervention group's mean score decreased to 7.72 (1.830) at the post-intervention time-point but increased between the post-intervention and follow-up time-points to 9.36 (SD=1.789). For the control group, the mean score decreased slightly between baseline and the post-intervention time-point, from 12.31 (SD=1.530) to 11.61 (SD=2.276), and the score was similar at the follow-up time-point, 11.55 (SD=1.993). Overall, these results indicate that in the intervention group there was decrease in

[15] First trimester: First three months of pregnancy (1-12 weeks).
[16] Second trimester: Four to six months of pregnancy (13-27 weeks).
[17] Third trimester: From seven months onwards (28-40 weeks).
[18] Mode: The number which appears most often in a set of numbers. There can be two or more modal values.
[19] Refer to Chapter Four, Section 4.6.1 for details of the scale.

depressive symptoms at post-intervention, but with an increasing trend at follow-up. In contrast, for the control group the mean score was similar at all time-points.

Table 5.3: Means and standard deviations for depressive symptom scores at each time-point

Variable (PHQ-9) at each time-point	**Control Group (n=35)** M±SD	**Intervention group (n=35)** M±SD
Baseline (T1)	12.31±1.530	11.51±1.541
Post-intervention (T2)	11.61±2.276	7.72±1.830
Follow-up (T3)	11.55±1.993	9.36±1.789

1) M= Mean
2) SD= Standard deviation

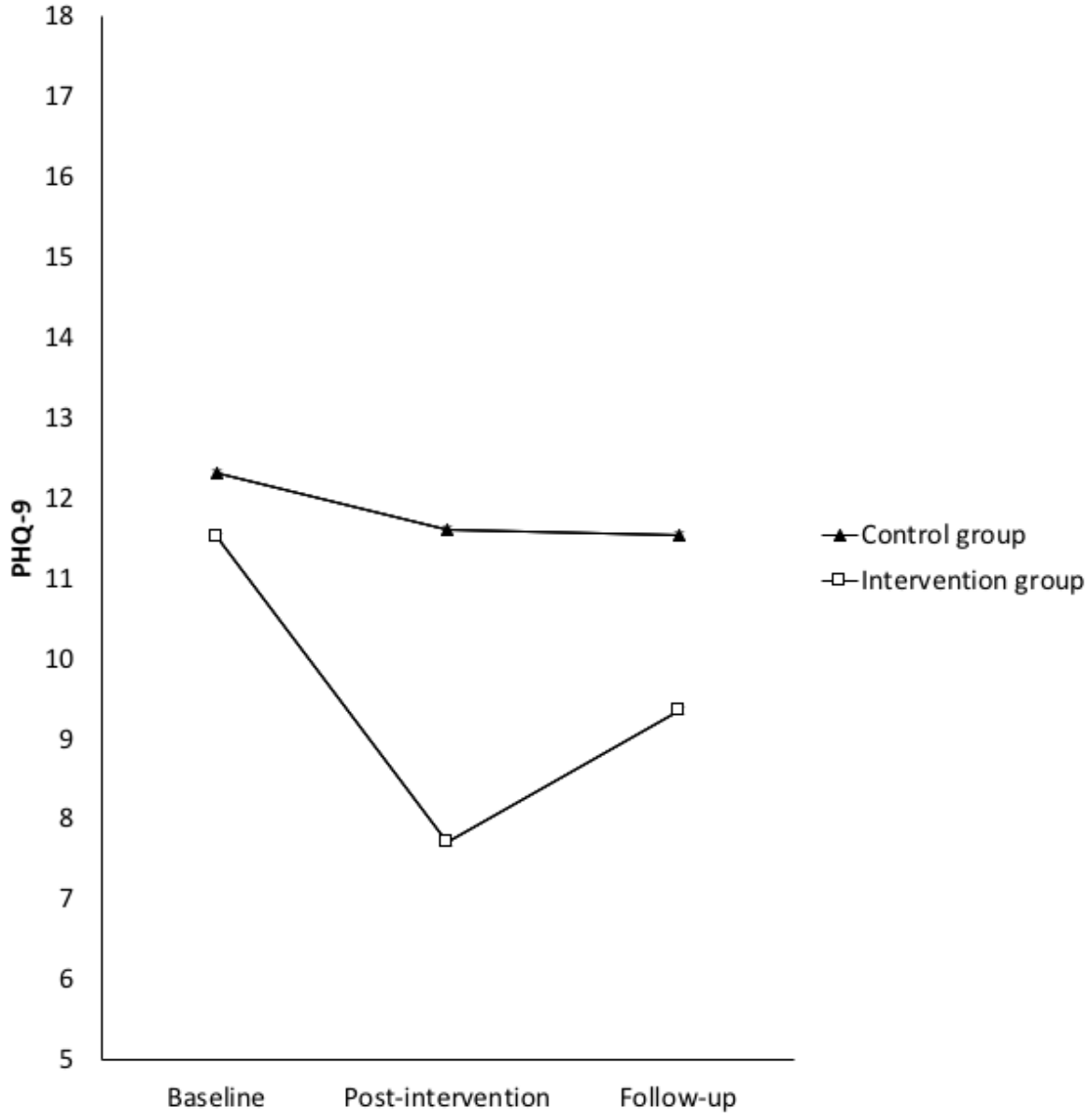

Figure 5.2 Depressive symptom outcomes at baseline, post-test, and follow-up time-points

A mixed model repeated measures (MMRM) analysis of variance (ANOVA) was conducted on PHQ-9 total scores. The findings showed that there was a significant main effect for time (F (2, 59.212) =31.868, p= 0.0001), and a significant main effect for group (F (1, 62.824) =40.356, p.= 0.0001). These findings indicate that the scores for both groups varied at each time-point and changed over time. The interaction of group and time on PHQ-9 scores was also significant (F (2, 59.212) =6.912, p= 0.0001) (Table 5.4), indicating that the intervention group showed more improvement in depressive symptoms than the control group at each time-point.

Table 5.4: Fixed effects of time and group on depressive symptoms scores

Variable (PHQ-9)	df*	*F***	Sig.***
Time	59.212	31.868	0.0001
Group	62.824	40.356	0.0001
Time*Group	59.212	16.912	0.0001

*df=degrees of freedom, **F=ratio of two mean square,
***Sig.=statistical significance or p value

A planned contrast, conducted to explore the difference in the amount of change in both groups from baseline to post-intervention, showed that the intervention group had a significantly lower PHQ-9 score than the control group (t (61.238) = –5.437, p=.0001). This indicates that the intervention group showed a significantly greater decrease in depressive symptoms than the control group at post-intervention time-point, with a decrease in the mean score by 3.12 points (95% CI=1.97–4.26). Another planned contrast, testing the difference in change from baseline to follow-up, was also found to be significant in the control and intervention groups (t (61.206) = –3.096, p=.003), indicating that the improvement in the intervention group was also significant at follow-up time-point. The mean difference between the two groups was 1.63 (95% CI=0.57–2.68) (Table 5.5).

Table 5.5: Main effects of intervention and control groups on depressive symptoms

Variable (PHQ-9)	**Estimates**	**Std. Error**	**df**	***t***	**Sig.(*p*)**	**95% CI**	
						Lower bound	Upper bound
T1–T2 (Intervention vs control)	–3.120520	.573891	61.238	5.437	0.0001	–4.267995	–1.973045
T1–T3 (Intervention vs control)	–1.629071	.526258	61.206	3.096	0.003	–2.681317	–0.576826

T1=Baseline; T2=Post-intervention; T3=Follow-up

The residuals[20] of the model were analysed. The analysis showed no substantial deviation from normality, with symmetrical distribution of the data and no significant skewedness. The pattern indicated that the MMRM analysis presented a reasonable fit for the data in the study (Table 5.6).

Table 5.6: Analysis of residuals of depressive symptoms scores

	Skewness+ Std. error*		**Mean+ Std. error**	
	Control group	Intervention group	Control group	Intervention group
Baseline	–.306+.398	.483+.398	.00+2.58	.00+.260
Post-intervention	–.356+.421	.365+.434	–.007+.408	.023+.339
Follow-up	.558+.434	.795+.441	–.154+.37	.07+.338

*Std. error = Standard error

Effect size[21] at post-intervention was large (effect size=1, 95% CI=0.501–1.496) and indicated the intervention had a positive effect. However, at follow-up the effect size was small-to-medium (effect size=0.4, 95% CI= –0.009–0.941) (Table 5.7). This shows that at post-intervention, intervention group participants experienced a significant reduction in their depressive symptoms. This decreased to a small-to-medium effect at the follow-up time-point but showed that the effect of the intervention was still present at that time-point. The number of participants needed to treat (NNT)[22] to reduce individual PHQ-9 scores to 9 or below was 2

[20] Residual is defined as the difference between the observed value of the dependent variable and the predicted value. Each data point has one residual.
[21] Effect size: 0.2=small, 0.5=medium, 0.8=large.
[22] Number needed to treat is the number of the participants needs to be treated or participate in a programme in order to prevent one adverse outcome (in the present study, to prevent the development of major depressive symptoms (Mendes, Alves & Batel-Marques, 2017).

(95% CI), which signifies that to reduce one participant's PHQ-9 score to 9 or below (mild-to-no depressive symptoms) at least two participants needed to participate in the intervention.

Table 5.7: Effect size for depressive symptoms

	Effect size	95% confidence interval	
		Lower bound	Upper bound
At post-intervention	1 (large)	0.501	1.496
At follow-up	0.4 (small)	–0.009	0.941

5.4.2 Self-esteem

The Rosenberg Self-Esteem Scale (RSS) was used to test whether the intervention had any effect on the self-esteem level of participants. Scores on the RSS range from 0 to 30, with higher scores indicating higher self-esteem[23]. Mean RSS scores for the two groups over three time-points are shown in Table 5.7 and Figure 5.3. Both groups had similar low self-esteem scores at baseline (intervention group mean=13.81, SD=1.862; control group mean=13.03, SD=1.804). Between baseline and post-intervention, there was a slight increase in the mean self-esteem score in the intervention group, from 13.81(SD=1.804) to 15.62 (SD=1.425), but between post-intervention and follow-up, the mean score decreased slightly to 15.02 (SD=1.427). In the control group, mean scores remained very similar from baseline (mean=13.03, SD= 1.804) to post-intervention (13.52, SD=2.064) and follow-up (mean 13.55; SD=2.010). Overall, there was a slight increase in the mean self-esteem score in the intervention group at post-intervention, followed by a small fall at follow-up, whereas the mean self-esteem score in the control group remained similar at all three data collection time-points.

Table 5.8: Means and standard deviations for self-esteem scores at each time-point

Variable at each point of time	**Control group (n=35)** M±SD	**Intervention group (n=35)** M±SD
Baseline	13.03±1.862	13.81±1.804
Post-intervention	13.52±2.064	15.62±1.425
Follow-up	13.55±2.010	15.04±1.427

1) M= Mean
2) SD= Standard deviation

[23] Refer to Chapter Four, Section 4.6.1 for details of the scale.

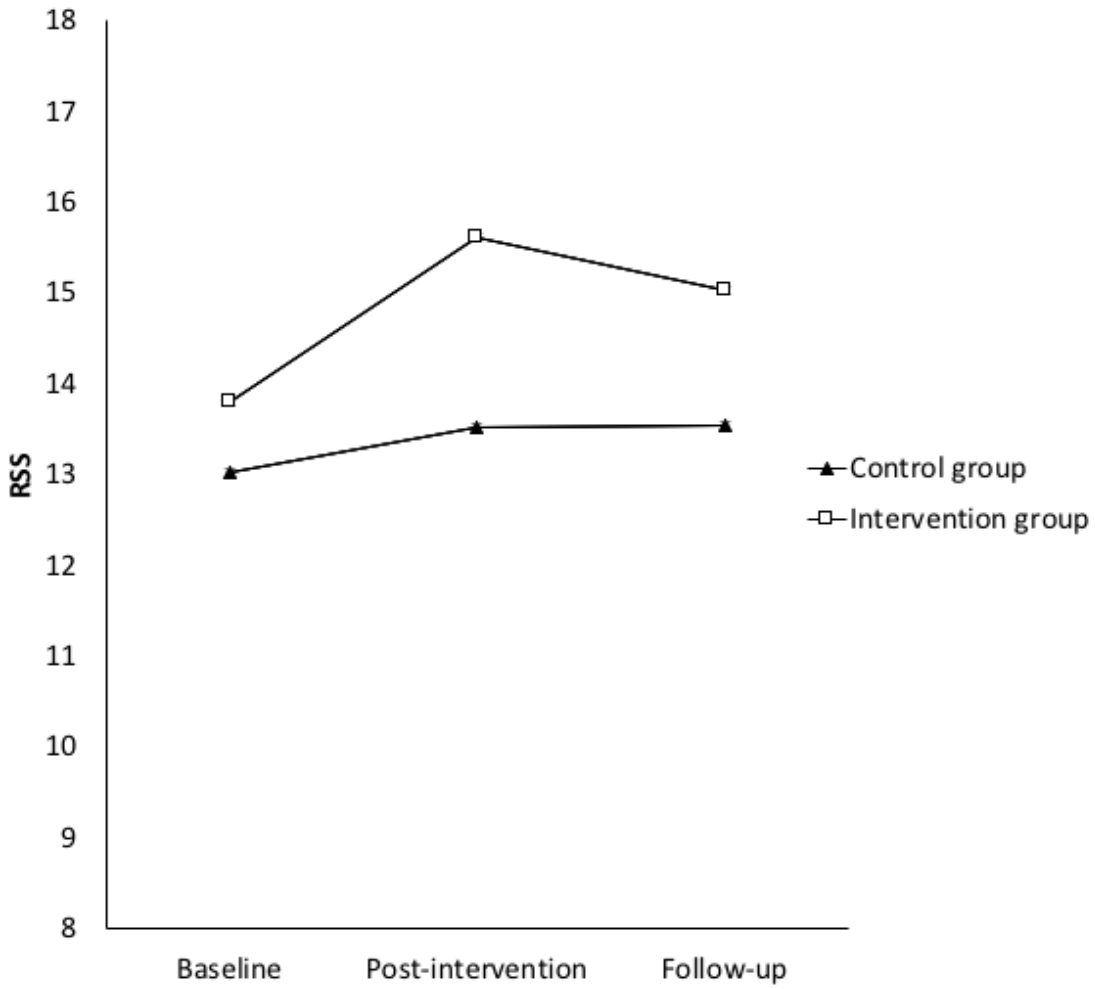

Figure 5.3: Self-esteem outcomes at baseline, post-intervention, and follow-up time-points

The MMRM ANOVA conducted on RSS scores showed that there was a significant main effect for time (F (2, 60.460) =8.671, p=.0001) and a significant main effect for groups (F (1, 61.816) =17.302, p=.0001). These findings indicate that there were changes in both groups over time, with the intervention group scoring higher than the control group. However, the interaction of group and time was not significant (F (2, 60.460) =3.048, p=.06), indicating that the intervention group did not show significant improvement in self-esteem compared with the control group at any time-point (Table 5.9).

Table 5.9: Fixed effects of time and group on self-esteem scores

Variable (RSS)	df*	*F***	Sig.***
Time	60.460	8.671	0.0001
Group	61.816	17.302	0.0001
Time*Group	60.460	3.048	0.006

*df=degrees of freedom, **F=ratio of two mean squares,
***Sig.=statistical significance or p value

A planned contrast was conducted to explore the difference in the degree of change from pre-intervention to post-intervention between intervention and control groups on self-esteem scores. This showed that the intervention group had a higher self-esteem score than the control group at the post-intervention time-point (t (61.478) =2.404, p=.019), with a mean improvement of 1.3 points (95% CI=0.220–2.30). However, the planned contrast assessing the difference in change from baseline to follow-up between the two groups was not significant (t (62.232) =1.470, p=.147). This indicated that between baseline and follow-up the intervention group did not show a significant improvement in self-esteem scores, with a difference of only 0.799 points (95% CI= –0.28–1.88) between the mean scores (Table 5.10).

Table 5.10: Main effects on self-esteem scores

	Estimates	Std. Error	df	*t*	Sig.(p)	95% CI	
						Lower bound	Upper bound
T1–T2 (Intervention Vs control)	1.307745	.543958	61.478	2.404	.019	0.220204	2.395285
T1–T3 (Intervention Vs control)	.799120	.543527	62.232	1.470	.147	–0.287295	1.885534

T1=Baseline; T2= Post-intervention; T3= Follow-up

The residuals of the model were also examined and normality in the presentation of the residual data was established. There was no significant positive or negative skewedness on the graph, indicating a reasonable fit for the chosen model for the data (Table 5.11).

Table 5.11: Analysis of residuals of self-esteem score

	Skewness+ Std. error*		Mean+ Std. error	
	Control group	Intervention group	Control group	Intervention group
Baseline	.046+.409	–.088+.398	.00+.32	.00+.260
Post-intervention	–.390+.421	–.302+.434	.01+.37	.023+.339
Follow-up	–.294+.434	.314+.441	.112+.37	.07+.338

*Std. error= Standard error

Effect size analyses of RSS self-esteem scores at post-intervention and follow-up periods were found to be small at post-intervention (effect size=0.2, 95% CI= –0.293–0.646) and very small at follow-up (effect size=0.13, 95%CI= –0.333–0.605) (Table 5.12).

Table 5.12: Calculation of effect size for self-esteem

	Effect size	95% confidence interval	
		Lower bound	Upper bound
At post-intervention	0.2 (small)	–0.293	0.646
At follow-up	0.13(very small)	– 0.333	0.605

5.4.3 Quality of life (QoL)

The WHOQOL-Bref scale measures individuals' QoL based on their self-perceptions in the context of their culture and value systems, and personal goals, standards and concerns[24]. The scale contains two global questions of perception of QoL and general health satisfaction, and four domains containing a total of 24 questions: physical health, psychological health, social relationships and environmental health. The score of each domain is initially transformed and then presented in a 0 to 100 scale, with higher scores denoting higher QoL.

5.4.3.1 Physical health

The physical health domain of the QoL scale contains seven questions featuring individuals' perceptions of different aspects of their physical health such as activities of daily living, work capacity, energy, sleep, pain and morbidity. The mean scores in the physical health domain in the current study are illustrated in Table 5.11 and Figure 5.4. The graph shows similar mean scores in both groups at baseline (intervention group mean=43.34, SD=11.140; control group mean=41.33, SD=10.555). Between baseline and post-intervention, there was an increase in the mean score of the intervention group to 54.86 (SD 8.943), with a slight decrease between post-intervention and follow-up to 50.79 (SD= 8.107). For the control group, the mean scores for the domain remained similar but with a slight decrease at each time-point (Table 5.11).

In summary, there was an increase in the mean score of the physical health domain of the QoL scale in the intervention group between baseline and post-intervention, followed by a slight decrease between post-intervention and follow-up. The control group, however, showed no apparent changes in mean scores across the three time-points.

[24] Please refer to Chapter Four, Section 4.6.1.

Table 5.13*:* Means and standard deviations for physical health domain of WHOQOL-Bref

Variable at each point of time	Control group (n=35) M± SD	Intervention group (n=35) M± SD
Baseline (T1)	41.33±10.555	43.34±11.140
Post-intervention (T2)	40.71±12.54	54.86±8.943
Follow-up (T3)	40.10±10.564	50.79±8.107

1) M= Mean
2) SD= Standard deviation

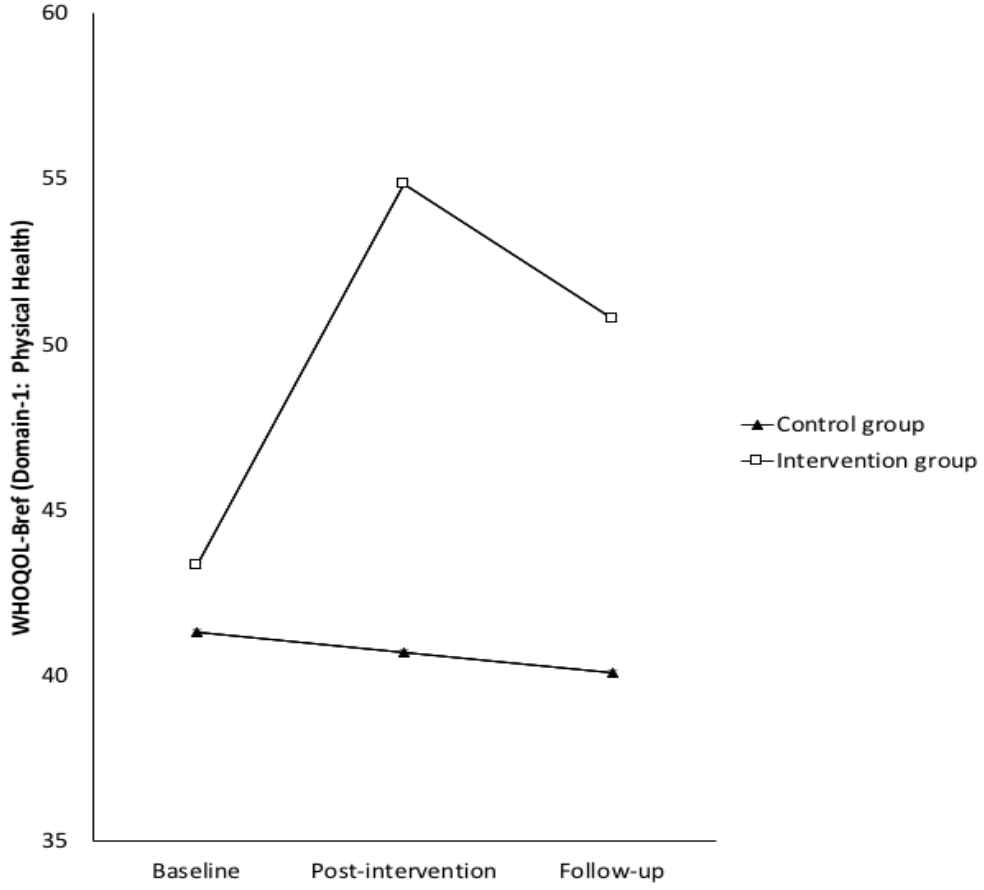

Figure 5.4: WHOQOL-Bref (physical health domain) outcomes at baseline, post-intervention, and follow-up time-points

A MMRM ANOVA conducted on the physical health domain scores of the QoL scale showed there were significant main effects for group (F (1, 63.686) =14.905, p=.0001) and time (F (2, 59.632) =8.074, p=.0001). This indicates that scores in both groups differed at each time-point and changed over time. The interaction between time and group on the physical health domain was also found to be significant (F (2, 59.632) =10.437, p=.0001), signifying that the

intervention group showed greater improvement than the control group in this domain at each time-point (Table 5.14)

Table 5.14: Fixed effects of time and group on physical health domain scores of WHOQOL-Bref

	df*	*F***	Sig.(*p*)***
Time	59.632	8.074	0.0001
Group	63.686	14.905	0.0001
Time*Group	59.632	10.437	0.0001

*df=degrees of freedom; ***F*=ratio of two mean square; ***Sig=statistical significance or *p* value

A planned contrast analysis was conducted to explore the difference in the amount of change between the two groups from baseline to post-intervention. This showed that the intervention group scored significantly higher in the physical health domain than the control group at the post-intervention time-point (t (60.658) =4.442, p=0.0001). The mean improvement in the intervention group at the post-intervention time-point was 11.71 points (95% CI=6.44–16.99). Another planned contrast analysis was conducted to assess the difference in the amount of change from baseline to follow-up was also significant in both groups (t (61.863) = –3.970, p=0.0001). This time the mean improvement was 8.71 points (95% CI=4.32–13.09) (Table 5.15).

Table 5.15: Main effects of intervention and control groups on physical health domain scores of WHOQOL-Bref

	Estimates	Std. Error	df	*t*	Sig.(*p*)	95% CI	
						Lower bound	Upper bound
T1–T2 (Intervention Vs control)	11.715909	2.637483	60.658	4.442	0.0001	6.441335	16.990483
T1–T3 (Intervention Vs control)	8.712927	2.194505	61.863	3.970	0.0001	4.325979	13.099874

T1=Baseline; T2= Post-intervention; T3= Follow-up

The residuals of the model were analysed at all three time-points and showed no substantial deviation from normality, with non-significant skewedness and symmetrical distribution of the data (Table 5.16).

Table 5.16: Analysis of residuals of physical health domain

	Skewness+ Std. error*		Mean+ Std. error	
	Control group	Intervention group	Control group	Intervention group
Baseline	.686+.409	.391+.414	.00+1.83	.00+1.96
Post-intervention	.249+.421	–.317+.434	.119+2.252	.43+1.47
Follow-up	.384+.434	–.125+.441	.47+1.96	.42+1.96

*Std. Error= Standard error

A simple effect size analysis for the domain showed a small-to-medium effect (effect size 0.5, 95% CI= –0.012–0.938) at the post-intervention period and a small effect (effect size 0.4, 95% CI= –0.105–0.840) at the follow-up time-point (Table 5.17). These findings indicate that the intervention had a small effect on the women's perception of QoL in the physical health domain.

Table 5.17: Calculation of effect size for physical health domain of WHOQOL-Bref

	Effect size	95% confidence interval	
		Lower bound	Upper bound
At post-intervention	0.5 (small-to-medium)	–0.012	0.938
At follow-up	0.4 (small)	– 0.105	0.840

5.4.3.2 Psychological health

The psychological health domain of the QoL scale contains six questions regarding an individual's perceptions of the psychological aspects of life, such as positive and negative feelings, self-esteem, spirituality, thinking, learning and concentration. The mean scores on the psychological health domain are illustrated in Table 5.18 and Figure 5.5. The mean score at baseline in the psychological health domain in the intervention group was slightly higher than the control group (intervention group mean=49.914, SD=10.062; control group mean=43.33, SD=11.518). Between baseline and post-intervention, the mean score for the intervention group increased slightly to 53.86 (SD=7.923), with a small decrease at follow-up to 51.39 (SD= 7.908). The mean score of the control group remained similar between baseline and post-intervention (42.84, SD=11.338) and there was no notable change in mean score between post-intervention and follow-up (42.76, SD=10.796). Overall, mean scores for

the control group on the psychological domain of WHOQOL-Bref scale remained similar at all three time-points. However, the mean score in the intervention group increased slightly

between baseline and post-intervention but showed a small decrease between post-intervention and follow-up.

Table 5.18: Means and standard deviations for psychological health domain of WHOQOL-Bref

Variable at each point of time	Control Group (n=35) M±SD	Intervention group (n=35) M±SD
Baseline (T1)	41.33±11.518	49.91±10.062
Post-intervention (T2)	42.84±11.338	53.86±7.923
Follow-up (T3)	42.76±10.796	51.39±7.908

1) M= Mean
2) SD= Standard deviation

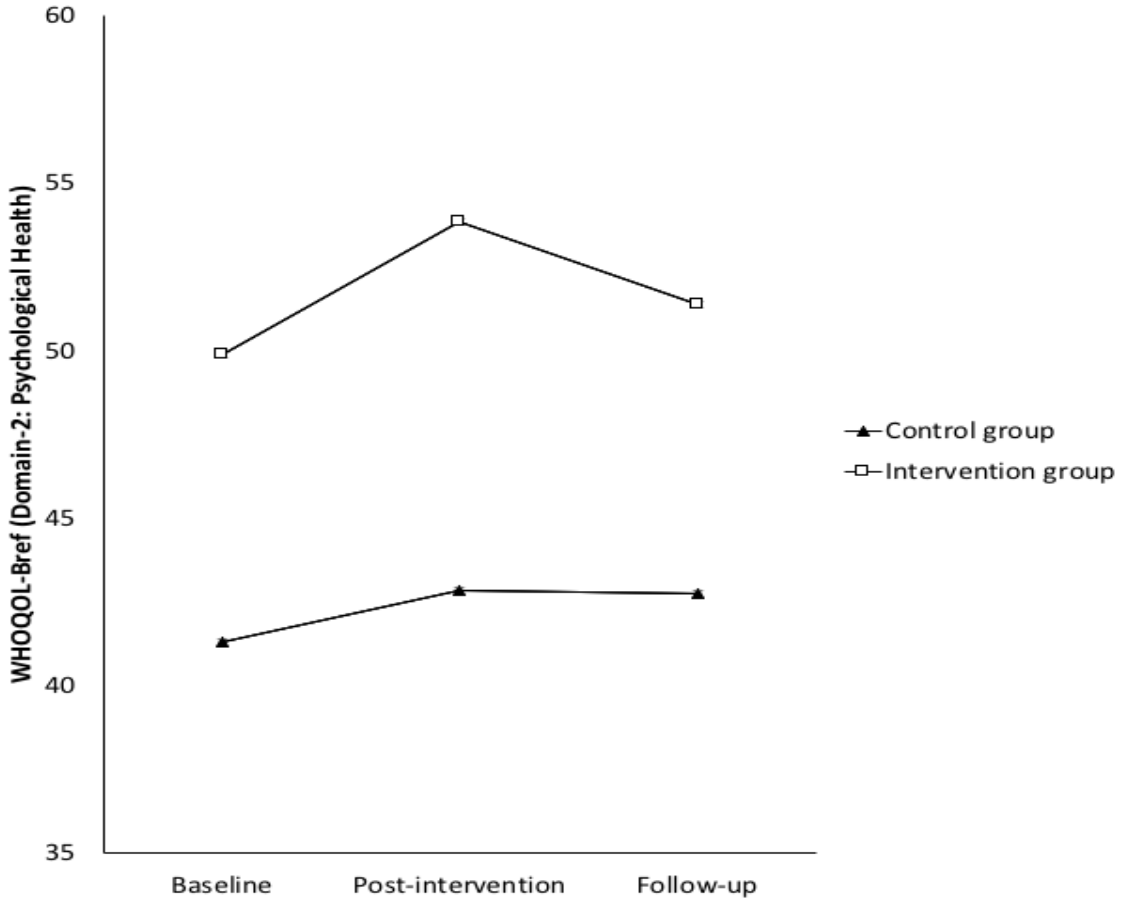

Figure 5.5: WHOQOL-Bref (psychological health domain) outcomes at baseline, post-intervention, and follow-up time-points

Table 5.19: Fixed effects of time and group on psychological health domain scores of WHOQOL-Bref

	df*	*F***	Sig.(*p*)***
Group	62.244	17.110	.0001
Time	58.619	1.596	.211
Time*Group	58.619	2.279	.111

*df=degrees of freedom; ***F*=Ratio of two mean square; ***Sig.=statistical significance or *p* value

A MMRM ANOVA conducted on the psychological health domain scores showed that the main effect of group on the domain was significant (*F* (1, 62.224) =17.110, *p*=.0001). However, there was no significant main effect of time on the domain (*F* (2, 58.619) =1.596, *p*=.211). The interaction between group and time on the psychological domain was also not significant (*F* (2, 58.619) =2.279, *p*=.111). This indicates that although there were differences in the groups' mean score at each time-point, over time the intervention group did not show any significant improvement in the domain in comparison with the control group (Table 5.19).

A planned contrast conducted to examine the difference in change between the groups from baseline to post-intervention found a significant difference (*t* (60.482) =2.111, *p*=.039). This indicates that the intervention group showed greater improvement in the domain than the control group. The mean improvement in the intervention group was 4.76 points (95% CI=0.25–9.28) between these two time-points. Another planned contrast analysis was conducted to assess the difference in change from baseline to follow-up. This showed that there were no significant differences between groups from baseline to follow-up (*t* (60.248) =1.126, *p*=.265). The mean score difference between the groups was only 2.81 points (95% CI= –2.18–7.80), indicating that the intervention group did not show any more improvement than the control group at follow-up time-point (Table 5.17).

The residuals of the model were examined at all three time-points and found to be within acceptable limits with normal distribution of data, indicating a reasonable fit for the chosen model for the data (Table 5.21).

The effect size for the domain was found to be small-to-medium at post-intervention (effect size=0.3, 95% CI = –0.135–0.809) and at follow-up time-points (effect size=0.3, 95% CI = –0.196–0.746) (Table 5.22).

Table 5.20: Main effects of intervention and control groups on psychological health domain scores of WHOQOL-Bref

	Estimates	Std. Error	df	*t*	Sig.(*p*)	95% CI	
						Lower bound	Upper bound
T1–T2 (Intervention Vs control)	4.767410	2.258333	60.482	2.111	.04 (<0.005)	0.250812	9.284008
T1 –T3 (Intervention Vs control)	2.812238	2.497110	60.248	1.126	.27 (>0.005)	–2.182304	7.806779

T1=Baseline; T2=Post-intervention; T3=Follow-up

Table 5.21: Analysis of residuals of psychological health domain

	Skewness+ Std. error*		Mean+ Std. error	
	Control group	Intervention group	Control group	Intervention group
Baseline	.149+.409	–.413+.414	.00+2.00	.00+1.77
Post-intervention	–.419+.421	–.855+.434	.29+2.03	–.025+1.47
Follow-up	–.143+.434	–001+.441	.72+2.004	–.027+1.49

*Std. error= Standard error

Table 5.22*:* Calculation of effect size for psychological health domain of WHOQOL-Bref

	Effect size	95% confidence interval	
		Lower bound	Upper bound
At post-intervention	0.3 (small-to-medium)	–0.135	0.809
At follow-up	0.3 (small-to-medium)	– 0.196	0.746

5.4.3.3 Social relationships

The social relationship domain of the WHOQOL-bref scale comprises three questions regarding individuals' perception of personal relationships, social support and sexual activity. The mean scores on the social relationship domain for the control and intervention groups are outlined in Table 5.23 and Figure 5.6. Mean scores for both groups were similar at baseline (intervention group 50.78, SD=18.883; control group 47.70, SD=21.882). Between baseline and post-intervention there was a sharp increase in the intervention group mean score (64.41, SD=19.391) followed by a slight decrease between post-intervention and follow-up (60.71, SD=19.714). In the control group, there was little change in mean score between baseline and

post-intervention (49.19, SD=19.391) and at follow-up the mean score was similar to baseline (51.07, SD= 19.714).

