Multi Centre RCT of a group psychological intervention for postnatal depression in British mothers of South Asian origin (ROSHNI-2)

ROSHNI-2

Study Protocol Version 1.1 [26th July 2016]

Sponsor: Lancashire Care NHS Foundation Trust

RESEARCH REFERENCE NUMBERS

FUNDER REFERENCE **- HTA 14/68/08**

TRIAL REGISTRY NUMBER AND DATE – (Registration in progress)

PROTOCOL: VERSION **1 [July 2016]**

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:
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Name (please print):

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Position:

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Chief Investigator:

Signature: Date:
..../...../.....

Name: (please print):

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Statistician: Date:

Signature:

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Name: (please print):

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Position:

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TRIAL SUMMARY

Trial Title	Multi centre **R**CT of a group psych**O**logical intervention for po**S**tnatal depression in Britis**H** mothers of South Asia**N** orig**I**n – ROSHNI-2 (The word Roshni means light in Urdu/Hindi)	
Internal ref. no. (or short title)	ROSHNI-2	
Clinical Phase	Phase III	
Trial Design	Multi centre Randomised Controlled Trial	
Trial Participants	Self-ascribed British women of South Asian origin, over the age of 16 years and living with their infants up to the age of 12 months (1Year), who meet the criteria for ICD-10 depression,	
Planned Sample Size	720 women	
Intervention duration	The Positive Health Programme (PHP) is a Cognitive Behavioural Therapy (CBT) based culturally adapted group intervention. The 12 group sessions are educational life skills classes, based on a CBT model. Each session will last for 60-90 minutes, and will be delivered weekly for two months, and then fortnightly for further two months.	
Follow up duration	Follow up will be at 04 months (end of intervention) and 12 months after the baseline.	
Planned Trial Period	48 months	
	Objectives	Outcome Measures
Primary	To evaluate the clinical effectiveness of a culturally adapted group psychological intervention (Positive Health Programme, PHP) in primary care for British South Asian (BSA) mothers with postnatal depression compared with treatment as usual (TAU).	Recovery from depression as measured by (HDRS score 7 or less) at 4 months (end of intervention).
Secondary	To evaluate the impact of the intervention on secondary outcomes (cost effectiveness, health status and quality adjusted life years, parenting competence, social function, anxiety, satisfaction with care) compared to treatment as usual.	**Treatment response:** measured at 4 and 12 months using HDRS. The definition of treatment response will be a reduction of 50% or more in the participant's baseline HDRS score **Patient Health Questionnaire (PHQ-9)** (Kroenke et al., 2001): The PHQ-9 is a valid measure of severity of depression and is the main

		outcome measure for depression used by the Improving access to psychological therapies (IAPT) programme (IAPT, 2012). **Generalized Anxiety Disorder 7 (GAD-7)** (Spitzer et al., 2006): is a self-report questionnaire for screening of generalized anxiety disorder. **Health status and Quality Adjusted Life Years:** This will be measured using the EuroQol Group 5-level version of the EQ-5D (EQ-5D-5L), Urdu version) (Herdman & Gudex et al., 2011; Janssen & Pickard et al., 2013). **The Parenting Sense of Competence scale (**Johnston & Mash 1989**):** measures parental competence on 2 dimensions: Satisfaction and Efficacy. **Social functioning:** This measure was specifically created for BSA women in the SITARA trial (Gater et al., 2010) using an approach suggested by Bolton & Tang (2002) which described the development process for a cross-cultural and gender-specific function assessment. **IAPT Healthy Minds Patient Experience Questionnaire. (Steine et al., 2001).** This measure allows the patients to self-report their experiences of the intervention they undertook. **Other Measures:** **Economic Patient Questionnaire (EPQ):** Cost data will be collected using an Economic Patient Questionnaire.

ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Trial Management Group (TMG) will be established and will include those individuals responsible for the day-to-day management and governance of the study including the Chief Investigator, co-investigators and identified collaborators, the study statistician and the study manager. Notwithstanding the legal obligations of the Sponsor and Chief Investigator, the TMG will have operational responsibility for the conduct of the study including monitoring overall progress to ensure the protocol is adhered to and to take appropriate action to safeguard the patients and the quality of the study.

The TMG will meet at least quarterly once the study is actively recruiting. Minutes will be taken at TMG meetings and copies of the minutes will be filed in the Study Master File. The study manager and CI will ensure that all relevant issues and actions discussed during the meeting are followed up and resolved.

Trial Steering Committee (TSC): The TSC will meet at least annually and include the independent chair, site leads plus an additional independent member, a service user representative, an independent statistician, health economist, clinician and members from the voluntary sector and the assembly will be conducted as a Trial Steering Committee (TSC) meeting. The independent chair of our TSC is Professor Cindy-Lee Dennis from the University of Toronto.

The role of the TSC is to take responsibility for the scientific integrity of the study, the scientific validity of the study protocol, assessment of the study quality and conduct (to ensure that the study is being conducted in accordance with the principles of GCP and the relevant regulations) as well as for the scientific quality of the final study report. Decisions about the continuation or termination of the study or substantial amendments to the protocol are the responsibility of the TSC.

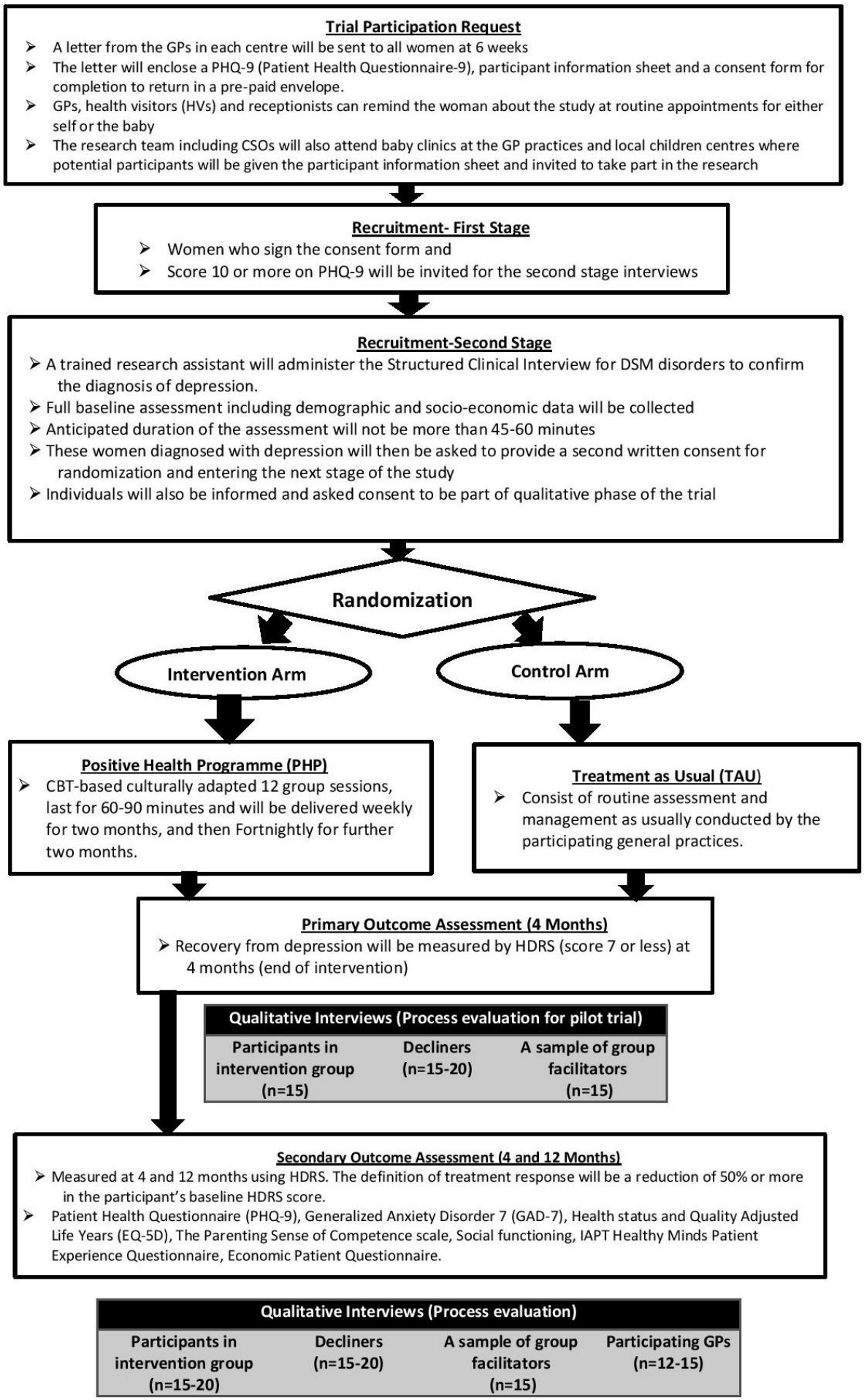
TSC meetings will be organised by the CI via the study manager. Minutes will be taken at TSC meetings and copies of the minutes will be filed in the Study Master File. The study manager and CI will ensure that all relevant issues and actions discussed during the meeting are followed up and resolved.

