Informed Consent Form

Health Care Professional (Consultant Gynaecologist)

Research Project: "The Effectiveness of Psychopharmacological Intervention versus Cognitive Behavioural Couple Therapy and Their Combination in Perinatal Distressed Couples: A Randomized Clinical Trial"

Principal Investigator: Ms Sameera Shafiq (Ph.D. Scholar and Lecturer)
Department of Psychology, University of Gujrat, Gujrat, Pakistan.

Unique Protocol ID: UOG/ORIC/2022/393

Brief Title: Cognitive Behavioral Couple Therapy for Perinatal Distress

Registration: NCT06001021

Initial Registration: 26th June, 2023.

Initial Approval and Public Release Date: 13th August, 2023.

Sponsor/Funder: Nil

The informed consent form consists of two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

PART I: Information Sheet

Introduction

I am Ms. Sameera Shafiq/Mrs Sameera Ahmed conducting a research study on couple's perinatal distress. I am going to give you information and invite you to be part of this research as a health care professional.

Purpose of the Research

Perinatal Distress (such as depression and/or anxiety) is a growing concern nowadays and is observed in couples (wives and husbands) during antenatal and postnatal period. It might effect the family and the foetus-infant badly if left unnoticed. NICE guidelines have recommended screening and treating perinatal women for depression and anxiety (see Annexure A). Researches showed that perinatal distress can be treated with psychotropic medications, cognitive behavioural therapy and/or a combination of both. The reason we are doing this research is to find out if the medications (antidepressant and/or anxiolytics) are better than cognitive behavioural therapy or combination of both as a treatment for perinatal distress in the couples.

Type of Research Intervention

This research study involves the following treatments

1) Medications (antidepressants and/or anxiolytics).
2) Cognitive Behavioural Therapy without Zikr.
3) Cognitive Behavioural Therapy with Zikr.
4) Combination of medications and cognitive behavioural therapy.
5) Combination of medications, cognitive behavioural therapy, and zikr.

Participant Selection

We will inviting all women (4th month to 7th month in antenatal period; after a week till one year of a child in postnatal period) and selecting willing couples with perinatal distress (high-risk) who attends gynaecology of the hospital to participate in the research with the treatment offered for free. The age range will be between 19 to 45 years.

Voluntary Participation

Participation in this research is entirely voluntary. It is participant's' choice whether to participate or not. If participants choose not to participate in this research project, they will offer the treatment that is routinely offered in this clinic/hospital. Participants may change your mind later and stop participating even if you agreed earlier.

Information on the Trial Medicine [Antidepressants and anxiolytics]

1) The antidepressants and/or anxiolytics safe in antenatal (2nd and 3rd trimester) and postnatal period will be prescribed.

2) Anxiolytics used to control symptoms of anxiety without serious impairment of normal physical or mental function. Antidepressants reduce mood swings and improve overall wellbeing.

3) Some common side effects of antidepressants include feeling agitated, shaky, indigestion and stomach aches, diarrhoea or constipation, loss of appetite, dizziness, not sleeping well, or feeling very sleepy, headaches. Some short-term side effects of anxiolytics can include Low heart rate, Low blood pressure, Irregular breathing, Confusion, Dizziness, Nausea. These side effects are temporary and will be settled down in two weeks and the medication will start working for normalization of mood and/or reduction of anxiety.

Procedures and Protocol

We will ask willing participants (screened for high risk) to select one of their preferred treatment modes out of the following

1) Medications (antidepressants and/or anxiolytics).
2) Cognitive Behavioural Therapy without Zikr.
3) Cognitive Behavioural Therapy with Zikr.
4) Combination of medications and cognitive behavioural therapy.
5) Combination of medications, cognitive behavioural therapy, and Zikr.

A list of willing participants will be prepared. Each participant will have one in five chances of getting the preferred treatment mode. There will be two groups (experimental and control). To put people into one of the two groups, we will select by chance as for instance by random number generated by a research assistant.

Participants will not know to which group they actually belong. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results. If there are anything participants are concerned about or that is bothering them about the research they will talk to the researcher, research assistant, gynaecologist or staff.

A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. We want to know whether medicine is good, we give some people the medicine and some people the pretend or dummy medicine. For the research to be good, it is important that participants do not know whether they have been given the real medicine or the pretend or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does. But the participants given placebo will be informed in the end of the study and will be given treatment with medication.