Table 5.23: Means and standard deviations for social relationship domain of WHOQOL-BREF

Variable at each point of time	Control group (n=35) M±SD	Intervention group (n=35) M±SD
Baseline (T1)	47.70±21.882	50.78±18.883
Post-intervention (T2)	49.19±19.391	64.41±19.391
Follow-up (T3)	51.07±19.714	60.71±19.714

3) M= Mean
4) SD= Standard deviation

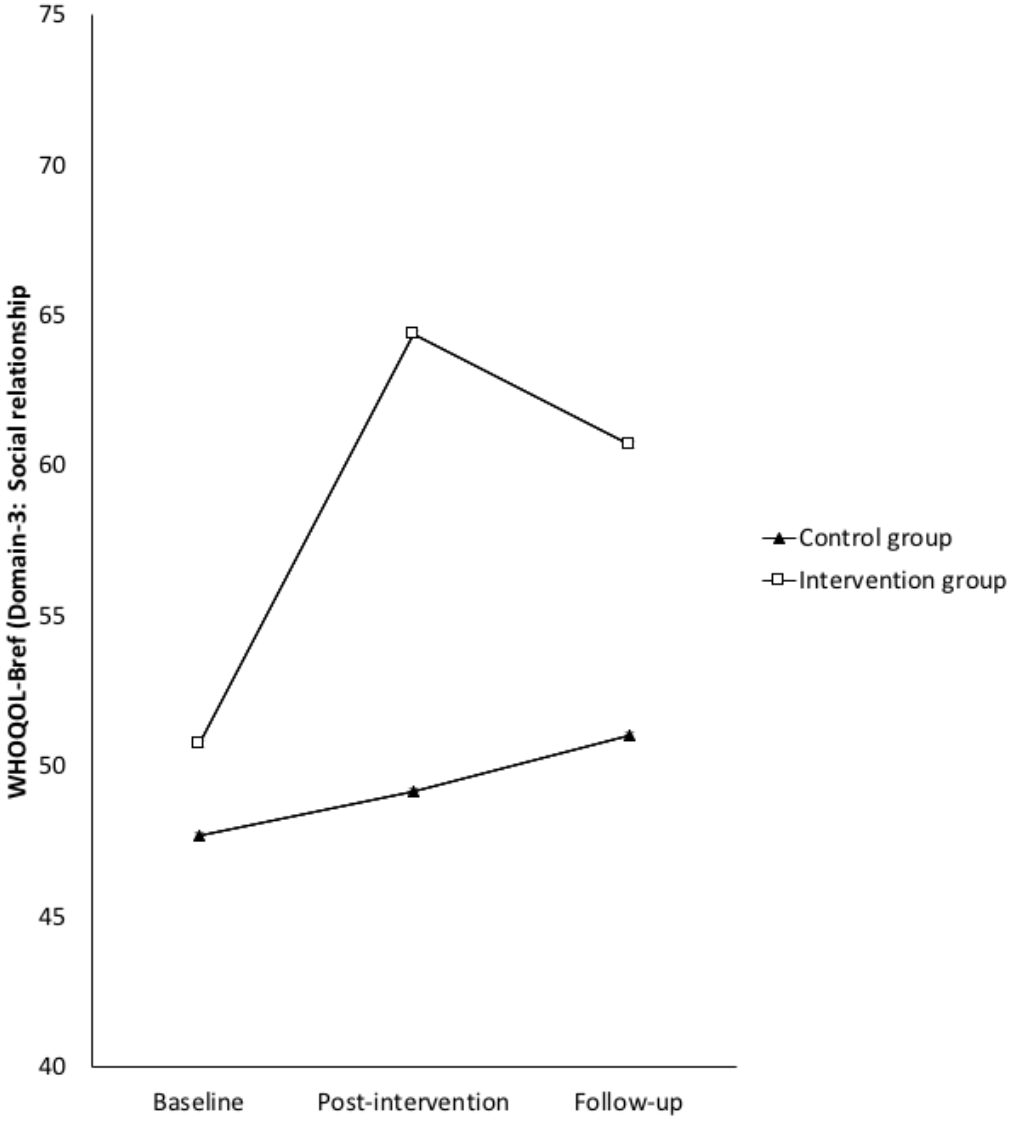

Figure 5.6: WHOQOL-Bref (social relationship domain) outcomes at baseline, post-intervention, and follow-up time-points

A MMRM ANOVA conducted on the social relationship domain showed that there was a significant main effect of group on the domain (F (1, 62.551) =4.565, p=.04). The main effect of time on the domain was also significant (F (2, 59.844) =7.048, p=.0001). This indicates that the score in each group was different at each time-point and the scores changed over time. Moreover, the interaction between time and group on the social relationship domain was significant in the analysis (F (2, 59.844) =4.312, p=.02). This indicates that the intervention group showed greater improvement in the domain than the control group at each time-point.

Table 5.24: Fixed effects of time and group on social relationship domain scores of WHOQOL-Bref

	df**	*F*	Sig.(*p*)
Group	62.551	4.565	0.04
Time	59.844	7.048	0.0001
Time*Group	59.844	4.312	0.02

1) **df**=degrees of freedom
2) ***F***=ratio of two mean square
3) **Sig**.=statistical significance or *p* value

A planned contrast analysis showed that there were significant differences between the groups in the changes from baseline to post-intervention (t (60.567) =2.710, p=.0001). This indicates that between baseline and post-intervention, the intervention group scored significantly higher than the control group. The mean improvement in the group was 10.413 points (95% CI=2.72–18.09). However, the difference in change from baseline to follow-up in both groups was not significant (t (61.386) =1.512, p=.136), which signifies that from baseline to follow-up the intervention group did not show any greater significant improvement than the control group. The mean difference between these two time-points was 6.586 (95% CI= –2.12–15.29).

Table 5.25: Main effects of intervention and control groups on social relationship domain scores of WHOQOL-Bref

	Estimates	**Std. Error**	**df**	***t***	**Sig.(p)**	**95% CI**	
						Lower bound	Upper bound
T1–T2 (Intervention Vs control)	10.413455	3.842630	60.567	2.710	0.0001	2.728531	18.098378
T1–T3 (Intervention Vs control)	6.586492	4.355165	61.386	1.512	0.136	–2.121091	15.294075

T1=Baseline; T2=Post-intervention; T3= Follow-up

An analysis was conducted to examine the residuals of the domain. The residuals showed substantial deviation from normality, with irregular non-symmetrical distribution of the data. This was addressed with a square root transformation of the data, which did not change the significance or the outcome of the data (Table 5.26).

Table 5.26: Analysis of residuals of social relationship domain

	Skewness+ Std. error		Mean+ Std. error	
	Control group	Intervention group	Control group	Intervention group
Baseline	–.28+.409	–.009+.414	.00+3.80	.00+3.33
Post-intervention	–.026+.421	–1.359+.434	–.43+3.48	1.28+2.57
Follow-up	–.138+.434	–.87+.441	.84+3.66	.82+2.65

*Std. error= Standard error

The effect size analysis for the domain showed a small-to-medium effect (effect size 0.4, 95% CI= –0.097–0.850) at the post-intervention time-point. At follow-up the effect was found to be small (effect size 0.2, 95% CI= –0.240–0.700) (Table 5.27).

Table 5.27: Calculation of effect size for social relationship domain of WHOQOL-Bref

	Effect size	95% confidence interval	
		Lower bound	Upper bound
At post-intervention	0.4 (small-to-medium)	–0.097	0.849
At follow-up	0.2 (small)	– 0.240	0.700

5.4.3.4 Environment

The environment domain of the QoL scale contains eight questions relating to individuals' perceptions of the system and environment in which they live, including financial resources, safety, security, access to health and social care, transport, opportunities for recreation and leisure activities. The mean scores for the environment domain for the control and intervention groups are outlined in Table 5.28 and Figure 5.7. Mean scores were similar in both groups at baseline (intervention group 38.22, SD=15.182; control group 35.00, SD=13.189). Mean scores in the control group were similar to baseline at both post-intervention and follow-up (post-intervention mean 36.84, SD=12.710; follow-up mean 36.76, SD= 12.249). In the intervention group there was an increase in the mean score between baseline and post-

Table 5.28: Means and standard deviations for environment domain of WHOQOL-BREF

Variable at each point of time	Control Group (n=35) M±SD	Intervention group (n=35) M±SD
Baseline (T1)	35.00±13.189	38.22±15.182
Post-intervention (T2)	36.84±12.710	47.24±13.100
Follow up (T3)	36.76±11.249	44.39±13.107

1) SD=standard deviation
2) M=Mean

intervention (47.24, SD=13.100) followed by a slight decrease between the post-intervention and follow-up (44.39, SD=13.107).

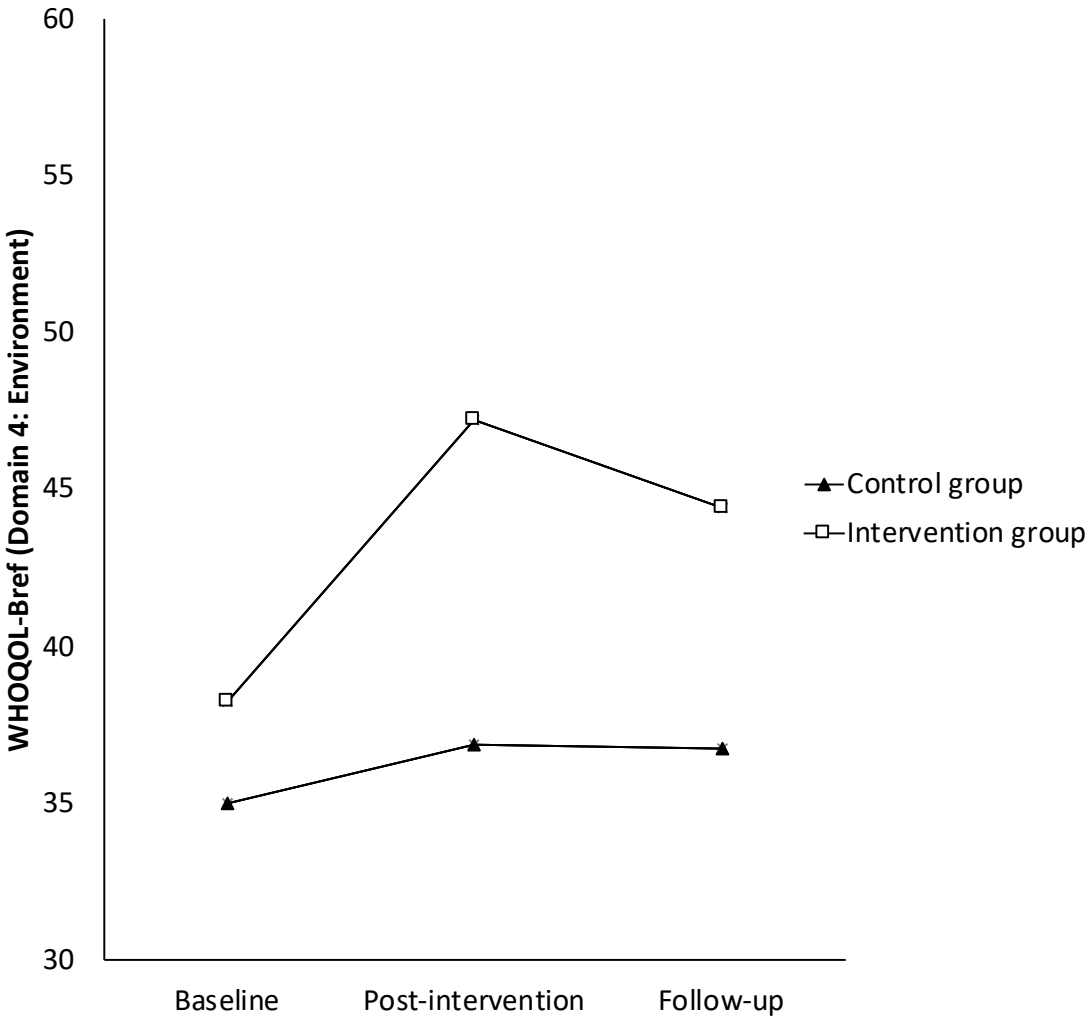

Figure 5.7: WHOQOL-Bref (Environment) outcomes at baseline, post-test, and follow-up time-points

A MMRM ANOVA conducted on the environment domain of the QoL scale showed that there was a significant main effect for time (F (2, 59.254) =8.995, p=.03), and a significant main effect for group (F (1, 63.257) =5.117, p=.03) in this domain. These indicated that the scores were different at each time-point in both groups. The interaction between time and group was also significant (F (2, 59.254) =4.184, p=.020) (Table 5.24), signifying that the intervention group scored higher and showed greater improvement in the domain than the control group at each time-point.

A planned contrast was conducted to investigate the difference in the amount of change from baseline to post-intervention between intervention and control groups. This showed that the changes were significant, with the intervention group showing greater improvement than the control group (t (60.019) =2.890, p=.005). The mean difference in the improvement was 6.53 points (95% CI=2.01–11.05). Another planned contrast to investigate the changes in groups from baseline to follow-up assessment was also found to be significant (t (60.962) =2.014, p=.048). This indicated that from baseline to follow-up time-points the intervention group scored higher than the control group. The mean improvement in the score was 4.47 points (95% CI=0.31–8.91) between baseline and follow-up.

Table 5.29: Fixed effects of time and group on environment domain scores of WHOQOL-Bref

	df**	*F***	Sig.(*p*)***
Group	63.257	5.117	0.03
Time	59.254	8.995	0.03
Time*Group	59.254	4.184	0.02

****df**=degrees of freedom; *****F***=ratio of two mean square; ******Sig**.=statistical significance or *p* value

Table 5.30: Main effects of intervention and control groups on environment domain scores of WHOQOL-Bref

	Estimates	Std. Error	df	*t*	Sig.(p)	95% CI	
						Lower bound	Upper bound
T1–T2 (Intervention Vs control)	6.529553	2.259450	60.019	2.890	0.005	2.010010	11.049097
T1–T3 (Intervention Vs control)	4.468685	2.219068	60.962	2.014	.048	0.031327	8.906043

The residuals of the models were examined at all three time-points and showed no substantial deviation from normality, indicating an acceptable fit for the model with data (Table 5.31).

Table 5.31: Analysis of residuals of environment domain

	Skewness+ Std. error		Mean+ Std. error	
	Control group	Intervention group	Control group	Intervention group
Baseline	.35+.409	.69+.414	0.00+2.29	.00+2.68
Post-intervention	.40+.401	–.54+.434	.322+3.28	.97+2.43
Follow-up	–.108+.434	.481+.441	.79+2.08	.74+2.47

*Std. error= Standard error

The effect size for the domain was found to be small-to-medium at post-intervention and follow-up time-points (post-intervention effect size=0.3, 95% CI= –0.137–0.807; follow-up effect size 0.3, 95%CI = – 0.213–0.729) (Table 5.26).

Table 5.32: Calculation of effect size for environment domain of WHOQOL-Bref

	Effect size	95% confidence interval	
		Lower bound	Upper bound
At post-intervention	0.3 (small-to-medium)	–0.137	0.807
At follow-up	0.3 (small-to-medium)	– 0.213	0.729

5.4.3.5 Overall QoL

The first global question in the WHOQOL-Bref scale separately examines individuals' perceptions of their overall QoL. Respondents can choose from a five-point Likert scale to answer the question, ranging from '1' (very poor) to '5' (very good). In the present study, the majority (79.7%) of the women perceived their QoL to be either poor or very poor at baseline (table 5.33). Only three (4.7%) women regarded their QoL as either good or very good at baseline.

Table 5.33: Perception of overall QoL among the women at different time-point

	Baseline		**Post-intervention**		**Follow-up**	
	n (%)	Cumulative %	n (%)	Cumulative %	n (%)	Cumulative %
Very poor	27 (42.2)	42.2	10 (16.7)	16.7	7 (12.3)	12.3
Poor	24 (37.5)	79.7	16 (26.7)	43.3	26 (45.6)	57.9
Neither poor, neither good	10 (14.3)	95.3	30 (50)	93.3	23 (40.4)	98.2
Good	2 (3.1)	98.4	4 (6.7)	100	1 (1.8)	100
Very good	1 (1.6)	100	0		0	

The mean scores for the overall QoL in the control and the intervention group are illustrated in Table 5.34 and Figure 5.8. The graph shows that at baseline both groups had similar mean scores (intervention group mean=1.90 SD=0.165; control group mean=1.78, SD=0.160). Between baseline and post-intervention, there were a slight increase in the mean score of the intervention group to 2.699 (SD= 0.154), with a slight decrease between post-intervention and follow-up to 2.447 (SD=0.131). For the control group, the mean score remained similar at each time-point (Table 5.34).

Table 5.34*:* Means and standard deviations for overall QoL

Variable at each point of time	Control group (n=35) M± SD	Intervention group (n=35) M± SD
Baseline (T1)	1.788 ± 0.160	1.903 ± 165
Post-intervention (T2)	2.24 ± 0.149	2.669 ±.154
Follow-up (T3)	2.152 ± 0.129	2.447 ±.131

1) M= Mean
2) SD= Standard deviation

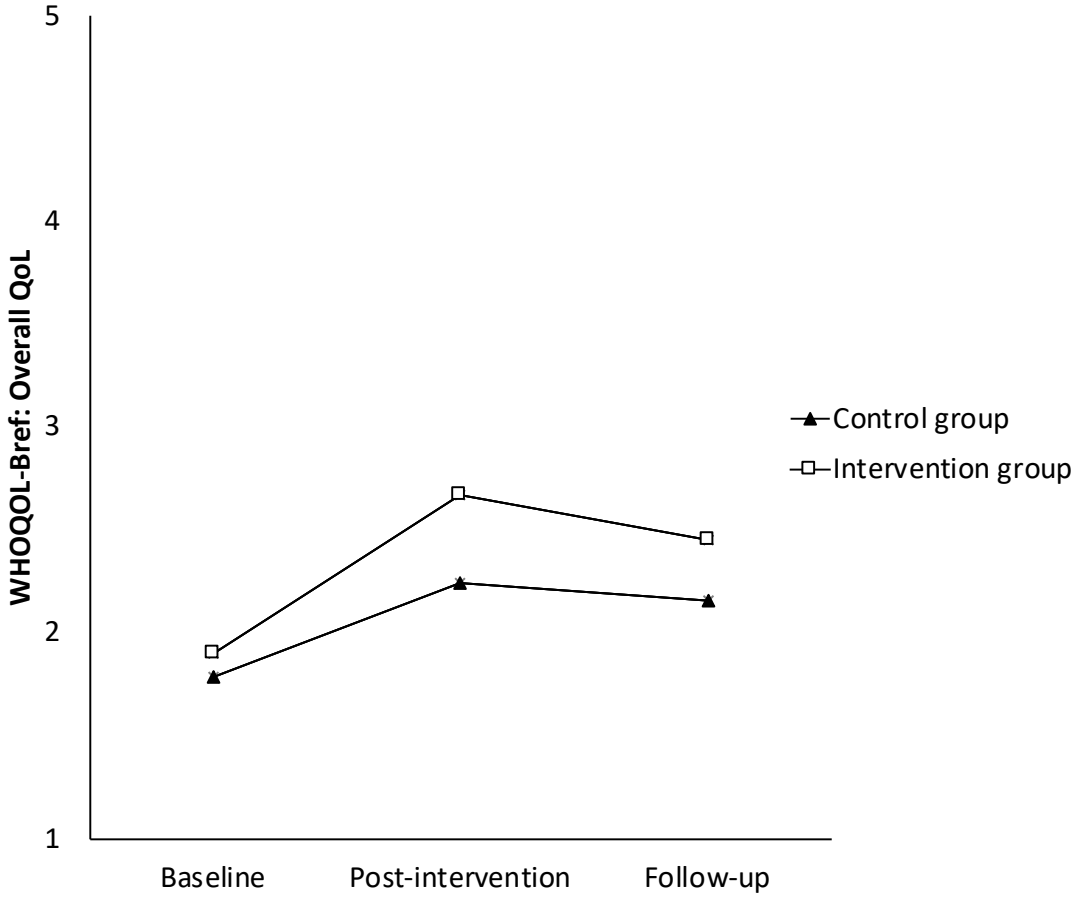

Figure 5.8: WHOQOL-Bref (overall QoL) outcomes at baseline, post-intervention, and follow-up time-points

A MMRM ANOVA conducted on the response to the global question on overall QoL showed that there was a significant main effect for time (F (2, 58.927) =12.283, p=.0001), indicating that the scores changed over time. However, there was no significant main effect for group (F (1, 61.204) =2.930, p=.092). The interaction between time and group was also not significant (F (2, 58.927) =0.760, p=.472) (Table 5.35), signifying that the intervention group did not show any greater improvement in its score than the control group at any time-point. This result was

also confirmed by a planned contrast that investigated the difference in the amount of change from baseline to post-intervention between the intervention and control groups. The analysis showed that the changes in the women's perception of their overall QoL was not significant in the intervention group in comparison to the control group at between baseline and post-intervention and between baseline and follow-up time-points. This indicates that women's perceptions of their QoL remained similar at all three time-point in the control and the intervention group. The intervention group did not show any improvement in their perception of QoL in comparison to the control group after receiving the intervention (Table 5.36).

Table 5.35: Fixed effects of time and group on overall QoL of WHOQOL-Bref

	df**	*F*	Sig.(*p*)
Group	61.204	2.930	.092
Time	58.927	12.283	.0001
Time*Group	58.927	.760	.472

****df**=degrees of freedom; ***F***=ratio of two mean square; **Sig**=statistical significance or *p* value

Table 5.36: Main effects of intervention and control groups on overall QoL

	Estimates	Std. Error	df	*t*	Sig.(*p*)	95% CI	
						Lower bound	Upper bound
T1–T2 (Intervention Vs control)	0.312518	.253417	60.482	1.233	.222	0.194308	0.819344
T1–T3 (Intervention Vs control)	0.180077	0.226433	61.091	.795	.430	0.2726	.632845

T1=Baseline; T2= Post-intervention; T3= Follow-up

5.4.3.6 Overall health satisfaction

The second global question in the WHOQOL-Bref scale evaluates individuals' overall satisfaction with their health. Respondents can choose from a five-point Likert scale to answer the question, ranging from '1' (very dissatisfied) to '5' (very satisfied). In the present study, more than half of the women (60.9%) were either dissatisfied or very dissatisfied with their overall health at baseline. Only 26.6% of the women were satisfied with their overall health at that time-point (Table 5.37).

Table 5.37: Overall health satisfaction among the women at different time-point

	Baseline		**Post-intervention**		**Follow-up**	
	n (%)	Cumulative %	n (%)	Cumulative %	n (%)	Cumulative %
Very dissatisfied	3 (4.7)	4.7	2 (3.3)	3.3	2 (3.5)	3.5
Dissatisfied	36 (56.3)	60.9	18 (30)	33.3	20 (35.1)	38.6
Neither dissatisfied, nor satisfied	8 (12.5)	73.4	17 (28.3)	61.7	22 (38.6)	77.2
Satisfied	17 (26.6)	100	23 (38.3)	100	13 (22.8)	100
Very satisfied	0		0	0	0	

The mean scores for the overall health satisfaction are illustrated in Table 5.38 and Figure 5.9. The graph shows that at baseline both groups had similar mean scores (intervention group mean=2.935 SD=0.195; control group mean=2.33, SD=0.155). Between baseline and post-intervention there was a slight increase in the mean score of the intervention group to 3.489 (SD= 0.143), with a slight decrease between post-intervention and follow up to 3.145 (SD=0.138). For the control group, the mean score remained similar at each time-point (Table 5.38).

Table 5.38*:* Means and standard deviations for overall health satisfaction

Variable at each point of time	Control group (n=35) M± SD	Intervention group (n=35) M± SD
Baseline (T1)	2.33 ± .155	2.935 ± .159
Post-intervention (T2)	2.525 ± .139	3.489 ±.143
Follow-up (T3)	2.398 ±.135	3.145 ±.138

1) M= Mean
2) SD= Standard deviation

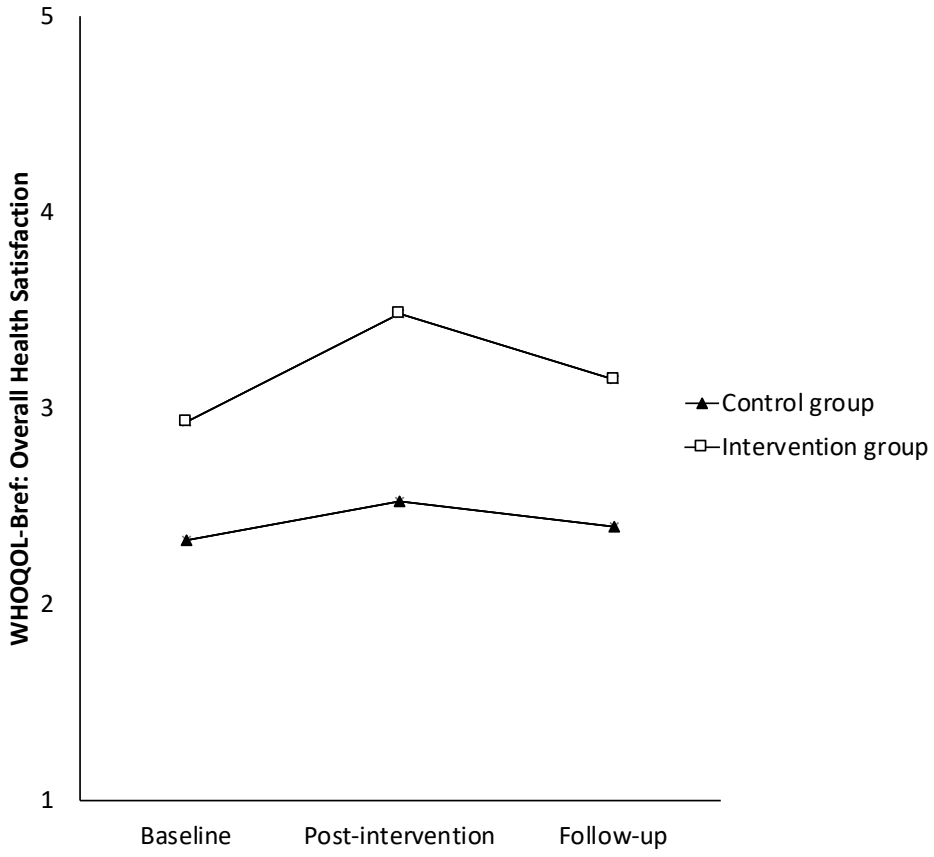

Figure 5.9: WHOQOL-Bref (overall QoL) outcomes at baseline, post-intervention, and follow-up time-points

A MMRM ANOVA conducted on the response to the global question showed that there was a significant main effect for time (F (2, 58.435) =6.639, p=.0001), indicating that the scores changed over time and a significant main effect for group (F (1, 61.684) =6.639, p=.003). This indicates that the scores of each group was different at each time-point and the scores changed over time. However, the interaction between time and group was not significant (F (2, 58.435) =1.214, p=.304) (Table 5.39), signifying that the intervention group did not show any greater improvement in their score than the control group at any time-point. This result was also

consistent with the findings of a planned contrast that investigated the difference in the amount of change, from baseline to post-intervention, between the intervention and control groups.

Table 5.39: Fixed effects of time and group on overall health satisfaction of WHOQOL-Bref

	df**	*F*	Sig.(*p*)
Group	61.684	20.653	.0001
Time	58.435	6.639	.003
Time*Group	58.435	1.214	.304

****df**=degrees of freedom; ***F***=ratio of two mean square; **Sig**=statistical significance or *p* value

The analysis showed that the changes in the women's perceptions of their overall health satisfaction was not significant in the intervention group in comparison to the control group between baseline and post-intervention and between baseline and follow-up time-points. This indicates that the women's perceptions of their health remained similar at all three time-points in the control and the intervention group, and the intervention group did not show any improvement in their perception of health satisfaction in comparison to the control group after receiving the intervention (Table 5.40).

Table 5.40: Main effects of intervention and control groups on overall health satisfaction

	Estimates	Std. Error	df	*t*	Sig.(*p*)	95% CI	
						Lower bound	Upper bound
T1–T2 (Intervention Vs control)	0.330774	.212861	59.78	1.554	.125	0.095043	0.756591
T1–T3 (Intervention Vs control)	0.114252	0.170369	59.39	.671	.505	0.226608	.455113

T1=Baseline; T2= Post-intervention; T3= Follow-up

5.5 Summary

The sociodemographic characteristics of both groups were similar. There was a 14.2% attrition of participants from both groups at post-intervention and a 18.6% attrition at follow-up. A logistic analysis indicated that the likelihood of missing data was not dependent on any variable. Overall, the results of the study showed that the intervention group had a significant decrease in depressive symptoms and a slight increase in self-esteem and perception of QoL compared with the control group at the post-intervention data collection. The improvement in

these parameters was more significant during the post-intervention period than the follow-up period. The control group did not show any notable changes at any time-points in the study. This low-intensity peer-based intervention showed some significant positive results in reducing depressive symptoms and a mild effect in increasing self-esteem and QoL in the intervention group.

CHAPTER SIX

Process Evaluation of the Pregnant Women

6.1 Introduction

In this chapter, the findings of the process evaluation of the intervention group of pregnant women (hereafter, the women) who participated in the Thinking Healthy Programme–Peer delivered (THPP) programme, are presented. The combined quantitative and qualitative process evaluation aimed to explore the women's perspectives about the usefulness of the programme. The process evaluation occurred at the end of the programme delivery, and entailed the women completing a questionnaire and taking part in an individual face-to-face interview with the researcher. The questions focused on the programme content, perceptions of the peers' capacity to deliver the programme, and the women's overall views of the programme. The chapter commences with a summary of the sociodemographic data of the women who took part in the process evaluation. This is followed by a presentation of the themes and sub-themes relating to the process evaluation data.

6.2 Sociodemographic data

A convenience sample of 21 of the 29 intervention group participants was selected for the process evaluation, with at least two women from each peer's group. Their mean age was around 22.9 years, ranging from 18 to 32 years. Other sociodemographic indicators were similar to those of the intervention group participants[25].

6.3 Themes

Themes, sub-themes and codes extracted from the qualitative part of the process evaluation of the women are summarised in Table 6.1. The findings of the quantitative part of the process evaluation are presented in Table 6.2.

Four themes and related sub-themes were abstracted from the data summarising their views about the THPP programme: (1) perceived benefits of the programme, (2) advantages of having peers deliver the programme, (3) family and community support during the programme, and (4) recommendations for improving the programme.

[25] Please refer to the Chapter 5, Section 5.3 for detailed sociodemographic data for all the pregnant women participants.

Table 6.1 Summary of themes, sub-themes and codes

Themes	Sub-themes	Codes
Perceived benefits of the programme	Increase in knowledge and skills	Knowing about depressive symptoms Knowing about the solution
	Coping with depressive symptoms	Reduction in depressive symptoms Following the learned skills after delivery of the baby
	Benefits of completing the daily homework tasks	Benefits of completing the health charts
Perceived advantages of having peers deliver the programme	Advantages in the peer being a local woman	Advantages of being well-known in the community Advantage of speaking the same local dialect
	Benefit of the peer being a mother	Previous experience of pregnancy
Family and community support during the programme	Participation in the programme	Childcare and household work assistance
	Practising learned skills	Support from family and community members
Recommendations for improving the programme		Information on raising healthy newborn Information on improving communication skills

Table 6.2: Findings of the process evaluation (quantitative data)

		Strongly agree n (%)	Agree n (%)	Neither agree, nor disagree n (%)	Disagree n (%)	Strongly disagree n (%)
1.	The techniques taught in the education programme have helped me to cope with day-to-day depressive symptoms.	**1 (4.8)**	**20 (95.2)**	-	-	-
2.	In my opinion, the programme is useful in helping pregnant women deal with day-to-day depressive symptoms.	**1 (4.8)**	**19 (90.5)**	**1(4.8)**	-	-
3.	Overall, the length of the education programme was about right	-	**19 (90.5)**	**1 (4.8)**	**1 (4.8)**	-
4.	Overall, the content of the education programme was easy to understand.	**1 (4.8)**	**20 (95.2)**	-	-	-
5.	Overall, I found the exercises and homework helpful after each session.	**1 (4.8)**	**20 (95.2)**	-	-	-
6.	I plan to continue use the techniques and advice taught during the education programme after the delivery of my baby.	-	**15 (71.4)**	**5 (23.8)**	**1(4.8)**	-
7.	Overall, I was satisfied with the peer who delivered the education program.	**2 (9.5)**	**18 (85.7)**	**1 (4.8)**	-	-
8.	The peer was supportive and non-judgmental.	-	**21 (100)**	-	-	-
9.	The peer was successful in delivering each session effectively.	-	**21(100)**	-	-	-
10.	My family was supportive of me during the education program.	**2 (9.5)**	**19 (90.5)**	-	-	-
11.	I would recommend others to take part in this peer-led psychoeducation programme in future.	**5 (23.8)**	**16 (76.2)**	-	-	-
12.	Having received the education programme, I feel more confident now in dealing with day-to-day depressive symptoms.	**1 (4.8)**	**20 (95.2)**	-	-	-
13.	Having received the education programme, I feel confident about my parenting role after the birth of my baby.	**1 (4.8)**	**20 (95.2)**	-	-	-

6.3.1 Perceived benefits of the programme

The women described their perspective of the THPP programme. Most were glad to participate in the programme and explored the benefits that they experienced during the process. Three sub-themes were abstracted from the data encapsulating the women's view on the perceived usefulness of the programme: (1) increase in knowledge and skills, (2) reduction in depressive symptoms, (3) benefits of completing the daily homework tasks.

6.3.1.1 Increase in knowledge and skills

The women commented about how participating in the programme had improved their understanding of depressive symptoms, and how they acquired new skills to help them cope with some of the most frequent depressive symptoms they encountered. Before their participation, they assumed that most pregnant women experienced that depressive symptoms were an integral part of being pregnant. This incorrect assumption was reinforced by family members and other mothers in their community who had told them that the symptoms would improve as their pregnancy progressed.

> *This is something I never knew. I had no knowledge that these symptoms may be linked to mental stress. Everyone said these are normal during pregnancy* (Interviewee 1).

Another participant stated that she was not to able attend the antenatal clinic for regular check-ups and was glad that she had the opportunity to learn about the depressive symptoms in her own home. Before attending the programme, she thought these symptoms would resolve gradually on their own, even though the symptoms were worsening progressively.

> *I was not able to go to the clinic and learn these things, I thought these* (symptoms) *were normal and would resolve themselves, but they were getting worse day by day* (Interviewee 6).

The women stated that in every session of the programme they learned something new and had received information about recognising and coping with symptoms. Before their involvement in the programme, they had little or no knowledge about strategies for coping with these problems. The women were glad that they had the chance to learn about them by participating in the programme.

I could not sleep at first, and I hated it. No one could advise me (about) *what should I do. I was happy that I could at least get some advice on that* (Interviewee 8).

6.3.1.2 Coping with depressive symptoms

The women described their views about the effect of attending the programme on their depressive symptoms. Most (n=19) agreed that the techniques introduced helped them to deal with their depressive symptoms. They found the strategies taught helped them cope with the most commonly encountered depressive symptoms, like sleeplessness and anorexia. They also commented that the practical measures provided by the peers were easy to follow and incorporate into their daily routine.