KEY WORDS: *Postnatal Depression, Cultural Adaptation, Mental Health, Cognitive Behavioural Therapy, British South Asian, RCT*

LIST OF ABBREVIATIONS

AMP	Access to Mental Health Care in Primary Care
BSA	British South Asian
CBT	Cognitive Behaviour Therapy
CI	Chief Investigator
CRF	Case Report Form
CTA	Clinical Trial Authorisation
DMEC	Data Monitoring and Ethics Committee
EU	European Union
GCP	Good Clinical Practice
GP	General Practitioner
IAPT	Improving Access to Psychological Therapies
ICF	Informed Consent Form
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials Number
MAHSC-CTU	Manchester Academic Health Sciences Centre-Trial Coordination Unit
NICE	National Institute for Health & Care Excellence
NHS R&D	National Health Service Research & Development
OA	Outcome Assessor
PHP	Positive Health Programme
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
PND	Postnatal Depression
QA	Quality Assurance
QC	Quality Control
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TAU	Treatment As Usual
TMG	Trial Management Group
TSC	Trial Steering Committee

ROSHNI 2 Main Study Flowchart



STUDY PROTOCOL

1 Study Identifiers

1.1 Full title of the study

Multi Centre RCT of a group psychological intervention for postnatal depression in British mothers of South Asian origin (ROSHNI-2)

1.2 Acronym

ROSHNI-2 (The word Roshni means ‘light’ in Urdu/Hindi)

1.3 NIHR Reference Number

No: HTA 14/68/08

2 Background

Approximately 20% of all new mother’s experience some form of depressive symptomatology in the postnatal period (Husain et al., 2012; Gavin et al., 2005) and no coordinated, evidence-based approach for management exists for the British South Asian (BSA) women. According to the Chief Medical Officer’s report for 2014, mental illness led to the loss of 70 million working days up 24% since 2009 (CMO, 2014) and the access to services needed to improve as a large number of people with a mental illness did not receive treatment. Postnatal depression is a major public health concern because of its impact on the mother, infant and the family (Stein et al., 2014). Higher rates of postnatal depression (PND) in South Asian women living in high income countries suggest ethnicity/ cultural differences to be a significant risk factor for developing PND (Nilaweera et al., 2014). PND is a treatable disorder (Howard et al., 2014; Dennis, 2014), and antidepressants are effective, but new mothers may be reluctant to take such medications (Howard et al., 2014; Kim et al., 2014). Cognitive Behavioural Therapy (CBT) is recommended by the National Institute for Health & Care Excellence (NICE) as a first-line treatment for PND (NICE, 2014). However, despite Increasing Access to Psychological Therapies (IAPT) and other attempts to increase capacity, access to CBT remains limited with long waiting lists.

BSA women are considered 'hard to engage ‘in interventions due to language and cultural barriers. Our previous research (Chaudhry et al., 2008; Gater et al., 2010; Husain et al., 2012) indicated that BSA women with depression lack social support and experience marked difficulties, particularly in marital and close relationships. Furthermore, they lack fluency in English and the resources to obtain help (Gater et al., 2010; Chaudhry et al., 2012). Isolation and lack of social support are therefore important elements to be addressed in interventions for depression. There is however little empirical evidence addressing the adaptation of evidence based treatments/interventions to ensure their applicability to specific ethnic communities (Miranda et al., 2003; Lau, 2006). Studies evaluating a culturally sensitive psychosocial group intervention for the treatment of depression in BSA women have

suggested an improvement in depression and participants' self-confidence at the end of the intervention [Chaudhry et al., 2008; Gater et al., 2010; Lovell et al., 2014; Khan, 2012).

In addition to cultural appropriateness of interventions, poor access to mental health care by BSA women is an important issue (National Institute for Mental Health in England, 2003; Husain et al., 2014). Existing methodological approaches in the design and delivery of interventions can enable some understanding of addressing such mental health needs of hard-to-reach groups (Bristow et al., 2011). The AMP (Access to Mental Health in Primary Care) NIHR-funded Programme (RP-PG-0606-1071) is an example of a programme which sought to address poor access to mental health services by people from hard to reach communities informed by their exploration of existing conceptual models of access (Gask et al., 2012) the AMP programme adopted a model including community engagement, improvement in patient-service interface and tailoring of psychosocial interventions to the needs of certain under-served groups.

Group CBT may offer a solution by reducing therapist time. We have developed and tested the Positive Health Programme (PHP), a culturally adapted group CBT intervention for PND (Khan, 2012; Husain et al., 2014) and the results show that the mothers found the PHP intervention to be acceptable and reported benefits such as improved mood and increased self-esteem. Almond and Lathlean (Almond & Lathlean, 2011) reported ethnic disparities in the provision and access to PND services. Department of Health (DoH) policy documents have raised the issue of improving access to appropriate mental health care for ethnic minorities (DoH, 2005 & 2011; National Institute for Mental Health in England, 2003). Psychological therapies must be culturally adapted to meet the needs of minority communities, who are often excluded because of gender or language and cultural differences. Our completed NIHR funded trial has provided the evidence for the feasibility of the proposed trial. A total of 83 mothers were included in the trial, 42 randomised to the Positive Health Programme (PHP) intervention and 41 to the routine treatment. Four groups were completed successfully across Manchester and Lancashire and with reasonable attendance (64% of the 42 randomised). The recruitment figures (n=615) and trial retention figures (See appendix 4) at the end of intervention (79%) highlight the ability of the research team to engage with the population (Masood et al,2014). The findings of a nested qualitative study show that interventions targeting PND in BSA women will need to pay particular attention to ways of improving engagement with the family, self-esteem, social support, independent coping strategies, childcare and transport provision and using the group discussion and communication techniques (story telling). The participants reported a positive change in their attitudes, behaviour and confidence level.

We have gained knowledge as to how best to recruit and retain BSA mothers with PND in a Randomised Controlled Trial (RCT). We are now confident that we will be able to screen 5265 and recruit and treat 720 mothers with PND across five centres in the UK. A larger trial is needed to test the findings of the exploratory trial, to test both short and longer term outcomes and to answer additional research questions, including cost effectiveness of PHP. The results of the proposed trial will provide evidence for this intervention and the importance of cultural adaptation of existing technologies for excluded groups with unmet needs. The results will inform the next update of the NICE PND guidelines.

3 Research objectives

The aim of this proposed study is to evaluate the clinical and cost effectiveness of a culturally adapted group psychological intervention (Positive Health Programme, PHP) in primary care for British South Asian (BSA) women with postnatal depression compared with treatment as usual (TAU). The study has both quantitative and qualitative components.

Diagnosis of depression: SCID

The full baseline assessment will be carried out after the diagnosis of depression using Structured Clinical Interview for DSM Disorders (SCID) (Spitzer et al., 1992). It is a semi-structured interview which will be administered to confirm the diagnosis of Major Depressive Episode. The interview consists of standardized diagnostic questions arranged in modules corresponding to each DSM-V Axis I disorder. The SCID has been used in a large RCT of psychological intervention for postnatal depression with a multicultural population in Canada (Dennis et al., 2012). It was used for assessing post-natal depression across seven countries (Gorman et al., 2004). It has been successfully used in a large (n=900) CBT perinatal depression trial in rural Pakistan (Rahman et al., 2008)

The objectives of the quantitative study are:

To evaluate the short term and long term effectiveness of the intervention (PHP) on rates of recovery from postnatal depression in BSA women compared to treatment as usual.

Primary Outcome:

To evaluate the short term 4 months (end of intervention) effectiveness of the intervention on rates of recovery from postnatal depression. Recovery will be a score of 7 or less (Frank et al, 1991; Rush et al, 2006) as measured by Hamilton Depression Rating Scale (HDRS) (Hamilton 1967).