Description of the Process

During the research a couple has to make ten visits to attend ten sessions in the hospital.

- In the first visit, rapport will be build and pre-test assessment will be done in the following two approaches

Quantitative Approach

- Indigenously developed Parental Perinatal Distress Scale (PPDS).
- Urdu version (Akhtar, Rahman, Husain, Chaudhry, Duddu,… & Husain, 2010) of Multidimensional Social Support Scale (Zimet, Dahlem, Zimet, & Farley, 1988).
- Urdu version (Shujja, Adil, Randall, Bodenmann, & Malik, 2020) of Dyadic Coping Inventory (Bodenmann, 2008).
- Urdu version (Choudhry, Al-Worafi, Akram, Ahmed, Anwar ul Haq, Khan,… & Golden, 2018) of Flourishing Scale (Diener, Wirtz, Tov, Kim-Prieto, Choi, Oishi, & Biswas-Diener, 2009).
- Urdu version (Lodhi, Raza, Montazeri, Nedjat, Yaseri, & Holakouie-Naieni, 2017) of World Health Organization's Quality of Life Brief (WHOQOL Group, 1998).

Qualitative Approach

- Semi-structured interview will be conducted to explore the present stressors and expectations and perceptions about effectivity of treatments for perinatal distress among couples.

Group 1 will be given medications or placebo for two weeks and/or for four to five weeks maximum. They have to visit after two weeks for post-test assessment. As explained before, neither participant will know whether they have received the medicine or the placebo. But in the end placebo participants will be debriefed and will be continued with real medication. Consultant gynaecologist will prescribe medication after thorough risk-benefit evaluation.

Group 2, Group 3, and Group 4 will continue the following sessions

- In the second session, participants will be psycho-educated for perinatal period distress, couples' physical and mental health and impact on the foetus-infant, prevalence of depression and anxiety and significance of identification. Progressive muscle relaxation exercise will be carried out along with deep breathing. Feedback on the session will be taken.
- In the third session, participants will be psycho-educated for the theoretical model of cognitive behavioural couple therapy with some historical highlights and empirical standing. Thought log will be given for homework. Feedback for deep breathing and progressive muscle relaxation will be carried out.
- In the fourth, fifth, sixth, seventh, eighth and ninth session, feedback will be taken on homework and session. Various techniques of Cognitive Behavioural Couple Therapy will be applied based on the nature and contents of identified precipitating, perpetuating, and present stressors. In addition, relevant techniques will be incorporated from other modalities with eclecticism. Tasbeeh (see Shafiq et al., 2022) in Zikr will be given to group 3 and group 5 who opted for it in screening process.
- In the tenth visit, feedback on session and homework will be taken. post-test assessment will be done in the following two approaches

Group 5 will be exposed to one of the two conditions. 50% couples will get placebo and 50% will receive the routine treatment care with no intervention. However, after the completion of the research, this waitlist group (control) will be briefed and will be delivered with intervention mode of treatment.

Quantitative Approach

- Indigenously developed Parental Perinatal Distress Scale (PPDS)
- Urdu version (Akhtar, Rahman, Husain, Chaudhry, Duddu, & Husain, 2010) of Multidimensional Social Support Scale (Zimet, Dahlem, Zimet, & Farley, 1988).
- Urdu version (Shujja, Adil, Randall, Bodenmann, & Malik, 2020) of Dyadic Coping Inventory (Bodenmann, 2008).
- Urdu version (Choudhry, Al-Worafi, Akram, Ahmed, Anwar ul Haq, Khan, … & Golden, 2018) of Flourishing Scale (Diener, Wirtz, Tov, Kim-Prieto, Choi, Oishi, & Biswas-Diener, 2009).

- Urdu version (Lodhi, Raza, Montazeri, Nedjat, Yaseri, & Holakouie-Naieni, 2017) of World Health Organization's Quality of Life Brief (WHOQOL Group, 1998).

Qualitative Approach

- Semi-structured interview will be conducted to explore the present stressors and expectations and perceptions about effectivity of treatments for perinatal distress among couples.

Duration

The research takes place over from 15th August, 2023 to 30th October, 2023. Screening with PPDS will be carried out on the couples who visit gynaecological ward of the hospital in July. After screening, enrolment, and signed informed consent, it will be necessary for participants to come to the clinic/hospital for 10 days in total, for one hour session each day in last week of August (two days per week, each for one hour) till September. A follow-up visit after two weeks in October is compulsory. In a follow-up qualitative approach of interviewing will be used.