She (the peer) *asked* (me) *not to stress. I was advised to eat properly, stay among people, and invite family members to stop worrying…* (the peer) *advised us to rest. I felt good when I was not worrying* (Interviewee 21).

She asked me not to worry, and my child will be healthy. (She also) *Told me to do things to improve my sleep. I could not eat before; now I can. This is how it helped* (Interviewee 18).

One of the women narrated that she adopted the learned strategies to remain active in her day-to-day life, and perceived that this was beneficial in helping her to cope with her depressive symptoms.

It (the programme) *was very useful. I used to kill time idly… So, after she* (the peer) *taught us, I tried staying active.* (Interviewee 16).

Most (n=20) of the women agreed that they would use the strategies taught in the sessions after the delivery of their babies. However, one woman indicated that she might not get enough time to practice these strategies after the birth of her baby because of the increased commitments to looking after her baby.

I cannot, because my workload will increase (after the delivery of the baby) (Interviewee 20).

6.3.1.3 Benefits of the daily homework tasks

After the end of each session, peers provided the women with weekly Health Charts as part of their daily homework. The charts focused on diet, rest, exercise, and adopting strategies to improve their relationship with others and between themselves and their unborn baby. The

women narrated that the daily homework task was very beneficial in reinforcing important behaviours introduced in the preceding session of the programme. They noted that by completing the Health Charts, they were able to practise the learned skills and incorporate them into their daily routine.

> *I have been eating, sleeping and doing exercise, as advised. I feel better doing so. She* (the peer) *gave us some papers* (Health Charts) *to complete. By completing these* (the Health Charts), *I could practice them daily. That helped me acquire the skills* (Interviewee 5).

Four women mentioned that they particularly liked to follow the steps in the Exercise Chart. They felt good after doing the exercises and perceived that it helped them deal with the depressive symptoms like tiredness and sleeplessness.

> *I liked that she* (the peer) *taught us exercises* (Interviewee 4).

> *She* (the peer) *asked us to stretch our legs, bend them* (exercise) (Interviewee 12).

6.3.2 Perceived advantages of having peers deliver the programme

The women described their views about the peers as the delivery agent of the programme. All agreed that they were satisfied with their peer and peers were successful in delivering the programme efficiently. Two sub-themes were abstracted from the data describing the advantages of the peer being the delivery agent: (1) advantages in the peer being a local woman, (2) benefit of the peer being a mother.

6.3.2.1 Perceived advantages of being a local woman

Most women knew their peers well before participating the programme. The peers were well-known in their communities because of their employment and engagement in health promotion activities, or because they came from prominent families. The women stated that because the peers were known to them beforehand, they felt comfortable in attending the sessions with the peers. The women's families were also happy because the peer belonged to the same community and they had met her before. As the sessions proceeded, the participants became more comfortable in sharing their problems with the peers.

> *She* (One of the peers) *taught us before about vaccines, and I was happy that she was delivering the programme to me. My family was also happy (*Interviewee 8).

I knew her (the peer) *before and, hence, I could talk to her freely, discuss my problems* (Interviewee 11).

We knew her before this project. My family is always welcoming to her and let me take part in the sessions (Interviewee 9).

The women also narrated that the sessions were more understandable because the peers communicated with them in their local language. This was an important consideration because most women were unsure initially whether they would be able to understand the content of the programme if were delivered in the national Bengali language.

We spoke the same language, and I could understand her (Interviewee 15).

The women perceived that the peers were very helpful and willing to address any uncertainties they had about the content of the sessions. They stated that they could ask the peers multiple times about any queries they had.

Things I could not understand, I asked (the peer), *and I asked again and again* (Interviewee 15).

6.3.2.2 Perceived benefits of peer being a mother

The women described the advantages of the peer also being a mother. They stated that because the peers were mothers and had gone through the pregnancy experience, they were able to share their pregnancy-related problems with the peers openly. The women reported that the peers compared their own experience of pregnancy-related depressive symptoms with the women's and provided suggestions to cope with these problems. One participant said that she followed her peer's advice to pray and read the Holy Book regularly. In this case, the peer discussed how following this step had helped her cope with the mental stress she suffered during her pregnancy.

I leaned about sleeping well, eating healthy. She advised me to recite the Quran regularly. It (the peer's advice) *served me well in every case* (Interviewee 10).

The women also said that they appreciated the way peers were empathetic with them regarding their problems. They reported that the peers were active listeners and understood what the women were going through during their pregnancy. It made them feel comfortable to talk with

the peers. The women thought this as an opportunity to share their stories with others because they did not often get the chance to talk with others in the family.

> *I don't get much opportunity to talk to people because my mother-in-law thinks I will get bad ideas from others. So, she does not allow me to talk with others much. I was happy that I could talk to the peer and share some of my problems with her* (Interviewee 8).

> *The peer taught us. She was also a mother, so she knew about pregnancy. She* (said) *also had those problems* (depressive symptoms) *at that time. So, I was happy that I could share my problems too* (Interviewee 11).

6.3.3 Family and community support during the programme

The women described the degree of support they received from their families and community during their participation in the programme. All agreed that they received good support from their families to take part in the programme and obtained childcare and household work support during the sessions.

> *My mother-in-law helped me during the session with household work, so that I could concentrate* (on the sessions) (Interviewee 1).

One of the women commented that her neighbour was also very helpful and provided her with childcare support to enable her to attend the sessions.

> *I asked for help from my next-door neighbours* (during the session) (Interviewee 3)

The women acknowledged that they had received good support from their family members to follow the strategies taught in the sessions and to complete the daily Health Charts.

> *I needed help from my husband* (to complete the Health Charts), *because I could not read* (the Health Charts) *properly* (Interviewee 2).

On the Rest Chart, the women were asked to rest at regular intervals throughout the day. One woman acknowledged that her mother-in-law encouraged her to rest in the afternoon and helped with her household work during this time.

> *My mom-in-law let me sleep in the daytime after listening to the peers. She also helped with looking after the children* (During the rest time) (Interviewee 7).

6.3.4 Recommendations for improving the programme

The women made two recommendations for improving the programme. The first recommendation was that the sessions should contain information and suggestions about raising a newborn baby. This is because they perceived that most of their depressive symptoms resulted from frustration at not having enough information on raising babies. Furthermore, because of limited access to healthcare facilities and other resources, some women could not get advice from health professionals available in their local regions.

> *If I could learn a little bit more about how to look after my child, it would be useful* (Interviewee 17).

> *I wanted to know more about raising the baby after the delivery* (Interviewee 2).

The second recommendation, suggested by two women, was that the session on improving relationships with others (i.e., family members, neighbours and friends) should contain more information. The session focused on strategies to improve the women's relationships with significant others. The women reported that they wanted to follow the advice taught in the session, but sometimes they were shy about initiating conversations. They felt that they would benefit from knowing more about how to improve their communication skills before sharing their problems with others.

> *I wish I could know more about interacting with others. I could not do so because I was shy about sharing my problems with others. I did not know what to say* (Interviewee 15).

> *It was alright* (the sessions), *but there could be more on interaction* (improving relationships*) with others* (Interviewee 12).

6.4 Summary

The process evaluation indicated that the women reported an increase in their knowledge of depressive symptoms during pregnancy and skills on how to cope with these symptoms. They perceived that the programme was helpful in reducing their depressive symptoms. They were happy that they knew their peers beforehand because this made them feel more comfortable in openly disclosing their depressive symptoms with the peers. The women were also glad that the peers communicated with them in their local dialect because they were unsure whether they would be able to understand the programme if it was delivered in the national Bengali language. They stated that they received good support from their families and community to

attend the sessions. They also made two recommendations for improving the programme. First, they suggested that the sessions should contain more information on caring for a newborn. Second, they proposed that the session focusing on relationships with others should contain more information about improving their communication skills to enable them to discuss their problems more openly.

CHAPTER SEVEN

Process Evaluation of the Peers

7.1 Introduction

In this chapter, the findings of the qualitative and quantitative process evaluation for the peers who delivered the THPP programme to the intervention group of pregnant women, are presented. The aim of the process evaluation was to evaluate the peers' perspectives about the programme. The peers completed a questionnaire and an individual face-to-face qualitative interview with the researcher, where they answered questions about, and described their views and experiences during the delivery of, the programme. The chapter commences with a summary of the peers' sociodemographic data, followed by a presentation of the themes, sub-themes and codes relating to the process evaluation data.

7.2 Sociodemographic data

Eight local mothers meeting the eligibility criteria were approached to take part in the study. Six consented to take part in the study. The rest of the mothers could not take part in the study because one had very young children to look after and another woman was unable to obtain permission from her family to take part in the study. All six peers took part in the mandatory preparatory workshop. However, one withdrew from the study after the workshop because of her family commitments. The remaining five peers continued with the study and delivered the programme to the intervention group. The mean age of the peers were 29.5 years, ranging from 24 to 36 years. Only one peer had completed twelfth grade education, while the others had completed tenth grade. All peers were mothers and lived in the local community in their respective data collection sites. At the end of the programme delivery, all five took part in the process evaluation.

7.3 Themes

Three themes and related sub-themes were abstracted from the data encapsulating the peers' view of the peer-supported programme: (1) Underlying motivation to undertake the peer role, (2) Overall experience of the programme, and (3) Recommendations for improving the programme. The themes, sub-themes and codes (qualitative outcomes) are summarised in Table 7.1 and the findings of the quantitative part of the process evaluation are presented in Table 7.2.

Table 7.1: Summary of themes, sub-themes and codes

Themes	Sub-themes	Codes
Underlying motivation to undertake the peer role	Altruistic motivation to help other pregnant women	Desire to help pregnant women in need in their community Contribution to Bangladeshi society in general
	Desire to learn new knowledge and skills	An opportunity to learn new knowledge and skills Use of the acquired skills in personal life
Overall experience of the programme	Benefits of the preparatory workshop	Understanding peers' responsibility Information about the programme Support from the researcher
	Delivering the programme	Delivering the sessions in participants' homes Peer–pregnant women interaction Perceived usefulness of the programme
	Family and community support	Support from the peers' family Support from the participants' family
Recommendations for improving the programme	Increasing the duration of the programme	Maintaining the time schedule Increasing the duration of the study Adding more information
	Inclusion of other groups of women participants	Inclusion of women from different age and status groups Programme for local and breastfeeding mothers

Table 7.2: Findings of the process evaluation of the peers (quantitative data)

		Strongly agree n (%)	Agree n (%)	Neither agree nor disagree n (%)	Disagree n (%)	Strongly disagree n (%)
1.	I was satisfied with my role as a peer and being the delivery agent for the Thinking Healthy Peer-Delivered education programme.	**4 (80%)**	**1 (20%)**	-	-	-
2.	In my opinion, the programme is useful in helping pregnant women deal with day-to-day depressive symptoms.	-	**5 (100%)**	-	-	-
3.	The content of the programme manual was easy to understand.	-	**5 (100%)**	-	-	-
4.	Overall, the length of the education programme was about right.	-	**5 (100%)**	-	-	-
5.	Time allocated for each session was adequate for effective intervention delivery.	-	**5 (100%)**	-	-	-
6.	The training and supervision provided by the researcher was adequate to help me with the intervention delivery.	**2 (40%)**	**3 (60%)**	-	-	-
7.	Overall, the information booklet contained useful information I could make use of during the intervention delivery.	-	**5 (100%)**	-	-	-
8.	The intervention manual was helpful during intervention delivery.	-	**5 (100%)**	-	-	-
9.	After participating in the programme, my knowledge and understanding about dealing with antepartum depression and depressive symptoms has improved.	**1 (20%)**	**4 (80%)**	-	-	-

7.3.1 Underlying motivation to participate in the study

Peers described their underlying reasons for taking part in the programme. Two sub-themes were abstracted from the data: altruistic motive to help other pregnant women, and desire to learn new knowledge and skills.

7.3.1.1 Altruistic motivation to help other pregnant women

The peers described how their altruistic desire to help pregnant women experiencing depressive symptoms in their community inspired them to take part in the study. They reported that they had experienced similar symptoms of depression with no knowledge of how to deal with them during their own pregnancies. Participating in the programme improved their knowledge about coping with such symptoms. They thought their participation would provide them with the opportunity to share their recently acquired knowledge with other pregnant women to help them cope with depressive symptoms.

> *I could help mentally stressed mothers— that was my motivation. I joined the programme from this point of view; nothing else. With my work I could reduce their stress; that was my only inspiration* (Peer 1).

They also perceived their peer role as an opportunity to contribute to their community and to Bangladeshi society.

> *We could teach something to these pregnant women; that is why I joined this programme …it also benefitted us, improved us. We gave something to the society*… (Peer 4).

Another peer stated that some women had little or no access to such education programmes because the communities in which they lived were geographically remote from the centre of the sub-district town and low-resourced. She acknowledged that through participating in the programme she was able to support the women and teach them new skills to help them cope with day-to-day stresses throughout their pregnancy.

> *My motivation was that, we worked for free, served the pregnant women…and pregnant women with us were well supported, they were assisted, they learned a lot from us and that, indeed, facilitated them, to develop* (Peer 3).

7.3.1.2 Desire to learn new knowledge and skills

Apart from their altruistic desire to help others in their community, the peers were motivated to take part in the study because they wanted to improve their own knowledge and skills about coping with depressing symptoms. All the peers agreed that involvement in the programme had increased their knowledge and understanding in dealing with depressive symptoms during pregnancy. They stated that they had had little prior knowledge about these symptoms and how to cope with them. Therefore, participation in the study gave them an opportunity to learn about depressive symptoms in more detail.

> *Surely, it improved my knowledge. Plus, they* (the sessions) *also helped us with learning* (Peer 3).

All the peers stated that after their marriages and giving birth to children they were unable to continue with their own education because of increased family commitments. Therefore, by participating in the study, they felt that they had the opportunity to learn new knowledge and skills.

> *I was motivated by the fact that this was a chance for me to learn... I have been out of education for a long time... After my marriage I seldom got the chance to read any books because of all those household chores and raising children… and I could also teach others; that was my inspiration* (Peer 5).

> *My knowledge will increase; we can teach something to these pregnant women. That's why I joined the programme* (Peer 4).

One peer acknowledged that she was inspired to undertake the peer role so that she could use the acquired skills during her next pregnancy:

> *I mean, I will be a mother again someday* (she expected she would have another baby), *and I also intend to do as advised* (in the programme) … (Peer 5).

The peers stated that they wished they had known about this information during their own pregnancies when they had experienced similar symptoms. They also found the learned skills to be beneficial in their daily lives.

7.3.2 Overall experience of the programme

The peers described their overall experience throughout the preparation for and delivery of the programme. They all agreed or strongly agreed that they were satisfied with their role a peer and were happy that they had volunteered to be the delivery agent of the antenatal part of the THPP. They described the benefits of the preparatory workshop, explored the practical aspects of working as a peer in local communities and described how the workshop improved their confidence to fulfil the role. Their experiences were reflected in three sub-themes: benefits of the preparatory workshop, delivering the programme, and family and community support.

7.3.2.1 Benefits of the preparatory workshop

The peers commented about their preparation to undertake the role of peer. Before their involvement in delivering the programme, they were asked to attend a preparatory workshop comprising five half-day sessions conducted by the researcher. The aim of the workshop was to prepare the peers to fulfil the peer-led role.

All agreed or strongly agreed that the preparatory workshop sessions were very helpful and sufficient in preparing them to undertake the peer-led role. Participation in the workshop made them feel more confident about delivering the programme to the pregnant women. They also acknowledged that although they found the role challenging initially, the workshop provided them with a clear understanding of the role.

> (We) *had understood everything after the training and the acting* (role playing during the preparatory workshop). *The training helped me…Otherwise, it would have been difficult… It helped us to learn. I did not know a lot of things* (that were) *taught in the programme* (Peer 3).

> *I did not face any problem* (during the programme delivery). *Most of my confusion* (regarding the programme) *was cleared* (answered to my satisfaction) *during the meetings* (workshop) (Peer 4).

All the peers agreed that the booklet and other materials provided were useful to help them with the delivery of the programme. They all agreed that the content of the booklet was straightforward to read and understandable, and they were able to refer to the materials during the programme to assist them to answer questions from the women.

No, it was not hard (to understand the booklet). *I could understand the information in the book* (Peer 6).

The booklet was very easy to understand, And I used it to answer the participants' questions (Peer 4).

7.3.2.2 Delivering the programme

The peers commented about the practical aspects of delivering the programme to the women, including delivery in the participants' homes, the degree of peer-to-pregnant women interaction, and the peers' perspective on the usefulness of the programme. They all agreed that the time allocated to each session was adequate to cover the content of the booklet. From their perspective, the women in the intervention group were glad to be able to participate in the programme and accepted the peers unreservedly in their peer-led role. The peers stated that the women seemed to have little or no prior knowledge about depressive symptoms and were keen to learn about these symptoms during the programme.

I advised them about things; they accepted those gladly. They listened to me very well (Peer 5).

They understood me... we were approached by them (regarding their queries) *...our language was comprehensible to them…* (Peer 3).

The peers stated that they were always welcomed by the women at the beginning of each session. Although the women were hesitant in the initial sessions, gradually they became open to peers about their depressive symptoms. They listened to the peers attentively while they talked. According to the peers, the women were happy to learn that some of their day-to-day depressive symptoms could easily be addressed by taking straightforward measures which were easy to follow.

They (The women) *gladly responded to us. Happily, they accepted it* (the information we shared) *...and also managed time for us... joined us enthusiastically.* (Peer 1).

One peer, who was working in a casual position in a health project that aimed to increase awareness of the need for timely vaccination of newborn babies in her community, claimed this was advantageous for her as most of her intervention group of pregnant women and their families knew her beforehand. Hence, she found it easier to fulfil her role as a peer.

> *It was easier for me. I have worked on projects before, so everybody knew me. They could understand me… when I went* (to their home) *they listened to me accordingly, understood me, and that made them happy* (Peer 4).

Another peer commented that it was helpful being able to communicate in the same local dialect as her participants. From this peer's perspective, all the women felt comfortable communicating in their local language with her rather than the national Bengali language. While most women could understand Bengali, they were not fluent in speaking the language. Hence, they were happy that the peers communicated with them in their local dialect.

> *Mine and their language was similar, so they understood* [sic] (Peer 4).

One peer acknowledged that, initially, it was difficult for the women to understand the sessions, but gradually they were able to follow her explanation.

> *Yes, very well* (responded to the sessions). *Although at first, they hesitated; later they were glad…I talked to them, explained mental stress to them, and I could make them understand that… though they could not understand at first, they could* (eventually) (Peer 6).

All the peers agreed that the programme was useful in helping the women to deal with their day-to-day depressive symptoms. In their view, the most favourable aspect of the programme was that the women learned skills that they did not know beforehand. The skills helped them to modify or change their unhealthy behaviours to healthy ones and helped them deal with depressive symptoms. According to the peers, most women experienced problems with insomnia, anorexia and tiredness. The fact that the sessions contained information on how to deal with these common problems made the programme relevant and practical for the women.

> *They can now reduce mental stress, like this… And also, they can follow a healthy food habit… otherwise they could not eat properly or sleep well* (Peer 5).

The peers indicated that most of the women were unable to take time out from their routine family responsibilities to care for themselves. Some women were unable to visit their nearest public antenatal clinic because of the long distance and transportation costs, despite the minimal attendance fee and distribution of free vitamins and other common over-the-counter

drugs by the clinic. According to their peers, through participating in the study the women were able to acquire practical knowledge on following a healthy diet and sleep routine and other aspects of pregnancy that, in turn, helped them cope with their pregnancy-related day-to-day depressive symptoms. They were also happy that the sessions were delivered in their own homes because they did not have to spend extra time travelling elsewhere to participate in the programme.

> *Well, everyone managed time* (out from their family commitments) *to listen* (to me)*, and did as advised, and that worked for them to reduce stress …* (Peer 1).

> *Mothers in this area were suffering… they were assisted a bit by us... they could also* (learn) *about their children…raising them up... and also, they could be more aware* (of depressive symptoms) (Peer 3).

> Some (of the women) lived very far *away and were very poor to attend the clinic* (antenatal clinic). *That's why they were happy that we were visiting their home* (Peer 6).

7.3.2.3 Family and community support

All the peers stated that they received good support from their own families and local communities to participate as peers in the programme. In addition, their families helped by sharing some of their household chores and childcare responsibilities while they delivered the programme.

> *There was no restraint* (problem). *My family inspired me to do so* (take part in the study) (Peer 4).

> *I usually scheduled the sessions at the weekends so that my husband could look after the children* (Peer 6).

The peers also commented that the women and their families were very welcoming and cooperative with them during each session of the programme. One peer stated, however, that a few of the women found it challenging at times to attend each session in full, because they claimed they were too busy attending to their routine household chores and childcare responsibilities.

The participants' families were also helpful. Only sometimes they (the participants) *had to leave in the middle of the session as they had to attend to a family member* (Peer 4).

7.3.3 Recommendations for improving the programme

The peers made three recommendations for improving the programme. The first recommendation was about increasing the duration of the programme. They felt that it should be longer than five weeks. They indicated that if the programme was longer, it would have helped the women experiencing depressive symptoms to learn and practise more skills to help them cope with these symptoms. They also suggested that the women would benefit if the programme could be extended into the postnatal period.

Well, in a short period of time we have provided pregnant mothers with this programme, which helped them a lot. If the time period was a little longer it would have been better (Peer 1).

If the programme could be extended after the delivery of the baby, it would have been more beneficial to the women (Intervention group pregnant women) (Peer 6).

The second recommendation was that the sessions should provide more information about raising newborn babies. The peers indicated that many new mothers in their area struggled with various aspects of caring for a newborn and had little access to resources to help them to cope with this new role. They usually relied on the advice of older people and other mothers in their community. However, most of this advice was not evidence-based and was of limited help to them in dealing with the routine problems they faced while raising their newborn. This led the mothers to feel more mentally stressed about their forthcoming parenting role. Hence, the peers felt that if the sessions contained more information on newborn care, the women would have benefited more so and would have been more confident in their parenting role.

If mothers were instructed more, more improvements would be possible (Peer 3).

If some improvements (more information could be included in the session) *were made, we will learn more, give more to the mothers* (Peer 3).

Finally, the peers recommended that the programme should be accessible to other women beside pregnant women, including immediately postnatal mothers, breastfeeding mothers, and women who are yet to have children. The peers commented that in their local community they had encountered a significant number of women who suffered from depressive symptoms. The

majority of these women have little or no access to healthcare facilities or any other resources to help them cope with these symptoms. If they had an opportunity to take part in such programmes, they would be able to learn more about how to cope with depressive symptoms.

> *We only provided this to the pregnant mothers. Other than that, there are breastfeeding mothers and women like them* (newly married, non-married) … *So, if we could also provide them with such programs, it would have been very helpful* (Peer 1).

> *I think this programme does not end here; there should be other programs* (like this). *And in that case, if you* (can) *help the mothers who also suffer from this stress as well, besides the pregnant mothers, that would be very useful* [sic] (Peer 1).

7.4 Summary

This process evaluation indicated that the peers were motivated to take part in the study because of their altruistic desire to help pregnant women in need and to contribute to the local community in general. They were motivated to become involved in the project because they thought it was an excellent opportunity to learn new knowledge and skills, which, in turn, they could put to good use in their own lives.

The peers found the preparatory workshop beneficial and sufficient in preparing them to undertake their role in the delivery of the programme. They perceived that the programme materials were straightforward to use and understandable and found them helpful if any queries arose during the delivery of the programme. During the delivery of the programme, the peers received good support and cooperation from their own families and community to carry out the peer-led role. They also received good support from the pregnant women's families, and the women were willing participants. The peers perceived that the programme was useful in helping the women to cope with their mild-to-moderate depressive symptoms and acknowledged that participation as peers improved their own knowledge and skills about this issue. The peers made suggestions about improving the programme, including extending its duration into the postnatal period and offering it to a wider range of women.

CHAPTER EIGHT

Discussion and conclusion

8.1 Introduction

In this chapter, the findings of the pilot study and process evaluation are discussed. It begins with a critical examination of findings related to participants' sociodemographic characteristics, followed by the primary and secondary outcomes of the study. Next is a discussion of the findings of the process evaluation containing the pregnant women participants' and peers' perspectives about the usefulness of the programme. Then, the strengths and limitations of the study are presented. Finally, the clinical, community and research implications are outlined, and the conclusions of the study are presented.

8.2 Sociodemographic characteristics

Data collection for the study took place in a rural region of Bangladesh. The mean age of the pregnant women participants (hereafter, the women) in the present study was 22.91 years, ranging from 18 to 32 years. The women's religion was Muslim (85.71%) or Hindu (14.29%). This reflects the national distribution of these religions in Bangladesh, where 88.3% of the population are Muslim and 10.5% are Hindu (Gausia et al., 2009). The sociodemographic characteristics of the women were similar to other studies conducted in the rural area of the country. In particular, studies by Gausia, Fisher, Ali, and Oosthuizen (2009) and Nasreen, Kabir, Forsell, and Edhborg (2011) specifically included discussion of the sociodemographic characteristics of pregnant women suffering from depressive symptoms during pregnancy in rural Bangladesh. The mean age of participants in the Nasreen et al. (2011) study was 24.58 years, and in the Gausia, Fisher, Ali, and Oosthuizen (2009) study 26.8 years.

The women in the present study had low levels of education. Almost 6% (n= 4) of the women had received no formal education while 37% (n=26) had received only primary school education, from grades 1 to 5. However, these findings were an improvement on those of Gausia et al. (2009), also conducted in a rural area of Bangladesh, where around 20% of participants had never attended school and 25% had only attended primary school up to Grade 5. A possible explanation for this difference is that primary school enrolment rates have improved in recent years in rural Bangladesh because of initiatives such as compulsory

attendance and free distribution of books and other educational materials (Richards & Vinning, 2016). Nearly half the women in the present study (48.6%) had been educated to between grades 6 and 10. However, despite this improvement, the percentage continuing in education beyond Grade 10 remains low. Only 8.6% (n=6) participants in the present study attended senior school after Grade 10. This finding is similar to the Gausia et al. (2009) study, where only 5% of their participants attended senior school beyond Grade 10.

In the current study, 34.3% (n=24) of the women were pregnant with their first child. This finding is consistent with the demographic characteristics of participants in the Nasreen et al. (2011) study, where 28% of the participants were expecting their first child, and the Gausia et al. (2009) study where 30% of the participants were primigravidae. In the present study, 30% of the women had one child, 25.7% had two children and 10% had three or four children; the modal number of children was 2 or 3, which is consistent with the findings of the Nasreen et al. (2011) study.

More than half the women in the present study had not attended an antenatal clinic in a healthcare facility at the time of recruitment. The remainder (47.1%) had had attended at least one antenatal check-up in public or private healthcare facilities. Nasreen et al. (2011) found 44% of women had attended an antenatal clinic. However, Finlayson and Downe (2013), in their qualitative study of reasons for low attendance at antenatal clinics in LMICs, identified low education, low socioeconomic background, and high parity as some of the reasons for not attending recommended antenatal check-ups. Even where the antenatal care was provided for free or for a token fee, pregnant women could not attend the clinics because of other expenses related to the visit such as the cost of transportation, medicines and routine laboratory investigations (Finlayson and Downe, 2013). Similarly, several women in the present study also indicated that, because of the long distance of the healthcare facilities from their home and limited financial resources, they were unable to attend for regular antenatal check-ups. The low level of antenatal clinics attendance in the present study may be partly attributed to the fact that a significant percentage (41.4%) of the women were either in their first trimester (22.9%) or in their early second trimester (18.6%) of pregnancy at the time of recruitment. Benova et al. (2018), in their study on attendance, coverage and content of antenatal care in LMICs, like Nepal, Indonesia, Nigeria, Rwanda, Columbia, reported that around one-third of pregnant women, who had attended at least one antenatal check-up, did so after the first trimester. Moreover, Islam and Masud (2018) in their study on the determinants of frequency and

contents of antenatal check-ups in Bangladesh reported that only 50% of pregnant women attended at least one antenatal check-up during their pregnancy (Islam & Masud, 2018). Just over 20% of the mothers never attended any antenatal clinic during the period and only 22% of the pregnant women had attended all four recommended antenatal check-ups (Islam & Masud, 2018). However, this was an increase on the 2004 attendance of only 17% (Pulok et al., 2016). Islam and Masud (2018) also outlined that only 6% of the women attended eight or more antenatal check-ups.

In contrast to the 30.1% of the participants in the Nasreen et al. (2011) study, only 5.7% of the women in the present study reported having a history of mental illness. This finding suggests that there may have been underreporting of mental illness by these women. Limited access to mental health care facilities, stigma and lack of education regarding mental health care, low education levels and low socioeconomic background is associated with under-reporting of mental illness (Patel & Saxena, 2014). In the present study, 116 pregnant women were screened before participation, and 73 (62.9%) had PHQ-9 scores of 10 or more, indicating that they were experiencing moderate depressive symptoms. Of these, three had PHQ-9 scores above 14, indicating the presence of major depressive symptoms requiring referral for further evaluation. This prevalence is significantly higher than that reported in previous studies in Bangladesh (Atif, Lovell, & Rahman, 2015; Fisher et al., 2012), but it is in accordance with findings from other community-based studies, where as many as 59.5% of pregnant women in LMICs were reported to have been experiencing depressive symptoms (Atif, Lovell, & Rahman, 2015). There is insufficient evidence in existing literature to pinpoint the exact prevalence of antepartum depressive symptoms in pregnant women, particularly in LMICs. The findings from the current study, undertaken in rural Bangladesh, indicate that significant proportions of the women experienced depressive symptoms. Hence, there may be a greater need for mental health care in these regions than estimated by governments. For these reasons, more research is warranted to identify the exact prevalence rates of antepartum depressive symptoms in LMICs like Bangladesh and to also estimate the need to extend mental health care to these low-resourced areas to facilitate access by pregnant women.

8.3 Depressive symptoms

The primary aim of this study was to pilot test the effectiveness of a peer-based low-intensity psychosocial intervention in reducing mild-to-moderate depressive symptoms in pregnant women residing in a low-resource setting in rural Bangladesh. The first finding of the study was that the intervention group showed significant improvement in their symptoms compared with the control group. The primary outcome showed that improvement in depressive symptoms was significant from baseline to post-intervention and baseline to follow-up, but not from post-intervention to follow-up. From post-intervention to follow-up, the intervention group showed an increase in mean PHQ-9 score, indicating that the effect of the peer support programme was diminishing at the one-month follow-up assessment. Nevertheless, the intervention group's mean PHQ-9 score at follow-up remained below 10[26] (Table 5.3, Figure 5.2) and lower than the baseline mean score. This implies that the intervention group still demonstrated some improvement in their depressive symptoms at follow-up and did not have mild to moderate depressive symptoms[27] that were present at baseline. Moreover, the intervention group's mean PHQ-9 score was still lower than the mean score of the control group, indicating that the effect of the programme was still present at the follow-up period

t-intervention, the findings of the present study are consistent with those in a comparative study where the effectiveness of peer support was compared with that of interpersonal psychotherapy on pregnant women experiencing depressive symptoms (Field, Diego, Delgado, & Medina, 2013). In their pilot study, Field et al. (2013) randomly assigned 44 participants to peer support or interpersonal psychotherapy groups and collected data at baseline, post-intervention (after 12 weeks' therapy) and follow-up (12 weeks post-intervention). Participants' sociodemographic characteristics were similar to those in the current study regarding age, gestational period and socioeconomic status. Field et al. (2013) found that participants who received peer support showed an improvement in their symptoms from baseline to post-intervention and the improvement was comparable to that in the group receiving interpersonal psychotherapy. However, similar to the findings of the current study, Field et al. (2013) indicated that participants' depressive and anxiety symptoms partially recurred after the post-intervention period.

[26] Please refer to Chapter Four, Section 4.4.2.1 for eligibility criteria of the participants.
[27] Please refer to Chapter Four, Section 4.6.1 for interpretation of PHQ-9 scale.

The findings of the current study are also consistent with the result of a pilot RCT of a telephone-based peer support programme conducted in Vancouver, Canada, with 42 mothers at high risk of developing postpartum depression (Dennis, 2003). The results of the study showed that the intervention group experienced a significant improvement in depressive symptoms between baseline and eight weeks post-intervention when compared with the control group. In contrast to the current study, Dennis (2003) measured depressive symptoms with the EPDS and did not include any follow-up assessment of participants after eight weeks. However, in a follow-up larger scale RCT evaluating the same telephone-based programme, Dennis et al. (2009) reported that intervention group participants were more likely than the control group to show improvement in depressive symptoms at 12 weeks post-intervention. Moreover, and similar to the findings of the current study, these authors reported that the effects of the intervention were not significant at 24 weeks' follow-up and there was no significant difference between control and intervention group scores at that time-point.

Overall, the findings of the above studies, including the present one, indicate that over time the effects of peer support programmes may diminish or disappear. Extended intervention periods and periodic booster sessions may help to sustain the effects of such programmes over a longer period of time. Although antenatal depression literature is lacking on these points, literature from other fields of study support these premises. For example, in a systematic review and meta-analysis of school-based intervention programs aimed at reducing depression and anxiety in young people, Werner-Seidler, Perry, Calear, Newby, and Christensen (2017) identified periodic booster sessions as an important parameter under which intervention effects are most likely to persist for an extended period of time.

8.4 Self-esteem and quality of life

A secondary aim of the present study was to pilot test the effectiveness of the programme in improving pregnant women's self-esteem and QoL. Depressive symptoms invariably affect self-esteem and QoL and it is therefore useful to identify whether interventions aimed at reducing depressive symptoms have any secondary benefits for self-esteem and QoL (Crisp, Griffiths, Mackinnon, Bennett, & Christensen, 2014; Farrer, Christensen, Griffiths, & Mackinnon, 2012; Hughes, Seemann, George, & Willis, 2018). The findings of these secondary outcomes are discussed in the next two sections.

8.4.1 Self-esteem

Many studies indicate that low self-esteem and depression are strongly correlated (Orth, Robins, & Roberts, 2008). In the present study, all the women had moderate levels of depressive symptoms at baseline and 66.2% scored below the normal range (15–25) on the Rosenberg Self-esteem Scale (RSS). The highest score at baseline was 17, obtained by only two women, and this was close to the lower cut-off of the normal range on the scale. This indicates that depressive symptoms could have been a risk factor for low self-esteem in this sample or, conversely, that low self-esteem might be a risk factor for developing depressive symptoms. In their longitudinal study, Steiger, Fend, and Allemand (2015) tested the 'vulnerability model,' which posits that low self-esteem is a risk factor for developing depression, and the 'scar model,' which hypothesises that depressive symptoms contribute to the development of low self-esteem. That study was conducted in Frankfurt, Germany, with the aim of testing whether the effect of depression on self-esteem (and *vice versa*) persisted over a time span of three decades from adolescence to middle adulthood. Baseline data were collected from students aged 12 to 16 years with follow-up data collected for the next four years, and further data collected in middle adulthood (45 years). The findings of the study showed that self-esteem and depression were reciprocally related, and either can lead to the other.