Secondary Outcomes:

Treatment response: Will be measured at 4 and 12 months using **Hamilton Depression Rating Scale (HDRS)** (Hamilton, 1967). The definition of treatment response will be a reduction of 50% or more in the participant's baseline HDRS score. HDRS has been reported to give valid and reliable results in primary care setting; we have used the HDRS in Manchester with British South Asian women (Gater et al, 2010) and in our ROSHNI-D exploratory trial (Masood et al, 2014)

1. **Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001):** The PHQ-9 is a valid measure of severity of depression and is the main outcome measure for depression used by the Improving access to psychological therapies (IAPT) programme (IAPT Reports, 2012).

2. **Generalized Anxiety Disorder 7 (GAD-7) (Spitzer et al., 2006):** is a self-report questionnaire for assessment of severity of generalized anxiety disorder. The GAD-7

has seven items, which assess severity of symptoms of generalized anxiety disorder. The questionnaire is scored according to a 4-point Likert-scale ranging from 'not at all' to 'nearly every day'.

3. **Health status and Quality Adjusted Life Years:** This will be measured using the EuroQol Group 5-level version of the EQ-5D (EQ-5D-5L), Urdu version) (Herdman et al., 2011; Janssen & Pickard et al., 2013). This is a standardised instrument that measures five health dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) on 5 levels. Utility values will be generated based on population tariffs. These are anchored by 0 (dead) and 1 (full health)

4. **The Parenting Sense of Competence scale (Johnston & Mash, 1989):** measures parental competence on 2 dimensions: Satisfaction and Efficacy. The scale is scored using a 16 item Likert-scale questionnaire (on a 6-point scale ranging from strongly agree to strongly disagree), there are a number of 9 items for the satisfaction domain and 7 for the efficacy domain.

5. **Social functioning:** This measure was specifically created for BSA women in the SITARA trial (Gater et al., 2010) using an approach suggested by Bolton & Tang, (2002) which described the development process for a cross-cultural and gender-specific function assessment.

6. **IAPT Healthy Minds Patient Experience Questionnaire (Steine et al., 2001):** This measure allows the individual to self-report their experiences of the intervention they undertook. The measure has been translated into commonly used South Asian languages.

We anticipate that the duration of the assessment will not be more than 45-60 minutes. In our exploratory ROSHNI-D trial we administered a greater number of measures but none of the participants reported any difficulty in completing the assessments. We have included the measures which are of interest to the women and the family.

Other Measures:

1. **Economic Patient Questionnaire (EPQ):** Cost data will be collected using an Economic Patient Questionnaire (EPQ) data collection form (see data collection below).
2. **Process evaluation:** The study will explore the acceptability of the intervention to women. In addition, we will explore experiences of training and delivering the intervention from the perspective of the group facilitators, and perspectives of GPs participating in the study.

The objectives of the qualitative study (Semi-structured Interviews) are:

a) To explore early barriers and enablers to study participation in order to optimise on-going trial recruiter training and trial recruitment rates.

b) To identify reasons for continuing or not continuing with the study

c) To examine the acceptability of the group intervention from the perspective of British South Asian Women and their families.

d) To explore views of the General Practitioners (GPs) on the group psychological intervention and its impact on practice

e) To explore perspectives of group facilitators (group psychological intervention deliverers) about training and delivery of the intervention

4 Methods

4.1 Design

A multi-centre Randomised Controlled Trial (RCT) comparing Treatment as Usual (TAU) plus the Positive Health Programme (PHP) with TAU in British South Asian (BSA) women with postnatal depression. The current study involves 5 centres (Northwest, Yorkshire, East Midlands, Glasgow & London). The addition of extra centres around the UK will allow us to recruit the number of participants needed for us to robustly answer the question of whether the group psychological intervention is effective and value for money.

There is an 18-month internal pilot phase with clear stop/go criteria to prove viability to proceed to a full trial across all study sites.

4.1.1 Success criteria for internal pilot phase

Success in the pilot would be to recruit at least 200 participants during the internal pilot study phase (months 5-14). In case of difficulties in achieving recruitment targets between months 5 to 14 we will investigate the possible shortfalls and formulate a 'rescue plan' in month 14 or before which will be presented to the Trial Steering Committee for approval and submitted to the HTA for final decision. The predetermined Stop-Go criteria are as follows:

i. GO if 180 or more patients are recruited into the study (the Target minus 10%)
ii. Implement rescue plan if >120 (60%) but<180 (90%) recruited in the study
iii. STOP if <120 (60%) recruited in the study.

4.1.2 Target population

Self-ascribed British South Asian women meeting DSM-V depression criteria, aged 16 years or above and having a child up to 12 months of age.

4.1.3 Setting

Participants will be recruited from general practices, appropriate community venues and children's centres in areas of high South Asian density in Northwest England, Yorkshire, East Midlands, London & Glasgow.

4.1.4 Sample size

In this trial women receiving a group therapy are being compared with women receiving treatment as usual. Due to interaction between participants, outcomes for women in the same therapy group are likely to be more similar than those for women in different groups. This leads to a clustering effect in the group therapy arm similar to that found in cluster randomised trials. This trial design has been called **a *partially nested design*** as participants in the intervention arm are nested in therapy groups whereas participants in the control arm are not (Walwyn & Roberts, 2009).

Sample size calculation and data analysis needs to take account of the partial clustering. Statistical methods for the ***partially nested design*** are described in Roberts & Roberts (Roberts & Roberts, 2005). Other international groups evaluating psychological treatments for PND suggest that a 20% absolute decrease in the number of mothers with depression post-treatment is the effect that would be considered clinically meaningful, warranting the effort to develop and implement such treatments (Dennis et al., 2012). On the recommendation of the Board we will be looking at a difference of 15% between the two groups. Our exploratory trial suggests that a 75% follow-up rate can be achieved at 4 months.

Assuming this follow-up rate and an initial group size of 9 women the mean group size will be 6.75 women. With 40 groups of size 9 and 360 control subjects the trial will have 90% power to detect a clinically important difference between a 55% recovery rate in the intervention and a 40% recovery rate in the control assuming an ICC for group treatment of 0.05, a 75% follow-up and a 5% significance level (Batistatou et al., 2014). We are not aware of reliable data regarding the magnitude of therapy group clustering in this setting. Barrowclough et al (2006) give 30 estimates of the ICC for a group therapy ranging from 0 (95% C.I. 0 to 0.29) to a maximum of 0.257 (95% C.I. 0.02 to 0.67) with mean equal to 0.044 and median equal to 0. From the width of the confidence intervals, we see that there is appreciable uncertainty regarding these estimates. An ICC of 0.05 approximates to a moderate Cohen effect size (0.5) and this is close to the mean of the estimates from Barrowclough et al (2006). In the application, we note that the study is robust against larger values of the intra-cluster correlation for group treatment. For example, if the intra-cluster correlation coefficient is as large as 0.1, power will still be 86.7%. We therefore believe that the value of 0.05 is reasonable choice of ICC to use for sample size calculation.

To account for the unlikely possibility of higher than expected attrition, we will randomize 750 women. In the ROSHNI-D exploratory RCT (Masood et al, 2014) with a small research team, we were able to successfully screen 615 and randomise 83 mothers in one centre in a period of 12 months. With 5 centres and 22 months of recruitment, we anticipate that we will be able to recruit and randomise 720 subjects. We have learnt strategies for how best to recruit &

retain British South Asian mothers with postnatal depression in an RCT. We achieved high recruitment rates in this hard to engage group by publicising the study using posters and liaising with senior managers of community centres and local public health consultants. We will also publicise the study through community centres and local language radio channels.

Inclusion and Exclusion Criteria

4.1.2 Inclusion Criteria

- Self-ascribed British women of South Asian origin as defined by Office of National Statistics (ONS, 2011),
- over the age of 16 years and living with their infants up to the age of 12 months (1-Year),
- who meet the criteria for DSM-V depression, will be included in the study.

Participants who have completed the reply forms, have scored 10 or more on PHQ-9 and meet the inclusion criteria will be requested to provide a written consent for baseline assessments. Diagnosis of depression will be confirmed using SCID and if diagnosed as depressed the participant will undergo the full baseline assessment. The participants fulfilling the inclusion criteria will be randomized into the intervention or TAU group by the Clinical Trials Unit.

Low scorers on the PHQ-9 at first screen will be invited to complete a further PHQ-9 after 12-16 weeks if within the 52 weeks' postnatal period to ensure that later onset PND is not missed.

4.2.2 Exclusion Criteria

- Women with diagnosed physical or learning disability,
- Post-partum or other psychosis, and are actively suicidal (previous history of self-harm or suicide attempt).