Reimbursements

We will give participants [PKR. 500/-] to pay for their travel to the clinic. Participants will not be given any other money or gifts to take part in this research.

Confidentiality

The information that we collect from this research project will be kept confidential. Information about participants that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about participants will have a number on it instead of names. Only the researchers will know what participants' number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone and will be concealed in publication of a research article.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through journal publication to be widely available to the public in order that other interested people may learn from our research. However, the privacy and confidentiality of the participants will be maintained in the results.

Right to Refuse or Withdraw

Participants do not have to take part in this research if they do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. Participants will still have all the benefits that they would otherwise have at this clinic. Participants may stop participating in the research at any time without losing any of their rights as a patient here. Participants' treatment at this clinic/hospital will not be affected in any way.

Who to Contact

If you wish to ask questions later, you may contact any of the following:

Ms. Sameera Shafiq
Address: Office A212, Department of Psychology, Ibn-e-Khaldun Block, Department of Psychology, University of Gujrat, Gujrat.
Cell: +923345116648
Email: sameera.shafiq@uog.edu.pk

This proposal has been reviewed and approved by Institutional Review Board (IRB) UOG/ORIC/2022/393, UOG which is a committee whose task is to make sure that research participants are protected from harm.

References

Akhtar, A., Rahman, A., Husain, M., Chaudhry, I. B., Duddu, V., & Husain, N. (2010). Multidimensional scale of perceived social support: psychometric properties in a South Asian population. *Journal of Obstetrics and Gynaecology Research*, *36*(4), 845-851.

Bodenmann, G. (2008). Dyadisches Coping Inventar: Test manual [Dyadic Coping Inventory: Test manual]. Bern, Switzerland: Huber.

Choudhry, F. R., Al-Worafi, Y. M., Akram, B., Ahmed, M. A., Anwar ul Haq, M., Khan, T. M., ... & Golden, K. J. (2018). Factor structure of urdu version of the flourishing scale. *Frontiers in psychology*, *9*, 1513.

Diener, E., Wirtz, D., Tov, W., Kim-Prieto, C., Choi, D., Oishi, S., & Biswas-Diener, R. (2009). New measures of well-being: Flourishing and positive and negative feelings. Social Indicators Research, 39, 247-266.

Lodhi, F. S., Raza, O., Montazeri, A., Nedjat, S., Yaseri, M., & Holakouie-Naieni, K. (2017). Psychometric properties of the Urdu version of the World Health Organization's quality of life questionnaire (WHOQOL-BREF). *Medical journal of the Islamic Republic of Iran*, *31*, 129.

Shafiq, S., Bano, Z., Randhawa, S. S., Khan, K. H., Muhammad, Q. U., & Muhammad, A. (2022). Effectiveness of adapted cognitive behaviour therapy for dysthymia: An evidence based case study. *JPMA. The Journal of the Pakistan Medical Association*, *72*(3), 554-556.

Shujja, S., Adil, A., Randall, A. K., Bodenmann, G., & Malik, F. (2020). Psychometric properties and validity of Dyadic Coping Inventory-Urdu Version for use in Pakistan. *Interpersona: An International Journal on Personal Relationships*, *14*(2), 183-199.

Whoqol Group. (1998). Development of the World Health Organization WHOQOL-BREF quality of life assessment. *Psychological medicine*, *28*(3), 551-558.

Zimet, G.D., Dahlem, N.W., Zimet, S.G. & Farley, G.K. (1988). The Multidimensional Scale of Perceived Social Support. Journal of Personality Assessment, 52, 30-41.

Informed Consent Form

Health Care Professional (Consultant Gynaecologist)

Research Project: "The Effectiveness of Psychopharmacological Intervention versus Cognitive Behavioural Couple Therapy and Their Combination in Perinatal Distressed Couples: A Randomized Clinical Trial"

Principal Investigator: Ms Sameera Shafiq (Ph.D. Scholar and Lecturer)
Department of Psychology, University of Gujrat, Gujrat, Pakistan.

Unique Protocol ID: UOG/ORIC/2022/393

Brief Title: Cognitive Behavioral Couple Therapy for Perinatal Distress

Registration: NCT06001021

Initial Registration: 26th June, 2023.