In the present study, results showed that after participating in the programme, the control and intervention groups showed changes in self-esteem scores over time. However, the intervention group showed greater improvement in self-esteem from baseline to post-intervention than the control group. This change indicated that the intervention had some immediate effect. Nevertheless, the improvement was not significant from baseline to follow-up, which indicates that the effects of the intervention were not maintained at one-month follow-up assessment. This finding is similar to that of Crisp et al. (2014), who investigated the secondary benefits of an online intervention for reducing depressive symptoms in a population of 762 adults with significant psychological distress. The secondary benefits evaluated in the study were self-esteem, QoL and self-empowerment. Crisp et al. (2014) also used the RSS to measure self-esteem. Findings of their study showed that there were changes in self-esteem scores across all groups over time, with the intervention group showing greater improvement than the control group immediately post-intervention. However, at six-month follow-up there was no significant difference between the groups.

Overall, the findings of the present study indicate that the peer-based intervention might have some positive effects on participants' self-esteem level, but this needs further evaluation in future studies. In the present study, the majority of the women had low self-esteem scores at baseline and in that regard, it is noteworthy that, in the process evaluation, some of the women called for measures to improve their communication skills with others. One possible reason for this might be attributed to the fact that individuals with low self-esteem tend to focus on how other people perceive them in social settings and are over-sensitive to criticism (Sowislo & Orth, 2013). Consequently, they frequently become shy and lonely, and avoid social interaction and sharing their inner thoughts, opinions and emotions with others (Sowislo & Orth, 2013).

8.4.2 Quality of life

In the present study, the majority (79.7%) of women at baseline indicated they perceived their QoL to be poor or very poor. Similarly, 60.9% of them were dissatisfied or very dissatisfied with their overall health. These findings might be attributable to their limited access to affordable health care, compounded by illiteracy and poverty (Bayeh, 2016; Ginsburg et al., 2014; Peters et al., 2008). In addition, the dominant patriarchal culture of Bangladesh society and women's lower status in the community might contribute to this finding (Bayeh, 2016; Yount, Miedema, Martin, Crandall, & Naved, 2016; Ziaei, Frith, Ekstrom, & Naved, 2016). Subsequent assessment at post-intervention and follow-up showed that there were no significant changes in scores in the perception of QoL and overall health satisfaction in either the control or intervention group. This indicated that the intervention did not affect the women's overall perception of QoL or overall health satisfaction at any time. This finding is consistent with the findings of systematic reviews on the effect of peer-based interventions for depression or depressive symptoms by Fuhr et al. (2014) and Pitt et al. (2013). Both reviews reported the findings of RCTs in terms of clinical and psychosocial outcomes, including QoL, and showed that the interventions had no significant effects on participants. Similar to the current study, there were no significant changes in QoL scores for intervention and control groups at different data collection time-points. In contrast to the present study, the studies included in these systematic reviews did not use the WHOQOL-BREF to measure QoL or did not report scores for the four domains of the QoL scale. Nevertheless, a cross-sectional survey using WHOQOL-BREF conducted on an elderly population with depression showed that depression affected all four aspects (physical, psychological, environment, social relationships) measured by WHOQOL-BREF, in addition to overall QoL and health satisfaction (Gulinello,

et al., 2015). Noting this finding, in the current study the researcher analysed and compared data for all four aspects of the QoL scale. Women in the intervention group showed significant improvement in all four QoL domains at the immediate post-intervention period compared with those in the control group. The improvement in the physical health domain was still present at the follow-up period, while the effect of peer support was not sustained at one-month follow-up for the other three domains. There is a lack of research examining the effects of peer support for depression on the different domains of the QoL scale, particularly in pregnant women. However, the findings support evidence from a recent study that examined the effects of CBT for chronic pain and depressive symptoms on QoL, measured by WHOQOL-BREF (Hughes, Seemann, George, and Willis, 2018). The study showed that depressive symptoms were directly related to low QoL and participants who received the CBT intervention showed improvement across all four domains of the QoL scale. The improvement in the physical health domain was significant, similar to the current study, whereas the effects in the other three domains were smaller. The intervention used in the present study was also based on the principles of CBT and intervention participants showed a similar effect. However, in contrast to the present study, participants in the Hughes et al. (2018) study also showed improvement in health satisfaction and overall QoL, whereas in the present study the women did not show improvement in these two attributes.

Overall, findings about changes in the women's QoL in the present study were mixed, with overall QoL and health satisfaction unchanged after participation in the programme. This may be attributable, in part, to the women's demographic and socioeconomic characteristics at the time of data collection. However, despite having no effect on overall QoL and health satisfaction, the intervention had a significant post-intervention effect on all four domains of the QoL scale. A possible explanation for this finding might be that the pilot study was a small study and lacked power. Hence, a larger study with larger sample size and power may be able to indicate the exact effect of the intervention on participants' QoL. The findings also showed that the positive effects were not maintained at one-month follow-up. A longer intervention and periodic booster sessions may produce different results in a larger RCT.

8.5 Pregnant women's experience of peer support

A secondary aim of the present study was to conduct a process evaluation to evaluate the pregnant women's perspectives about the usefulness of the programme. Overall, they perceived that participation in the programme increased their knowledge of depressive symptoms during

pregnancy and helped them cope with these symptoms. They found the content of the programme easy to understand and incorporate in their daily life. The women's perspective on the programme was similar to the perspective of participants in the earlier study of the THPP (Atif et al., 2017). Participants in the Atif et al. (2017) study also found the THPP intervention acceptable and perceived some reduction in their depressive symptoms following participation.

With regard to the delivery of the intervention, women in the present study perceived that the peers were successful in delivering the intervention effectively. One of the main advantages of using peers in the current study was that, being local women, they spoke with participants in the local Chittagonian dialect[28]. Although oral communication was in the local dialect, the women did not report any difficulties in understanding the written content of the intervention presented in the national Bengali language.

The peers were previously known to the women and their families and, hence, the women were comfortable about participating in the programme and sharing their problems with the peers. In addition, because the women's families knew the peers, they were comfortable and welcoming towards the peers. The family members also supported the women in adopting the skills taught in the programme. Most women indicated that they were able to seek help from their family with tasks like completing the health charts and sharing household work with others to allow them to implement the skills taught in each session. This finding is noteworthy in the context of the present study settings, because in the original THPP study by Atif et al. (2017), some participants reported a lack of co-operation from their families and, consequently, difficulties in following the skills taught in the programme. In addition to the lack of adequate support from the family, participants also reported their concerns regarding maintenance of confidentiality of their participation and even withdrew because of fear of stigmatisation from the local community (Atif et al., 2017). While no women in the present study withdrew for such reasons or expressed similar concerns, one woman indicated that she was not able to follow some of the skills, such as talking with friends or neighbours to increase interaction with others, because her family did not want her to talk with other people for reasons unrelated to stigma of depression. This indicates that families play an important part in the successful implementation of the intervention. If families are not supportive, the women might not be able

[28] Chittagonian dialect is a dialect of the Bengali language and is spoken by people in the Chittagong and Cox's Bazar district in Bangladesh, particularly in the southeast part of the country (Haque, 2015).

to follow the programme content and, consequently, may face difficulties in coping with depressive symptoms.

Another advantage of having peers in the present study was that they were mothers themselves. Because the peers were mothers and had gone through the experience of pregnancy, the women perceived that they were empathetic and understood their problems. The women also stated that because of their participation in the programme, they understood that they were not the only ones with these problems and that the peers also experienced similar problems during pregnancy. Hence, the women were more open about sharing their problems with the peers. This also gave them a greater sense of belonging in their community. Subsequently, the women perceived participation as an opportunity to share their stories with another person, because they did not often get the opportunity to talk with other family members regarding these problems. This indicated that peer support provided the women with an alternative support system and they felt less isolated because of the supportive connection with their peers during the programme. This finding is also consistent with the finding of the Atif et al. (2017) and Dennis (2010) studies, where participants were more attached to and comfortable with their peers because the peers had gone through the experience of pregnancy.

The findings of the present study also showed that the intervention could be delivered to participants with little or no education. Despite their low level of education, the women did not have difficulty in understanding the content of the programme. In addition, the findings of the process evaluation showed that the women were able to get help from their immediate partner or other family members to complete the health charts. This indicates that this type of peer-based approach is appropriate and feasible for women with little or no education in rural Bangladesh.

Overall, women in the current study perceived the intervention to be useful, and this was similar to the participants in the original THPP study, despite the geographical and cultural differences. Hence, as in the rural contexts of Pakistan and India, the findings of the present study indicate that this peer-based intervention may be acceptable among pregnant women in rural Bangladesh. The original THPP was delivered across antenatal and postpartum periods over a six-month period, while this study was delivered just in the antenatal period and for five weeks.

8.6 Peers' experience of delivering the intervention

Another secondary aim of the present study was to conduct a process evaluation to evaluate the peers' perspectives about the usefulness of the programme. Peers stated that they were motivated to participate in the study because of their altruistic desire to help others and the opportunity to learn new knowledge and skills about depressive symptoms. Similar findings have been reported in other peer support studies, where peers were motivated to participate because of their desire to help other individuals (Atif et al., 2017; McLeish & Redshaw, 2015). In a qualitative study on peer support in pregnancy and early parenthood, McLeish and Redshaw (2015) evaluated peers' perception on delivering peer support. Forty-seven peer volunteers from nine peer support projects in UK were interviewed where they provided their views and discussed their experiences while delivering peer support services. Consistent with the findings of the present study, peers in the McLeish and Redshaw (2015) study indicated that they wanted to help other pregnant women and mothers to avoid the difficulties that they faced during their own pregnancies. In turn, the peers were able to experience the sense of equality, trust and connection with the women they supported during the delivery of the programmes.

In the present study, all peers indicated that participation in the study had improved their knowledge about dealing with depressive symptoms. They also stated that this was an opportunity for them to learn new knowledge and skills because they had been out of formal education for a long period due to their family commitments and child-bearing responsibilities after marriage. This finding is consistent with the findings of the Atif et al. (2017) study, where peers described their participation as an opportunity to acquire new knowledge and use that knowledge for potential employment opportunities in the future.

The peers in the present study were satisfied with their role and found the content of the intervention easy to understand and relevant to pregnant mothers. This indicates that the intervention was acceptable and practicable for delivery by local mothers (i.e., peers) in a rural area of the country. This, in turn, indicates that local mothers with high school level education can be a potential human resource to deliver such low-intensity intervention to pregnant mothers with depressive symptoms. Lack of adequate financial and human resources is a major challenge for extending evidence-based psychosocial programmes in rural regions of LMICs

like Bangladesh (Patel & Kirkwood, 2008). Hence, the findings of the present study suggest that training local mothers to provide mental support for pregnant women with depressive symptoms might be a suitable low-cost means of extending mental health care in low resourced areas of LMICs like Bangladesh. In this regard, it is important to emphasise the need for proper training and supervision of peers to prepare them for the programme. The peers in the present study indicated that, initially, they were uncertain if they would be able to fulfil the peer role in the study. However, after undertaking the preparatory workshop they felt prepared for the role and their uncertainties were resolved. In addition, the intervention manual and other materials provided were useful in delivering the intervention to the women. In addition to the preparatory workshop, peers took part in fortnightly meetings with the researcher to discuss any queries and issues during the intervention delivery. The same approach was followed in the early study of the original THPP intervention (Atif et al., 2017).

Peers in the present study reported that they did not encounter unanticipated challenges during the intervention delivery and stated they were welcomed by the women and their families during the sessions. However, the study had a small sample size and most of the women and their families knew their peers beforehand. In the original THPP study by Atif et al. (2017) some peers indicated that participants were concerned about confidentiality issues with their peers. In future larger studies of the programme, these challenges need to be carefully evaluated and considered before designing and implementing the intervention.

Overall, the process evaluation of peers provided evidence that local mothers with a minimum of tenth-grade education, and with adequate supervision and training, are capable of delivering the intervention without facing challenges from the community.

8.7 Study strengths

Four methodological strengths were identified in the study. These were: incorporating the components of an RCT, inclusion of a process evaluation, inclusion of a representative sample of the data collection site, and the high participation rate of participants.

8.7.1 Incorporating components of an RCT

The first strength was that the study used a pilot RCT to evaluate the peer-based intervention. A pilot trial is considered a miniature version of a full-scale RCT, incorporating the three main features: inclusion of a control group, randomisation, and manipulation of the intervention

group (LoBiondo-Wood, Haber, & Titler, 2018). The inclusion of a control group minimises confounding bias, factors or variables that may have an effect on the main dependant variable of the sample population (LoBiondo-Wood et al., 2018). Similarly, the process of randomisation minimises the risk of selection bias. In the present study, randomisation was undertaken by the Principal Supervisor who was not directly involved in the recruitment process. The intervention group in the present study received the intervention as part of the manipulation to evaluate whether there were any changes in depressive symptoms (outcome variable). Inclusion of these three properties of an RCT is a potential strength in the design aspects of a pilot trial which, in turn, aids in designing further large-scale studies of the intervention.

8.7.2 Inclusion of a process evaluation

The second strength of the current study is that it included a mixed-methods process evaluation with the peers and women. Process evaluation plays an essential role in helping researchers understand the practicability of an intervention in a given setting or population and offers valuable information for further design and implementation of the programme in that setting (Moore et al., 2015; Nakkash et al., 2012). While RCTs provide guidance for determining the effect size of interventions, process evaluations provide information on the quality of the delivery of interventions and how specific interventions can be replicated in particular settings (Moore et al., 2015). In the present study, through the process evaluation, the women participants provided their perceptions of the usefulness of the programme along with recommendations for further improvements. Peers were also able to share their views on, and experiences of, delivering the intervention. They provided information on the reasons for their participation, challenges and problems they faced during the intervention delivery and recommendations to improve the experience of peers. Similarly, all this information helped to identify factors that need to be considered for successful implementation of the intervention in future research. The findings from the process evaluation also indicated the components or activities that related to the outcomes of the RCT. Such information will guide changes and improvements required before using the intervention in a larger scale RCT.

In addition to the process evaluation, the present study followed the five steps of Borrelli's (2011) treatment implementation process for ensuring the overall treatment fidelity of the intervention. The steps ensure fidelity in study design, provider training, treatment delivery, treatment receipt and treatment enactment (Bellg et al., 2004; Borrelli, 2011). Specific

methodological strategies[29] were adhered to throughout the intervention delivery to ensure treatment fidelity at each step. These, in turn, ensured that the study tested the intervention ethically and efficiently. Subsequently, this approach helped with the maintenance of the quality of the design and the effective delivery of the intervention.

8.7.3 Representative sample of the data collection site

The third strength of the study was that the participants were a reasonably representative sample of pregnant women residing in this part of rural Bangladesh. In most earlier studies evaluating the prevalence of antepartum depressive symptoms, recruitment of pregnant women took place in antenatal clinics or tertiary teaching hospitals (Fisher et al., 2012) and only included those women who were likely to attend health care facilities for an antenatal check-up appointment. Consequently, women not attending antenatal care did not have the opportunity to participate. However, in the current study, local health workers and family welfare visitors played an important role in in the recruitment of pregnant women. These staff routinely collect up-to-date information on pregnant women in villages as part of their job responsibilities. In the present study, they approached pregnant women in their homes during routine visits, informed them about the study and asked about their willingness to participate. The women who expressed their willingness were asked to attend the local community clinic on a specified date to take part in the screening process. Consequently, the researcher was able to approach increased numbers of potential participants in a short period of time, in addition to potential participants arriving at the clinic as usual. As a result, more than half the women in the present study came from a disadvantaged group with limited or no access to rural health care facilities for pregnant women. Existing literature is consistent with this approach and provides evidence that primary health workers are a vital part of community-based interventions in rural settings in LMICs (Barry, Clarke, Jenkins, & Patel, 2013; Patel & Saxena, 2014; Sikander et al., 2015). To gain access to potential participants and accelerate the recruitment process, it is important to involve health care professionals in primary health care in LMICs settings.

8.7.4 High participation and low attrition rate of participants

The fourth strength of the present study was the high participation rate and comparatively low attrition rate (14.2% at post-intervention and 18.5% at follow-up) among the participants. The

[29] Refer to Chapter 4, Section 4.9.1.

main causes of attrition were inability to contact the recruited participants by the given mobile telephone contact number (n=5), women relocating to their parents' home to give birth (n=2), and delivery of the baby before the final data collection (n=6). The high participation rate might be attributable to the very limited mental health support available for the pregnant women in rural Bangladesh. Thus, participants might have considered the study as an additional support during their pregnancy. The culture of respect in south Asian countries for individuals considered to hold a position of authority (in this instance, the researcher) or higher social esteem (the peers) might also have played some part in high study retention rate (McCann, Songprakun, & Stephenson, 2016). Finally, the researcher's weekly follow-up telephone call to each of the intervention group participants might have had a positive influence on the retention rate in the study (McCann et al., 2016).

8.8 Study limitations

There were four methodological limitations to the study. These were limitations in the questionnaires, collection of data by the researcher herself, challenge in recruiting the peers, and limitation in monitoring the peers.

8.8.1 Limitations in the questionnaires

The first limitation was that the sociodemographic questionnaire did not include certain important variables that would have been useful in identifying factors contributing to depressive symptoms in women, including history of intimate partner and/or family violence, previous history of miscarriage or abortions, and whether the current pregnancy was planned or unplanned. Examination of these factors would have given a wider picture of the underlying reasons for depressive symptoms in the women. In addition, data regarding the number of antenatal check-ups attended and any history of screening for depressive symptoms during the antenatal check-ups were not collected**.** Data on the latter could have indicated whether pregnant women in this rural part of Bangladesh are screened for depressive symptoms during their antenatal care. In addition, the process evaluation did not include any questions evaluating the women's perception of the group session.

8.8.2 Limitation in the data collection

The second limitation was that all outcome and process evaluation data were collected by this Ph.D. student researcher. Furthermore, although the outcome questionnaires were designed to

be completed by the participants themselves, this was not feasible in the current study. More than half of the women had little or no formal education and were unable to read the questions or complete the questionnaire themselves. If they had been asked to do so, there was a possibility that they might have refused, or misinterpreted some of the questions. So, to maintain consistency, the researcher asked the questions herself and gave a detailed explanation of each question. A potential consequence of these circumstances is that the women may have provided socially desirable responses to the questionnaires and process evaluation to please the researcher. The phenomenon of participants tending to present themselves favourably when answering questionnaires is a common psychological construct in social science research (McKibben & Silvia, 2017). As McKibben and Silvia (2017) point out, social desirability may lead to higher scores in questionnaires used in some studies. To avoid or minimise this limitation in future studies, it is preferable that an independent researcher collects outcome and process evaluation data.

8.8.3 Limitation in recruiting the peers

The third limitation was the potential challenge of recruiting suitable peers. Peers had to meet certain eligibility criteria; for example, having at least tenth-grade education. However, during recruitment the researcher found that most women with tenth-grade education were in paid employment outside the family home and did not have enough time to participate as peers in the study. In addition, some potential peers who were not working outside the family home could not participate because of their own household responsibilities and lack of permission from their husbands and families-in-law to become involved in external activities. This was unsurprising given the current cultural and economic context of rural Bangladesh. In their discussion of women's empowerment in Bangladesh, Nazneen, Sultan, and Hossain (2010) reported that women's position in families, society and state is similar despite the class differences in the country. A woman's identity as an individual human being is often obscured by her identity as daughter, wife or mother. Women are expected to care for their children and older family members and are discouraged from taking part in economic activities, particularly in rural areas of the country (Nazneen et al., 2010). In addition to this, dominant traditional patriarchal attitudes and highly prevalent gender discrimination limit women's choices about taking part in activities outside the home, despite recent social and economic progress in Bangladesh (Nazneen et al., 2010; Yount et al., 2016). However, several studies from rural regions of the country also have reported that, in recent years, women with tenth-grade

education have had numerous opportunities to become involved in economic activities outside the family home (Faraizi, Rahman, & McAllister, 2010; Khan & Rahman, 2015; Kumar, Hossain, & Gope, 2013). Extensive development of projects by, and availability of microfinance loans from, non-government organisations, particularly BRAC (Bangladesh Rural Advancement Committee), have provided increased employment and entrepreneurship opportunities for rural women in Bangladesh (Faraizi et al., 2010; Khan & Rahman, 2015).

To recruit the peers in the current study, health staff in local public healthcare facilities, especially health workers and family welfare visitors, contacted potential peers who met the eligibility criteria to ascertain their willingness to participate in the study. In the end, all the peers recruited were either working part-time or came from educated, well-known and well-respected families residing at the data collection site. Singla et al. (2014), in their qualitative study on preferred characteristics of peers for delivering a mental health care programme, suggested that participants preferred their peers to be better educated and have a higher socioeconomic status than themselves, and to be well-respected in their communities. These characteristics improved peers' acceptability to intervention participants and helped in the effective delivery of the programmes.

8.8.4 Limitation in monitoring the peers during intervention delivery

The fourth limitation of the present study was that because of the limited scope of this Ph.D. study and limited human resources, there was no direct way to assess the competence of the peers. While the researcher monitored peers when they delivered their first session to the women, there was no systemic way to monitor and supervise the delivering of subsequent sessions. It was also not possible to determine any possible bias by the peers to the intervention group women. In future studies, this limitation could be overcome by random direct observation or video recording of sessions.

8.9 Implications of the findings

The study has clinical, community and research implications which can help guide the advancement of maternal mental health care in rural Bangladesh.

8.9.1 Clinical and community implications

The sociodemographic characteristics of the women in the current study showed that attendance at antenatal clinic was very low, and nearly half the women had not attended any antenatal clinic at the time of recruitment, despite the minimal cost of attending public healthcare facilities. The findings suggest that the long distance of antenatal clinics from the women's homes, and limited financial resources, were some of the barriers to them attending antenatal care regularly. This indicates the need to increase develop greater access to healthcare facilities. Programmes should also be developed to encourage early antenatal attendance by pregnant women in rural Bangladesh. In recent years, there has been an emphasis in the health system on improving maternal health care in rural regions (Pulok et al., 2016). Findings from this study suggest that there should also be a focus on educating pregnant women about mental health issues and when to seek help. In addition, routine antenatal screening for depressive symptoms should be introduced during antenatal check-ups in rural healthcare facilities. For this to happen, existing healthcare professionals need adequate training and supervision from specialist mental health care professionals to enable them to provide minimal mental health care to those in need. There is also need for systems through which pregnant women with significant depressive symptoms and other mental health care problems can be identified and referred for further affordable and specialist mental health evaluation.

The study findings highlighted the low QoL and self-esteem of most of the women. In future, studies might include identifying the causes for such outcomes and placing emphasis on the importance of women-focused health initiatives in the area. Such initiatives might help reduce gender inequalities and give greater access to the minimum health care required for women residing in rural areas of Bangladesh.

The findings of this pilot study provide preliminary evidence to suggest that a peer-delivered low-intensity psychosocial intervention is practicable for implementation in the low-resource context of rural Bangladesh. The basic cognitive and behavioural skills taught in the programme may help pregnant women residing in these regions to cope with their day-to-day depressive symptoms regardless of their socioeconomic condition and educational background. Furthermore, the peer-based programme is low-cost because it uses very few human resources and does not require health professionals for delivery. Hence, it could be made readily accessible to pregnant women in rural Bangladesh. The findings indicate the potential of the antenatal part of the THPP programme as a stand-alone intervention for dealing with mild-to-moderate antepartum depressive symptoms. The findings also show the scope of peer support

programmes for extending mental health care to pregnant women in rural areas of LMICs. Peer-led services may be considered as a low-cost adjunct to existing antenatal services in low-resource areas of these countries. However, the recruitment of peers needs to be carefully monitored and supervised by health professionals to achieve the maximum efficacy of such programmes.

8.9.2 Research implications

Although the peer-based intervention used in this study led to some improvement in participants' depressive symptoms, the results need to be evaluated in a large-scale RCT. Results of pilot RCTs always need to be considered cautiously, and the current study is no exception. The results of such studies should not be used for hypotheses testing or effect size estimation of an intervention (Leon, Davis, & Kraemer, 2011). Insufficient knowledge about an intervention in a particular participant population and small sample size are two primary reasons why pilot RCTs are not used to test hypotheses (Leon et al., 2011). The findings of such studies should be used as a guide, considering all the facts and limitations, in planning and implementing larger-scale studies. The findings can also be used to modify any methodological limitations in such studies. Only a larger efficacy study with a large sample size and a longer follow-up period can be used to evaluate the effectiveness of an intervention. Such studies, like RCTs, can also be used to determine the actual effect size of the intervention. However, caution needs to be taken in using the effect size of a pilot RCT for calculating the sample size for a larger RCT. This is because using the pilot study effect size can lead to Type 1 (false positive)[30] or Type 2 (false negative)[31] errors in a study (Akobeng, 2016; Lee, Whitehead, Jacques, & Julious, 2014; Leon et al., 2011). If the effect size of a pilot study is too large, it may eventually lead to the calculation of a small sample size for the subsequent RCT, which, in turn, may be inadequate to test the real efficacy of an intervention (Leon et al., 2011). Similarly, if the effect size of a pilot study is too small, there is the risk that further development of the intervention may be terminated even though the intervention might have been useful in a carefully planned study. In summary, the findings of the current study provide useful background information for planning a larger RCT to estimate the effect size and effectiveness of such peer-based interventions in rural LMICs. Currently, there are very few studies that

[30] Type 1 or false positive errors occurs when the result of a trial incorrectly shows that an intervention is effective and inaccurately rejects the null hypothesis.
[31] Type 2 or false negative errors occurs when the trial result inaccurately concludes that an intervention has no effect, when in fact there is significant effect (Akobeng, 2016).

provide information on peer-based studies in rural LMICs, particularly in Bangladesh. Hence, the results of this study can be vital for designing and implementing a larger RCT that will evaluate the safety, efficacy and effectiveness of the intervention used in this study as an intervention for reducing antepartum depressive symptoms.

8.10 Conclusion

Antepartum depressive symptoms have a high prevalence rate and exert significant negative impacts on mothers' and babies' health. Despite these significant adverse effects, the majority of women suffering from antepartum depressive symptoms in LMICs like Bangladesh have limited or no access to mental health facilities. There is evidence that peer support programmes may have beneficial effects in reducing depressive symptoms in these individuals.

In this thesis, the researcher has provided preliminary evidence that a peer-based, low intensity programme may be an effective alternative to provide mental health care to pregnant women in rural Bangladesh. The findings offer a unique insight into the scope of a peer-based intervention in reducing depressive symptoms in pregnant women with low levels of education and from low socioeconomic backgrounds. The findings also indicated that the intervention exerted small positive effects on the women's self-esteem and QoL. Although small, the slight positive changes may be associated with significant improvements in participants' self-esteem and QoL in a large population study. In addition, the findings of the process evaluation suggest that the intervention was perceived as useful and practicable to the recipient pregnant women. The peers who delivered the intervention also suggested that their role as peer was rewarding and they did not face particular challenges during the intervention delivery. This indicates that a peer-based, low intensity intervention has the potential to increase the reach of mental health care programmes into rural areas of the country. For these reasons, a further RCT with an adequate sample size should be conducted to confirm the effectiveness of the intervention. Data from this pilot RCT will be valuable in designing and planning such a large-scale study. If proved effective in further large-scale studies, incorporating such peer-support programmes within a primary healthcare framework may make a significant contribution to helping pregnant women to cope with their depressive symptoms and give them better access to low-cost, minimal mental health care in their local community.

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Appendix A

Participants information sheet - pregnant women version

(English and Bengali version)

Participant information and consent form
(Pregnant women version)

Full Project Title: **A pilot randomised controlled trial of a peer-based low-intensity psychosocial intervention for reducing depressive symptoms in pregnant women in rural Bangladesh**

1. Introduction

My name is Rehenuma Tarannum. I am Ph.D. research student at Victoria University, Melbourne, Australia. I would like to invite you to take part in a research project looking at an educational programme to reduce mental stress during pregnancy. It will be conducted under the supervision of Professor Terence McCann and Professor Mary Carolan-Olah from the College of Health and Biomedicine at Victoria University, Melbourne, Australia. The aim of the project is to examine if taking part in this education programme led by women in your area-

- Will reduce any mental stress you may be experiencing.
- Will increase your self-esteem and quality of life.

2. Purposes and Background
The purpose of the study is to examine how useful is the programme is to assist you in reducing mental stress during pregnancy.

A total of 70 pregnant women and 6 peers will be invited to take part in the study.

You are invited to take part in the study if you are:

- **Currently pregnant in between 20 and 30 weeks of pregnancy.**
- **Aged 18 years or above.**
- **Scoring certain point in screening tools.**
- **Not suffering from or diagnosed with any medical complications of pregnancy, on the date of signing the consent form.**
- **Not receiving any treatment for depression or other mental health disorder.**

The results of this research will be used by Dr. Rehenuma Tarannum to obtain a PhD degree.

3. What does participation in this research project involve?

Procedures

All Pregnant women selected for the study, will be divided equally in two groups— intervention and control group. If you are allocated to the intervention group, you will receive a 5week educational programme delivered by a peer, a mother from your own community. Each weekly session will last approximately one hour and you will receive 4 individual face-to-face sessions in your own home or a place of convenience and one final group session with 5/6

other pregnant women in the intervention group. The purpose of the intervention is to teach you skills and provide support to deal with day-to-day stress you encounter during your pregnancy.

If you are allocated to the control group you will receive a small brochure containing information about different types of mental stress associated with pregnancy. You will not receive any intervention.

All the pregnant women will be asked to complete some questionnaires 3 times during the study: at the beginning of the delivery of the intervention (Week 0), at the end of the intervention period (Week 6) and at follow-up (week 10). The questionnaires will take around 15-20 minutes to complete. In addition, mothers in the intervention group will also be asked take part in a 15-20-minute interview, which will be audio-recorded. In the interview, they will be asked about their opinion of the therapy.

Support from your family members during the project is very important for participation in this study. Unfortunately, we cannot include you in the study if your family does not support your participation. So, please discuss your participation thoroughly with your family members before deciding to take part in the study. In addition, we would be very grateful if one of your key family members (husband or mother-in-law) would be present with you in individual sessions 1 and 3 (however, family member's presence in these sessions is not compulsory, and their non-participation will not affect your involvement in the study). So, please discuss this too with your family members.

Reimbursement

You will not be paid for participating in this study, but you will be compensated for expenses incurred as a result of participating. You will receive an amount of $20 (1,160 taka).

4. What are the possible benefits of participation in the study?

There may be no direct benefit for you by participating in the study. However, you may gain some benefits from taking part in the educational programme, which is designed to assist you to deal with mental stress that can affect your pregnancy. You may also find it beneficial to talk with your peers about things that cause you mental stress.

5. What are the possible risks of participation in the study?

There is a low risk to you in taking part in the study. In case you develop mild emotional distress that does not resolve on its own during your time in the study, an appointment will be arranged for you with the antenatal clinic at the Chakaria Health Complex.

6. Do I have to take part in the study?

Participation in this project is voluntary. You don't have to take part if you don't want to. If you decide to take part and later change your mind, you are free to leave the project at any stage. Your participation or non-participation in this project will not affect your pregnancy in any way.

7. How will I be informed of the final results of this study?

If you wish to know about the final result of the study, a summary will be sent to you after completion of the study.

8.What will happen to information about me?

During the project all the information will be stored in password-protected file in the project supervisors' and the student researcher's computers, in Australia. Only the supervisors and the student researcher will have access to the data. After completion of the study, an electronic copy of the data will be securely stored in College of Health and Biomedicine and will be destroyed after 5 years (hard copies will be shredded and electronic data will be deleted).

Any information collected in the project that can identify you will remain confidential and will only be used for the purpose of this study. It will not be disclosed anywhere without your permission, unless required by law.

In accordance with the Australian and Victorian privacy law and Bangladesh information law, you have the right to access information collected and stored by the research team about you. Please contact one of the researchers if you would like to access your information.

9. Is this research project approved?

Permission to conduct this study has been granted by Victoria University Human Research Ethics Committee and Bangladesh Medical Research Council. The project will be carried out in accordance with the rules of ethical conduct in human research of Australia and Bangladesh to protect the interests of people who agree to participate in human research studies.

Contact details

If you require further information or have any problems concerning the project you can contact the researchers any time:

1. **Professor Terence McCann**

Office: +61 3 9919 2325
Mobile: +61 403 209 453
Email: Terence.McCann@vu.edu.au

2. **Professor Mary Carolan-Olah**
Office: +61 3 9919 2585
Mobile: +61 423 356 298
Email: mary.carolan@vu.edu.au

3. **Dr Rehenuma Tarannum**

National telephone: +8801799948673/

Email: Rehenuma.tarannum@live.vu.edu.au

Any queries about your participation in this project may be directed to the chief or associate investigator listed above. If you have any queries or complaints about the way you have been treated, you may contact the Ethics Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC, 8001, email researchethics@vu.edu.au or phone +61 3 9919 4781 or +61 3 9919 4461.