Current use of anti-depressant medication; a prior self-reported common mental illness, including prior postnatal depression, will not be an exclusion criterion.

4.3 Recruitment & Consent

A letter from the participating general practices in each centre will be sent to all women at 6 weeks postnatal informing them about the trial, inviting their participation and requesting to send the reply form with their contact details. The letter will enclose a PHQ-9 (Kroenke et al., 2001), participant information sheet and a reply form for completion to return in a pre-paid envelope with the local site University/Trust address on it. Postal and telephone reminders will be made to non-responders. In addition, the practice records will flag non-responders so that

GPs, health visitors and receptionists can remind the woman about the study at routine appointments for either self or the baby. At this stage, women will be required to send the reply forms with their contact details to be given to the research team, for possible inclusion in the study.

Additional methods of recruitment will be used to make recruitment more efficient and allow the intervention to be accessible to a wider range of BSA mothers similar to the methods used in the ROSHNI-D exploratory RCT. Potential participants will be identified using Practice-based electronic case records. With the GP's permission, identified mothers will be contacted directly by phone via the practice or in person, in both cases by a CSO along with a bilingual research assistant. The CSO will have access to health visitor records to identify eligible South Asian women. The GP practices will be paid for the services rendered to the research study. The research team will also attend baby clinics at the GP practices and local children centres where potential participants will be given an invitation to take part in the study by verbally explaining the study and giving them the participant information sheet and the reply form.

Women who sent the reply form and have scored 10 or more on PHQ-9 will be invited to provide written consent for the trial participation and baseline assessment. The women who fulfil the inclusion criteria will be contacted either by the research team to book an appointment at the primary care clinic, children's centre or at home. All participants will have time to consider and ask questions of the research team before providing written informed consent if they wish a trained research assistant will administer the Structured Clinical Interview for DSM (SCID) disorders (Spitzer et al., 1992) to confirm the diagnosis of depression. These women, if diagnosed depressed, will then be randomised to the PHP group or TAU. They will be ensured that entering or leaving the study does not affect their access to usual health care. In both arms, usual health care is available as required.

We know from ROSHNI-D that the process of family engagement has to start from the time of screening. Family is kept informed how the trial is a leading research project which is catering to the cultural needs of underserved groups. If the participants allow, the researchers will share the study information with other family members and will provide contact details for a bilingual senior investigator who would talk to the family and provide reassurance if needed.

For recruitment, based on our completed exploratory trial (Masood et al,2014), we estimate that we will identify more than 1400 eligible women with high PHQ-9 scores from the participating general practices over 22 months from the five trial sites. If the CSO's screen 10-12 women/week, and research assistants interview 3-4 women per week, we envisage completing the case finding and recruitment in 22 months. Based on our previous trials with depressed BSA women we expect to gain consent of 75% of the depressed mothers to the trial (Masood et al, 2014; Gater et al, 2010). These are conservative figures and we estimate that the actual numbers will be much higher.

4.3.1 Publicising the study

As in the exploratory trial (Masood et al, 2014), we will use culturally appropriate strategies to promote the trial. Liaison with the community has already been initiated through awareness talks in partnership with voluntary sector organisations. These organisations have already been invited to comment upon the design of the trial and the content of the intervention. Information about the study in the form of posters and information leaflets in the five study languages (English, Urdu, Hindi, Bengali, Gujarati) will be made available. The research team will also conduct regular liaison meetings with the local health visiting teams, general practices and children's centres to promote the study in these areas.

Posters to promote the research will be put up at medical practices, community centres and local children centres such as Sure Start. These posters and other promotional material has been designed in collaboration with the service user group.

We will not only promote our study in health services but we will also place posters in local community groups, temples, mosques and local stores and media to advertise the study to a wider audience. To raise further awareness of the research, we will identify local pharmacies in areas with a high South Asian population and leaflets advertising the study with contact details and information on the study will be available for anyone interested to know more about the study.

4.3.2 Allocation to intervention (PHP) and treatment as usual (TAU) groups

Consenting eligible women will be randomised via an independent remote telephone randomisation service based at the Manchester, Manchester Academic Health sciences Centre-Trials Coordination Unit (MAHSC -CTU). The intervention group therapy is based on groups of 9 patients. After each block of 18 women have been recruited into the trial in each centre, women will be block randomised to the two treatments to give 9 intervention and 9 control participants. The randomisation will therefore be stratified by centre using a block size of 18. All efforts will be made to ensure that the time period between consent for randomisation and the actual randomisation will be no more than 4 weeks. The GP will be informed about their patient's participation in the trial by a letter.

It is not possible to blind participating mothers, their GPs, or practice health visitors to treatment group. Outcomes will be collected by an outcome assessor (OA) unaware of treatment allocation and also with a self-report measure (PHQ-9). We propose to minimize selection bias and external validity by recruiting mothers from different geographical areas across the UK and by keeping exclusion criteria to a minimum.

4.4 Outcome Measures & Data Collection

4.4.1 Intervention

The Positive Health Programme (PHP) is CBT-based culturally adapted group intervention. CBT is recommended by the National Institute for Health & Clinical Excellence (NICE) as a first-line treatment for PND (NICE,2014). However, despite Increasing Access to

Psychological Therapies (IAPT) and other attempts to increase capacity, access to CBT remains limited with long waiting lists. Group CBT may offer a solution by reducing therapist time. We have developed and tested the Positive Health Programme (PHP), a culturally adapted group CBT intervention for PND (Masood et al,2014 & Khan 2012) and the results show that the mothers found the PHP intervention to be acceptable and reported benefits such as improved mood.

Besides group therapy, the intervention group will consist of study assessments and routine assessment and management by general practice. GPs will be informed about an individual patient's psychiatric diagnosis and participation in the study.

At the beginning of each group session participants are reminded about confidentiality and an assurance from the facilitators. Some of the group sessions will be digitally recorded for quality checks. The participants will be informed about it and consent will be obtained. The 12 group sessions are educational life skills classes, based on a CBT model. Each session will last for 60-90 minutes and will be delivered weekly for two months, and then fortnightly for further two months. The intervention group therapy is based on groups of 9 patients. The intervention is manual based and could be delivered by clinical staff including assistant psychologists and Increasing Access to Psychological Therapies (IAPT) psychological well-being practitioners after receiving relevant training.

The group sessions will take place at children's centres such as Sure Start and other appropriate community venues located in the participating trial sites. This is to ensure the location is convenient for the mothers and appropriate childcare can also be arranged at such a venue. When working with multiple ethnicities, venues need to be at a neutral site not seemed to be 'owned' by any particular ethnic group or religious sect and Sure Start centres are considered very acceptable to the BSA community and families. We know that attending the group psychological intervention at children's centre appeals more to the South Asian mothers, as it is more acceptable within the family rather than going for "therapy" or "treatment". Group sessions are offered at timings convenient to most women. Crèche facilities will be provided for each session and payment will be made for transport. South Asian refreshments will be organised for the group sessions.

The Positive Health Programme (PHP) manual assisted group psychological intervention has been developed and tested in a PhD project (Khan, 2012) followed by an exploratory trial by our team (Masood et al., 2014). The manual, which has been refined based on the findings of the exploratory trial, will be used in the proposed study. These manuals are available in English, Urdu, Hindi, Bengali and Gujarati.

4.4.2 Treatment as usual (TAU)

Treatment as usual will consist of routine assessment and management as usually conducted by the participating general practices. The participants randomised to this group will receive assessments at baseline, at 4 months and 12 months after baseline along with TAU as ascertained by their treating GP. A researcher will make an appointment convenient to the participant prior to the assessment. In case of cancellations appointments will be rescheduled

according to the convenience of the participant. The treatment as usual in primary care may include active monitoring, referral to IAPT or other services, prescription of antidepressants.

4.4.3 Outcome measures and assessment

The assessments will be at baseline, at 4 months (end of intervention) and then 12 months after baseline. Demographic and socio-economic data will also be collected including data on employment status and functioning. We anticipate that the duration of the assessment will not be more than 45-60 minutes. In our exploratory ROSHNI-D trial, we administered a greater number of measures but none of the participants reported any difficulty in completing the assessments. We have included the measures, which are of interest to the women and the family.

All assessments, questionnaires, patient information sheet and the manual will also be available in Urdu/Hindi/Bengali/Gujarati. All of these measures have been used in our previous research in similar population and no incidence of discomfort or harm has been reported.

For further information on outcome measures please see section 3 ‘Research Objectives’.