Initial Approval and Public Release Date: 13th August, 2023.

Sponsor/Funder: Nil

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a health care professional (Consultant Gynaecologist) in this research.

Name of a Consultant Gynaecologist: _____

Signature and Stamp of Consultant Gynaecologist _____

Informed Consent Form

Distressed Couples (High-Risk) in Perinatal Period

Research Project: "The Effectiveness of Psychopharmacological Intervention versus Cognitive Behavioural Couple Therapy and Their Combination in Perinatal Distressed Couples: A Randomized Clinical Trial"

Principal Investigator: Ms Sameera Shafiq (Ph.D. Scholar and Lecturer)
Department of Psychology, University of Gujrat, Gujrat, Pakistan
Unique Protocol ID: UOG/ORIC/2022/393

Brief Title: Cognitive Behavioral Couple Therapy for Perinatal Distress

Registration: NCT06001021

Initial Registration: 26th June, 2023.

Initial Approval and Public Release Date: 13th August, 2023.

Sponsor/Funder: Nil

The informed consent form consists of two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

PART I: Information Sheet

Introduction

I am Ms Sameera Shafiq/Mrs. Sameera Ahmed conducting a research study on couple's perinatal distress. I am going to give you information and invite you to be part of this research. Before you decide, you can talk to anyone (especially your gynaecologist) you feel comfortable with about the research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the gynaecologist or the staff.

Purpose of the Research

Perinatal Distress (such as depression and/or anxiety) is a growing concern nowadays and is observed in couples (wives and husbands) during antenatal and postnatal period. It might effect the family and the foetus-infant badly if left unnoticed. NICE guidelines have recommended screening and treating perinatal women for depression and anxiety. Researches showed that perinatal distress can be treated with psychotropic medications, cognitive behavioural therapy and/or a combination of both. The reason we are doing this research is to find out if the medications (antidepressant and/or anxiolytics) are better than cognitive behavioural therapy or combination of both as a treatment for perinatal distress in the couples.

Type of Research Intervention

This research study involves the following treatments

6) Medications (antidepressants and/or anti-anxiolytics).
7) Cognitive Behavioural Therapy without Zikr.
8) Cognitive Behavioural Therapy with Zikr.
9) Combination of medications and cognitive behavioural therapy.
10) Combination of medications, cognitive behavioural therapy, and zikr.

Participant Selection

We are inviting all women (4th month to 8th month in antenatal period; after a week till one year of a child in postnatal period) and selecting willing couples with perinatal distress (high-risk) who attends gynaecology of the hospital to participate in the research with the treatment offered for free. The age range will be between 19 to 45 years.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offer the treatment that is routinely offered in this clinic/hospital. You may change your mind later and stop participating even if you agreed earlier.

Information on the Trial Medicine [Antidepressants and Anxiolytics]

1) The antidepressants and/or anxiolytics safe in antenatal (2nd and 3rd trimester) and postnatal period will be prescribed.

2) Anxiolytics used to control symptoms of anxiety without serious impairment of normal physical or mental function. Antidepressants reduce mood swings and improve overall wellbeing.

3) Some common side effects of antidepressants include feeling agitated, shaky, indigestion and stomach aches, diarrhoea or constipation, loss of appetite, dizziness, not sleeping well, or feeling very sleepy, headaches. Some short-term side effects of anxiolytics can include Low heart rate, Low blood pressure, Irregular breathing, Confusion, Dizziness, Nausea. These side effects are temporary and will be settled down in two weeks and the medication will start working for normalization of mood and/or reduction of anxiety.

Procedures and Protocol

We will ask you to select one of your preferred treatment modes out of the following

6) Medications (antidepressants and/or anti-anxiolytics).
7) Cognitive Behavioural Therapy without Zikr.
8) Cognitive Behavioural Therapy with Zikr.
9) Combination of medications and cognitive behavioural therapy.
10) Combination of medications, cognitive behavioural therapy, and Zikr.

A list of willing participants will be prepared. Each participant will have one in five chances of getting the preferred treatment mode. There will be two groups (experimental and control). To put people into one of the two groups, we will select by chance as for instance by random number generated by a research assistant.

Participants will not know to which group they actually belong. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results. If there is anything you are concerned about or that is bothering you about the research please talk to me or my research assistant or your gynaecologist.