অংশগ্রহণকারীর সম্মতিপত্র (গর্ভবতী নারীর জন্য প্রযোজ্য):

কর্মসূচীর শিরোনামঃ বাংলাদেশে গ্রামাঞ্চলে বসবাসরত গর্ভবতী মহিলাদের মানসিক চাপ ও দুশ্চিন্তা কমানোর লক্ষ্যে একটি স্বল্পমাত্রা শিক্ষামূলক মনসামাজিক কার্যক্রমের সম্ভাব্যতা ও গ্রহণযোগ্যতা যাচাই '

১। সূচনাঃ

আমার নাম রেহনুমা তারান্নুম। আমি অস্ট্রেলিয়ার মেল্বূর্নে অবস্থিত ভিক্টোরিয়া বিশ্ববিদ্যালয়ে অধ্যয়নরত পি এইচ ডি ডিগ্রীর গবেষণা ছাত্রী । গর্ভাবস্থার মানসিক চাপ ও দুশ্চিন্তা নিয়ন্ত্রণের উপায় এর উপর পরিচালিত একটি শিক্ষামূলক গবেষণা কর্মসূচীতে অংশগ্রহণের জন্য আপনাকে আমন্ত্রণ জানাচ্ছি। অস্ট্রেলিয়ার মেলবোর্নে অবস্থান্নত ভিক্টোরিয়া ইউনিভার্সিটির স্বাস্থ্য ও জৈব-চিকিৎসা বিভাগের অধ্যাপক টেরেন্স ম্যাক-কান ও সহযোগী অধ্যাপক মেরী ক্যারোলান-ওলাহ এর সার্বিক তত্বাবধানে এই গবেষণা কর্মসূচীটি আয়োজন করা হবে। '

এই গবেষণাটির মূল উদ্দেশ্য এটি যাচাই করা যে, আপনাদের সমকক্ষ একজন স্থানীয় মা দাড়া পরিচালিত এই শিক্ষামূলক কার্যক্রম এ অংশগ্রহণের ফলে

- গর্ভাবস্থায় আপনারা মানসিক চাপ ও দুশ্চিন্তা অনুভব করেন তার কোন পরিবর্তন হয় কিনা।
- আপনাদের আত্মসম্মানবোধ ও জীবনের গুনগতমানের কোন পরিবর্তন হয় কিনা।

২। উদ্দেশ্য ও পটিভূমিঃ

এই সমীক্ষার উদ্দেশ্য হলো গর্ভকালীন সময়ে সৃষ্ট মানসিক ধকল কমাতে এই কর্মসূচী আপনার জন্য কতখানি সহায়ক তা পরীক্ষা করে দেখা। এই কর্মসূচীতে অংশগ্রহণের জন্য মোট ৭০ জন গর্ভবতী মহিলা এবং আপনারই এলাকার ৬ জন সমবয়সী (অগর্ভবতী) মাকে আমন্ত্রণ জানানো হবে।

আপনাকে এই কর্মসূচীতে অংশগ্রহণ করার জন্য আমন্ত্রণ জানানো হবে যদিঃ

- বর্তমানে আপনি ২০ থেকে ৩০ সপ্তাহ মাঝামাঝি গর্ভবতী হোন;
- আপনার বয়স ১৮ বছর বা তার উপরে হয়;
- যাচাইকারী পরীক্ষায় নির্দিষ্ট নাম্বার অর্জন করেন
- সম্মতিপত্র স্বাক্ষরের তারিখে হর্ভকালীন চিকিৎসাজনিত জটীলতা দ্বারা আক্রান্ত বলে সনাক্ত না হন
- **বিষণ্ণতা বা অন্য কোনো মানসিক স্বাস্থ্য সমস্যার জন্য চিকিৎসা গ্রহণ করছেন না।**

এই গবেষণা কর্মসূচীর ফলাফল ডঃ রেহনুমা তারান্নুম কর্তৃক পি এইচ ডি ডিগ্রী অর্জনের কাজে ব্যবহার করা হবে।

৩। এই গবেষণা কর্মসূচীতে অংশগ্রহণ করা মানে কি বোঝায়?

কার্যপদ্ধতিসমূহঃ

কর্মসূচীর জন্য বাছাইকৃত মহিলাদেরকে সমানভাবে দুইটি দলে ভাগ করা হবে- কার্যক্রমে অংশগ্রহণকারী ও নিয়ন্ত্রণকারী দল। আপনি যদি হস্তক্ষেপ দলে অন্তর্ভূক্ত হোন তাহলে আপনাকে আপনার একজন সমসাময়িক, যিনি আপনাদেরই এলাকার একজন মা- দ্বারা ৫ সপ্তাহব্যাপী শিক্ষামূলক কর্মসূচী প্রদান করা হবে। প্রত্যেকটি অধিবেশন মোটামুটি এক ঘন্টাব্যাপী অনুষ্ঠিত হবে এবং আপনি নিজের বাসায় বা অন্য কোনো সুবিধাজনক অবস্থান থেকে ৪টি সামনাসামনি অধিবেশন অংশগ্রহণ করতে পারবেন, শেষের অধিবেশনটি কর্মসূচিতে অংশগ্রহণকারী দলে অন্তর্ভুক্ত অন্য ৫/৬ জন গর্ভবতী মহিলার সঙ্গে একত্রে হবে। কর্মসূচির উদ্দেশ্য হল গর্ভকালীন সময়ে যে সব দৈনন্দিন ধকলের সম্মূখীন হতে পারেন তা মোকাবেলা করার দক্ষতা শেখানো।

পক্ষান্তরে যদি নিয়ন্ত্রণকারী দলে অন্তর্ভুক্ত হোন তাহলে আপনি গর্ভকালীন সময়ে যে সব দৈনন্দিন ধকলের সম্মূখীন হতে পারেন সে সংক্রান্ত একটি পুস্তিকা সরবরাহ করা হবে। আপনি কোনো কার্যক্রমে অংশগ্রহণের সুযোগ পাবেন না।

সমীক্ষা চলাকালীন সময়ে অংশগ্রহণকারী প্রত্যেক গর্ভবতী মহিলাকে তিনবার কিছু প্রশ্নমালা পূরণ করতে বলা হবে। কর্মসূচী শুরুর পূর্বে (সপ্তাহ ০), কর্মসূচী শেষ হওয়ার পর (সপ্তাহ ৬), এবং ফোলো-আপের পর্যালোচনার সময় (সপ্তাহ ১০)।

এই কর্মসূচীতে অংশগ্রহণের জন্য আপনার পরিবারবর্গের গুরুত্বপূর্ণ। অতি দূঃখের সহিত জানানো যাচ্ছে যে, পরিবারবর্গের সম্মতি ব্যাতীরেকে আপনাকে কর্মসূচীতে অন্তর্ভুক্তি আমাদের পক্ষে অসম্ভব। অতএব, অংশগ্রহণের বিষয়টি বিশদভাবে আপনার পরিবারবর্গের সাথে আলোচনা করে নিন। অধিকন্তু ১ম ও ৩য় একক অধিবেশন চলাকালে আপনার পরিবারের একজন মুখ্যপ সদস্যের (স্বামী বা শ্বাশুড়ী)উপস্থিতি একান্ত কাম্য (তবে তাঁদের উপস্থিতি বাধ্যতামূলক নয় এবং তাঁদের অনুপস্থয়ি আপনার কর্মসূচীতে অংশগ্রণের ক্ষেত্রে কোনো বাঁধার সৃষ্টি করবে না)। এই বিষয়টিও আপনার পরিবারবর্গের সাথে আলাপ আলোচনা করে নিবেন।

পূনঃর্ভরণ/ খরচকৃত টাকা মিটিয়ে দেয়াঃ

এই কর্মসূচীতে অংশগ্রহণের জন্য আপনাকে কোনো অর্থ দেয়া হবে না। তবে অংশগ্রহণ বাবদ আপনার খরচাদি মিটীয়ে দেয়া হবে। এজন্য আপনাকে ২০ ডলার (১২০০ টাকা) দেয়া হবে।

৪। এই কর্মসূচীতে অংশগ্রহণের সাম্ভাব্য সুবিধা কি?

এই কর্মসূচীতে অংশগ্রহণের ফলে হয়ত সরাসরিভাবে আপনার কোনো সুবিধা হবে না। তবে এই শিক্ষামূলক কার্যক্রম সম্পর্কে আপনি কিছু জ্ঞানলাভ করতে পারবেন, যা আপনাকে গর্ভকালীন মানসিক দুশ্চিন্তা ও চাপ কমাতে সাহায্য করবে। এছাড়া কি সব বিষয় আপনার মানসিক ধকল সৃষ্টি করতে পারে সে ব্যাপারে আপনার এলাকার সমসাময়িকদের সাথে আলাপ করে লাভবান হতে পারবেন।

৫। এই কর্মসূচীতে অংশগ্রহণে সাম্ভাব্য ঝুঁকিসমূহ কি কি?

এই কার্যক্রমে খুবই সামান্য ঝুঁকি আছে। তা সত্বেও যদি কোনো কারণে আপনি সামান্য আবেগ-আপ্লুত হয়ে পড়লে, আপনাকে চকরিয়া উপজেলা স্বাস্থ্য চিকিৎসার কমপ্লেক্সের জন্ম-পূর্বকালীন ক্লিনিকে আপনার চিকিৎসার ব্যবস্থা করা হবে।

৬।আমাকে এই কর্মসূচীতে অংশগ্রহণ করতেই হবে?

এই কর্মসূচীতে অংশগ্রহণ সম্পূর্ণ ঐচ্ছিক। আপনি যদি অংশগ্রহণ করতে না চান তাহলে করতে হবে না। যদি আপনি অংশগ্রহণের সিদ্ধান্ত নিয়ে মত পরিবর্তন করেন, আমি যেকোনো সময় কর্মসূচী ছেড়ে যেতে সক্ষম। এ কর্মসূচীতে অংশগ্রহণ করা বা না করা কোনোভাবে আপনার গর্ভাবস্থার উপর প্রভাব ফেলবে না।

৭। এই কর্মসূচির চূড়ান্ত ফলাফল সম্বন্ধে কিভাবে অবহিত করা হবে?

আপনি যদি চূড়ান্ত ফলাফল সম্পর্কে জানতে আগ্রহী হন, তাহলে কর্মসূচী শেষে আপনাকে একটি সারাংশ পাঠিয়ে দেয়া হবে।

৮। আমার সম্পর্কে নেয়া তথ্যাদি কি করা হবে?

কর্মসূচী চলাকালে সব তথ্যাদি পাসওয়ার্ড দ্বারা সংরক্ষিত নথিতে গবেষণাকারী ছাত্রীর ও তত্বাবোধায়কদের কম্পিউটারে (অস্ট্রেলিয়া) ধারণ করে রাখা হবে। কেবলমাত্র গবেষণাকারী ছাত্রী ও তত্বাবোধায়কগণ সে তথ্যাদি উদ্ধার করতে পারবেন। কর্মসূচী শেষে তথ্যাদির এলেক্ট্রনিক কপি নিরাপদভাবে স্বাস্থ্য ও জৈবচিকিৎসা মহাবিধ্যালয়ে রাখা থাকবে এবং পাঁচ বছর হয়ে গেলে তা বিনষ্ট করে ফেলা হবে(যান্ত্রিকভাবে ছিঁড় ফেলা হবে এবং এলেক্ট্রনিক কপি বিনষ্ট করে/মুছে ফেলা হবে।)

অস্ট্রেলিয়া ও ভিক্টরিয়া এবং বাংলাদেশের একান্ততা ও তথ্য অধিকার আইন মোতাবেক এই কর্মসূচীর আওতায় আপনার ক্ষেত্রে সংগৃহীত তথ্যাদি উদ্ধার করার সম্পূর্ণ অধিকার আনার আছে। যদি আপনি নিজের তথ্য জানতে চান তাহলে যে কোনো গবেষণাকারীর সঙ্গে এ ব্যাপারে যোগাযোগ করতে পারেন।

৯। এ গবেষণা কর্মসূচীটি কি অনুমোদিত?

এই গবেষোণা কর্মসূচীটি পরিচালনার জন্য ভিক্টোরিয়া বিশ্ববিদ্যালয়ের মানব গবেষণা নৈতিকতা কমিটী ও বাংলাদেশ চিকিৎসা গবেষণা পরিষদ অনুমোদান প্রদান করা হয়েছে। এই গবেষণা কর্মসূচীটি মানব গবেষোণা পরিচালনা সংক্রান্ত অস্ট্রেলিয়া ও বাংলাদেশের নৈতিক আচরণ বিধি-বিধান অনুসারে পরিচালিত হবে যাতে করে এই মানব গবেষণা কর্মসূচীটিতে অংশগ্রহণে সম্মত সকলের স্বার্থ রক্ষিত হয়।

কর্মসূচি সম্পর্কিত কোনো বিষয়ে জানতে চাইলে কিংবা অভিযোগ বা সমস্যা থাকলে নিম্নাংশে সংযোজিত 'যোগাযোগের ঠিকানায়' উল্লেখিত ব্যাক্তিবর্গের শরণাপন্ন হোন।

যোগাযোগের ঠিকানাঃ

১। প্রফেসর টেরেন্স ম্যাকান
অফিসঃ+৬১৩৯৯১৯২৩২৫
মোবাইলঃ +৬১৪০৩২০৯৪৫৩
ইমেইলঃ Terence.McCann@vu.edu.au

২। প্রফেসর ম্যারি ক্যারোলান-ওলাহ
অফিসঃ +৬১৩৯৯১৯২৫৮৫
মোবাইলঃ +৬১৪২৩৩৫৬২৯৮
ইমেইলঃ mary.carolan@vu.edu.au

৩। ডঃ রেহনুমা তারান্নুম
মোবাইলঃ ০১৭৯৯৯৪৮৬৭৩
ইমেইলঃ Rehenuma.tarannum@live.vu.edu.au

এই কর্মসূচীতে অংশগ্রহণ সংক্রান্ত যে কোনো প্রশ্ন উপরোক্ত প্রধান বা সহকারী গবেষক সমীপে পাঠানো যেতে পারে। তাছাড়া আপনার প্রতি আচরণের সাপেক্ষে কোনো প্রশ্ন বা অভিযোগ থাকলে যোগাযোগ করুন এই ঠিকানায়: **Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC 8001, email <researchethics@vu.edu.au> or phone +61 3 9919 4781 or +61 3 9919 4461**

Appendix B

Consent form (pregnant women)

(English and Bengali version)

CONSENT FORM FOR PARTICIPANTS (Pregnant women version)

INFORMATION TO PARTICIPANTS:

We would like to invite you to take part in a research project looking at an educational programme to reduce mental stress during pregnancy. It will be conducted under the supervision of Professor Terence McCann and Professor Mary Carolan-Olah from the College of Health and Biomedicine at Victoria University, Melbourne, Australia. The title of the project is, **'A pilot randomised controlled trial of a peer-based low-intensity psychosocial intervention for reducing depressive symptoms in pregnant women in rural Bangladesh.** The aim of the project is to examine if taking part in this education programme delivered by local mother from your area -

- Will reduce any mental stress you may be experiencing.
- Will increase your self-esteem and quality of life.

Please read the Information to Participant Sheet carefully before signing this form. Ask questions about anything you don't understand or want to know more about (contact information given at the end of this sheet). Discuss with your family before you decide to take part in the study.

If you decide to take part in the study, you will be asked to sign this consent form. By signing the form, you indicate that you:

- Understand what the research project is about and all the information given in this information sheet.
- Consent to take part in the study and have discussed your involvement with your family.
- Consent to involve in the intervention described.

CERTIFICATION BY PARTICIPANT:

I, (Participant's name)

Of (Address)

Certify that I am at least 18 years old and that I am voluntarily giving my consent to participate in the above-mentioned study.

I certify that the objectives of the study, together with any risks and safeguards associated with the procedures listed hereunder to be carried out in the research, have been fully explained to me by the student researcher Rehenuma Tarannum and that **I freely consent to participation involving the below mentioned procedures:**

- To take part in the 5 weeks educational programme, if allocated in intervention group.
- To complete the required questionnaires related to the study.
- To take part in a short interview after the intervention delivery, if allocated to the group that undertakes the programme.

I certify that I have had the opportunity to have any questions answered and that I understand that I can withdraw from this study at any time and that this withdrawal will not jeopardise me in any way.

I have been informed that the information I provide will be kept confidential.

Name:

Signature:

Date:

Declaration by student researcher
I have provided all the information about the research project, its procedure and risks verbally to this participant and I believe that the participant has understood the information.

Name: Rehenuma Tarannum

Signature:

Date:

Witness:

Signature:

Date:

Any queries about your participation in this project may be directed to the researchers.

Contact details:
If you require further information or have any problems concerning the project you can contact the researchers any time:

1. **Professor Terence McCann**

Office: +61 3 9919 2325
Mobile: +61 403 209 453
Email: Terence.McCann@vu.edu.au

2. **Professor Mary Carolan-Olah**
Office: +61 3 9919 2585
Mobile: +61 423 356 298
Email: Mary.Carolan@vu.edu.au

3. **Dr Rehenuma Tarannum**
National telephone: +8801799948673

Email: Rehenuma.tarannum@live.vu.edu.au

Any queries about your participation in this project may be directed to the chief or associate investigator listed above. If you have any queries or complaints about the way you have been treated, you may contact the Ethics Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC, 8001, email researchethics@vu.edu.au or phone +61 3 9919 4781 or +61 3 9919 4461.

অংশগ্রহণকারীর সম্মতিপত্র (গর্ভবতী নারীর জন্য প্রযোজ্য):

অংশগ্রহণকারীর জন্য সরবরাহকৃত তথ্যাবলী:

গর্ভাবস্থায় মানসিক চাপ ও দুশ্চিন্তা নিয়ন্ত্রণের উপায় এর উপর পরিচালিত একটি শিক্ষামূলক গবেষণা কর্মসূচীতে অংশগ্রহণের জন্য আপনাকে আমন্ত্রণ জানাচ্ছি। অস্ট্রেলিয়ার মেলবোর্ন এ অবস্থিত ভিক্টোরিয়া ইউনিভার্সিটি এর স্বাস্থ্য ও জৈব-চিকিৎসা বিভাগের অধ্যাপক টেরেন্স ম্যাক-কান ও সহযোগী অধ্যাপক মেরী ক্যারোলান-ওলাহ এর সার্বিক তত্বাবধানে এই গবেষণা কর্মসূচীটি সংগঠিত হচ্ছে; যার শিরোনাম , 'বাংলাদেশের গ্রামাঞ্চলে বসবাসরত মহিলাদের গর্ভাবস্থায় মানসিক চাপ ও দুশ্চিন্তা কমানোর লক্ষ্যে একটি স্বল্পমাত্রার শিক্ষামূলক মনসামাজিক কার্যক্রমের সম্ভাব্যতা ও গ্রহণযোগ্যতা যাচাই '।

এই গবেষণা কর্মসূচীটির মূল উদ্দেশ্য এটি যাচাই করা যে, আপনাদের মতই স্থানীয় একজন মা দ্বারা পরিচালিত এই শিক্ষামূলক কার্যক্রমে অংশগ্রহণের ফলে

- গর্ভাবস্থায় আপনারা যে মানসিক চাপ ও দুশ্চিন্তা অনুভব করেন তার কোন পরিবর্তন হয় কিনা এবং
- আপনাদের আত্মসম্মানবোধ ও জীবনের গুনগতমান মানে কোন পরিবর্তন হয় কিনা।

এই গবেষণা কার্যক্রম এর ফলাফল ডাঃ রেহেনুমা তারান্নুম এর পি. এইচ. ডি. ডিগ্রি অর্জনে ব্যবহৃত হবে।

এই সম্মতিপত্রটি স্বাক্ষরের পূর্বে অনুগ্রহপূর্বক সংযুক্ত 'অংশগ্রহণকারীর জন্য সরবরাহকৃত তথ্যাবলী' ভালভাবে পড়ে দেখুন। কোনো বিষয় সম্পর্কে জানতে চাইলে কিংবা বুঝতে সমস্যা হলে প্রশ্ন করুন অথবা এই কাগজের নিম্নাংশে সংযোজিত 'যোগাযোগের ঠিকানায়' উল্লেখিত ব্যাক্তিবর্গের শরণাপন্ন হোন।

অংশগ্রহণকারীর ঘোষণাঃ

আমি (অংশগ্রহণকারীর নাম) _____

(অংশগ্রহণকারীর ঠিকানা) _____,

এই মর্মে প্রত্যয়ণ করছি যে আমার বয়স কমপক্ষে ১৮ বছর এবং আমি উপরে বর্ণিত সমীক্ষায় সেচ্ছায় অংশগ্রহণের সম্মতি প্রদান করেছি।

আমি এই মর্মে প্রত্যয়ণ করছি যে, গবেষণা কর্মসূচীর উদ্দেশ্যাবলী ও এর পদ্ধতির সাথে জড়িত কোনো ঝুঁকি এড়াতে গৃহীত নিরাপত্তাব্যাবস্থা গবেষণারত ছাত্রী ডঃ রেহনুমা তারান্নুম কর্তৃক আমাকে অবহিত করা হয়েছে এবং নীচের প্রক্রিয়াটিতে অংশগ্রহণের জন্য আমি স্বেচ্ছায় সম্মতি প্রদান করলাম।

- অংশগ্রহণকারী কোনো দলে আমার অন্তর্ভুক্তি সাপেক্ষে ৫ সপ্তাহব্যাপী শিক্ষামূলক কার্যক্রমে নিযুক্ত হওয়া।
- নির্ধারিত প্রশ্নমালা পূরণ পূর্বক শিক্ষামূলক কার্যক্রম সমাধা করা।
- নিযুক্ত দল কর্তৃক নির্বাচিত হওয়া পূর্বক কর্মসূচী শেষে একটি সংক্ষিপ্ত সাক্ষাৎকারে অংশগ্রহণ।

আমি এই মর্মে প্রত্যয়ণ করছি যে, আমার সব প্রশ্নের উত্তর দেয়ার সুযোগ আমাকে দেয়া হয়েছে এবং আমি যে কোনো সময় এই কর্মসুচী থেকে নিজেকে প্রত্যাহার করে নিতে পারবো এবং তা আমাকে কোনোভাবেই ক্ষতিগ্রস্ত করবে না।

আমার দ্বারা সরবরাহকৃত সকল তথ্যাদি গোপন রাখা হবে বলে আমাকে জানানো হয়েছে।

নামঃ_____

স্বাক্ষরঃ_____

তারিখঃ_____

গবেষণারত ছাত্রী কর্তৃক ঘোষণাঃ
আমি এই গবেষণা কর্মসূচী সম্পর্কিত তথ্যাদি, এর পদ্ধতি ও ঝুঁকি সম্বন্ধে অংশগ্রহণকারীকে মৌখিকভাবে অবহিত করেছি। আমার বিশ্বাস অংশগ্রহণকারীর জন্য তা বোধগম্য ছিল।

নামঃ ডাঃ রেহেনুমা তারান্নুম

স্বাক্ষরঃ

তারিখঃ

সাক্ষীর নাম ঃ

সাক্ষীর সাক্ষর ঃ

কর্মসূচি বিষয়ক যেকোনো অভিযোগ অথবা তথ্য জানার জন্য নিম্নের যেকোনো গবেষণাকারীদের সাথে যোগাযোগ করুনঃ

১। □□□□□□□ টেরেন্স ম্যাক-কান

অফিস ঃ +৬১ ৩ ৯৯১৯ ২৩২৫

মোবাইল ঃ +৬১ ৪০৩ ২০৯ ৪৫৩

Office: +61 3 9919 2325

Mobile: +61 403 209 453

Email: Terence.McCann@vu.edu.au

২। □□□□□□ □□□□□□□ মেরী ক্যারোলান-ওলাহ

অফিস ঃ +৬১ ৩ ৯৯১৯ ২৫৮৫

মোবাইল ঃ +৬১ 823 ৩৫৬ 298

Email: Mary.Carolan@vu.edu.au

৩। ডাঃ রেহেনুমা তারান্নুম

মোবাইল ঃ +৮৮০১৭৯৯৯৪৮৬৭৩

Email: Rehenuma.tarannum@live.vu.edu.au

এই কর্মসূচীতে অংশগ্রহণ সংক্রান্ত যে কোনো প্রশ্ন উপরোক্ত প্রধান বা সহকারী গবেষক সমীপে পাঠানো যেতে পারে। তাছাড়া আপনার প্রতি আচরণের সাপেক্ষে কোনো প্রশ্ন বা অভিযোগ থাকলে যোগাযোগ করুন এই ঠিকানায়।

Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC 8001, email <researchethics@vu.edu.au> or phone +61 3 9919 4781 or +61 3 9919 4461

Appendix C

Participants information sheet – Peer version

(English and Bengali version)

Participant information and consent form
(Peer version)

Full Project Title: **A pilot randomised controlled trial of a peer-based low-intensity psychosocial intervention for reducing depressive symptoms in pregnant women in rural Bangladesh**

1. Introduction

My name is Rehenuma Tarannum. I am a Ph.D. research student in Victoria University, Australia. I would like to invite you to take part in a research project looking at an educational programme to reduce mental stress during pregnancy. It will be conducted under the supervision of Professor Terence McCann and Professor Mary Carolan-Olah from the College of Health and Biomedicine at Victoria University, Melbourne, Australia. The aim of the project is to examine if taking part in this education programme led by local women like you -

- Will reduce any mental stress you may be experiencing.
- Will increase your self-esteem and quality of life.

2. Purposes and Background

The purpose of the study is to examine how useful is the programme is to assist you in reducing mental stress during pregnancy.

A total of 70 pregnant women and 6 peers will be invited to take part in the study.

You are invited to take part in the study if you are:

- **A mother residing in the local community.**
- **Aged 18 years or above.**
- **Having 10th grade or higher school level education**.

The result of this research will be used by Rehenuma Tarannum to obtain a Ph.D. degree.

3. What does participation in this research project involve?

Procedures

You will be responsible to deliver the educational programme to at least 5-6 pregnant women. You will deliver one-hour weekly sessions for 5 weeks in pregnant women's home or other place of convenience. Your responsibility will be to deliver the sessions and ensure that the pregnant woman has understood all parts of the sessions.

You will meet the student researcher prior to the beginning of the programme to:

- Attend 4 days (25 hours) training session, during which you will;
- Obtain information about the project and expectation of your role.

- Obtain information about educational programme that you will deliver.
- Obtain information about improving your basic communication skill and qualities of helpful peer support.
- Take part in role-playing during the training sessions to improve your delivery of the intervention sessions.
- Learn the importance of confidentiality and privacy of participants.

You will be provided with a take-home booklet containing detailed information to help you deliver the programme effectively. You will also receive weekly telephone call from the researcher to ensure that you have delivered the sessions according to the programme protocol and to discuss any issues or concerns you have.

You will also attend a fortnightly meeting with the researcher to help you maintain your skills over time. You will be asked to take part in a short audio-recorded interview to describe your experience and views about the programme at the end of the programme delivery.

Reimbursement

You will not be paid for participating in this study, but you will be reimbursed for expenses (travelling cost, telephone calls and other expenses) incurred as a result of participating. You will receive an amount of $50 (3,400 taka).

4. What are the possible benefits?

There may be no direct benefit for you by participating in the study. However, you will gain some knowledge about this educational programme to reduce day-today stress symptoms in pregnant women. The techniques you learn during the intervention may also benefit yourself, should you become pregnant at some stage in the future. In addition, you may find it rewarding to help other pregnant women in the community experiencing mental stress.

5. What are the possible risks?

There is a very low risk for you taking part in this study. In an unlikely event that you become mildly upset or distressed due to participation in the research, an appointment for you will be arranged at the antenatal clinic of Chakaria Health Complex.

6. Do I have to take part in the study?

Participation in this project is voluntary. You don't have to take part if you don't want to. If you decide to take part and later change your mind, you are free to leave the project at any stage.

7. How will I be informed of the final results of this study?

If you wish to know about the final result of the study, a summary will be sent to you after completion of the study.

8. What will happen to information about me?

During the project, all the data will be stored in password-protected file in the supervisors and the student researchers' computers. Only the supervisors and the student researcher will have access to the data. After

completion of the study, an electronic copy of the data will be securely stored in college of Health and Biomedicine and will be destroyed after 5 years (hard copies will be shredded and electronic data will be deleted).

Any information collected in relation with this research project that can identify you will remain confidential and will only be used for the purpose of this study. It will not be disclosed anywhere without your permission, unless required by law.

In accordance with the Australian and Victorian privacy and Bangladesh information law you have the right to access information collected and stored by the research teal about you. Please contact one of the researchers if you would like to access your information.

9. Is this research project approved?

The permission to conduct this study has been granted by Victoria University Human Research committee and Bangladesh Medical Research Council.

The project will be carried out in accordance with the rules of ethical conduct in human research of both Australia and Bangladesh to protect the interests of people who agree to participate in human research studies.

Contact details

If you require further information or have any problems concerning the project you can contact one of the researchers at any time:

1. **Professor Terence McCann**

Office: +61 3 9919 2325
Mobile: +61 403 209 453
Email: Terence.McCann@vu.edu.au

2. **Professor Mary Carolan-Olah**
Office: +61 3 9919 2585
Mobile: +61 423 356 298
Email: Mary.Carolan@vu.edu.au

3. **Dr Rehenuma Tarannum**
National telephone: +8801799948673

Email: Rehenuma.tarannum@live.vu.edu.au

Any queries about your participation in this project may be directed to the chief or associate investigator listed above. If you have any queries or complaints about the way you have been treated, you may contact the Ethics Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC, 8001, email researchethics@vu.edu.au or phone +61 3 9919 4781 or +61 3 9919 4461.

অংশগ্রহণকারীর সম্মতিপত্র (সমকক্ষ/সমসাময়িক মা দের জন্য):

কর্মসূচীর শিরোনামঃ বাংলাদেশে গ্রামাঞ্চলে বসবাসরত গর্ভবতী মহিলাদের মানসিক চাপ ও দুশ্চিন্তা কমানোর লক্ষ্যে একটি স্বল্পমাত্রা শিক্ষামূলক মনসামাজিক কার্যক্রমের সম্ভাব্যতা ও গ্রহণযোগ্যতা যাচাই '

১। সূচনাঃ

আমার নাম রেহনুমা তারান্নুম। আমি অস্ট্রেলিয়ার মেল্বূর্নে অবস্থিত ভিক্টোরিয়া বিশ্ববিদ্যালয়ে অধ্যয়নরত পি এইচ ডি ডিগ্রীর গবেষণা ছাত্রী । গর্ভাবস্থার মানসিক চাপ ও দুশ্চিন্তা নিয়ন্ত্রণের উপায় এর উপর পরিচালিত একটি শিক্ষামূলক গবেষণা কর্মসূচীতে অংশগ্রহণের জন্য আপনাকে আমন্ত্রণ জানাচ্ছি। অস্ট্রেলিয়ার মেলবোর্নে অবস্থান্নত ভিক্টোরিয়া ইউনিভার্সিটির স্বাস্থ্য ও জৈব-চিকিৎসা বিভাগের অধ্যাপক টেরেন্স ম্যাক-কান ও সহযোগী অধ্যাপক মেরী ক্যারোলান-ওলাহ এর সার্বিক তত্বাবধানে এই গবেষণা কর্মসূচীটি আয়োজন করা হবে। '

এই গবেষণাটির মূল উদ্দেশ্য এটি যাচাই করা যে, আপনাদের মত একজন মা দ্বারা পরিচালিত এই শিক্ষামূলক কার্যক্রম এ অংশগ্রহণের ফলে গর্ভবটি মহিলারা গর্ভাবস্থায়

- যে মানসিক চাপ ও দুশ্চিন্তা অনুভব করেন তার কোন পরিবর্তন হয় কিনা।
- তাদের আত্মসম্মানবোধ ও জীবনের গুনগতমানের কোন পরিবর্তন হয় কিনা।

২। উদ্দেশ্য ও পটিভূমিঃ

এই সমীক্ষার উদ্দেশ্য হলো গর্ভকালীন সময়ে সৃষ্ট মানসিক দুশ্চিন্তা ও চাপ কমাতে সমকক্ষ স্থানীয় মা দের দ্বারা পরিচালিত এই কর্মসূচী গর্ভবতী মহিলাদের জন্য কতখানি সহায়ক তা পরীক্ষা করে দেখা। এই কর্মসূচীতে অংশগ্রহণের জন্য মোট ৭০ জন গর্ভবতী মহিলা এবং স্থানীয় এলাকার ৬ জন somokokkho/সমবয়সী (অগর্ভবতী) মাকে আমন্ত্রণ জানানো হবে।

আপনাকে এই কর্মসূচীতে অংশগ্রহণ করার জন্য আমন্ত্রণ জানানো হবে যদিঃ

- **স্থানীয় এলাকায় বসবাসরত একজন মা হন।**
- **আপনার বয়স ১৮ বৎসর বা তার উপরে হয়।**
- **আপনার দশম শ্রেণি বা তার চেয়ে বেশী শিক্ষাগত যোগ্যতা থাকে।**

এই গবেষণা কর্মসূচীর ফলাফল ডঃ রেহনুমা তারান্নুম কর্তৃক পি এইচ ডি ডিগ্রী অর্জনের কাজে ব্যবহার করা হবে।

৩। এই গবেষণা কর্মসূচীতে অংশগ্রহণ করা মানে কি বোঝায়?

কার্যপদ্ধতিসমূহঃ

এই গবেষণা কার্যক্রমে অংশগ্রহন করলে আপনি ৫-৬ জন গর্ভবতী মহিলাদের জন্য ৫ সপ্তাহ ব্যপী একটি শিক্ষামূলক কার্যক্রম পরিচালিত করবেন । এই কর্মসূচি তে প্রতি গর্ভবতী মহিলাদের জন্য সপ্তাহে একটি করে অদিবেশন পরিচালনা করতে হবে। প্রত্যেকটি অধিবেশন মোটামুটি এক ঘন্টাব্যাপী অনুষ্ঠিত হবে। কর্মসূচিটির মাধ্যমে আপনি গর্ভকালীন সময়ে গর্ভবতি মহিলারা যে সব দৈনন্দিন যে মানসিক চাপ ও দুশ্চিন্তার সম্মূখীন হতে পারেন তা মোকাবেলা করার দক্ষতা শেখাবেন ।

শিক্ষামূলক কার্যক্রম টি সুন্দরভাবে পরিচালনার জন্য আপনাকে ৪ দিনের প্রশিক্ষণ কর্মশালায় অংশগ্রহণ করতে হবে। এই প্রশিক্ষণ এ অংশগ্রহণ এর ফলে আপনি জানতে পারবেন

- **এই গবেষণা কর্মসূচি তে আপনার প্রত্যাশিত ভূমিকা ও করনিয় সম্পর্কে**
- **কিভাবে আপনার মৌলিক যোগাযোগ দক্ষতা ও সমসাময়িক ভূমিকা পালন এ উনুত করা যায় তার সম্পর্কে**
- **কিভাবে শিক্ষামূলক কার্যক্রমের প্রতিটি অধীবেশন পরিচালনা করতে হবে তার সম্পর্কে । এর জন্য ৪ দিনের প্রশিক্ষণ কর্মশালায় অধিবেশন গুলো অভিনয়ের মাধ্যমে পরিচালনা করা শিখবেন**
- **গবেষণা কর্মসূচির তথ্যাদির গোপনীয়তা রক্ষার প্রয়োজনীয়তা ও উপায় সম্পর্কে।**

কার্যকর ভাবে এই কর্মসূচি পরিচালনার জন্য আপনাকে বিশদ তথ্য সমৃদ্ধ একটি পুস্তিকা দেয়া হবে। আপনি শিক্ষামূলক কার্যক্রম টী সঠিকভাবে গর্ভবতী মাদের কাছে পৌঁছে দিচ্ছেন কিনা তা নিশ্চিত হওয়ার জন্য গবেষণাকারী ছাত্রী আপনাকে প্রতি সপ্তাহে অন্তত একবার ফোন করবেন এবং প্রতি দুই সপ্তাহে নির্বাচিত ৬ সমসাময়িক মা দের সাথে সাক্ষাতকার করবেন।

সপূনঃর্ভরণ/ খরচকৃত টাকা মিটিয়ে দেয়াঃ

এই কর্মসূচীতে অংশগ্রহণের জন্য আপনাকে কোনো অর্থ দেয়া হবে না। তবে অংশগ্রহণ বাবদ আপনার খরচাদি মিটীয়ে দেয়া হবে। এজন্য আপনাকে ৫০ ডলার (3000 টাকা) দেয়া হবে।

৪। এই কর্মসূচীতে অংশগ্রহণের সাম্ভাব্য সুবিধা কি?