4.4.4 Data Collection Qualitative Interviews

In the pilot phase we will explore barriers to recruitment and retention and personal experiences from perspectives of women (completer’s and decliners) and therapists. These interviews will offer opportunities to cover, in-depth, a range of topics relevant to the research questions, but also allow for exploration and probing of issues raised during the interview. Topic guides for the pilot phase have been developed and the topic guides for the main trial will be developed through discussion, reviewing the data received in the pilot phase with reference to the published literature.

Process evaluation

Methods:

Recruitment and sampling: At the baseline assessment for the main study, individuals will be informed about the qualitative element of the trial and asked to consent to the possibility of being contacted by the qualitative research team to take part in an interview. A purposeful sampling strategy will be used to identify potential interviewees, maximum variation sampling techniques will be used so that patients of different socio-economic background and age are invited for interview. Patients will be sampled across the five centres for the main trial.

Interviews will be held with women after the primary outcome measure has been obtained (at 4 months’ post-randomisation) to avoid the possibility of bias that might be introduced by the qualitative interview having a supportive role. Individuals will be interviewed within 8 weeks of their primary outcome measures being taken.

We will invite a sample of GPs (n=15) in participating practices to be interviewed, and we will interview up to 15 group facilitators.

Qualitative methods will be employed to explore participant and professional experiences. Semi-structured interviews offer opportunities to cover, in-depth, a range of topics relevant to the research questions, but also allow for exploration and probing of issues raised during the interview. A purposive sample of women who attended all the group sessions (n=15-20), and a sample of those who dropped out (n=15-20) will be invited to be interviewed to explore acceptability of the group meetings, perspectives on discussing problems in front of other women, views on the role of the group facilitator, how their families view attendance, and impact on current situation. A sample of group facilitators (n=15) will be interviewed to explore barriers and enablers to the group work. Interviews with participating GPs (n=12-15) will explore perspectives on the impact of the intervention on practice work, and the management of BSA women with PND, and the changes required in order to integrate this intervention into routine care.

Trial participants, GPs and group facilitators will be contacted by the researcher to book an appointment and will be interviewed at a time and place that is convenient for them (e.g. their home, GP surgery or by telephone). Written consent to take part in an interview will be obtained from participants and GPs at the time of face-to-face interviews, or prior to telephone interviews. Telephone interviews will be conducted in the researcher's office with the proper telephoning interview equipment. These interviews will last up to an hour. With participant consent, they will be digitally recorded and transcribed verbatim. Women who do not speak English as their first language will be invited to be interviewed in their own language with interview recordings translated for analysis. We will follow current recommendations for conducting and reporting Cross-Language Qualitative Research where necessary (Squires, 2009), including piloting the translated interview guide prior to interview conduct, independently verifying interview translations and describing the role and credentials of the translator in any outputs (Atkin & Chattoo, 2006).

4.4.5 Data Collection: (Economic evaluation)

Cost data will be collected using an Economic Patient Questionnaire (EPQ) data collection form developed by the applicants and successfully used in previous completed trials of complex behavioural and psychological interventions in mental health. Each participant will be asked to complete the EPQ at baseline and each follow up assessment. This will ask whether the participant has been admitted to inpatient care (psychiatric or non-psychiatric) or used hospital outpatient services and the names of the hospitals attended. This information will be used by the researchers to identify case notes at the relevant hospitals and extract details of each admission and use of outpatient services. The EPQ will also ask for detailed information about what other, non-hospital based health and social care and third sector services were used and how often they were used. Information about use of additional sources of support such as faith healers and Imams and any personal expenses will also be asked for.

Each item of resource use will be multiplied by the unit cost specific to that item. Standard national unit costs will be used. Mental health hospital services will be costed using the relevant national reference costs for each type of admission or ward (published annually by the Department of Health). Medications will be costed using the British National Formulary.

Other services will be costed using the most detailed national unit cost available (e.g. Unit costs of health and social care published annually by the PSSRU, University of Kent).

Quality Adjusted Life Years (QALYs) will be the measure of health benefit for the primary analysis. QALYs gained from baseline to end of scheduled follow up will be estimated as the number of weeks multiplied by the utility of observed survival. The utility values will be estimated from the EuroQol EQ-5D-5L health status questionnaire completed at each follow up assessment and the associated published societal utility tariffs. It is anticipated that the new tariffs for the five level version of the EQ-5D will be available at the time of analysis. If this is not the case, then the published cross-walk value set will be used.

4.6 Withdrawal

The right of the participant to refuse to take part in the study, without giving reasons, must be respected. If a patient withdraws or is withdrawn from the study, it is not the intention to replace them. If the participant declines further participation, all the results of the evaluations and observations, together with a description of the reasons for withdrawal from the trial, will be recorded. Participants are able to withdraw their data at any time until the database is locked

5. Data Analysis

Prior to the start of recruitment, a detailed statistical analysis plan (SAP) will be drafted covering the analysis of clinical and the economic evaluation. This will be reviewed by the Trial Steering Committee (TSC) and the Data Monitoring and Ethics Committee (DMEC).

5.1 Statistical analysis of clinical outcome

The statistical analysis will be based on the principle of intention-to-treat subject to the availability of data. During the course of the trial data, periodic quality checks will be carried out blind to treatment allocation by the trial statistician. Once data entry has been completed preliminary data analysis will be carried out blind to treatment allocation, prior to un-blinding. Statistical analyses will then investigate baseline factors that predict non-response using a logistic random effects model as non-response may be clustered by therapy group.

5.2. Quantitative Data Analysis

The analysis of the primary outcome measure (Recovery at 4 months, end of intervention) and the further outcome (at 12 months) will use a logistic random effects model to estimate the odds-ratio of recovery between treatment with covariate (baseline severity of depression, parity, and education (<8 years, ≥ 8 year). Sensitivity analysis will be carried out under a range of assumptions regarding missing data informed by the analysis of non-response.

The treatment effect for quantitative secondary outcome measures will be estimated using a linear random effects model with a random coefficient for therapy group using the methods described by Robert & Robert (2005) for the analysis of a partially nested trial. Baseline value of the measure, parity and educational level will be included as covariates.

5.3 Qualitative Data Analysis

Data coding will be undertaken independently by three researchers (CC-G, P-Bee and the RA), with regular meetings to ensure that the emerging codes remain grounded in the original data. Qualitative analysis will initially draw on the principles of thematic analysis using constant comparison building up to a framework analysis. Framework Analysis is inductive which allows for the inclusion of priori as well as emergent concepts (Ritchie & Spencer, 1994). The method has five distinct phases; Familiarization, identifying a thematic framework, Indexing, charting, mapping and interpretation which are linked to each other to form a rigorous framework. These phases enable understanding and interpretation of data progressing from descriptive accounts to a conceptual explanation of what is happening as suggested by the data from the participants in the study (Furber, 2010). Framework method is quite good for taking fairly open questioning and directing it towards a particular research question. It provides a systematic way for combining results and coding from multiple researchers and potentially different datasets. It's a good way to get an overview of the results and the distribution of themes within and across groups 'to eyeball the data. Professional software will be used to support qualitative data analysis.

5.4 Economic evaluation analysis

The economic analysis will estimate the costs of health and social care and quality adjusted life years (QALYs) from a broadly societal perspective. This will include NHS secondary and primary care services, formal, independent and voluntary social care services and patient and family expenditure. The key determinants of total direct costs are expected to be those associated with the use of NHS hospital inpatient, outpatient and clinic services provided for the initial trial interventions and associated follow-up. The time horizon for the primary economic analysis will be the periods from baseline to end of 12 month scheduled follow up. Multiple imputation and censored data analysis techniques will be used to separately impute missing data due to missing observations in participants who complete follow up, and missing follow up data for participants who do not complete follow up. The primary analysis will use intent to treat approach. The primary and sensitivity economic analyses will be controlled for key baseline covariates or characteristics. The covariates will be pre-specified and identified from previous studies that they may affect the costs or outcomes of care (Davies et al., 2008). Regression models will be used to estimate incremental costs and outcomes.

6 Ethical Issues

6.1 Ethical Considerations

The members of the research team have considerable clinical and research experience, including the management of difficult situations arising in research interventions and interviews. Some participants may be vulnerable and our team will ensure close supervision of researchers to safeguard maternal and child welfare. All research staff working on the project will be provided with appropriate training regarding good clinical practice in research, taking informed consent, and use of the assessment tools. Research staff and therapists will be provided with regular supervision throughout the duration of the project. Detailed guidance on safeguarding maternal and child welfare will be outlined in the programme Standard Operating Procedures (SOPs), including instructions that researchers should take if they identify any safeguarding concerns (i.e. researchers will first contact one of the senior experienced clinical applicants on the programme grant to discuss their concerns and to identify what actions to undertake).

