

Triple P for Baby: an intervention to help parents prepare for the transition to parenthood

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Registration date 04/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/10/2019	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Becoming a parent is one of the most exciting journeys people undertake in their lifetime. However, although we know that the family environment is really important for the health and well-being of babies, new parents don't receive much information about this. We are carrying out this study to evaluate the potential benefits of a new parenting programme called Triple P for Baby, which is specifically designed to support first-time parents. Triple P for Baby aims to reduce parental stress associated with becoming a first time parent; help parents develop confidence in their ability to deal with their new baby; increase the use of positive coping methods; improve the quality of the couple relationship; and extend parents social support networks.

Who can participate?

Couples expecting their first baby who are able to participate in the programme when between 20 and 35 weeks pregnant and are due to give birth at the Princess Royal Maternity Hospital in Glasgow.

What does the study involve?

We are evaluating Triple P for Baby to see if it benefits first-time parents. This means that we need to compare two groups of parents:

1. Parents who get normal NHS care during their pregnancy the care as usual group
2. Parents who get normal NHS care PLUS Triple P for Baby the Triple P group

If you take part in our study you will be in one of these groups. If you are in the Triple P for Baby group you and your partner will go to 4 group sessions before your baby is born. These groups are normally at the Princess Royal Maternity Hospital in Glasgow or at Glasgow Caledonian University and last about 2 hours. After your baby is born you will get 4 phone sessions. One of the people who ran your Triple P for Baby group will phone, you so you will know this person. Each phone call will last about half an hour.

If you are in the Care-as-Usual group you will attend all of the normal NHS antenatal and postnatal appointments. You won't attend any Triple P for Baby sessions.

In order for us to evaluate the programme all participants in both groups are asked to complete

surveys at four different stages; 1) at registration, 2) when your baby is 6-10 weeks old, 3) when your baby is 12 months old and 4) when your baby is 2 years old.

What are the possible benefits and risks of participating?

Triple P for Baby has the potential to improve family relationships, support infant development, prevent future behavioural and emotional problems in children and reduce psychological adjustment difficulties in new parents after the baby arrives.

The research will not involve procedures which could cause risk to the participating couples and their baby and there are no expected adverse events associated with the intervention.

Where is the study run from?

Parenting & Family Support Research Programme at Glasgow Caledonian University (UK)

When is the study starting and how long is it expected to run for?

July 2011 to December 2013

Who is funding the study?

National Health Service Greater Glasgow & Clyde (NHSGGC)

Who is the main contact?

Dr Kerri McPherson

(updated 08/10/2019, previously: Dr Elizabeth McGee)

Contact information

Type(s)

Scientific

Contact name

Dr Kerri McPherson

Contact details

Department of Psychology
Glasgow Caledonian University
Cowcaddens Road
Glasgow
United Kingdom
G4 OBA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Triple P for Baby: A longitudinal, randomised controlled trial of an intervention to help parents prepare for the transition to parenthood

Study objectives

Triple P for Baby is a parenting programme that aims to prevent parental psychopathology by reducing parental stress associated with the transition to parenthood, increasing the use of adaptive emotional coping strategies, improving the quality of the couple relationship and by improving the extent and quality of the parents social support network.

Triple P for Baby also aims to reduce family risk factors by increasing parents' competence in dealing with common infant behaviours (e.g., crying), reducing parents use of coercive and punitive parenting practices (e.g., shaken baby syndrome), and by improving parents' communication about parenting issues. Finally, Triple P for Baby aims to promote healthy infant development by improving the parent-infant relationship during the first twelve months, increasing the quality of a safe and engaging environment for the infant, and by increasing parents confidence and competence in teaching infants new skills and behaviours.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West of Scotland Research Ethics Committee, 01/06/2011, ref: 11/AL/0056

Study design

Two-arm longitudinal randomised controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Parenting programme; parental stress

Interventions

Current interventions as of 18/06/2013:

Intervention Condition: Triple P for Baby:

Triple P for Baby consists of a total of eight sessions: four 2-hour groups sessions that are delivered prenatally, followed by four weekly 30-minute telephone consultations with the Triple P facilitator starting when the baby is six weeks old. Triple P for Baby targets the following key areas: fostering realistic expectations about the changes throughout the transition to parenthood as well as realistic expectations about infants behaviour and development, protecting the couple relationship, introducing parents to skills and competencies of dealing with infants, promoting increased confidence in new parents about their abilities as parents, and conveying a set of adaptive strategies for emotion regulation, such as relaxation or seeking social support. Data will be collected at four time points: T1) pre-intervention, T2) post-intervention (when baby is 6-10 weeks old, T3) 12-month follow-up & T4) 24 month follow-up.