এই কর্মসূচীতে অংশগ্রহণের ফলে হয়ত সরাসরিভাবে আপনার কোনো সুবিধা হবে না। তবে এই শিক্ষামূলক কার্যক্রম সম্পর্কে আপনি কিছু জ্ঞানলাভ করতে পারবেন, যা আপনাকে গর্ভকালীন মানসিক দুশ্চিন্তা ও চাপ কমাতে সাহায্য করবে। এছাড়া কি সব বিষয় আপনার মানসিক ধকল সৃষ্টি করতে পারে সে ব্যাপারে আপনার এলাকার সমসাময়িকদের সাথে আলাপ করে লাভবান হতে পারবেন।

৫। এই কর্মসূচীতে অংশগ্রহণে সাম্ভাব্য ঝুঁকিসমূহ কি কি?

এই কার্যক্রমে খুবই সামান্য ঝুঁকি আছে। তা সত্বেও যদি কোনো কারণে আপনি সামান্য আবেগ-আপ্লুত হয়ে পড়লে, আপনাকে চকরিয়া উপজেলা স্বাস্থ্য চিকিৎসার কমপ্লেক্সের জন্ম-পূর্বকালীন ক্লিনিকে আপনার চিকিৎসার ব্যবস্থা করা হবে।

৬।আমাকে এই কর্মসূচীতে অংশগ্রহণ করতেই হবে?

এই কর্মসূচীতে অংশগ্রহণ সম্পূর্ণ ঐচ্ছিক। আপনি যদি অংশগ্রহণ করতে না চান তাহলে করতে হবে না। যদি আপনি অংশগ্রহণের সিদ্ধান্ত নিয়ে মত পরিবর্তন করেন, আমি যেকোনো সময় কর্মসূচী ছেড়ে যেতে সক্ষম। এ কর্মসূচীতে অংশগ্রহণ করা বা না করা কোনোভাবে আপনার গর্ভাবস্থার উপর প্রভাব ফেলবে না।

৭। এই কর্মসূচির চূড়ান্ত ফলাফল সম্বন্ধে কিভাবে অবহিত করা হবে?

আপনি যদি চূড়ান্ত ফলাফল সম্পর্কে জানতে আগ্রহী হন, তাহলে কর্মসূচী শেষে আপনাকে একটি সারাংশ পাঠিয়ে দেয়া হবে।

৮। আমার সম্পর্কে নেয়া তথ্যাদি কি করা হবে?

কর্মসূচী চলাকালে সব তথ্যাদি পাসওয়ার্ড দ্বারা সংরক্ষিত নথিতে গবেষণাকারী ছাত্রীর ও তত্বাবোধায়কদের কম্পিউটারে (অস্ট্রেলিয়া) ধারণ করে রাখা হবে। কেবলমাত্র গবেষণাকারী ছাত্রী ও তত্বাবোধায়কগণ সে তথ্যাদি উদ্ধার করতে পারবেন। কর্মসূচী শেষে তথ্যাদির এলেক্ট্রনিক কপি নিরাপদভাবে স্বাস্থ্য ও জৈবচিকিৎসা মহাবিধ্যালয়ে রাখা থাকবে এবং পাঁচ বছর হয়ে গেলে তা বিনষ্ট করে ফেলা হবে(যান্ত্রিকভাবে ছিঁড় ফেলা হবে এবং এলেক্ট্রনিক কপি বিনষ্ট করে/মুছে ফেলা হবে।)

অস্ট্রেলিয়া ও ভিক্টরিয়া এবং বাংলাদেশের একান্ততা ও তথ্য অধিকার আইন মোতাবেক এই কর্মসূচীর আওতায় আপনার ক্ষেত্রে সংগৃহীত তথ্যাদি উদ্ধার করার সম্পূর্ণ অধিকার আনার আছে। যদি আপনি নিজের তথ্য জানতে চান তাহলে যে কোনো গবেষণাকারীর সঙ্গে এ ব্যাপারে যোগাযোগ করতে পারেন।

৯। এ গবেষণা কর্মসূচীটি কি অনুমোদিত?

এই গবেষোণা কর্মসূচীটি পরিচালনার জন্য ভিক্টোরিয়া বিশ্ববিদ্যালয়ের মানব গবেষণা নৈতিকতা কমিটী ও বাংলাদেশ চিকিৎসা গবেষণা পরিষদ অনুমোদান প্রদান করা হয়েছে। এই গবেষণা কর্মসূচীটি মানব গবেষোণা পরিচালনা সংক্রান্ত অস্ট্রেলিয়া ও বাংলাদেশের নৈতিক আচরণ বিধি-বিধান অনুসারে পরিচালিত হবে যাতে করে এই মানব গবেষণা কর্মসূচীটিতে অংশগ্রহণে সম্মত সকলের স্বার্থ রক্ষিত হয়।

কর্মসূচি সম্পর্কিত কোনো বিষয়ে জানতে চাইলে কিংবা অভিযোগ বা সমস্যা থাকলে নিম্নাংশে সংযোজিত 'যোগাযোগের ঠিকানায়' উল্লেখিত ব্যাক্তিবর্গের শরণাপন্ন হোন।

যোগাযোগের ঠিকানাঃ

১। প্রফেসর টেরেন্স ম্যাকান
অফিসঃ+৬১৩৯৯১৯২৩২৫
মোবাইলঃ +৬১৪০৩২০৯৪৫৩
ইমেইলঃ Terence.McCann@vu.edu.au

২। প্রফেসর ম্যারি ক্যারোলান-ওলাহ
অফিসঃ +৬১৩৯৯১৯২৫৮৫
মোবাইলঃ +৬১৪২৩৩৫৬২৯৮
ইমেইলঃ mary.carolan@vu.edu.au

৩। ডঃ রেহনুমা তারান্নুম
মোবাইলঃ ০১৭৯৯৯৪৮৬৭৩
ইমেইলঃ Rehenuma.tarannum@live.vu.edu.au

এই কর্মসূচীতে অংশগ্রহণ সংক্রান্ত যে কোনো প্রশ্ন উপরোক্ত প্রধান বা সহকারী গবেষক সমীপে পাঠানো যেতে পারে। তাছাড়া আপনার প্রতি আচরণের সাপেক্ষে কোনো প্রশ্ন বা অভিযোগ থাকলে যোগাযোগ করুন এই ঠিকানায়: **Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC 8001, email <researchethics@vu.edu.au> or phone +61 3 9919 4781 or +61 3 9919 4461**

Appendix D

Consent form (Peer version)

(English and Bengali version)

CONSENT FORM FOR PARTICIPANTS (Peer version)

INFORMATION TO PARTICIPANTS:

We would like to invite you to take part in a research project looking at an educational programme to reduce mental stress during pregnancy. It will be conducted under the supervision of Professor Terence McCann and Professor Mary Carolan-Olah from the College of Health and Biomedicine at Victoria University, Melbourne, Australia. The title of the project is, **A pilot randomised controlled trial of a peer-based low-intensity psychosocial intervention for reducing depressive symptoms in pregnant women in rural Bangladesh**. The aim of the project is to examine if taking part in this education programme delivered by local women like you -

- Will reduce any mental stress following participation in the study pregnant women may be experiencing during pregnancy.
- Will increase pregnant women's self-esteem and quality of life following participation.

Please read the Information to Participant Sheet carefully before signing this form. Ask questions about anything you don't understand or want to know more about (contact information given at the end of this sheet.

If you decide to take part in the study, you will be asked to sign this consent form. By signing the form, you indicate that you:

- Understand what the research project is about and all the information given in this information sheet.
- Consent to take part in the study and have discussed your involvement with your family.
- Consent to be involved in the education programme described.

CERTIFICATION BY PARTICIPANT:

I, (Participant's name)

Of (Address)

Certify that I am at least 18 years old and that I am voluntarily giving my consent to participate in the study above mentioned study.

I certify that the objectives of the study, together with any risks and safeguards associated with the procedures listed hereunder to be carried out in the research, have been fully explained to me by the **Student Researcher Rehenuma Tarannum** and that **I freely consent to participation involving the below mentioned procedures:**

- **To deliver weekly session of the educational programme to at least 5 or 6 pregnant women in for 5 weeks.**
- **To take part in 4 full days training programme and fortnightly supervision meeting for preparation of peers.**
- **To take part in a short interview at the end of the intervention delivery.**

I certify that I have had the opportunity to have any questions answered and that I understand that I can withdraw from this study at any time and that this withdrawal will not jeopardise me in any way.

I have been informed that the information I provide will be kept confidential.

Name:

Signature:

Date:

Declaration by student researcher:
I have provided all the information about the research project, its procedure and risks verbally to this participant and I believe that the participant has understood the information.

Name: Dr. Rehenuma Tarannum

Signature:

Date:

Witness:

Signature:

Date:

Any queries about your participation in this project may be directed to the researchers.

Contact details:
If you require further information or have any problems concerning the project you can contact the researchers any time:
1. **Professor Terence McCann**
International telephone: +61 3 9919 2325
Email: Terence.McCann@vu.edu.au

2. **Professor Mary Carolan-Olah**
International telephone: +61 3 9919 2585
Email: Mary.Carolan@vu.edu.au

3. **Dr Rehenuma Tarannum**
National telephone: +88031657619
Email: Rehenuma.tarannum@live.vu.edu.au

Any queries about your participation in this project may be directed to the chief or associate investigator listed above. If you have any queries or complaints about the way you have been treated, you may contact the Ethics Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC, 8001, email researchethics@vu.edu.au or phone +61 3 9919 4781 or +61 3 9919 4461.

অংশগ্রহণকারীর সম্মতিপত্র (সমসাময়িক/ সমকক্ষ মা দের জন্য) :

অংশগ্রহণকারীর জন্য সরবরাহকৃত তথ্যাবলী:

গর্ভাবস্থায় মানসিক চাপ ও দুশ্চিন্তা নিয়ন্ত্রণের উপায় এর উপর পরিচালিত একটি শিক্ষামূলক গবেষণা কর্মসূচীতে অংশগ্রহণের জন্য আপনাকে আমন্ত্রণ জানাচ্ছি। অস্ট্রেলিয়ার মেলবোর্ন এ অবস্থিত ভিক্টোরিয়া ইউনিভার্সিটি এর স্বাস্থ্য ও জৈব-চিকিৎসা বিভাগের অধ্যাপক টেরেন্স ম্যাক-কান ও সহযোগী অধ্যাপক মেরী ক্যারোলান-ওলাহ এর সার্বিক তত্বাবধানে এই গবেষণা কর্মসূচীটি সংগঠিত হচ্ছে; যার শিরোনাম , 'বাংলাদেশের গ্রামাঞ্চলে বসবাসরত মহিলাদের গর্ভাবস্থায় মানসিক চাপ ও দুশ্চিন্তা কমানোর লক্ষ্যে একটি স্বল্পমাত্রার শিক্ষামূলক মনসামাজিক কার্যক্রমের সম্ভাব্যতা ও গ্রহণযোগ্যতা যাচাই '।

এই গবেষণা কর্মসূচীটির মূল উদ্দেশ্য এটি যাচাই করা যে, আপনাদের মতই স্থানীয় একজন মা দ্বারা পরিচালিত এই শিক্ষামূলক কার্যক্রমে অংশগ্রহণের ফলে

- গর্ভবতী মহিলারা গর্ভাবস্থায় যে মানসিক চাপ ও দুশ্চিন্তা অনুভব করেন তার কোন পরিবর্তন হয় কিনা এবং
- তাদের আত্মসম্মানবোধ ও জীবনের গুনগতমান মানে কোন পরিবর্তন হয় কিনা।

এই সম্মতিপত্রটি স্বাক্ষরের পূর্বে অনুগ্রহপূর্বক সংযুক্ত 'অংশগ্রহণকারীর জন্য সরবরাহকৃত তথ্যাবলী' ভালভাবে পড়ে দেখুন। কোনো বিষয় সম্পর্কে জানতে চাইলে কিংবা বুঝতে সমস্যা হলে প্রশ্ন করুন অথবা এই কাগজের নিম্নাংশে সংযোজিত 'যোগাযোগের ঠিকানায়' উল্লেখিত ব্যাক্তিবর্গের শরণাপন্ন হোন।

আপনি অংশগ্রহণে আগ্রহী হলে আপনাকে এই সম্মতিপত্রটি স্বাক্ষর করতে হবে। এটি সাক্ষরের মাধ্যমে আপনি ঘোষণা করছেন যে ঃ

- আপনি এই গবেষণা কার্যক্রম সম্পর্কে এবং সম্মতিপত্রে সরবরাহকৃত সকল তথ্য বুঝতে পেরেছেন।
- গবেষণা কার্যক্রমে অংশগ্রহণে আপনার সম্মতি আছে এবং তা নিয়ে আপনি পরিবারবর্গের সহিত আলাপ করেছেন।
- এই শিক্ষামূলক গবেষণা কর্মসূচীটিতে জড়িত হতে সম্মত।

অংশগ্রহণকারীর ঘোষণাঃ

আমি (অংশগ্রহণকারীর নাম)_____

(অংশগ্রহণকারীর ঠিকানা)_____,
এই মর্মে প্রত্যয়ণ করছি যে, আমার বয়স কমপক্ষে ১৮ বছর এবং আমি উপরে বর্ণিত সমীক্ষায় স্বেচ্ছায় অংশগ্রহণের সম্মতি প্রদান করেছি।

আমি এই মর্মে প্রত্যয়ণ করছি যে, গবেষণা কর্মসূচীর উদ্দেশ্যাবলী ও এর পদ্ধতির সাথে জড়িত কোনো ঝুঁকি এড়াতে গৃহীত নিরাপত্তাব্যাবস্থা গবেষণারত ছাত্রী ডঃ রেহনুমা তারান্নুম কর্তৃক আমাকে অবহিত করা হয়েছে এবং নীচের প্রক্রিয়া গুলোতে অংশগ্রহণের জন্য আমি স্বেচ্ছায় সম্মতি প্রদান করলাম।

- এই কার্যক্রমের আওতায় বক্তৃতার মাধ্যমে সপ্তাহে এক ঘন্টা করে পাঁচ সপ্তাহে ৫-৬ জন গর্ভবতী মহিলাদেরকে শিক্ষামূলক কর্মসূচী প্রদান।
- সহকর্মীদের জন্য আয়োজিত ৪ দিনব্যাপী প্রশিক্ষন এবং পাক্ষিক ভিত্তিতে আয়োজিত প্রস্তুতি কার্যক্রম সভায় অংশগ্রহন।
- কার্যক্রম টি ইতি-পূর্বক একটি সংক্ষিপ্ত সাক্ষাৎকারে অংশগ্রহণ।

আমি এই মর্মে প্রত্যয়ণ করছি যে, এই গবেষণা সম্পর্কিত আমার সব প্রশ্নের উত্তর আমাকে দেয়া হয়েছে। আমাকে জানানো হয়েছে যে, যে কোনো সময় এই কর্মসুচী থেকে নিজেকে প্রত্যাহার করে নিতে পারবো এবং তা আমাকে কোনোভাবেই ক্ষতিগ্রস্ত করবে না।

আমার দ্বারা সরবরাহকৃত সকল তথ্যাদি গোপন রাখা হবে বলে আমাকে জানানো হয়েছে।

নামঃ_____

স্বাক্ষর:_____

তারিখঃ_____

গবেষণারত ছাত্রী কর্তৃক ঘোষণাঃ
আমি এই গবেষণা কর্মসূচী সম্পর্কিত তথ্যাদি, এর পদ্ধতি ও ঝুঁকি সম্বন্ধে অংশগ্রহণকারীকে মৌখিকভাবে অবহিত করেছি এবং আমার জানামতে অংশগ্রহণকারী আমার দেয়া সকল তথ্য বুঝতে পেরেছে।
নামঃ ডাঃ রেহেনুমা তারান্নুম

স্বাক্ষরঃ

তারিখঃ

সাক্ষীর নাম ঃ

সাক্ষীর সাক্ষর ঃ

কর্মসূচি বিষয়ক যেকোনো অভিযোগ অথবা তথ্য জানার জন্য নিম্নের যেকোনো গবেষণাকারীর সাথে যোগাযোগ করুনঃ

১। অধ্যাপক টেরেন্স ম্যাক-কান

অফিস ঃ +৬১ ৩ ৯৯১৯ ২৩২৫

মোবাইল ঃ +৬১ ৪০৩ ২০৯ ৪৫৩

Office: +61 3 9919 2325
Mobile: +61 403 209 453
Email: Terence.McCann@vu.edu.au

২। সহযোগীঅধ্যাপক মেরী ক্যারোলান-ওলাহ

অফিস ঃ +৬১ ৩ ৯৯১৯ ২৫৮৫

মোবাইল ঃ +৬১ 823 ৩৫৬ 298

Email: Mary.Carolan@vu.edu.au

৩। ডাঃ রেহেনুমা তারান্নুম

মোবাইল ঃ +৮৮০১৭৯৯৪৮৬৭৩

Email: Rehenuma.tarannum@live.vu.edu.au

এই কর্মসূচীতে অংশগ্রহণ সংক্রান্ত যে কোনো প্রশ্ন উপরোক্ত প্রধান বা সহকারী গবেষক সমীপে পাঠানো যেতে পারে। তাছাড়া আপনার প্রতি আচরণের সাপেক্ষে কোনো প্রশ্ন বা অভিযোগ থাকলে যোগাযোগ করুন এই ঠিকানায়।

Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC 8001, email <researchethics@vu.edu.au> or phone +61 3 9919 4781 or +61 3 9919 4461

Appendix E

Interview schedules (Pregnant women)

(English and Bengali version)

Interview schedule for pregnant women in the education programme group of the Thinking Healthy Peer-Delivered programme

- Thank you for agreeing to take part in this interview.
- The purpose of the interview is to seek your opinion about, and obtain suggestions for improving, the Thinking Healthy Peer-delivered Education Programme you took part in about antenatal depression.
- There are two parts to this interview: (i) Several short questions where you will be given a range of fixed responses to choose from, and (ii) a series of in-depth questions from which you can talk freely.
- In total, it will take about 20 minutes to complete the whole interview.
- The interview will be audiotape recorded.
- All answers you give are confidential and you cannot be identified in any thesis or publications from this study.
- Are there questions you wish to ask about this part of the study?

- Switch on the audio recorder.

Interview schedules for pregnant women:

		Strongly agree	Agree	Neutral	Disagree	Strongly Disagree
1	The techniques taught in the education programme have helped me to cope with day to day depressive symptoms					
2	The time allocated to each session was about right					
3	Overall, the length of the education programme was about right					
4	Overall, the content of the education programme was easy to understand.					
5	Overall, I found the exercises and homework helpful after each session.					
6	I plan to continue use the techniques and advice taught during the education programme after the delivery of my baby.					

7	Overall, I was satisfied with the peer who delivered the education program.				
8	The peer was supportive and non-judgmental.				
9	The peer was successful in delivering each session effectively.				
10	My family was supportive of me during the education programme.				
11	I would recommend others to take part in this peer-led psychoeducation programme in future				
12	Having received the education programme, I feel more confident now in dealing with day-to-day depressive symptoms.				
13	Having received the education programme, I feel confident about my parenting role after the birth of my baby.				

Qualitative questions:

1. In what ways, if any, was the education programme helpful in assisting you to cope with day-to-day stressors and depressive symptoms during pregnancy?

2. In what ways, if any, are you going to continue using the techniques learned from the education programme after the delivery of your baby and in future?

3. Which parts of the education programme sessions were most helpful, if any, in assisting you to cope with depressive symptoms?

4. What parts of the sessions, if any, were difficult to understand? How can these parts be improved?

5. What benefits, if any, did you experience from having a peer as the person delivering the education program?

6. After taking part in the education programme, in what ways, if any, has your knowledge and understanding of antenatal depression improved?

7. What additional things, if any, should be included in the education programme to improve your knowledge and understanding of antenatal depression?

Thanks for your time and valuable opinion.

Closure

1. Debrief the participant.
2. Ascertain if there are any questions that he/she wishes to ask.
3. Information about gaining access to the results of the study.
4. Switch off the tape recorder.

Rehenuma Tarannum
s4538259
College of Health & Biomedicine, Victoria University

গর্ভবতী মহিলাদেরকে একজন সমসাময়িক দ্বারা প্রদানকৃত মানসিক ধকল কমানো সংক্রান্ত স্বাস্থ্যসম্মতভাবে চিন্তাভাবনা সংক্রান্ত শিক্ষামূলক কর্মসূচীর দলীয় সাক্ষাৎকারের প্রশ্নাবলী ও নির্ধারিত উত্তরাদি সময়সূচী/তফসিল ঃ

- এই সাক্ষাৎকারে অংশগ্রহণ করতে সম্মত হওয়ার জন্য আপনাকে ধন্যবাদ।
- এই সাক্ষাৎকারের উদ্দেশ্য হলো স্বাস্থ্যসম্মতভাবে চিন্তাভাবনা প্রকল্পের আওতায় সন্তান জন্মানোর পূর্বে মানসিক ধকল কমানো সংক্রান্ত একজন সমসাময়িক দ্বারা প্রদানকৃত শিক্ষামূলক কর্মসূচীতে অংশগ্রহণ করেছের সেটা উন্নত করার ব্যাপারে আপনার মতামত ও পরামর্শ নেয়া।
- এই সাক্ষাৎকারের দুইটি অংশ আছেঃ (১) কয়েকটি ছোট প্রশ্ন যেগুলোর কিছু নির্দিষ্ট উত্তর দেয়া থাকবে যার মধ্যে থেকে আপনাকে যে কোন একটি বেছে নিতে হবে এবং (২) কয়েকটি বিশদ প্রশ্ন যেগুলোর ব্যাপারে আপনি খোলা মন নিয়ে আলাপ করতে পারবেন।
- সম্পূর্ণ সাক্ষাৎকারের জন্য মোটামোটি ২০ মিনিট সময় লাগবে।
- সাক্ষাৎকারটি টেপরেকর্ডারের মাধ্যমে ধারণ করে রাখা হবে।
- আপনার দেয়া সব উত্তর সম্পূণভার্বে গোপনীয় এবং এই সমীক্ষা বা প্রকাশনা থেকে কোনোভাবে আপনাকে চিহ্নিত করা সম্ভব হবে না।
- আপনি কি সমীক্ষার এই অংশ সম্পর্কে কোন প্রশ্ন জিজ্ঞাস করতে চান?
- টেপরেকর্ডারটি চালু/অন করুন।

গর্ভবতী মহিলাদের সাক্ষাৎকারের প্রশ্নাবলী ও নির্ধারিত উত্তরাদিঃ সময়সূচী/তফসিলঃ

		পুরাপুরি একমত	একমত	নিরপেক্ষ	একমত নন	একবারে একমত নন
১	এই শিক্ষামূলক কর্মসূচীতে যে সব কৌশল শেখানো হয়েছে সেগুলো আমার দৈনন্দিন ধকল মোকাবেলায় সহায়তা করেছে					
২	প্রতি অধিবেশনের জন্য নির্ধারিত সময় মোটামোটি সঠিক ছিল					
৩	সার্বিকভাবে, শিক্ষামূলক কর্মসূচীর মেয়াদ মোটামোটি সঠিক ছিল					
৪	সার্বিকভাবে, শিক্ষামূলক কর্মসূচীর বিষয়বস্তু সহজে বোঝার মত ছিল					
৫	সার্বিকভাবে, প্রত্যেক অধিবেশন শেষে দেয়া অনুশীলন ও ঘরে করার কাজ বেশ সহায়ক বলে আমার মণে হলো					

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৬	এই শিক্ষামূলক কর্মসূচীতে দেয়া পরামর্শ ও কৌশলসমূহ আমি আমার সন্তান প্রসবের পরও ব্যবহার করবো বলে আমি আশা করছি				
৭	সার্বিকভাবে, শিক্ষামূলক কর্মসূচীর বক্তৃতা প্রদানকরী সমসাময়িকের ব্যাপারে আমি সন্তুষ্ট				
৮	সমসাময়িক সহায়ক ছিলেন এবং একেবারে ছিদ্রান্বেষণী ছিলেন না				
৯	সমসাময়িক প্রতিটি অধিবেশন প্রদানে সফল ছিলেন				
১০	শিক্ষামূলক কর্মসূচী চলাকালীন সময় আমার পরিবার আমাকে সমর্থন করেছে				
১১	ভবিষ্যতে সমসাময়িক দ্বারা পরিচালিত এধরণের শিক্ষামূলক কর্মসূচীতে অংশগ্রহণ করার জন্য অন্যান্যদেরকে আমি পরামর্শ দেবো				
১২	শিক্ষামূলক কর্মসূচীতে অংশগ্রহণের পর দৈনন্দিন ধকলের উপসর্গ মোকাবেলায় আমি সক্ষম বলে আমি আত্মবিশ্বাসী				
১৩	শিক্ষামূলক কর্মসূচীতে অংশগ্রহণের পর আমি আমার সন্তান প্রসবের পর আমার মাতৃত্ব ভূমিকা সম্পর্কে আমি আত্মবিশ্বাসী				

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১। শিক্ষামূলক কর্মসূচীটি আপনার গর্ভকালীন দৈনন্দিন ধকল ও এর উপসর্গ মোকাবেলায় কিভাবে সহায়ক, যদি থাকে, বলে মণে করেন?

২। শিক্ষামূলক কর্মসূচীতে যে সব কৌশল শিখেছেন সেগুলো কি আপনি আপনার সন্তান প্রসবের পর ও ভবিষ্যতে ব্যবহার করবেন কি, যদি করেন কিভাবে করবেন?

৩। আপনার ধকলকারী উপসর্গ মোকাবেলায় শিক্ষামূলক কর্মসূচীর কোন অংশ সব চেয়ে বেশী সহায়ক ছিল, যদি থাকে?

৪। অধিবেশনগুলোর কোন অংশগুলো, যদি থাকে, বুঝতে মুশকিল ছিল? এই অংশগুলো কি ভাবে উন্নত করা যেতে পারে?

৫। শিক্ষামূলক কর্মসূচী সমসাময়িক দ্বারা প্রদাণের ফলে আপনি কি কি সুবিধাদি, যদি থাকে, অর্জন করেছেন?

Rehenuma Tarannum
s4538259
College of Health & Biomedicine, Victoria University

৬। শিক্ষামূলক কর্মসূচীতে অংশগ্রহণের ফলে/পরে সন্তান জন্মপূর্বকালীন ধকল সম্পর্কে আপনার জ্ঞান ও বোঝাপড়া কি উন্নত হয়েছে, যদি হয়ে থাকে?

৭। সন্তান জন্মপূর্বকালীন ধকল সম্পর্কে আপনার জ্ঞান ও বোঝাপড়া বাড়ানোর জন্য এই শিক্ষামূলক কর্মসূচীতে আর কি কি বিষয় অন্তর্ভুক্ত করা প্রয়োজন বলে আপনি মনে করেন, যদি কিছু থাকে?

আপনার মূল্যবান সময় ও মতামত প্রদানের জন্য আপনাকে ধন্যবাদ।

সমাপ্তিঃ

১. অংশগ্রহণকারীকে উন্মোচন করুন।

২. অংশগ্রহণকারীকে জিজ্ঞাসা করে নিশ্চিত হোন তিনি কোন প্রশ্ন করতে চান কি না।

৩. এই সমীক্ষার তথ্যাদি/ফলাফল পাওয়ার ব্যাপারে উপায় জানানো।

৪. টেপ-রেকর্ডারটি অফ করে দিন।

Appendix F

Interview schedules (Peer version)

(English and Bengali version)

Interview schedule of Peers for qualitative process evaluation

Thank you for agreeing to take part in this interview.

- The purpose of the interview is to seek your opinion about, and suggestions for improving, the psychoeducation program.
- Most of the questions are related to your experience during the project and opinion of the Thinking Healthy Peer-Delivered program.
- There are two parts to the interview: (i) Several short questions where you will be given a range of fixed responses to choose from, and (ii) a series of in-depth questions from which you can talk freely.
- In total, it will take about 20 minutes to complete the whole interview.
- The interview will be audiotape recorded.
- All answers you give are confidential and you cannot be identified in any thesis or publications from this study.
- Are there questions you wish to ask about this part of the study?
    - Answer questions to her satisfaction.
- Switch on the audio recorder.

Interview schedule for Peers:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1 I was satisfied with my role as a peer and being the delivery agent for the Thinking Healthy Peer-Delivered education program					
2 In my opinion, the programme is useful in helping pregnant women deal with day-to-day depressive symptoms					
3 The content of the programme manual was easy to understand					
4. Overall, the length of the programme was adequate for effective intervention delivery					
5. Time allocated for each session was adequate for effective intervention delivery					
6 The training and supervision provided by the researcher was adequate to help me with the intervention delivery					
7 Overall, the information booklet contained useful information I could make use during intervention delivery.					
8 The intervention manual was helpful during intervention delivery.					
9 After participating in the programme, my knowledge and understanding about dealing with antepartum depression and depressing symptoms has improved					

Qualitative questions

1. What was your motivation towards taking part in the study and work as a peer?
2. In your opinion, how did the pregnant women receiving the intervention felt about the intervention delivery?
3. Did you encounter any challenges or difficulties from your family or local community to play the part as a peer and take part in the study?
4. Did you encounter any difficulties understanding the content of the intervention manual? If yes, please explain
5. Any recommendation for further improvement in the training program?
6. What additional information, if any, could be included in the THPP program?
7. What advantages, if any, are there to deliver the intervention as a peer in local community?
8. What disadvantages, if any, are there to deliver the intervention as a peer in local community?

Thank you for your time and valuable opinion.

Closure

5. Debrief the participant.
6. Ascertain if there are any questions that he/she wishes to ask.
7. Information about gaining access to the results of the study.
8. Switch off the tape recorder.

সমসাময়িক দ্বারা প্রদানকৃর্ত মানসিক ধকল কমানো সংক্রান্ত স্বাস্থ্যসম্মতভাবে চিন্তাভাবনা সংক্রান্ত শিক্ষামূলক কর্মসূচীর গুনগতমান প্রক্রিয়া নির্ণয়ের জন্য সাক্ষাৎকারের সময়সূচী/তফসিল ঃ

- এই সাক্ষাৎকারে অংশগ্রহণ করতে সম্মত হওয়ার জন্য আপনাকে ধন্যবাদ।
- এই সাক্ষাৎকারের উদ্দেশ্য হলো শিক্ষামূলক কর্মসূচী সম্পর্কে আপনার মতামত জানা এবং উন্নত করার ব্যাপারে আপনার পরামর্শ নেয়া।
- বেশীরভাগ প্রশ্ন হলো শিক্ষামূলক কর্মসূচী সম্পর্কে আপনার অভিজ্ঞতা এবং সমসাময়িক দ্বারা বক্তৃতার মাধ্যমে প্রদানকৃত স্বাস্থ্যসম্মতভাবে চিন্তাভাবনা সংক্রান্ত শিক্ষামূলক কর্মসূচী।
- এই সাক্ষাৎকারের দুইটি অংশ আছেঃ (১) কয়েকটি ছোট প্রশ্ন যেগুলোর কিছু নির্দিষ্ট উত্তর দেয়া থাকবে যার মধ্যে থেকে আপনাকে যে কোন একটি বেছে নিতে হবে এবং (২) কয়েকটি বিশদ প্রশ্ন যেগুলোর ব্যাপারে আপনি মন খুলে আলাপ করতে পারবেন।
- সম্পূর্ণ সাক্ষাৎকারের জন্য মোটামোটি ২০ মিনিট সময় লাগবে।
- সাক্ষাৎকারটি টেপরেকর্ডারের মাধ্যমে ধারণ করে রাখা হবে।
- আপনার দেয়া সব উত্তর সম্পূণভার্বে গোপনীয় এবং এই সমীক্ষা বা প্রকাশনা থেকে কোনোভাবে আপনাকে চিহ্নিত করা সম্ভব হবে না।
- আপনি কি সমীক্ষার এই অংশ সম্পর্কে কোন প্রশ্ন জিজ্ঞাস করতে চান? [অংশগ্রহণকারীর নিজের সন্তুষ্টির জন্য তাকে প্রশ্ন করার সূযোগ দিন এবং এগুলোর উত্তর দিন]।
- টেপরেকর্ডারটি চালু/অন করুন।
- সমসাময়িক মহিলাদের সাক্ষাৎকারের সময়সূচী/তফসিলঃ

		পুরাপুরি একমত	একমত	নিরপেক্ষ	একমত নন	একেবারে একমত নন
১	এই শিক্ষামূলক কর্মসূচীতে সমসাময়িক হিসেবে ও বক্তৃতা প্রদানকরী হিসেবে আমার ভূমিকা নিয়ে আমি সন্তুষ্ট					
২	আমার মতে, কর্মসূচীটি গর্ভবতী মহিলাদের দৈনন্দিন ধকল মোকাবেলা করতে সহায়ক					
৩	কর্মসূচীর পুস্তিকাটির বিষয়বস্তু সহজে বোঝার মত ছিল					
৪	সার্বিকভাবে, শিক্ষামূলক কর্মসূচীটির মেয়াদ হস্তক্ষেপ কর্মসূচী প্রদানের জন্য পর্যাপ্ত ছিল					
৫	প্রত্যেক অধিবেশনের জন্য বরাদ্দকৃত সময় কার্যকর হস্তক্ষেপ কর্মসূচী প্রদানের জন্য পর্যাপ্ত ছিল					
৬	গবেষণাকারী ছাত্রী কর্তৃক প্রদানকৃত প্রশিক্ষণ ও তত্বাবোধান আমার দ্বারা হস্তক্ষেপ কর্মসূচী প্রদানের জন্য পর্যাপ্ত ছিল					

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৭	সার্বিকভাবে, কর্মসূচীর পুস্তিকাটি হস্তক্ষেপ কর্মসূচীর বক্তৃতা প্রদানকালে ব্যবহার্য্য মূল্যবান তথ্যাদি সম্বলিত ছিল
৮	হস্তক্ষেপ কর্মসূচীর বক্তৃতা প্রদানকালে কর্মসূচীর পুস্তিকাটি খুব সহায়ক ছিল
৯	কমসূচীতে অংশগ্রহণের পর সন্তান জন্মপূর্বকালীন ধকল ও ধকলের উপসর্গ সনাক্ত ও মোকাবেলায় করণীয় সম্পর্কে আমার জ্ঞান ও সমঝোতা দুইটিরই উন্নতি হয়েছে

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১। শিক্ষামূলক কর্মসূচীটি আপনার অংশগ্রহণে এবং সমসায়িক হিসেবে কাজ করতে আপনার কি প্রেরণা/উদ্দেশ্য ছিল?