When conducting research with this group of women it is important to consider the potential impact on participants. A distress policy has been formulated. A number of practical measures will be taken to minimise distress and risk to participants. These include:

- When taking consent, researchers will explain to participants that they can take time in answering questions and do not have to answer questions that they do not want to;
- At the baseline interview, researchers will ask participants if they would like to nominate a contact for support, should they become distressed;
- During the interview, researchers will closely monitor participants for signs for distress and, if observed, will take appropriate action, including: asking the participant if they would like to take a short break, skipping questions that cause particular distress, or offering to complete the interview at another time.

Safety protocols have been developed to ensure that participants, their families, and the researcher remain safe when making contact, conducting research, and afterwards. This includes the following precautions:

- On initial contact researchers will establish an appropriate contact number and time for future contact between themselves and participants;
- If participants would like to keep their participation in the research confidential from other people, researchers will establish how to manage the situation if conversations are overheard (e.g. they can start discussing safety of electrical appliances in the home). This is because there is a risk that telephone conversations may still be overheard;
- At all points of contact, researchers will confirm that they are speaking with the participant and will not leave information with any other household member.
- Researchers will ensure that the location(s) where an interview takes place is private and secure and cannot be overheard. Interviews will be conducted either in a secure room at the NHS Trust or, if deemed safe, at participants' home. If interviews are to take place at participant's home, the researcher will first discuss any immediate or peripheral safety issues with support providers or relevant professionals and clarify if it is safe for them to conduct interviews in the home.

- Researchers will have access to a mobile phone and lone worker device at all times during interviews and will give details of interview locations, start times and approximate end times to colleagues at their research department; lone worker policy will be adhered to
- After the interview, researchers will ask participants how they feel and if they would like to discuss anything further with their responsible clinician.

NHS lone worker policy detailing the above steps is in place for this research study. Research assistants will assess the monitoring of risk at each contact point. The researchers will complete the risk assessments forms with the participant. If at any time they feel the risk of self-harm or suicidal ideation has increased, the researcher will inform the PI or person in charge immediately after leaving the premises about the risk assessment form so that necessary action could be taken. In addition, participants will be informed of ways they can seek help if they feel worse, or suicidal. Standard response protocols and record keeping will track and audit communication with participants deemed to be at potential risk, including informing the local PI and phoning/ texting/emailing/faxing the person's GP if suicidality or risk to the baby/others is identified.

6.2 Anticipated risks and benefits

This study does not involve any known physical risks or harm to participants or the researchers. However sometimes, talking about personal experiences and feelings may be difficult and can cause emotional upset. The protocol for assessing and reporting risk and the distress policy for the study have been formulated and will be followed in case of such scenarios.

6.3 Obtaining consent

Written consent will be obtained by the trained Research Assistants (RA) and Research Technologists (RT), suitably qualified and experienced, GCP-trained and delegated by the PI to undertake this activity. Participants will be consented prior to any trial-related procedures being undertaken.

6.4 Retention of study documentation

Consent forms and paper copies of assessment tools will all be stored in locked filing cabinets in secured offices at all sites. After completion of the study the paper data will be securely transferred to the lead site. All computerised data will be encrypted and password protected. Prior to the qualitative interviews and the therapy sessions, the need to digitally record the interviews and a few therapy sessions for quality check will be explained to the interviewees and group participants, ensuring that their names would be kept confidential and only identification numbers would be used for the dissemination of research. Interviews will be recorded only after participant's written consent. These will then be transcribed. Recordings

will be stored in a secure location and will be destroyed at the end of the trial. All the medical data will be kept for 10 years.

6.5 Confidentiality

All participants will be given a research ID number and their name or identification will not be disclosed anywhere. Direct quotations will be used for dissemination of results using research ID's. All the data collected during the study will be shared by all the research team and the MAHSC-CTU Study monitor team. Dissemination of results including direct quotations will be used by using research ID.

7 Study Management

7.1 Responsibilities

Nusrat Husain and Karina Lovell along with the site leads will work with all research personnel and the group facilitators and will be responsible for the overall trial management and intervention implementation. Chris Williams, Najma Siddiqi, Ilyas Mirza and Richard Morris site leads, Atif Rahman and Terry Brugha have extensive multi-centre clinical trials experience will significantly assist in trial management. Nasim Chaudhry, Waquas Waheed, Najia Atif, Kamaldeep Bhui and Isaak Bhojani, Joe Kai co-applicants, will provide clinical guidance based on their extensive clinical experience and expertise. Linda Davies will be responsible for the economic evaluation. Ilyas Mirza, Chris Williams, Richard Morris and Najma Siddique site leads, will be responsible for assisting in the organization and implementation of participant screening, assessments and group interventions in their regions. Richard Elmsley will be responsible for data management and data analysis. Carolyn Chew-Graham and Penny Bee will lead qualitative work and process evaluation.

7.2 Study Sponsorship

Lancashire Care NHS Trust is the sponsor for this study. Delegated responsibilities, specified in the contract and delegation of duties log, will be assigned to the MAHSC-CTU to support the management of the study on behalf of the sponsor and to the participating sites recruiting patients into this study.

7.3 Trial Steering Committee (TSC):

In accordance with the Trial Terms of Reference for the TSC, periodically reviewing safety data and liaising with the DMEC regarding safety issues.

7.4 Data Monitoring and Ethics Committee (DMEC):

In accordance with the Trial Terms of Reference for the DMEC, periodically reviewing un-blinded overall safety data to determine patterns and trends of events, or to identify safety issues, which would not be apparent on an individual case basis.

8 Notification of deaths

"All deaths will be reported within 24 hours (when the researcher learns about it) to the sponsor irrespective of whether the death is related to disease progression, the trial intervention, or an unrelated event".

9 Suicide and suicide attempts

Due to the clinical characteristics of the target population being investigated, there is a risk of suicide or suicidal ideation in this population group. The study team will adhere to good clinical practice in assessing for suicide risk in participants during research encounters. All participants will be under the care of their GP. If suicide risk is detected, the protocol for assessing and reporting risk for the study will be followed.

10 Project Timetable & Milestones

The trial will be completed in 48 months. During the first 4 months, the research staff will be recruited and trained in study procedures and local mechanisms for screening and assessments will be implemented. Recruitment and training of group facilitators will be initiated and site initiation visits will be conducted. During months 5-18 we will conduct the internal pilot in the 4 new study centres. In this time period we will recruit participants, run the intervention and submit a report. Study processes in the North West centre will run alongside the internal pilot. A total of 22 months will be allotted for participant recruitment and data collection up to further 12 months to complete the follow up assessment after the end of intervention. The final six months will be spent on data cleaning, analysis, and writing draft manuscripts. The dissemination of research findings will be initiated as soon as any qualitative or quantitative results are available. The timetable of the project is presented in the form of Gantt chart. (See appendix 2, page 44).

11 Data Management Strategy

The CI (NH), site specific PI's and senior trial management team will have overall responsibility of the study data. The team will meet face to face and virtually as and when required to ensure data is accurate and up to date

11.1 Types of data.

Format and scale of the data

Data type		Types of Records	File type
The data will be anonymised and collated primarily in Microsoft Office to ensure file sharing ability. Data will be encrypted and password protected.	**Quantitative**	Clinical assessment measures	SPSS V.20 Stata V.13.1 Microsoft Excel Microsoft Access RedCap
	Qualitative	a) Participant semi-structured interviews b) GP & stakeholder semi structured interviews c) Group facilitator semi-structured interviews	NVivo Microsoft Word Microsoft Excel

11.2 Methodologies for data collection /generation

Data will be generated as outlined in the protocol; data for each participant will be collected at the relevant time points. We will adhere to the MRC Good Research Practice: Principles and Guidelines and local trust policies on data management to ensure that the primary/raw data is collected and retained safely.

Data quality and standards

We will maintain consistency and quality of all data by adhering to our protocol, Data created in the study will be continually monitored by the research team under the supervision of CI NH for any data discrepancies and to formulate strategies to ensure data integrity. We will also maintain site audits of the data and security protocols across each of the five sites. In addition, as per MRC guidance on good clinical practice we will pertain to data assurance principles as outlined by the ICH good clinical practice guidelines. Furthermore, all data for publication will be peer-reviewed internally before submission.