Care-as-Usual Control Condition:

Parents assigned to the CAU condition complete the assessment battery at the same four time points as the intervention group. Other than regarding issues of assessment, these parents will have no contact with the research team, but are free to access support from other community services and will be given appropriate referral information should they ask for assistance.

Previous interventions until 18/06/2013:

Intervention Condition: Triple P for Baby:

Triple P for Baby consists of a total of eight sessions: four 2-hour groups sessions that are delivered prenatally, followed by four weekly 30-minute telephone consultations with the Triple P facilitator starting when the baby is six weeks old. Triple P for Baby targets the following key areas: fostering realistic expectations about the changes throughout the transition to parenthood as well as realistic expectations about infants behaviour and development, protecting the couple relationship, introducing parents to skills and competencies of dealing with infants, promoting increased confidence in new parents about their abilities as parents, and conveying a set of adaptive strategies for emotion regulation, such as relaxation or seeking social support. Data will be collected at three time points: pre-intervention, post-intervention and at 3-month follow up.

Care-as-Usual Control Condition:

Parents assigned to the CAU condition complete the assessment battery at the same three time points as the intervention group. Once couples have successfully filled in all questionnaires, they will receive a copy of the Triple P for Baby parent workbook as a reward for their effort. Other than regarding issues of assessment, these parents will have no contact with the research team, but are free to access support from other community services and will be given appropriate referral information should they ask for assistance.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Primary outcome measures as of 11/12/2018:

Parents' mental health will be measured using the Depression, Anxiety, Stress Scales (DASS), Lovibond and Lovibond (1995). The DASS is a set of three self-report scales designed to measure the negative emotional states of depression, anxiety and stress.

Primary outcome measures as of 18/06/2013:

The primary outcome measures for the research focus on parent level effects. Measures marked with * indicate measures used for mothers only.

1. Parents Mental Health: Depression Anxiety Stress Scale (DASS)
2. Life Satisfaction: Satisfaction with Life Scale (SWLS)
3. Parenting Satisfaction & Efficacy/ Global Self Efficacy: What Being The Parent of a Baby is like (WBPB) Evaluation subscale (12 items)
4. Task Specific Self Efficacy: Maternal Self Efficacy Scale (MSES)*
5. Conflict over Parenting: Parent Problem Checklist

Previous primary outcome measures until 18/06/2013:

The primary outcome measures for the research focus on parent level effects. Measures marked with * indicate measures used for mothers only.

1. Individual Adjustment/ Postnatal Depression: Edinburgh Postnatal Depression Scale (EPDS)
2. Life Satisfaction: Satisfaction with Life Scale (SWLS)
3. Parenting Satisfaction & Efficacy/ Global Self Efficacy: What Being The Parent of a Baby is like (WBPB) Evaluation subscale (12 items)
4. Task Specific Self Efficacy: Maternal Self Efficacy Scale (MSES)*
5. Conflict over Parenting: Parent Problem Checklist

Secondary outcome measures

Secondary outcome measures as of 11/12/2018:

1. Life Satisfaction: Satisfaction with Life Scale (SWLS), Diener, Emmons, Larsen & Griffin, (1985). This questionnaire is administered at each time point: pre-intervention, post-intervention, 12 and 24 month follow-ups.
2. Parenting Satisfaction & Efficacy/ Global Self Efficacy: What Being the Parent of a Baby is like (WBPB), Evaluation subscale, Pridham & Chang, (1989). This measure is only administered post-intervention, 12 and 24 month follow-ups.
3. Task Specific Self Efficacy: Maternal Self Efficacy Scale (MSES), Teti & Gelfand, (1991)*. This measure is only administered post-intervention, 12 and 24 month follow-ups.
4. Relationship Satisfaction: Frequency and Acceptability of Partner Behaviour Inventory (FAPBI), Doss & Christensen, (2006). This questionnaire is administered at each time point: pre-intervention, post-intervention, 12 and 24 month follow-ups.
5. Division of Tasks: Household Task Checklist and Household and Baby Care Task Checklist. Spry, Morawska and Sanders (2009). This questionnaire is administered at each time point: pre-intervention, post-intervention, 12 and 24 month follow-ups.
6. Conflict over Parenting: Parent Problem Checklist, Dadds & Powell, (1991). This measure is only administered post-intervention, 12 and 24 month follow-ups.
7. Infant Behaviour: Baby Diary, Spry, Morawska and Sanders (2009).* This measure is only administered post-intervention, 12 and 24 month follow-ups.
8. Baby Behaviour Inventory (BBI), Spry, Morawska and Sanders (2009). This measure is only administered post-intervention, 12 and 24 month follow-ups.
9. Mother-infant attachment: Postpartum Bonding Instrument (PBI), Brockington et al., (2001)*. This measure is only administered post-intervention, 12 and 24 month follow-ups.
10. Social Support: Social Support Scale, Spry, Morawska and Sanders (2009). This questionnaire is administered at each time point: pre-intervention, post-intervention, 12 and 24 month follow-ups.
11. Programme Satisfaction: Client Satisfaction Questionnaire, Eyberg, (1993). This measure is only administered post-intervention, 12 and 24 month follow-ups.

Previous secondary outcome measures:

The secondary outcomes for the research focus on child level, couple level and consumer satisfaction and engagement. Measures marked with * indicate measures used for mothers only.

1. Relationship Satisfaction: Frequency and Acceptability of Partner Behaviour Inventory (FAPBI)
2. Division of Tasks: Household Task Checklist and Household and Baby Care Task Checklist developed for this study
3. Infant Behaviour: Baby Diary developed for this study*
4. Baby Behaviour Inventory (BBI) developed for this study
5. Mother-infant attachment: Postpartum Bonding Instrument (PBI)*
6. Social Support: Social Support Scale developed for this study
7. Programme Satisfaction: Client Satisfaction Questionnaire (treatment group only)

Overall study start date

01/06/2011

Completion date

03/05/2017

Eligibility

Key inclusion criteria

Couples:

1. Experiencing a first pregnancy (between 20 and 35 weeks gestation)
2. Have a significant other (i.e. father, partner) who is prepared to be involved in the programme
3. Absence of an intellectual disability or severe psychopathology which would impair participant's understanding of the material presented in the programme
4. Basic level of English literacy
5. Absence of a diagnosed genetic disorder or disability in the baby

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

160 couples

Key exclusion criteria

1. Expectant mothers who are not experiencing a first time pregnancy
2. Expectant mothers who are less than 20 weeks and more than 35 weeks gestation
3. Expectant mothers who do not have a significant other (i.e. father, partner)
4. Expectant mothers and/or fathers who have an intellectual disability or severe psychopathology are excluded to the extent they would significantly impair participant's understanding of materials and content presented in the programme
5. Couples who do not have a basic level of English literacy in order to understand the

programme with its associated exercises and materials

6. Couples, where the baby has been diagnosed with a genetic disorder or disability, as these would require special considerations which are not covered as part of Standard Triple P for Baby

Date of first enrolment

01/08/2011

Date of final enrolment

31/03/2014

Locations

Countries of recruitment

United Kingdom

Study participating centre

Glasgow Caledonian University

Glasgow

United Kingdom

G4 OBA

Sponsor information

Organisation

NHS Greater Glasgow and Clyde (UK)

Sponsor details

NHSGGC Children and Young People's Specialist Services

62 Templeton Street

Glasgow

United Kingdom

G40 1DA

Sponsor type

Government

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Government

Funder Name

NHS Greater Glasgow and Clyde (UK)

Results and Publications

Publication and dissemination plan

The research team intend to submit a paper outlining the main findings of the trial to a high-impact peer reviewed journal. A final report has been written and approved by the trial steering group, alongside an executive summary, and this will be made available on request.

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as consent obtained from participants explicitly states that "I am aware that information I provide will be used for data in a research study only, and will not be passed onto any other person."

IPD sharing plan summary

Not provided at time of registration