২। আপনার মতে গর্ভবতী মহিলারা হস্তক্ষেপ কর্মসূচী সম্পর্কে প্রদানকৃত বক্তব্য কেমনভাবে গ্রহণ করেছেন?

৩। এই শিক্ষামূলক কর্মসূচীতে সমসাময়িক হিসেবে কাজ করা বা সমসাময়িকর ভূমিকায় অংশগ্রহণ করার ব্যাপারে আপনার পরিবার বা স্থানীয় সম্প্রদায়ের কাছ থেকে কোন বিরোধিতার সম্মূখিন হতে হয়েছে কি?

৪। হস্তক্ষেপ পুস্তিকার বিষয়বস্তু বুঝতে আপনার কোন সমস্যা হয়েছিল? যদি সমস্যা হয়ে থাকে বিস্তারিত জানান।

৫। শিক্ষামূলক কর্মসূচীতে আরো কোন উন্নতি আনার ব্যাপারে আপনার পরামর্শ আছে?

৬। এই শিক্ষামূলক কর্মসূচীতে আর কি কি তথ্যাদি অন্তর্ভুক্ত করা যেতে পারে?

৭। শিক্ষামূলক কর্মসূচী স্থানীয় সম্প্রদায়ের সমসাময়িক দ্বারা বক্তৃতা প্রদানের ফলে কি সুবিধাদি লক্ষ করা গেছে, যদি থেকে থাকে?

৮। শিক্ষামূলক কর্মসূচী স্থানীয় সম্প্রদায়ের সমসাময়িক দ্বারা বক্তৃতা প্রদানের ফলে কি অসুবিধাদি লক্ষ করা গেছে, যদি থেকে থাকে?

আপনার মূল্যবান সময় ও মতামত প্রদানের জন্য আপনাকে ধন্যবাদ।

সমাপ্তি

1. অংশগ্রহণকারীকে উন্মোচন করুন।
2. অংশগ্রহণকারীকে জিজ্ঞাসা করে নিশ্চিত হোন তিনি কোন প্রশ্ন করতে চান কি না।
3. এই সমীক্ষার তথ্যাদি/ফলাফল পাওয়ার ব্যাপারে উপায় জানানো।

টেপ-রেকর্ডারটি অফ করে দিন।

Appendix G

Patient health questionnaire-9

(English and Bengali version)

Patient Health Questionnaire (PHQ-9)

Patient name: _____ Date: _____

1. Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all (0)	Several days (1)	More than half the days (2)	Nearly every day (3)
a. Little interest or pleasure in doing things.	❒	❒	❒	❒
b. Feeling down, depressed, or hopeless.	❒	❒	❒	❒
c. Trouble falling/staying asleep, sleeping too much.	❒	❒	❒	❒
d. Feeling tired or having little energy.	❒	❒	❒	❒
e. Poor appetite or overeating.	❒	❒	❒	❒
f. Feeling bad about yourself, or that you are a failure, or have let yourself or your family down.	❒	❒	❒	❒
g. Trouble concentrating on things, such as reading the newspaper or watching TV.	❒	❒	❒	❒
h. Moving or speaking so slowly that other people could have noticed. Or the opposite; being so fidgety or restless that you have been moving around more than usual.	❒	❒	❒	❒
i. Thoughts that you would be better off dead or of hurting yourself in some way.	❒	❒	❒	❒

2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

❒ Not difficult at all ❒ Somewhat difficult ❒ Very difficult ❒ Extremely difficult

TOTAL SCORE _____

রোগীর স্বাস্থ্য সংক্রান্ত প্রশ্নাবলী (PHQ-9)

রোগীর নাম_____তারিখ_____

১। পূর্বের/গত দুই সপ্তাহে নীচের সমস্যসমূহ কতবার সম্মূখীন হয়েছেন?

	মোটেও না (০)	কয়েকদিন (১)	অর্ধেকের বেশী সময় (৩)	প্রায় প্রতিদিন (৪)
ক। কাজকর্ম করতে আগ্রহ বা আনন্দ না পাওয়া।	☐	☐	☐	☐
খ। হতাশ, উদ্বিগ্ন, বিষাদ বা ধকল বোধ করা ।	☐	☐	☐	☐
গ। ঘুম পেতে বা ঘুমিয়ে থাকতে সমস্যা হওয়া বা বেশী ঘুমানো।	☐	☐	☐	☐
ঘ। ক্লান্ত বোধ করা বা শরীরে শক্তি না থাকা।	☐	☐	☐	☐
ঙ। অরুচি বা অতিরিক্ত রুচি/বেশী খেয়ে ফেলা।	☐	☐	☐	☐
চ। অনেক সময় নিজেকে বেহুদা/অকাজের বলে মণে হওয়া।	☐	☐	☐	☐
ছ। সংবাদপত্র পড়া বা টেলিভিশন দেখার উপর মনযোগ রাখতে সমস্যা হওয়া।	☐	☐	☐	☐
জ। এত ধীরে চলাফেরা করা বা কথা বলা যে অন্য ম্যনূষের নজরে আসে। অথবা এর বিপরীতঃ এত ছটফট বা অস্থির হওয়া যে স্বাভাবিকের তুলনায় বেশী চলাফেরা করা।	☐	☐	☐	☐
ঝ। নিজে মরে গেলেই ভাল হতো বা নিজেকে কোনভাবে আঘাত করার ব্যাপারে চিন্তা করা।	☐	☐	☐	☐

১। এপর্যন্ত যদি কোন সমস্যা সম্পর্কে কোন প্রশ্নের উত্তর 'হাঁ' দিয়ে থাকেন তাহলে এই সমস্যাগুলো, আপনার কাজ করতে, বাসায় সংসার সামলাতে বা অন্যন্য মানূষজনের সঙ্গে স্বাভাবিক ব্যবহার চালিয়ে যেতে, কতখানিক কঠিন করে তুলেছে?

☐ মোটেও কঠিন নয় ☐ কিছুটা কঠিন ☐ অনেকটা কঠিন ☐ অত্যন্ত কঠিন

প্রাপ্ত নম্বর _____

Appendix H

Rosenberg self-esteem scale

(English and Bengali version)

ROSENBERG SELF-ESTEEM SCALE

The scale is a 10-item Likert scale with items answered on a four point scale--from strongly agree to strongly disagree. The original sample for which the scale was developed consisted of over 5,000 High School Juniors and Seniors from 10 randomly selected schools in New York State.

Instructions: Below is a list of statements dealing with your general feelings about yourself. If you strongly agree, circle ***SA***; if you agree with the statement, circle ***A***; if you disagree, circle ***D***; and, if you strongly disagree, circle ***SD.***

1. On the whole, I am satisfied with myself.	***SA***	***A***	***D***	***SD***
2.* At times, I think I am no good at all.	***SA***	***A***	***D***	***SD***
3. I feel that I have a number of good qualities	***SA***	***A***	***D***	***SD***
4. I am able to do things as well as most other people	***SA***	***A***	***D***	***SD***
5.* I feel I do not have much to be proud of	***SA***	***A***	***D***	***SD***
6.* I certainly feel useless at times	***SA***	***A***	***D***	***SD***
7. I feel that I'm a person of worth, at least equal to others	***SA***	***A***	***D***	***SD***
8.* I wish I could have more respect for myself	***SA***	***A***	***D***	***SD***
9.* All in all, I am inclined to feel that I'm a failure	***SA***	***A***	***D***	***SD***
10. I take a positive attitude toward myself	***SA***	***A***	***D***	***SD***

Scoring:
-For questions 1, 3, 4, 7, and 10 score SA=3, A=2, D=1, and SD=0: Your Total_____
-For questions 2, 5, 6, 8, and 9 score SA=0, A=1, D=2, and SD=3: Your Total_____

Grand Total_____

Score between 15-25 are considered average

রোজেনবার্গ আত্ম-সম্মানবোধ মাপকাঠি/মাপদন্ড (RSE)

নীচে আপনার সাধারণ অনুভূতি সম্পর্কে কয়েকটা বক্তব্যের তালিকা দেয়া হলো। বক্তব্যগুলোর ব্যাপারে আপনি সম্পূর্ণ একমত, একমত বা একেবারে একমত নন তা ডান পাশের ছক পূরণ করে জানান।

	সম্পূর্ণ একমত	একমত	একমত নই	একেবারে একমত নই
১। সার্বিকভাবে আমি নিজেকে নিয়ে সন্তুষ্ট	☐	☐	☐	☐
২। মাঝেমধ্যে মণে জয় যে আমি একেবারে ভাল নই	☐	☐	☐	☐
৩। আমার মণে হয় আমার বেশ কয়েকটা ভাল গুন আছে	☐	☐	☐	☐
৪। অন্য মানূষের মতই আমি অনেক কিছু করতে পারি/সক্ষম	☐	☐	☐	☐
৫। আমার মণে হয় আমার গর্বিত হওয়ার মত তেমন কিছু নেই	☐	☐	☐	☐
৬। আনেক সময় আমার নিজেকে বেহুদা/অকাজের বলে মণে হয়	☐	☐	☐	☐
৭। আমার মণে হয় আমি একজন মূল্যবান মানূষ, অন্ততঃপক্ষে অন্যান্য মানূষের সমস্তরের	☐	☐	☐	☐
৮। আমার নিজের জন্য আরো আত্মোসম্মান থাকুক বলে কামনা করি	☐	☐	☐	☐
৯। সবদিক বিবেচনা করে আমি নিজেকে সম্পূর্ণ ব্যর্থ বলে অনুমান করি	☐	☐	☐	☐
১০। আমি নিজের প্রতি ইতিবাচক মনোভাব অবলম্বন করি	☐	☐	☐	☐

বিষয়বস্তুঃ এই মাপকাঠি/মাপদন্ডটি নিজের একটি আত্ম-সম্মানবোধ সংক্রান্ত একটি স্ব-বিবরণকৃত মাপকাঠি/মাপদন্ড বা সূচক।

নির্ভরযোগ্যতাঃ

এই মাপকাঠি/মাপদন্ডের আভ্যন্তরীণ সঙ্গতি ০.৭৭ থেকে ০.৮৮ এর মাঝামাঝি বিরাজ করে
এই মাপকাঠি/মাপদন্ডের পরীক্ষা/পনুঃপরীক্ষা নির্ভরযোগ্যতা ০.৮২ থেকে ০.৮৫ এর মাঝামাঝি বিরাজ করে

উপযুক্ততাঃ

নির্ণায়ক **উপযুক্ততা = ০.৫৫**

গঠন উপযুক্ততা = দুশ্চিন্তার সঙ্গে সঙ্গতি রেখে (-০.৬৪), ধকল (-০.৫৪) এবং anomie (-০.৪৩)

Appendix I

WHO Quality of Life – Bref scale

(English and Bengali version)

WHOQOL-BREF

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2.	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last four weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
4.	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
5.	How much do you enjoy life?	1	2	3	4	5
6.	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15.	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5

20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last four weeks.

		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	5	4	3	2	1

Do you have any comments about the assessment?

_____

_____

[The following table should be completed after the interview is finished]

		Equations for computing domain scores	Raw score	Transformed scores*	
				4-20	0-100
27.	**Domain 1**	(6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
28.	**Domain 2**	Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26) ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
29.	**Domain 3**	Q20 + Q21 + Q22 ☐ + ☐ + ☐	a. =	b:	c:
30.	**Domain 4**	Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:

* See Procedures Manual, pages 13-15

WHOQOL—BREF

গত চার সপ্তাহে আপনার জীবনধারা সম্পর্কে ভাবুন।

		খুবই খারাপ	খারাপ	ভালও না খারাপও না	ভাল	খুব ভাল
১।	আপনার জীবনের গুনগতমান কি ভাবে মূল্যায়ণ করবেন?	১	২	৩	৪	৫

		খুবই অসন্তুষ্ট	অসন্তুষ্ট	সন্তুষ্টও না অসন্তুষ্ট না	সন্তুষ্ট	খুবই সন্তুষ্ট
২।	আপনার স্বাস্থ্য সম্পর্কে আপনি কতটুকু সন্তুষ্ট?	১	২	৩	৪	৫

গত চার সপ্তাহে আপনি কিছু বিষয় কিভাবে অনুভত করেছেন সে সম্পর্কে প্রশ্ন জিজ্ঞেস করা হচ্ছেঃ

		একেবারে না	কিছুটা	সামান্য পরিমান	অনেকখানিক	অতিরিক্ত পরিমান
৩।	আপনার মতে আপনার যা করা প্রয়োজন তা ব্যথার কারণে কতখানিক করতে পারেন না বলে মণে করেন?	৫	৪	৩	২	১
৪।	আপনার দৈনন্দিন জীবনযাপনের জন্য কতখানিক চিকিৎসার প্রয়োজন হয় ?	৫	৪	৩	২	১
৫।	আপনি জীবনকে কতখানিক উপভোগ করেন?	১	২	৩	৪	৫
৬।	আপনার জীবন কতখানিক অর্থবহ বলে মণে করেন?	১	২	৩	৪	৫

		একেবারে না	কিছুটা	সামান্য পরিমান	অনেকখানিক	মাত্রাতিরিক্ত
৭।	আপনি কতখানিক মনযোগ রাখতে পারেন?	১	২	৩	৪	৫
৮।	আপনার দৈনন্দিন জীবনে আপনি কতখানিক নিরাপদ বোধ করেন?	১	২	৩	৪	৫
৯।	আপনার ভৌত পরিবেশ কতখানিক স্বাস্থ্যসম্মত?	১	২	৩	৪	৫

গত চার সপ্তাহে আপনি কিছু কাজ কিভাবে সম্পন্ন করতে পেরেছেন বা কিছু বিষয় কিভাবে অনুভুত বরেছেন সে সম্পর্কে নীচে প্রশ্ন জিজ্ঞেস করা হচ্ছেঃ

		একেবারে না	কিছুটা	মোটামোটি	ভাল	খুব ভাল
১০।	দৈনন্দিন জীবনের জন্য কি আপনার যথেষ্ঠ শক্তি থাকে?	১	২	৩	৪	৫
১১।	আপনি কি আপনার দৈহিক অবয়ব মেনে নিতে পারেন?	১	২	৩	৪	৫

১২।	আপনার চাহিদা মেটানোর জন্য কি আপনার সঙ্গে পর্যাপ্ত/যথেষ্ঠ টাকা আছে/থাকে?	১	২	৩	৪	৫
১৩।	আপনার দৈনন্দিন জীবনেযাপনের জন্য যে তথ্যাদি প্রয়োজন তা কতখানিক মজুদ?	১	২	৩	৪	৫
১৪।	চিত্তবিনোদনের জন্য আপনি কতখানিক সূযোগ পান?	১	২	৩	৪	৫

		খুবই খারাপ/কষ্ট করে	খারাপ/কষ্ট করে	ভালভাবেও না কষ্ট করেও না	ভালভাবে/সহজে	খুব ভালভাবে/সহজে
১৫।	কি ভাবে আপনি চলাফেরা করতে পারেন?	১	২	৩	৪	৫

		খুবই অসন্তুষ্ট	অসন্তুষ্ট	সন্তুষ্টও না অসন্তুষ্ট না	সন্তুষ্ট	খুবই সন্তুষ্ট
১৬।	আপনার ঘুমের পরিমান সম্পর্কে আপনি কতখানিক সন্তুষ্ট?	১	২	৩	৪	৫
১৭।	আপনার দৈনন্দিন জীবনেযাপনের ক্ষমতা সম্পর্কে আপনি কতখানিক সন্তুষ্ট?	১	২	৩	৪	৫
১৮।	কাজ করার ক্ষমতা সম্পর্কে আপনি কতখানিক সন্তুষ্ট?	১	২	৩	৪	৫
১৯।	আপনি নিজে কে নিয়ে কতখানিক সন্তুষ্ট?	১	২	৩	৪	৫
২০।	আপনার ব্যক্তিগত সম্পর্কসমূহের ব্যাপারে আপনি কতখানিক সন্তুষ্ট?	১	২	৩	৪	৫
২১।	আপনার যৌন-জীবন সম্পর্কে আপনি কতখানিক সন্তুষ্ট?	১	২	৩	৪	৫
২২।	আপনার বন্ধু-বান্ধবদেও কাছ থেকে যে সমর্থন পান সে ব্যাপারে আপনি কতখানিক সন্তুষ্ট?	১	২	৩	৪	৫
২৩।	আপনার বাসস্থানের অবস্থা সম্পর্কে আপনি কতখানিক সন্তুষ্ট?	১	২	৩	৪	৫
২৪।	স্বাস্থ্য সেবার প্রাপ্যতার সূযোগ সম্পর্কে আপনি কতখানিক সন্তুষ্ট?	১	২	৩	৪	৫
২৫।	আপনার যাতায়াত ব্যবস্থা সম্পর্কে আপনি কতখানিক সন্তুষ্ট?	১	২	৩	৪	৫

গত চার সপ্তাহে আপনি কিছু বিষয় কতবার অনুভুত বরেছেন সে সম্পর্কে নীচে প্রশ্ন জিজ্ঞেস করা হচ্ছেঃ

		কখনো না	কদাচিত	মাঝেমধ্যে	ঘন ঘন	সবসময়
২৬।	আপনার কখনো নেতিবাচক অনুভুতি হয়ে থাকে? যেমন হতাশা, উদ্বেগ, দুশ্চিন্তা, বিষাদ, ধকল?	৫	৪	৩	২	১

মূল্যায়ন সম্পর্কে কি আপনার কোন মন্তব্য আছে? থাকলে তা নীচে উল্লেখ বরুনঃ

_____

_____

[নীচের ছকটি সাক্ষাৎকার শেষ হয়ে যাওয়ার পর পূরণ করতে হবে]

		ডমেন স্কোর নির্ণয়ের জন্য সমীকরণ	কাঁচা স্কোর	রূপান্তরিত স্কোর	
				৪-২০	০-১০০
২৭।	ডমেন ১	(৬–প্রঃ৩) + (৬–প্রঃ৪) + প্রঃ ১০+ প্রঃ ১৫ + প্রঃ ১৬ + প্রঃ ১৭ + প্রঃ ১৮ □ + □ + □ + □ + □ + □ + □	ক=	খঃ	গঃ
২৮।	ডমেন ২	প্রঃ ৫ + প্রঃ ৬ + প্রঃ ৭ + প্রঃ ১১ + প্রঃ ১৯ + প্রঃ ১ + (৬–প্রঃ২৬) □ + □ + □ + □ + □ + □	ক=	খঃ	গঃ
২৯।	ডমেন ৩	প্রঃ ২০ + প্রঃ ২১ + প্রঃ ২২ □ + □ + □	ক=	খঃ	গঃ
৩০।	ডমেন ৪	প্রঃ ৮ + প্রঃ ৯ + প্রঃ ১২ + প্রঃ ১৩ + প্রঃ ১৪ + প্রঃ ২৩ + প্রঃ ২৪ + প্রঃ ২৫ □ + □ + □ + □ + □ + □ + □ + □	ক=	খঃ	গঃ

Appendix J

Approval letter from Victoria University Human Research Ethics Committee

Quest Ethics Notification - Application Process Finalised - Application Approved

quest.noreply@vu.edu.au

Thu 13/04/2017 15:01

To: Terence.McCann@vu.edu.au <Terence.McCann@vu.edu.au>;

Cc: Rehenuma Tarannum <rehenuma.tarannum@live.vu.edu.au>; Mary.Carolan@vu.edu.au <Mary.Carolan@vu.edu.au>;

Dear PROF TERENCE MCCANN,

Your ethics application has been formally reviewed and finalised.

» Application ID: HRE16-180
» Chief Investigator: PROF TERENCE MCCANN
» Other Investigators: PROF MARY CAROLAN-OLAH, PROF ABDUL MOTTALIB, MRS Rehenuma Tarannum
» Application Title: A pilot RCT to assess the feasibility of conducting a peer based low-intensity psychosocial intervention for reducing depressive symptoms in pregnant women in rural Bangladesh.
» Form Version: 13-07

The application has been accepted and deemed to meet the requirements of the National Health and Medical Research Council (NHMRC) 'National Statement on Ethical Conduct in Human Research (2007)' by the Victoria University Human Research Ethics Committee. Approval has been granted for two (2) years from the approval date; 13/04/2017.

Continued approval of this research project by the Victoria University Human Research Ethics Committee (VUHREC) is conditional upon the provision of a report within 12 months of the above approval date or upon the completion of the project (if earlier). A report proforma may be downloaded from the Office for Research website at: http://research.vu.edu.au/hrec.php.

Please note that the Human Research Ethics Committee must be informed of the following: any changes to the approved research protocol, project timelines, any serious events or adverse and/or unforeseen events that may affect continued ethical acceptability of the project. In these unlikely events, researchers must immediately cease all data collection until the Committee has approved the changes. Researchers are also reminded of the need to notify the approving HREC of changes to personnel in research projects via a request for a minor amendment. It should also be noted that it is the Chief Investigators' responsibility to ensure the research project is conducted in line with the recommendations outlined in the National Health and Medical Research Council (NHMRC) 'National Statement on Ethical Conduct in Human Research (2007).'

On behalf of the Committee, I wish you all the best for the conduct of the project.

Secretary, Human Research Ethics Committee
Phone: 9919 4781 or 9919 4461
Email: researchethics@vu.edu.au

This is an automated email from an unattended email address. Do not reply to this address.

Appendix K

Bangladesh Medical Research council ethics approval

বাংলাদেশ চিকিৎসা গবেষণা পরিষদ
Bangladesh Medical Research Council
BMRC

Ref: BMRC/NREC/RP/2016-2019/314 Date: 04/09/2017

National Research Ethics Committee

Registration Number: 055 19 06 2017.

Principal Investigator:
Professor Terence McCann
Professor of Mental Health Nursing
Building 4c, College of Health & Biomedicine
Victoria University, St Albans Campus
Mckechnie St, St Albans, Vic, 3012.

Title of the Project:
"A pilot RCT to assess the feasibility of conducting a peer based low-intensity psychosocial intervention for reducing depressive symptoms in pregnant women in rural Bangladesh"

Duration of Project: Three Years (From Septem, 2017 to August, 2020)

Budget: BDT- 5,90,000/-
In words: TK. Five Lacs Ninety Thousand only.

Subject: Ethical Clearance

With reference to your application on the above subject, this is to inform you that above mentioned Research Title has been registered and approved by the National Research Ethics Committee (NREC).

[redacted]
(Dr. Mahmood-uz-jahan)
Director

N.B: You are requested to follow the guidelines as mentioned at page two.

BMRC Bhaban, Mohakhali, Dhaka-1212, Bangladesh.

THE ETHICAL GUID ELINES TO BE FOLLOWED BY THE PRINCIPAL/ CO-INVESTIGATORS

- ❒ The rights and welfare of individual volunteers are adequately protected.
- ❒ The methods to secure informed consent are fully appropriate and adequately safeguard the rights of the subjects (in the case of minors, consent is obtained from parents or guardians).
- ❒ The Investigator(s) assume the responsibility of notifying the National Research Ethics Committee (NREC) if there is any change in the methodology of the protocol involving a risk to the individual volunteers.
- ❒ To report immediately to the NREC if any evidence of unexpected or adverse reaction is noted in the subjects under study.
- ❒ Project will be supervised by BMRC authority.
- ❒ This approval is subject to Principal Investigator's reading and accepting the BMRC ethical principles and guidelines currently in operation.
- ❒ You are requested to submit a report to the BMRC half yearly and after completion of the research work.

Checked by:

Appendix L
Trial registration confirmation with
Australian New Zealand Clinical Trail Registry

Your ACTRN (registration number): ACTRN12617000662369

info@actr.org.au

Mon 08/05/2017 12:09

To: Rehenuma Tarannum <rehenuma.tarannum@live.vu.edu.au>;

Cc: Terence.McCann@vu.edu.au <Terence.McCann@vu.edu.au>;

Dear REHENUMA TARANNUM and Terence McCann,

Re: A pilot RCT to assess the feasibility of conducting a peer based low-intensity psychosocial intervention for reducing depressive symptoms in pregnant women in rural Bangladesh.

Thank you for submitting the above trial for inclusion in the Australian New Zealand Clinical Trials Registry (ANZCTR).

Your trial has now been successfully registered and allocated the ACTRN: ACTRN12617000662369

Web address of your trial: http://www.ANZCTR.org.au/ACTRN12617000662369.aspx
Date submitted: 5/04/2017 4:10:34 PM
Date registered: 8/05/2017 12:07:25 PM
Registered by: REHENUMA TARANNUM
Principal Investigator: Terence McCann

If you have already obtained Ethics approval for your trial, please send a copy of at least one Ethics Committee approval letter to info@actr.org.au or by fax to (+61 2) 9565 1863, attention to ANZCTR.

Note that updates should be made to the registration record as soon as any trial information changes or new information becomes available. Updates can be made at any time and the quality and accuracy of the information provided is the responsibility of the trial's primary sponsor or their representative (the registrant). For instructions on how to update please see http://www.anzctr.org.au/Support/HowToUpdate.aspx.

Please also note that the original data lodged at the time of trial registration and the tracked history of any changes made as updates will remain publicly available on the ANZCTR website.

The ANZCTR is recognised as an ICMJE acceptable registry (http://www.icmje.org/faq.pdf) and a Primary Registry in the WHO registry network (http://www.who.int/ictrp/network/primary/en/index.html).

If you have any enquiries please send a message to info@actr.org.au or telephone +61 2 9562 5333.

Kind regards,
ANZCTR Staff
T: +61 2 9562 5333
F: +61 2 9565 1863
E: info@actr.org.au
W: www.ANZCTR.org.au

ANZCTR
Australian New Zealand Clinical Trials Registry

Appendix M

Peer Training manual

Peer Training manual And
Information Booklet

Introduction:
This training module and information booklet has been developed to help you with your role in this peer support programme to help pregnant women with mild-to-moderate depressive symptoms. This programme utilizes the antenatal part of the Thinking Healthy Peer-Delivered Programme (THPP), a psychoeducation programme, delivered through 5-weekly sessions (4 individual session and one group session) at pregnant women's homes or other convenient places.

To help you better understand your role the booklet has been divided into 4 sections. Lessons in each section will be provided in each day of the training programme . At the end of the four-days training programme , you will have gone through each section in each day and have knowledge on the content of the information booklet. The training programme and information on this booklet will help you become more confident in delivering the psychoeducation programme effectively to the recipient pregnant women.

Section One gives an overview of the project and the training programme, contains information about the concept of peer support programme, provides an overview of depression and depressive symptoms and the consequences of antenatal depression on a woman's and child's health. You will also know learn about the concept and role of cognitive behavioural therapy (CBT) in reducing depressive symptoms and the THPP programme .

In section two, the booklet contains information about improving basic communication and counseling skill. You will get ideas about the skills needed to deliver the THPP programme using CBT techniques, learn about the three steps of Thinking Healthy approach. You will also take part in role-plays about how to effectively engage with pregnant women and their families in your first meeting with them.

Section three is aimed at helping you understand and practice the delivery of antenatal sessions to pregnant women. You will learn the application of the THPP approach for the improvement of three areas of mother's daily life: personal health, relationships with people around them, and relationship with their child.

The final section gives you information about ethical aspects of this psychoeducation programme , including maintaining confidentiality and professional boundaries etc. You will also know about how to deal with any challenging situations that may arise during the delivery of the programme, ways to overcome them and the procedures to follow in case you face any uncomfortable situation.

You can use this information booklet as a reference throughout the program.

SUMMARY of the Information Booklet

Section 1:

1. Welcome, introduction and establishment of ground rules for participation
2. Introduction to peer support
3. Introduction to depression, depressive symptoms and causes and consequences of antenatal depression
4. Understand the cycle of mental distress and role of cognitive behavioral therapy
5. Introduction to the Thinking Healthy Programme -Peer delivered (THPP)

Section 2:

1. Communication and counseling skills needed for the delivery of THPP to the pregnant women

   a) Understand basic counseling skills
   b) Understand the principles of effectively engagement with the mother and her family

Section 3:

1. Understanding and practicing delivery of THPP individual sessions to mothers
2. Use role play to practice delivery of the group session

Section 4:

1. Maintaining professional boundaries
2. Maintaining privacy and confidentiality
3. Self-disclosure
4. Addressing the stigma of depression
5. Challenging situations and their likely solutions
6. Adverse events and the recommended procedures to follow

Section 1

- Introduction and establishment of ground rules for participation
- Introduction to peer support
- Introduction to depressive symptoms and causes and consequences of antenatal depression
- Understanding the cycle of mental distress and role of cognitive behavior therapy
- Introduction to the Thinking Healthy Programme -Peer delivered (THPP)

The Peers' Introduction

Ice-breaker activity:

- You will be paired with another peer in the room.
- Briefly introduce yourself to your partner by sharing basic information such as your name, interest, food preferences, number of children you have etc.
- You will have 10 minutes to talk to each other.
- At the end, each of you will introduce your partner to the rest of the group.

Establish the ground rules for participation in the training programme

- All information disclosed in the group should be kept confidential.
- Participants should:
- Show respect and consideration for each other.
- Avoid being judgmental of others.
- Maintain positive and supportive attitudes toward each other.
- Wait for their turn to speak and not interrupt one another.
- Pay attention to their trainer.
- Be punctual in attending the training sessions.

Introduction to peer support

1. Who are peers?

Peers are persons belonging to the same social group as another person. The groups may be based on some shared characteristics such as age, education level, gender, work occupation and situation, location, language, physical or emotional wellbeing, cultural identity, religion similar interests or personal circumstances, people with similar physical or mental health problems or experiences of disability etc.

In the context of Thinking Healthy Peer-Delivered programme, peers are women sharing similar experiences, like being a mother, living in a same community as the target population, and voluntarily delivering evidence-based psychosocial interventions for antenatal depression.

2. What is peer support

Peer support occurs when an individual provides social, emotional and practical help to other in a social group with similar experiences. Peer support can include a range of activities, from informal conversation between peers, through to formal programs that might involve trained and paid peer support workers. It can take place in person, by telephone or through the Internet; between two people, a small group or within a large group.

In THPP trained peer mothers will help pregnant women to deal with their day-to-day depressive symptoms.

3. Benefits of peer support programme for pregnant mothers with depressive symptoms

- Pregnant mothers residing in rural areas can learn about depressive symptoms, its effect and ways to deal with them through experiences and knowledge shared by trained peer mother.
- Peer support programme provides a chance to extend social, emotional and practical support to pregnant woman in rural areas with limited resources suffering from depressive symptoms.
- Peers can instil hope for the future in pregnant woman, help develop self-confidence in their future-parenting role, increase their self-esteem and overall quality of life.
- Support from another peer reduces isolation by connecting people in similar situations and building networks.
- Peer support programme s, if can be incorporated with the existing health care system in low-resource areas, can improve the overall service quality of the system by providing basic education and counselling to others in need.

3. Peer characteristic

Activity:

- The trainer will ask you to give some examples of characteristics that you think might be important for being a Peer.
- You will also be asked to give examples to demonstrate how the suggested characteristics are reflected in your day-to-day life.

✓ Below are some of the attributes that are important for a peer mother to possess to carry out her role in the THPP:

- Empathy
- Friendliness
- Respect
- Supportive
- Educate
- Enthusiastic

- ❖ Guide
- ❖ Sincerity
- ❖ Trustworthy
- ❖ Experience of being mother herself or knowledge of mother and child heath related issues

5.why are peers asked to do this role? Because our country has scarce health services, many people who are experiencing emotional or physical problems do not receive treatment. Therefore, there is a need for communities to use their own resources to help mothers who need emotional support. A peer volunteer who possesses the above qualities and is trained on THPP will be able to perform this role.

6. What peer support is NOT?

Activity

- ***Now that you know about the characteristics of a peer and their role, think about some points that does not characterize peer's role or peers are not supposed to do.***

- It is not giving advice – it is about sharing experiences and knowledge. For example, instead of saying "you should do it this way…" it should be said that, "this is what worked for other mother in similar situation like you…"
- It is not friendship. It is a professional relationship with clear boundaries.
- Peers are not professionals like psychiatrists, general practitioner, psychologist social worker or an expert on issues or problems. They can only provide limited support for which they are trained.
-

7. Will peers gain any benefits from the peer support role?

Activity

- ***Think about some benefits that you may gain from the peer support role in this project.***

Peer volunteering might help the peers to:

- Enhance their confidence and self esteem
- Increase their knowledge, experience and develop skills
- Improve their social status
- Gain personal satisfaction from benefitting others in community.

Introduction to depression, depressive symptoms and causes and consequences of antenatal depression

1. What is depression:

Depression is serious mental disorder that may affect one's physical and mental wellbeing. Everyone feels sad or low every now and then, but people with depression have this feeling more intensely for longer periods of time (weeks, months or year), and sometimes without any apparent reason. Depression affects one's feeling about them self and their surroundings and makes one's day-to-day life harder to manage.

Depression can affect any person irrespective of their age, sex, and marital status at any stage of life. But certain situations make us more vulnerable to develop depression and its symptoms; for example, starting a new life (e.g. after marriage or moving to new place), having a baby, retiring from or losing a job, losing someone close to you.

Women suffer from depression twice as much as men. They are more likely to have depression during pregnancy and the year following childbirth. For every 10 pregnant women, 1-to-2 of them will experience depression during pregnancy or following childbirth. In low-to-middle income countries, like Bangladesh, the prevalence of depression associated in these circumstances is much higher.

2. What are the depressive symptoms?

You may be depressed if, for more than two weeks, you've felt sad, down or miserable most of the time, or have lost interest or pleasure in your usual activities, and have also experienced several of the signs and symptoms across at least three of the categories below.

It's important to remember that we all experience some of these symptoms from time-to-time, and it may not necessarily mean you have depression. Equally, not everyone who is experiencing depression will have all of these symptoms.

- It is very important for you to understand that, in this psychoeducation programme, we will only deal with pregnant women having mild depressive symptoms. They will not have the disorder 'Depression'. The main objective of this programme is seeing whether this psychoeducation programme can help pregnant women deal with mild depressive symptoms so that they don't progress to develop further depressive episodes.