11.3. Data management, documentation and curation

Relevant data security and confidentiality standards will be applied (UoM Research Data Management Policy). Consent forms and paper copies of assessment tools will all be stored in locked filing cabinets in secured offices within participating sites. All computerised data will be encrypted and password protected and replicated on the LCFT server. All personal information collected and stored after selection into the study will be assigned by a reference number. Hardcopy data files will be stored securely at the CI's research office in-line and in accordance to the Trusts Good Research Guidelines Policy which states that, primary research data (and where possible/relevant specimens, samples, questionnaires, audiotapes, etc.) must be retained in their original form within the research establishment that generated them for a minimum of ten years from completion of the project (NHS Code of Practice Records Management). (Duration: a minimum of 10 years).

Metadata standards and data documentation

We will employ standardised operating procedures for the capture and management of metadata, and adhere to the MRC metadata standards.

Data preservation strategy and standards

Hardcopy data files will be stored securely at the CI's research office in-line with LCFT policy on storage of data (a minimum of 10 years). Access to data will be restricted via login and password.

Main risks to data security

The trial will be co-ordinated at LCFT under the direct supervision of CI NH. The study will be managed by the Trial Management Group and will follow MRC Good Clinical Practice in RCT guidelines, and appropriate Ethics and Research Governance arrangements to ensure minimisation of security risk.

1) Research staff will be properly trained and supervised- The responsibility of researchers will be clearly set out from the study outset.

2) Personal data- The dignity, rights, safety and wellbeing of participants are a primary consideration in the study with all data being encrypted and anonymised.

3) Data Protection- Assessments will be confidential and will be securely stored separately from personally identifying information. Data held on computer will conform to the Data Protection Act.

Arrangements will be in place to define and communicate clear quality standards. Appropriate delivery mechanisms will ensure these standards are met to reduce the risk to data security.

11.4 Protocol amendments

Any changes in research activity will be reviewed and approved by the CI and submitted in writing to the appropriate REC and local R&D for approval prior to enrolment into an amended protocol (Appendix 5)

11.5 Data sharing and access

The CI (NH), key investigators and collaborators will be responsible for access to the participant data, audio recordings and consent forms. The consent forms may also be accessed by the MAHSC-CTU and the NHS trust from which the participant is recruited for audit purposes.

11.6 Governance of access

The governance of access will be in-line with LCFT governance Policies and requests for access to the data by new members will be directed to the CI's.

11.7 The study team's exclusive use of the data

We will make data available to other researchers. However, we will hold the right to not share data for a period until we have gained sufficient publication of our work.

11.8 Regulation of responsibilities of users

We will implement Non-Disclosure Agreements with new users and our collaborators.

Relevant Policies

Policy	URL or Reference
ICH Good Clinical Practice Guidelines	http://ichgcp.net/introduction
MRC Guidelines on Good Research Practice	http://www.mrc.ac.uk/research/research-policy-ethics/good-research-practice/
MRC Data Sharing Policy	http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/policy/
MRC Metadata Standards	https://www.datagateway.mrc.ac.uk/forums/metadata-standards
IOM: strategies for the responsible sharing of clinical trial data	http://www.iom.edu/Activities/Research/SharingClinicalTrialData.aspx

12 Public and Patient Involvement and Engagement

There is planned PPI throughout the proposed research project as it has greatly helped us not only in recruitment & retention of participants in our RfPB trial (Masood et al, 2014) and previous studies but also in dissemination of the findings to key community influences using:

We have had initial discussions with institutions to hold workshops in temples, mosques and churches for further community engagement and to share our findings with the community. We will arrange workshops in the community on depression in general but particularly postnatal depression in BSA women. We will take feedback from these talks and carry out interviews to gain further qualitative information particularly how to address stigma.

We will work with the advisory group who are instrumental in engaging with the community Service users on the advisory board will be trained in research methods. Our team has significant expertise in this area and we have trained over 50 users & carers in research methods. The work KL and colleagues have carried out is cited as good practice by National Institute of Health & Care Excellence (NICE) & Mental Health Research Network (MHRN). We have been and will continue to organise an annual course on qualitative research methods and service users will be invited to attend. We have 2 service users as named collaborators.

13 Dissemination

The results of the study will be written up for academic publications in both peer reviewed and non-peer reviewed journals, and presented in national and international conferences, and further disseminated to interested local and national groups on behalf of all collaborators. All presentations and publications relating to the study will be authorised by the TMG and sponsor, on whose behalf publications should usually be made.

The ROSHNI-2 study will be promoted and the study findings disseminated in partnership with service users, carers and local voluntary organizations such as MIND. Results will be strategically publicized in all study sites throughout the country through a website and our media partners, such as Pendle Radio, Asian Image and local temples, mosques, churches and community centres using our existing networks across the study sites such as the BME Network Lancashire and the Centre for BME Health in East Midlands. These forums have a considerable reach within the communities we are working with.

We will send information about the research to staff at the British Council - which as a cultural exchange organisation is equally interested in work within the UK, as well as overseas. When moving from experimentation to implementation we will use our existing expertise (KL & RM) in working with NHS and voluntary sector in dissemination of training and information for the culture specific needs of this group. A key output will be a low cost dissemination manual. Based on the experience gained from the trial we propose to conduct an extensive round of consultations with NHS stakeholders and with key local, regional and national policy makers and commissioners to inform decision making about the dissemination of results for service improvements. These consultations will include service users from these communities and those who have participated in the trial.

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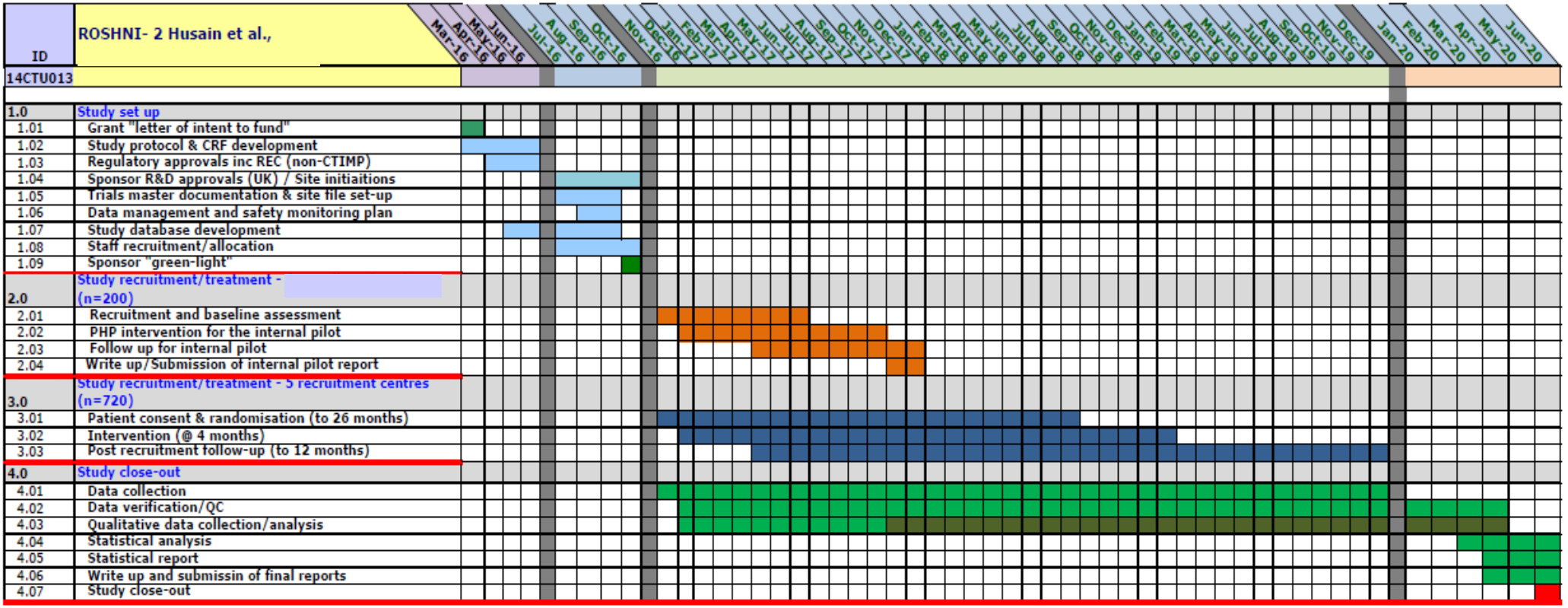
Appendices