A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. We want to know whether medicine is good, we give some people the medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you do not know whether you have been given the real medicine or the pretend or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does. But the participants given placebo will be informed in the end of the study and will be given treatment with medication.

Description of the Process

During the research a couple has to make ten visits to attend ten sessions in the hospital.

- In the first visit, rapport will be build and pre-test assessment will be done in the following two approaches

Quantitative Approach

- Indigenously developed Parental Perinatal Distress Scale (PPDS).
- Urdu version (Akhtar, Rahman, Husain, Chaudhry, Duddu,… & Husain, 2010) of Multidimensional Social Support Scale (Zimet, Dahlem, Zimet, & Farley, 1988).
- Urdu version (Shujja, Adil, Randall, Bodenmann, & Malik, 2020) of Dyadic Coping Inventory (Bodenmann, 2008).
- Urdu version (Choudhry, Al-Worafi, Akram, Ahmed, Anwar ul Haq, Khan,… & Golden, 2018) of Flourishing Scale (Diener, Wirtz, Tov, Kim-Prieto, Choi, Oishi, & Biswas-Diener, 2009).
- Urdu version (Lodhi, Raza, Montazeri, Nedjat, Yaseri, & Holakouie-Naieni, 2017) of World Health Organization's Quality of Life Brief (WHOQOL Group, 1998).

Qualitative Approach

- Semi-structured interview will be conducted to explore the present stressors and expectations and perceptions about effectivity of treatments for perinatal distress among couples.

Group 1 will be given medications or placebo for two weeks and/or for four to five weeks maximum. They have to visit after two weeks for post-test assessment. As explained before, neither you nor we will know whether you have received the medicine or the placebo. But in the end placebo participants will be debriefed and will be continued with real medication. Consultant gynaecologist will prescribe medication after thorough risk-benefit evaluation.

Group 2, Group 3, and Group 4 will continue the following sessions

- In the second session, you will be psycho-educated for perinatal period distress, couples' physical and mental health and impact on the foetus-infant, prevalence of depression and anxiety and significance of identification. Progressive muscle relaxation exercise will be carried out along with deep breathing. Feedback on the session will be taken.
- In the third session, you will be psycho-educated for the theoretical model of cognitive behavioural couple therapy with some historical highlights and empirical standing. Thought log will be given for homework. Feedback for deep breathing and progressive muscle relaxation will be carried out.
- In the fourth, fifth, sixth, seventh, eighth and ninth session, feedback will be taken on homework and session. Various techniques of Cognitive Behavioural Couple Therapy will be applied based on the nature and contents of identified precipitating, perpetuating, and present stressors. In addition, relevant techniques will be incorporated from other modalities with eclecticism. Tasbeeh (see Shafiq et al., 2022) in Zikr will be given to group 3 and group 5 who opted for it in screening process.
- In the tenth visit, feedback on session and homework will be taken. post-test assessment will be done in the following two approaches

Group 5 will be exposed to one of the two conditions. 50% couples will get placebo and 50% will receive the routine treatment care with no intervention. However, after the completion of the research, this waitlist group (control) will be briefed and will be delivered with intervention mode of treatment.

Quantitative Approach

- Indigenously developed Parental Perinatal Distress Scale (PPDS)
- Urdu version (Akhtar, Rahman, Husain, Chaudhry, Duddu, & Husain, 2010) of Multidimensional Social Support Scale (Zimet, Dahlem, Zimet, & Farley, 1988).
- Urdu version (Shujja, Adil, Randall, Bodenmann, & Malik, 2020) of Dyadic Coping Inventory (Bodenmann, 2008).
- Urdu version (Choudhry, Al-Worafi, Akram, Ahmed, Anwar ul Haq, Khan, … & Golden, 2018) of Flourishing Scale (Diener, Wirtz, Tov, Kim-Prieto, Choi, Oishi, & Biswas-Diener, 2009).
- Urdu version (Lodhi, Raza, Montazeri, Nedjat, Yaseri, & Holakouie-Naieni, 2017) of World Health Organization's Quality of Life Brief (WHOQOL Group, 1998).

Qualitative Approach

- Semi-structured interview will be conducted to explore the present stressors and expectations and perceptions about effectivity of treatments for perinatal distress among couples.