Depressive symptoms:

Feelings	Physical	Thoughts	Behaviour
• Sad • Guilt • Irritable • Frustrated • Lack of confidence • Unhappy • Indecisive • Disappointed • Miserable	• Tired all the time • Sick and run down • Headaches and muscle pains • Sleep problems • Loss or change of appetite • Significant weight loss or gain	• Unable to concentrate • 'I'm a failure' • 'It's my fault' • 'Nothing good ever happens to me.' • 'I'm worthless.' • 'Life's not worth living.' • 'People would be better off without me.'	• Not going out anymore • Not getting things done at home or work • Withdrawing from close family and friends • Not doing usual enjoyable activities •

3. Antenatal depression and its causes

Depression during pregnancy is called 'antenatal' depression; after childbirth, it is called 'postnatal' depression; the combined term (antenatal and postnatal) used is 'perinatal' depression. In the majority of cases depression begins during pregnancy and extends into the postnatal period.

The following are some of the reasons why women may suffer from depressive symptoms during pregnancy:

- Financial problems
- Interpersonal problems
- Marital issues
- Family problems
- Adverse life events such as bereavement, job loss
- Complications during pregnancy and child birth
- Hormonal changes

However, it is important to note that a woman can experience depressive symptoms during pregnancy without a definite cause. Hence, peers should not assume that familial or other circumstances are responsible for the woman's depressive symptoms.

4. Impact of antepartum depression on the mother's and child's health

Several studies from low-middle income countries have shown that antepartum depression exerts significant adverse effect on the pregnant women and her child's health. Below are the lists of detrimental effects that may happen due to antepartum depression:

Effects on pregnancy and women's health	Effects on child health
➢ Increased risk of pregnancy complications like • Preterm birth • Spontaneous abortion	➢ During pregnancy and delivery • Poor growth in utero resulting in low-birth weight baby

- Increased risk of developing depression and other serious mental disorder associated with pregnancy following childbirth.
- Suicidal tendency due to severe depression
- Poor parenting problems

- After delivery
  - Growth and nutritional problem
  - Increased risk of suffering from respiratory infections and diarrhoea
  - Developmental delay
  - Social and behavioral problem in later childhood

5. Cycle of mental distress and role of cognitive behavior therapy

Mental distress can impact the way a mother thinks, acts or feels. For instance, a mother experiencing mental distress could start thinking that she is incapable of taking good care of her children, a thought which can make her feel unhappy. Her low mood can affect her motivation to take care of her child, which, in turn, can make her lose confidence in her parenting skills, making her feel further distressed. The picture above can help the peers understand the strong link between a mother's thoughts, behaviour and feelings. A mother experiencing unhelpful thoughts or low mood can easily get caught in the vicious cycle of depression. It is important for the peers to understand these unhelpful thoughts, behaviors and feelings in order to help the pregnant women experiencing mental distress.

Cognitive behavioral therapy (CBT) is considered as the first line of treatment for depression and anxiety. It is a type of psychoeducation therapy that helps the person to change unhelpful or unhealthy habits of thinking, feeling and behaving. It involves the use of practical self-help strategies, which are designed to affect positive and immediate changes in the person's quality of life. CBT can be as effective as medication to treat depression. It is considered as the first line of therapy for depression and anxiety. THPP is based on the concept of CBT where peers will help the pregnant women to identify unhelpful behavioural contributing to their stress and then teach them to replace unhelpful behaviour into helpful behavior through practicing.

Read Rashida's Story

This is the story of 26-year-old Rashida. She was married four years ago and lived with her husband and in law's family. She had two children; a 3-year-old boy named Munna and a 2-year-old girl named Saleha. She was pregnant with her third child.

Her husband worked in a garment factory near his village. He started for work early in the morning and comes back by seven in evening. Rashida's mother-in-law had chronic health problems like arthritis and diabetes, which

prevents her from doing the household chores. As a result, Rashida had the full responsibility for taking care of her home as well as her children.

As Rashida's pregnancy progresses, she starts to lose interest in doing housework and feels tired all the time. Despite her condition she tries her best to take care of her children and family; however, it led her to pay less and less attention to her own health. During last few months of pregnancy, she started experiencing aches and pains. At night she experiences worrying thoughts about her health and her unborn child. She became concerned how she will manage the household responsibilities after her baby is born, without any help. Every morning she wakes up feeling tired. She struggles to do household chores and could not manage time to take rest. As a result, she felt exhausted at night. Her poor physical health had a considerable impact on her mood. At times, she used to get upset easily over minor issues and started crying. Rashida's condition was also impacting on her interest in activities, which she used to enjoy. She avoided socializing, tended to stay by herself and refused to share her problems with anyone. As a result, her family didn't know what was troubling her. Without any support from anyone she was getting more and more depressed.

Rashida's family was unable to understand what was wrong with her. Her mother-in-law believed that someone had cast an evil eye on her. She took Rashida to a spiritual healer but that did not help her. Rashida's husband was losing his patience with her and was increasingly spending most of his time outside the family home. His changed attitude towards was making her feel even sadder. She often got irritable and expressed her anger by shouting at her children, which she later regretted and felt guilty.

Rashida gave birth to an underweight baby girl. The community nurse told her to take extra care of the baby because of its low birth weight. Before the baby's birth, everyone, including Rashida, was hoping it would be a boy. However, the birth of the baby girl made Rashida felt unhappy. She thought that she had disappointed her family by giving birth to a baby girl, which made her feel guilty and devalued as a daughter-in-law.

After the delivery, Rashida became even busier with her domestic responsibilities. She kept herself busy with work and did not speak much about her problems. She was also worried about not feeling the same affection for her baby as she felt for Munna and Saleha. She also thought that her breast milk was not sufficient for her baby, which, according to her was the reason why the baby cries a lot. Her mother-in-law asked Rashida's sister to come and stay with them for a while to support Rashida. Despite this help she felt unsupported and her low mood persists.

Rashida's community nurse, a caring person, realized that Rashida needs help so she introduced her to Razia. Razia was a Peer Volunteer, who was committed to her work. As a mother herself, she knew that during pregnancy and after delivery women's need extra help and support to take good care of themselves and their newborns. Razia was trained in the Thinking Healthy Programme -Peer Delivered (THPP) and she felt that she might be able to support Rashida if she can deliver the intervention to her. With the help of THPP she could support Rashida to identify her unhealthy behavior and to recognize and practice healthy behavior, which could help her to feel better.

Activity:

- Have you ever met anyone in your village experiencing similar situation to Rashida?
- Identify Rashida's unhelpful thoughts and behaviours from the story

Below are some examples to facilitate the discussion:

Rashida's Unhelpful Thoughts	**Rashida's Unhelpful Behaviours**
Due to my circumstances there is nothing I can do to improve my health	Not eating a balanced diet

Housework is only my responsibility; nobody will help me out with it.	Not getting enough rest during day
I cannot sleep well at night	Not having enough sleep
I am failing as a mother	Getting worried
It is a struggle to take care of my children	Shouting at children
My family members are not happy having a baby girl	Distancing herself from her family

- Often mothers during the perinatal period can experience mental distress. It is important to understand that it is not their fault and they should not be blamed for it. However, when pregnant woman and mothers suffering from depressive symptoms are provided with an empathetic and supportive relationship it helps them to overcome it. Likewise, when Rashida is provided with attention and support.it will help her feel better. Her improved mental and physical wellbeing will enable her to take better care of her children and her family.

Notes:

Introduction to the Thinking Healthy Programme Peer Delivered (THPP)

1. What is THPP?

THPP is a psychoeducation programme developed for pregnant women and mothers after childbirth experiencing mental distress. The programme is based on the principle of cognitive behavioral therapy (discussed later). Although the complete THPP is delivered through antenatal and postnatal period, in this study only the antenatal part of the programme will be delivered to the pregnant women. The programme will be delivered in a simple and comprehensive manner, and important family members like husband and mother-in-law will be encouraged to participate.

2. Three steps of the Thinking Healthy approach

Please refer to the introductory session in the Job-Aid manual

Pregnant women experiencing mental distress frequently engage in unhelpful behaviours. They are unhelpful behaviours because they have a negative impact on their mood and thoughts. THP contains the following three steps that assist pregnant women to identify and change their unhelpful behaviour into helpful behaviour.

Step 1: Learning to identify unhelpful behaviour

In this step, the peers assist the pregnant woman to identify her unhelpful behaviour. For example, not having enough sleep or rest, ignoring her diet, avoiding people, and struggling to accomplish day-to-day tasks, not taking care of her hygiene.

Step 2: Learning to recognise helpful behaviour

In this step, the peers assist the pregnant woman to recognise helpful behaviour. For example, eating healthy, taking rest and ensuring good sleep, socializing with family and friends.

Step 3: Learning to replace unhelpful behaviours with helpful behaviours through practise

In this step, the peers assist the pregnant woman to implement these behaviours through problem-solving and practise, with the help of the charts in the Health Calendar.

The three steps described above will help the pregnant woman to improve her emotional and physical wellbeing, which will benefit her child's wellbeing.

3. Introducing the three areas of the programme

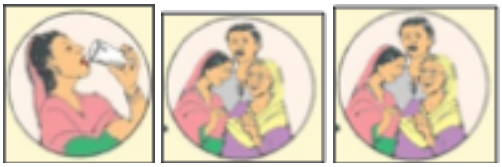
Mental distress during pregnancy and after childbirth could affect a mother's **personal health, her relationship with her child and with significant others**. For instance, a pregnant woman experiencing mental distress might not take a nutritious diet and become tired and weak. Her tiredness and weakness could then affect her ability to fulfill her day-to-day responsibilities making her feel anxious and stressed. Her stress could then affect her relationship with others or she might struggle to develop her relationship with her baby after it is born. The THPP focuses on these three areas to help the woman feel better. Pregnant woman and mothers do not need extra time to work on the above three areas instead they can be part of her day-to-day functioning.

a) Woman's Personal Health

It is important for a pregnant woman to take care of her health. This will keep her emotionally and physically well and she will be able to take care of her house and her family better. It becomes even more significant during pregnancy and after childbirth due to the increase in her caring responsibilities. A child born to a healthy mother is strong and active. Likewise, a pregnant woman who takes care of her diet and ensures she gets adequate rest helps the growth and development of her unborn child in her womb, which, in turn, contributes to the delivery of a healthy baby.

b) Relationships with people around the mother and child

The mother's relationship with people around her is important. A good relationship with significant others will ensure her of the support available, making her feel confident to provide quality care to her child. THPP has sessions to inform the mother how to strengthen her relationship with family members.



c) Mother-Child Relationship

A good mother-child relationship improves the physical and emotional wellbeing of the child, not only during early years but also throughout his/her adulthood. THPP has sessions to inform the mother on how to strengthen her relationship with her child even before birth.

Peers will focus on the above three key areas for the mother and child wellbeing. On days 2 and 3 peers will learn and practise, how the Thinking Healthy approach can be used to improve these three key areas.

Section 2

- Communication and basic counseling skills needed for the delivery of THPP to pregnant women:
    a) Understand key basic counseling skills

    b) Understand the principles of effectively engaging with the pregnant woman and her family

1. Skills needed for the delivery of THPP to the mothers

Peers need the following skills to deliver THPP to the mothers:

A. Willingness to help others
B. Using the key basic counseling skills.
C. Initiating contact with the mother and her family and engaging them in the programme .
D. Establishing ground rules with the intervention recipient.

A) Willingness to help others

Activity:

- *What are your aspirations for becoming peer?*
  - ☐ *Gain knowledge,*
  - ☐ *Gain experience,*
  - ☐ *Utilize their spare time effectively,*
  - ☐ *Get an opportunity to meet other mothers and*
  - ☐ *Aspiration to help others etc.*

❖ **Willingness to help others and to work for the betterment of the community is key motivators for peers to undertake the peer support role. Their decision to work as a peer reflects their desire to help others, which is highly appreciable and will help them to deliver the intervention effectively.**

❖

B) Using the key basic counseling skills

The following six key counseling skills are necessary for peers to establish a good relationship with the mothers and their families, and for the successful delivery of the THPP:

i. Empathic listening
ii. Asking open-ended question
iii. Being non-judgmental
iv. Treating the mothers with respect
v. Congruence (Genuineness)
vi. Encouraging the mothers

i. ***Empathetic Listening***

It is important for peers to listen to the pregnant women empathetically. Listening empathetically involves giving full attention to the mother while she is talking and understanding her feelings and experiences from her point of view. This also involves communicating this understanding back to the mother. For example, an empathetic response to a pregnant woman who talks about her adverse life experience could be: "*I am really saddened by what you have told me",* or "*I feel quite touched by what you have said"*. Empathetic listening helps pregnant women to appreciate peers as kind, compassionate and concerned individuals and encourages the women to share their problems.

Activity: Empathetic listening

You will be divided in Group A and B.

Group B will leave the room. While waiting outside, think about two interesting events of their life to share.

Group A stay inside for further instruction.

Instruction to Group:

Upon entering the room, each member of the Group A will be paired with another member of group B. Group B members will start talking. But Group A members will listen to them without paying attention and showing interest in them. For example, they could start looking around, checking their mobiles, yawning, looking outside the window. Allow 8-10 min to each pair to talk. Afterwards ask Group B to share their experiences.

Now ask members of Group B to share another life event and members of group A to listen to them with care and attention. Allow another 8-10 min and ask Group B the difference in this experience as compared to the previous experience.

- **Empathetic listening with care and attention make the other person feel valued. It helps to build rapport and encourages the other person to disclose her concerns and problems.**

<u>Ways of listening with attention and empathy</u>

- ✓ Sit opposite the mother with her body leaning slightly towards the mother and making appropriate eye contact.

- ✓ **Minimal Responses**: Give responses to ensure mother that she is being listened to, such as nodding your head, saying "*yes", "fine", "okay", "alright"*. This will make the mother feel that she is being listened to.
- ✓ **Acknowledge the mother's feeling:** For instance, a mother who talks about how terrible she has been feeling over the last few weeks and how she feels like crying all the time. Respond by saying, for example, "you sound very upset," or "it seems you are going through a rough period". These sorts of responses will encourage the mother to talk.
- ✓ **Summarizing:** Peers should repeat briefly what the mother has been saying, which will help the mother to reflect on her situation. For example, if a mother says to the peer, *"I am experiencing lots of aches and pains, and it is getting more and more difficult for me to look after myself. I am really worried now, how will I be able to manage the work if my condition keeps on getting worse?"* After

listening to the mother attentively, the peer can respond by saying, *"I understand that you are not feeling well at all these days and worried about your health deteriorating any further, is that right?"*

- ❖ Empathetic listening will enable the peer to understand the problems pregnant mothers are experiencing and encourage them to express their thoughts and feelings openly.

ii. ***Asking open-ended questions***

Peers should try to avoid asking questions that are likely to be answered by a 'yes' or 'no' response. Such questions fail to promote open communication between the peer and the pregnant woman. In contrast, open-ended questions allow the woman to understand her circumstances and to look for the solutions of her problems.

 **Activity:** Please tick which questions are open-ended and which are close-ended	Close ended questions	Open ended questions
Are you all right?		
What are the likely solutions of your problems?		
Have you got a solution to your problems?		
How does your family help with the housework?		
Do you worry about your children?		
How are you feeling today?		
Does your family help you with the housework?		
What is worrying you?		

iii. ***Showing a non-judgmental attitude***

It is important for peers to maintain a non-judgmental attitude whilst listening to the pregnant women. However, this is not always easy because we may be habitually judgmental towards others. For example, how often do we say or think that: "*she behaved in a certain manner because...," "she became unwell because...," or "her circumstances are like that because..."* It is challenging for peers to maintain a non-judgmental attitude while interacting with the pregnant women. However, peers can learn to adopt a non-judgmental attitude towards pregnant women experiencing depressive symptoms.

Everyone's life experiences and circumstances are different and therefore, it is important for peers to understand pregnant woman's experiences from their perspective. For example, if a pregnant woman claims that her mother-in-law is mistreating her. Rather than being judgmental and assuming that the pregnant woman is doing something wrong to be treated like this, the peer should show concern, explore further how she is being mistreated and how she feels about this mistreatment

It is important for peers to set aside their own life experiences to try to understand the problems pregnant women are experiencing, from their perspective. In doing this, it will help the pregnant women to trust the peers, feel valued and freely disclose their problems without inhibitions. It will further help the women to improve her self-acceptance and self- esteem.

iv. ***Treating the pregnant women with respect***

It is important for peers to treat the pregnant women and their families with respect. They need to remember that they are not superior to the pregnant women or to their family, and their involvement with the family is similar to an empathetic and concerned friend who means well for them. It is important for the peers to remember that if they treat the women and their families with respect they will also gain their respect.

v. ***Congruence (Genuineness)***

Congruence or genuineness means being real with someone and not acting or performing a role. When a peer is natural and spontaneous, it allows the recipient participant to be real and not pretentious.

vi. ***Encouraging the pregnant women***

It is important for peers to always encourage and support the pregnant women. Encouragement is important because the women will be asked to practise healthy activities between sessions, and the peer's encouragement is essential to initiating and maintaining their motivation. It is also important for peers to be generous in praising pregnant women for attempts they make to improve their situation.

Role Play 1:

Conduct a role-play where the peer is listening to the pregnant woman making use of the above basic counseling skills. Refer to the relevant Competency Assessment Checklist on page -- of this booklet

Guideline for *Role- plays:*

- ***Peers in the training room will be divided in pairs and asked to participate in different role-plays. Each member of a pair will take their turn as a peer and pregnant woman.***
- ***Before starting each role-play, peers will be given time to familiarize themselves with the relevant section of the Competency Assessment Checklists (appendix 1).***
- ***The student researcher will use the relevant section of the competency assessment checklist to record her observations and to give constructive feedback on the role-play. In addition, peers will also be encouraged to give constructive feedback on another peer's role-playing.***

C)

Initiating contact with the pregnant women and their family and engaging them in the programme

It is important for the peer to initiate the contact with the pregnant woman and her family appropriately. Contact with the family will be initiated when the peer is introduced to them through the student researcher.

Role Play 2:

Conduct a role-play where the student researcher will introduce the peer to the pregnant woman and her family (Refer to the relevant Competency Assessment Checklist on page -- of this booklet).

The student researcher will ensure that the following points are communicated to pregnant women and their families:

- Women need additional support during pregnancy. This support includes both physical and mental support.
- Thinking Healthy Programme Peer-Delivered offers mental support to the pregnant women. Trial of this programme has shown promising result as a way of extending mental support to pregnant women in low resource areas.
- This programme has been developed to be delivered by peers who are responsible women selected from local community and can be trusted by the pregnant women receiving the programme and their families.

- Peers have received training to deliver this psychoeducation programme . In addition, they receive regular supervision from the student researcher.
- Support from the family is very important in this psychoeducation programme . It is anticipated that family members will welcome the peers and allow delivering the psychoeducation programme to the pregnant woman. We also encourage husband or mother-in-law to be present in the sessions with the pregnant women. Support from the family will also enable the recipient pregnant women feel better which will have a positive impact on both herself and her unborn child's health.

Following the introduction by the student researcher, the peer should introduce herself by giving some basic information about her. This could include where she lives, her marital status, number of children or any other information she feels comfortable to share with the pregnant woman and her family.

The peer will then inform the mother and her family that:

- ✓ She will deliver the THPP to the pregnant woman. It focuses on the mental health of pregnant woman.

- ✓ The progress of any society depends upon the good health of its future generation.

- ✓ If our children are healthy and bright, they can deal with the challenges of life and become an asset for their family.

- ✓ To have healthy children, we need to look after and nurture them starting from the period when a woman is pregnant.

- ✓ Pregnant woman's health is very important for her child because her wellbeing impacts the health of her child.

- ✓ The family probably knows many good ways of bringing up children and looking after a pregnant woman, but we would like to share (not dictate) some new concepts.

- ✓ THPP cannot make life problems disappear. It does not offer monetary support or medical care.

- ✓ It can help pregnant women and families help themselves to achieve better health for both the women and the unborn child.

- ✓ To help us achieve this, we need the whole family to work as a team. I will work to guide you to achieve these aims.

- ✓ She will meet the pregnant woman four times individually at their homes or other place of convenience and one time at a group including other pregnant women over the period of 5 weeks.
- ✓ The session will be delivered weekly for 5 weeks. Each individual session will last up to one hour.
- ✓ Peers will not be able to aid the pregnant women outside their peer role, or to provide the pregnant woman and/or her family with any medical advice or financial support.

Role Play 3:

Conduct a role-play where peers will be *introducing themselves to the recipient pregnant woman and her family for the first time in introductory session.*

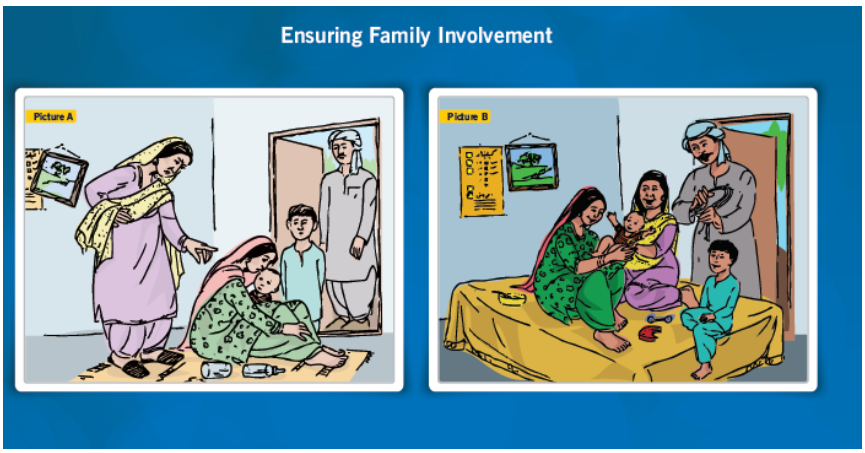
- Refer to the relevant Competency Assessment Checklist on page -- of this booklet

A Peer Volunteer can start her conversation by saying:

"First *of all, I would like to thank you and your family for allowing me to work with you. I would like to start by giving a brief introduction about myself. I live in your village; I am married and have xx children, xx girls and xx boy.*

I am a peer volunteer and I work with women who are pregnant. I will see you over a period of five weeks. I am going to deliver the intervention called the Thinking Healthy Programme Peer-Delivered (THPP). THPP has 5 antenatal sessions on improving pregnant woman and her unborn child's wellbeing. Each session will last for around one hour. Four of the individual sessions will be delivered to the woman in your home or a place of convenience; the group session will be delivered in a group setting.

A pregnant woman doesn't need extra time to engage in healthy activities, these activities can be incorporated in her day-to-day tasks and will have beneficial effects on the pregnant mothers and her unborn child's health. Support from the family is very important in this psychoeducation programme . We also encourage husband or mother-in-law to be present in the sessions with the pregnant women. Support from the family will also enable the recipient pregnant women feel better which will have a positive impact on both herself and her unborn child's health.



D) Establishing the ground rules

Refer to the ground rules from the Job-Aid manual of THPP

- Active participation.
- Being on time.
- Doing the homework.
- Express concerns to the peer.

Role Play 4:

Conduct a role-play where a peer is setting the ground rules with the pregnant woman and her family using the JOB-AID manual (page 10-11).

- Refer to the relevant Competency Assessment Checklist on page –of this booklet

Section 3

- Understand and practise delivery of THPP individual sessions to mothers through role play
- Practise delivery of the group session through role playing

Understanding and Practising delivery of THPP individual sessions to mothers

➢ **Assessing a pregnant mother's mood**

Please refer to the Job-Aid manual and Health Calendar for the Mood chart.

The first activity for each session includes assessment of the pregnant woman's mood using the Mood Chart. The Mood Chart consists of a visual scale of the woman's emotional state represented by 5 different facial expressions. These expressions range from very happy to very sad. Peers will show the pregnant woman, the Mood Chart and ask her to indicate which picture represents her emotional state of past week.

It is important for the peers to give ample time to the woman to talk about her mood and to express her concerns. Peers needs to listen to the mother using the key counseling skills discussed in previously in Day 2 of the training session.

***Role* play 1:**

Conduct a role-play where a peer will use the Mood Chart to assess the woman's mood. The peer should give the pregnant woman opportunity to talk about her feelings and concerns she has been experiencing over the last week. The peer should demonstrate the key counseling skills while listening to the mother.

- Refer to the relevant Competency Assessment Checklist on page – of this booklet

➢ **Using the three steps of the Thinking Healthy approach to improving the mother's personal health**

Please refer to the session 2 of THPP Reference manual to understand, how the Thinking Healthy approach can be used to improve pregnant women's personal health.

Role Play 2:

Conduct a role-play where a peer will be delivering individual session 2 that focuses on pregnant woman's personal health. Use Job-Aid (Page 13) and Health Calendar for the role-play; include the homework setting and problem-solving activity.

- Refer to the relevant Competency Assessment Checklist on page –of this booklet

➢ **Using three steps of the Thinking Healthy approach to improve pregnant woman's relationship with people around her**

Refer to session 3 of THPP Reference manual to understand how the Thinking Healthy approach can be used to improve pregnant women's relationship with people around her.

Role Play 3:

Conduct a role-play where a peer will be delivering individual session 3 that focuses on pregnant woman's relation with people around her. Use Job-Aid (Page 19) and Health Calendar for the role-play; include the homework setting and problem-solving activity.

- Refer to the relevant Competency Assessment Checklist on page –of this booklet

➢ **Using the three steps of the Thinking Healthy approach to improve the mother-child relationship**

Refer to the individual session 3 to understand how the Thinking Healthy approach can be used to improve, mother-child relationship.

Role Play 3:

Conduct a role-play where a peer will be delivering individual session 4 that focuses on mother-child relationship. Use Job-Aid (Page 25) and Health Calendar for the role-play; include the homework setting and problem-solving activity.

- Refer to the relevant Competency Assessment Checklist on page –of this booklet

Understanding and Practising delivery of the group session

➢ **Aims of the group session**

✓ Reinforce health-related messages and activities

- ✓ Enhance mother-child interaction
- ✓ Improve the mother's social support
- ✓ Learn from each other's experiences

Role Play 4:

In this role-play one peer will be delivering the group session and other peer will play the part of the pregnant women in the group.
Use Job-Aid manual (Page 67) .

- Refer to the relevant Competency Assessment Checklist on page –of this booklet

Section 4

- Maintaining professional boundaries
- Maintaining privacy and confidentiality
- Self-disclosure
- Tackling the stigma of depression
- Challenging situations and their likely solutions
- Adverse events and recommended procedures to follow

Maintaining professional boundaries

Clear professional boundaries are important to ensure peers' and women's safety, and they should be maintained at all times. Professional boundaries specify the limitations and responsibilities of the role of a peer. Discuss and clarify following points with the pregnant women to set clear professional boundaries in the introductory session:

- The peer's role is to deliver the THPP sessions in four individual and one group setting.
- They will visit the mothers at their home weekly
- Each home visit will last up to one hour.
- Apart from home visits, peers will meet the mothers during the final group session.
- Peers are unable to aid the mothers outside their peer volunteering role.
- Peers are unable to provide mothers and their families with any financial support or medical advice and/or assistance.

Maintaining privacy and confidentiality

The relationship that exists between the peers and the pregnant women is a professional relationship. This professionalism assures the women that they are free to discuss their problems freely without fear of disclosure of their personal information to others. It is the peers' responsibilities to maintain

pregnant women's privacy and confidentiality at all times and avoid disclosure apart from discussing matters with the researcher. Furthermore, any personal information about the mother, such as contact details will be kept secure. However, it is important for the peers to explain to the pregnant women and their families, circumstances under which they will be obliged to breach the confidentiality (Please see adverse events below).

Appropriate self-disclosure

Self-disclosure is a process of communication by which one person reveals information about himself or herself to another person. This can be made in response to a request by the pregnant women for specific information or may be offered voluntarily. When using self-disclosure, a peer will briefly and appropriately disclose information about herself in a facilitative manner. The purpose of this self-disclosure is to facilitate the process of engagement with the pregnant women and their families, and to encourage the women and families to disclose their problems/issues to the peer. However, the peer should ensure that the information she discloses is not distressful and does not cause any emotional harm to the pregnant woman. Furthermore, the peer should consider the repercussions of disclosing her own personal experiences to the pregnant women and their families.

Avoiding the stigma of depression

In order to ensure that the pregnant women participants are not stigmatised because of receiving the THPP, peers must make clear distinction between suffering from depression 'the disease' and mild depressive symptoms from the very beginning of the intervention delivery. Many women and their families do not see depression as a problem requiring intervention: some see it as a stigma.

The participant pregnant woman and families will be informed that a need has been identified through assessments for them to receive the intervention through trained peers. This intervention focuses on pregnant women and unborn baby's health. Health is a more universally understood and accepted concept than depression. Optimal development of the pregnant woman and unborn child can provide the pivot around which attitudes and thinking styles can be changed for the better. Family members may disagree on many things but baby's health is a common agenda for the families. Within this agenda, efforts to improve the physical and psychological health of the pregnant woman can be addressed without much resistance or stigma

Challenging situations for the peers and likely solutions

Peers may experience some challenging situations during their involvement in the study. At times these challenging situations require immediate decision-making. However, it is important that these decisions should be made in the best interest of the pregnant women and their family members.

Some likely challenging situations are outlined below. During the training the student researcher will ask the peers to explore ways, through group discussion, of dealing with these challenging situations most effectively.

Given below is the list of these challenges:

Challenging situation	**Likely solutions**
Due to her low mood, the pregnant woman might refuse to meet the peer.	The peer will explain to the woman that meeting with her will give her the opportunity to express her feelings and will facilitate her to take some steps to improve her mood. However, the peer should avoid putting any undue pressure on the pregnant women. It is entirely pregnant women's decision if she wishes to meet with

	the peer or not.
A woman's family might not want the peer to deliver the intervention.	For safety of the peers, pregnant women not having family support will not be included in the study.
The woman's family members might start believing that the peer is instigating hatred towards them.	The peer should encourage family's involvement right from the beginning to avoid this situation.
The woman's family members might undermine or try to prove the peer wrong.	The peer should explain to them that this is an evidence-based intervention. It has been delivered in the past and has been found to be effective in improving the mental wellbeing of the pregnant women.
The pregnant woman and her family start expecting some material benefits from the peer.	The peer should explain to the mother and her family that her role is only to deliver the intervention. She is doing this work voluntarily and has no material resources (like money, medicine or other items) to offer to them.
The woman and her family seek medical advice from the peer.	The peer should explain to the mother and her family that she has not been trained to give medical advice, and if they are experiencing health issues they should visit their local health complex.
The woman refuses to see the peer due to the fear of being stigmatised.	The peer should avoid using the word depression or mental distress to mothers. They should highlight that the intervention is aimed at the wellbeing of the pregnant woman and child.
The community's attitude towards the peer is critical and discouraging.	The peers are working voluntarily for the betterment of their communities and therefore should feel proud of their work. It may take some time before their communities recognize the significance of their roles.
The peer finds the work stressful.	Peers can directly call the student researcher or discuss her issues during group supervision with other peers. However, if the peer feels that her stress is getting worse, she has the option to discontinue her work as a

	peer.
The peer is getting upset because the pregnant woman is not engaging in any helpful activities.	Politely remind the peer that it is her role to deliver the intervention and highlight the importance of engaging in helpful activities. It is the pregnant woman's responsibility to incorporate these activities in her day-to-day activities. The peer should be reminded that some women need more time and effort to get motivated to practise helpful activities.
A peer might get de-motivated due to pregnant woman's condition not improving.	The peer should remember that in some cases in can be difficult to bring about a shift in the pregnant woman's mood especially when she has been experiencing low mood for a long time. She should not blame herself for the woman's persistent low mood.
The peer's own family members pressurise her to stop working.	The student researcher can contact peer's family to try to convince them, through addressing their concerns. However, if the peer's family members still wish her to stop visiting women in the community then it is within their rights to do so. It is advisable that peers should not disrupt their own family lives in order to carry out their peer support role.

Please note that there may be some unique challenges that may arise in the course of the delivery of the THPP. Such challenges will be discussed with the research team in order to find the best possible solution.

1.6 Adverse events (AEs) and recommended procedures to follow

In addition to the challenging situations outlined above, peers might experience some events, which are categorised as adverse events. These events, though unlikely to occur, may have serious implications for the pregnant woman and/or the peers. Therefore, the following procedures will be adhered to in the event of an adverse situation occurring.

Adverse event	**Recommended procedure**
Lack of improvement in, or persistent, low mood in the pregnant woman.	Lack of improvement in, or persistent low mood, is likely be detected by the peer through administration of the Mood Chart during each individual session. If the mother's mood is persistently low over the last two sessions, or is deteriorating, the peers should inform the student researcher immediately. *The peers are not expected to intervene themselves.*
Domestic violence/Victimisation of pregnant woman	If the peer witnesses any physical or emotional abuse of the pregnant woman, she needs to assess the situation for her own safety first. If the situation involves risk to her own safety, the peer should leave that place immediately. Report the event to the student researcher. If the woman during her session with the peer reports any physical abuse towards her, the peer should report this to the student researcher.

Other adverse events are

1. Hospital admissions due to serious medical complication of pregnancy
2. Miscarriages
3. Stigmatization

The peer should remember that her own safety is of paramount importance. In case where peer faces any uncomfortable situation, she should remove herself from the situation and report the incident immediately to the student researcher.

Pregnant women as a potential risk to others	If the pregnant women have reported thoughts of harming someone or has reported an incident where she has caused harm to others or herself, the peer volunteer should immediately report this to the student researcher. The student researcher will refer her to the antenatal clinic for further evaluation.

All the participants in this study will be given sufficient time to discuss their involvement in the project with their family before signing the consent form. Pregnant women not having family support to participate in this study will not be included. Hence, the likelihood of these events is highly unlikely. It is also anticipated that family will be supportive towards the pregnant women and welcoming towards the peers once they have agreed to take part in the project.

Appendix N

Support letter from Thinking Healthy Programme team

Human Development Research Foundation (HDRF)
House No. 6 Street No. 55 Sector F-7/4
Islamabad
PO Box No. 759
G-10 Markaz Islamabad 44000 Pakistan Phone: +92 51 2656172-3
Website: www.hdroundation.org Email: info@hdrfoundation.org

To Whom It May Concern,

The master trainer of the Thinking Healthy Programme Peer Delivered, Dr Najia Atif will provide a two-Day training via Skype to Rehenuma Tarannum to help her with training the peers of her PhD project with Victoria University, Australia. Dr. Najia will also provide monthly supervisions to her, over the period during which THPP will be delivered to the pregnant women.

Yours sincerely,

Atif Rahman
Professor of Child Psychiatry
University of Liverpool
Institute of Psychology, Health & Society
Child Mental Health Unit
Alder Hey Children's NHS Foundation Trust
Mulberry House, Eaton Road
Liverpool L12 2AP
UK
Email: Atif.Rahman@liverpool.ac.uk
Phone: +44(0)151 252 5509 (secretary Jacqueline Gray)
Fax: +44(0) 151 252 5285