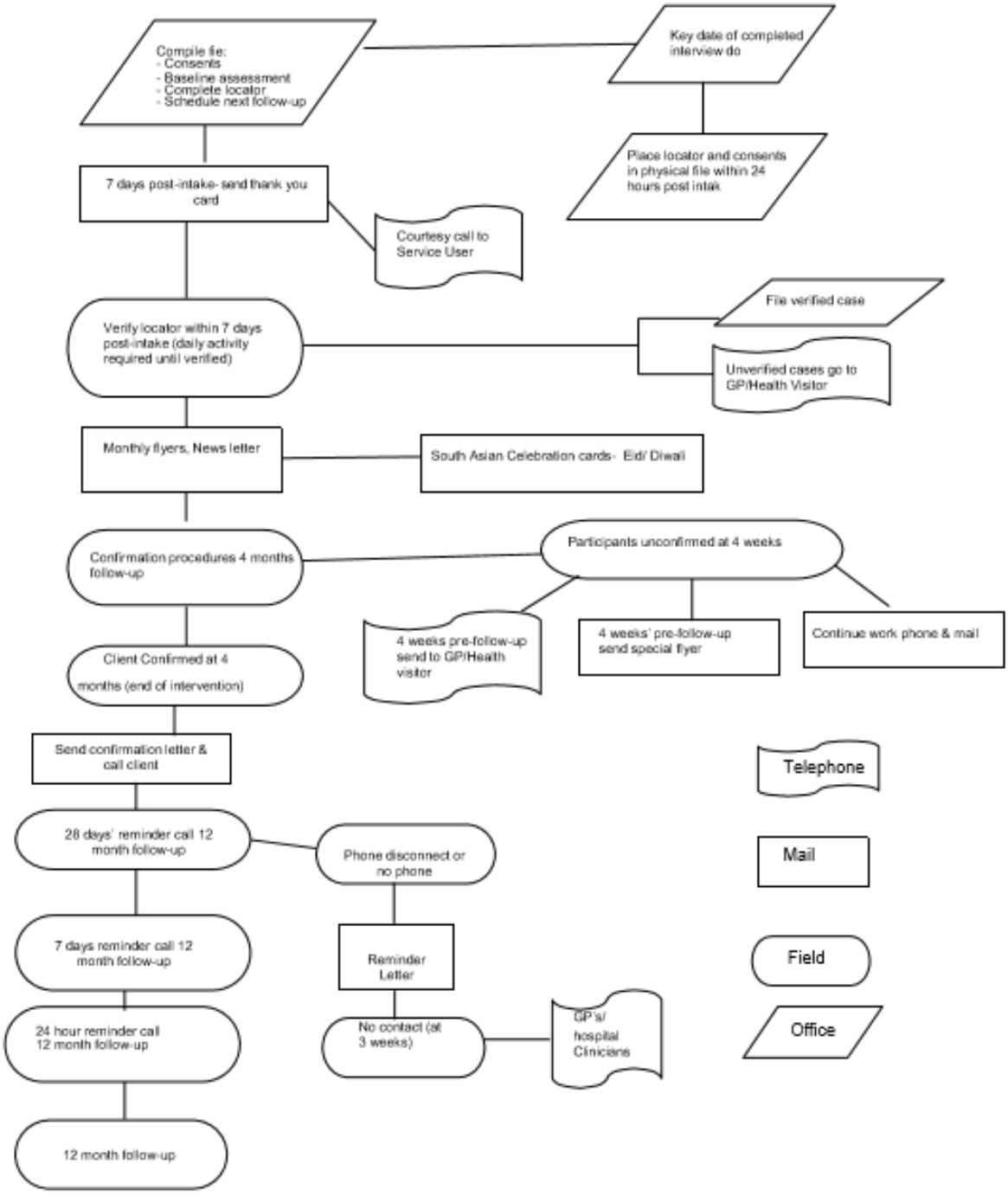
Appendix 1– Schedule of Assessments

Procedures	Visits (insert visit numbers as appropriate)			
	Screening	Baseline	4 months (End of intervention)	12 months
Informed consent	X			
Demographics		X		
Socio-economic data		X		
Study Assessments				
PHQ-9	X	X	X	X
HDRS		X	X	X
SCID		X		
GAD-7		X	X	X
EQ5-D		X	X	X
The Parenting Sense of Competence scale		X	X	X
Social Functioning		X	X	X
IAPT Healthy Minds Patient Experience Questionnaire		X	X	X
EPQ		X	X	X

Appendix 2, Gantt Chart Roshni 2



Appendix 3. Roshni-2 Engagement, Verification, Maintenance and Confirmation (EVMC) Protocol - Adapted from Scott, C. K. (2004) & Sullivan et al., (1996)



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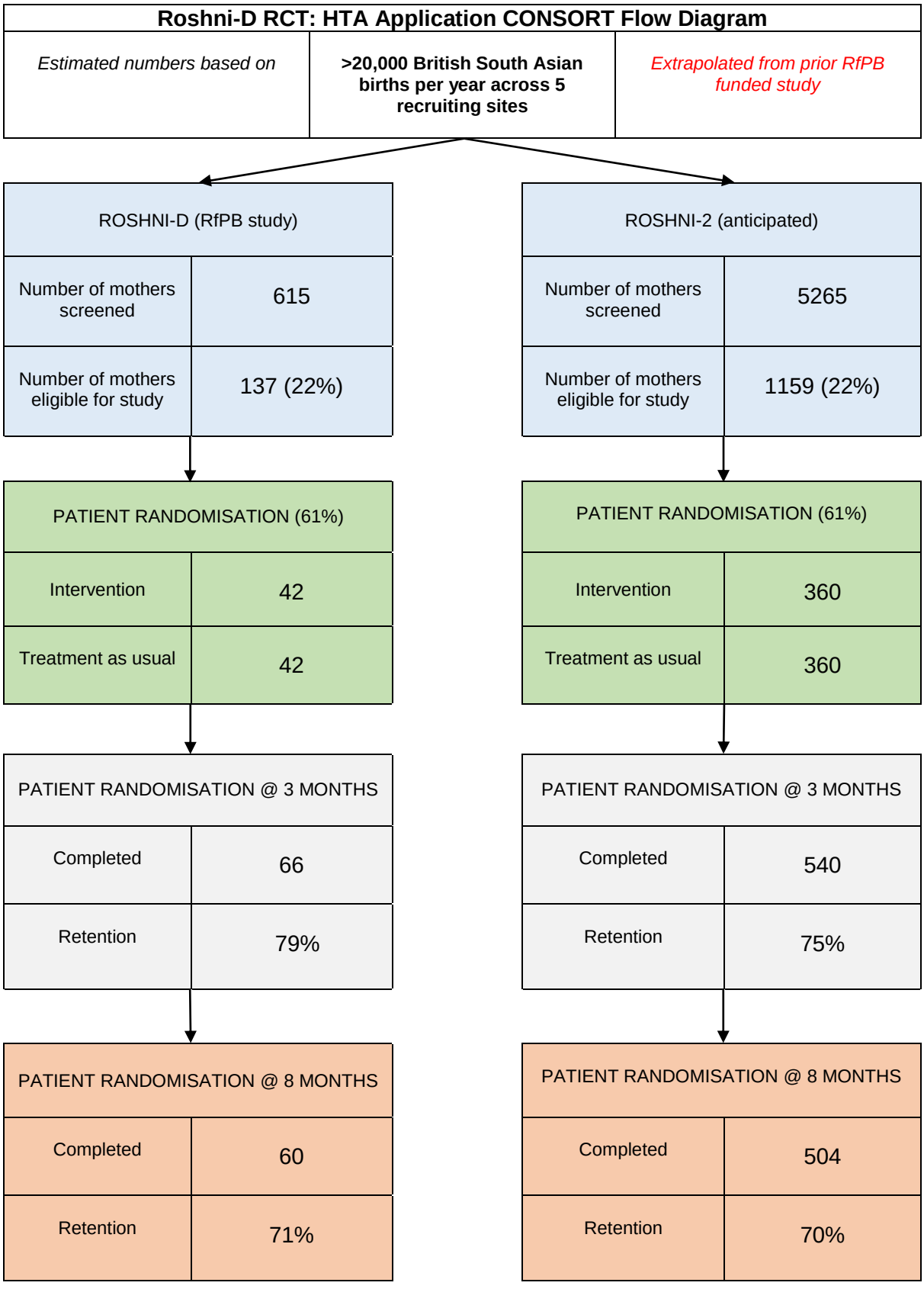
Appendix 4. Consort Diagram



Appendix 5– Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made