Duration

The research takes place over from 15th August, 2023 to 30th October, 2023. Screening with PPDS will be carried out on the couples who visit gynaecological ward of the hospital in August. After screening, enrolment, and signed informed consent, it will be necessary for participants to come to the clinic/hospital for 10 days in total, for one hour session each day in last week of August (two days per week, each for one hour) till September. A follow-up visit after two weeks in October is compulsory. In a follow-up qualitative approach of interviewing will be used.

Reimbursements

We will give you [PKR. 500/-] to pay for your travel to the clinic. You will not be given any other money or gifts to take part in this research.

Confidentiality

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone and will be concealed in publication of a research article.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through journal publication to be widely available to the public in order that other interested people may learn from our research. However, the privacy and confidentiality of the participants will be maintained in the results.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.

Who to Contact

If you wish to ask questions later, you may contact any of the following:

Ms. Sameera Shafiq
Address: Office A212, Department of Psychology, Ibn-e-Khaldun Block, Department of Psychology, University of Gujrat, Gujrat.
Cell: 03345116648
Email: sameera.shafiq@uog.edu.pk

This proposal has been reviewed and approved by Institutional Review Board (IRB) reference no. UOG/ORIC/2022/393, UOG which is a committee whose task is to make sure that research participants are protected from harm.

References

Akhtar, A., Rahman, A., Husain, M., Chaudhry, I. B., Duddu, V., & Husain, N. (2010). Multidimensional scale of perceived social support: psychometric properties in a South Asian population. *Journal of Obstetrics and Gynaecology Research*, *36*(4), 845-851.

Bodenmann, G. (2008). Dyadisches Coping Inventar: Test manual [Dyadic Coping Inventory: Test manual]. Bern, Switzerland: Huber.

Choudhry, F. R., Al-Worafi, Y. M., Akram, B., Ahmed, M. A., Anwar ul Haq, M., Khan, T. M., ... & Golden, K. J. (2018). Factor structure of urdu version of the flourishing scale. *Frontiers in psychology*, *9*, 1513.

Diener, E., Wirtz, D., Tov, W., Kim-Prieto, C., Choi, D., Oishi, S., & Biswas-Diener, R. (2009). New measures of well-being: Flourishing and positive and negative feelings. Social Indicators Research, 39, 247-266.

Lodhi, F. S., Raza, O., Montazeri, A., Nedjat, S., Yaseri, M., & Holakouie-Naieni, K. (2017). Psychometric properties of the Urdu version of the World Health Organization's quality of life questionnaire (WHOQOL-BREF). *Medical journal of the Islamic Republic of Iran*, *31*, 129.

Shafiq, S., Bano, Z., Randhawa, S. S., Khan, K. H., Muhammad, Q. U., & Muhammad, A. (2022). Effectiveness of adapted cognitive behaviour therapy for dysthymia: An evidence based case study. *JPMA. The Journal of the Pakistan Medical Association*, *72*(3), 554-556.

Shujja, S., Adil, A., Randall, A. K., Bodenmann, G., & Malik, F. (2020). Psychometric properties and validity of Dyadic Coping Inventory-Urdu Version for use in Pakistan. *Interpersona: An International Journal on Personal Relationships*, *14*(2), 183-199.

Whoqol Group. (1998). Development of the World Health Organization WHOQOL-BREF quality of life assessment. *Psychological medicine*, *28*(3), 551-558.

Zimet, G.D., Dahlem, N.W., Zimet, S.G. & Farley, G.K. (1988). The Multidimensional Scale of Perceived Social Support. Journal of Personality Assessment, 52, 30-41.

Informed Consent Form

High Risk for Distress Couples in Perinatal Period

Research Project: "The Effectiveness of Psychopharmacological Intervention versus Cognitive Behavioural Couple Therapy and Their Combination in Perinatal Distressed Couples: A Randomized Clinical Trial"

Principal Investigator: Ms Sameera Shafiq (Ph.D. Scholar and Lecturer)
Department of Psychology, University of Gujrat, Gujrat, Pakistan.

Brief Title: Cognitive Behavioral Couple Therapy for Perinatal Distress

Registration: NCT06001021

Initial Registration: 26th June, 2023.

Initial Approval and Public Release Date: 13th August, 2023.

Sponsor/Funder: Nil

PART II: Certificate of Consent

We have read the foregoing information, or it has been read to me. We have had the opportunity to ask questions about it and any questions that we have asked have been answered to my satisfaction. We consent voluntarily to participate in this research.

Names (optional): _____

Signatures _____