ISRCTN55209338 https://doi.org/10.1186/ISRCTN55209338

Parents As Partners coparenting programme with parents of infants who are more challenging to soothe

Submission date
11/09/2017

Recruitment status
No longer recruiting

Registration date
25/09/2017

Overall study status
Completed

Last Edited
09/08/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Research on whether early co-parenting programmes are helpful with parents of temperamentally reactive (difficult to soothe) infants, is an innovative and highly valuable area of study, not only for Malta but also internationally. Besides filling an important and crucial research gap that exists between the co-parenting relationship quality and such infants presenting with a reactive temperament, this research carries strong preventive qualities in terms of risks of development of child psychopathology (such as ADHD, Conduct Disorder, Autistic Spectrum Disorder and other child behavioural difficulties). The programme used in this study, called the Parents As Partners Programme (PasP), an evidence-based parenting programme, is also expected to greatly enhance the quality of relationships in young families who may be experiencing stress and may also be at the brink of breakdown. This becomes all the more threatening with infants that are more challenging to manage. Therefore a research of this quality and nature is important not only for families, but also for children and future society. The aim of this study is to examine if the PasP can enhance parent's ability to coparent and if it can positively impact children's behaviour.

Who can participate?
Parents over 18 years of age who have an eight month old infant visiting Well Baby Clinics.

What does the study involve?
Participating parents are randomly allocated to one of two groups. Those in the first group receive care as usual. Those in the second group receive the PasP programme, which helps participants support each other and explore their parenting and relationships for two or three months. Participants receive monthly phone calls to check their progress. All participants complete questionnaires after completing the programme around two or three months and again at six months.

What are the possible benefits and risks of participating?
Participants may benefit from gaining a deeper understanding about their relationship as a couple and as parents, as well as learn more about how they can work together as a team. The

risks involved may be connected to areas of conflict that are spoken about within the group, although prior to the commencement of the group, group leaders meet with all participants to evaluate safety.

Where is the study run from?
This study is being run by University of Malta, Department of Family Studies (Malta) and takes place in five health centres in Malta.

Who is funding the study?
1. University of Malta (Malta)
2. HSBC-Malta (Malta)

Who is the main contact?
Ms Ingrid Grech Lanfranco

Contact information

Type(s)
Public

Contact name
Ms Ingrid Grech Lanfranco

Contact details
University of Malta
No. 4, Wakefield
Triq F.X. Ebejer
Ta' L-Ibragg
Swieqi
Malta
SWQ2172

Additional identifiers

Protocol serial number
PasPgrp

Study information

Scientific Title
Does early co-parenting programmes with parents of infants with a highly reactive temperament help? A randomised controlled trail using Parents As Partners

Study objectives
Research Questions:
1. Does the Parents as Partners coparenting programme, delivered in the early stages following the birth of an infant with a highly reactive temperament enhance the parents' ability to coparent?
2. Does the same programme also positively change the descriptions given by the parents of the child's behaviour connected to temperament?

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Research Ethics Committee (UREC), 21/03/2017, ref: SWB 220/2016

Study design
Group designed randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Coparenting relationship and child temperament

Interventions
Participants are randomly allocated by a blinded uninvolved person, using participant reference numbers to aviod randomisation bias. Numbers are drawn randomly to either the intervention or the control group respectively.

The intervention consists of the Parents As Partners coparenting programme run by male /female co-facilitating couples. Participants are given the opportunity to explore how their relationship as a couple impacts the way they parent together, and the quality of relationships they each build with their child. They learn about how they support or can improve their support to each other, and how each are effected by their infant and by each other.

Case managers also contact both intervention and control group participants once monthly to check-in.

Provision of supervision to co-facilitating couples throughout programme. Both the intervention and control groups receive a monthly phone-call from their case manager. The phone call only serves as a check-in. All participants fill in the Parenting Stress Index, Coparenting Relationship Scale and the Infant Behaviour Questionnaire before the random allocation.

Both intervention and control groups fill in the Parenting Stress Index, Coparenting Relationship Scale and Early Childhood Behaviour Questionnaire after the completion of the Parents as Partners programme. This happens specifically 2 to-3 months following the completion of the latter programme, and again following a span of 6 months.

The Parents as Partners programme is only offered to the intervention group. Those in the control group receive the usual care.

Intervention Type
Behavioural

Primary outcome(s)

1. Parenting stress is measured using Parenting Stress Index-Short Form version 4 at month two and six
2. Co-parenting relationship is measured using the coparenting relationship scale at month two and six
3. Behaviour is measured using the Early Childhood Behaviour Questionnaire at month two and six

Key secondary outcome(s))
There are no secondary outcome measures.

Completion date
30/09/2019

Eligibility

Key inclusion criteria
1. Parents of 8 month old infants visiting Well Baby Clinics for 8 month follow-up
2. Maltese speaking
3. Parents over 18 years of age
4. Parenting infant together whether they live in the same household or not

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
57

Key exclusion criteria
1. Those parents who are parenting alone
2. Non Maltese-speaking
3. Children over 1 year of age at recruitment stage

Date of first enrolment
01/06/2017

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
United Kingdom

Malta

Study participating centre
University of Malta, Department of Family Studies
Malta
MSD

Study participating centre
Mosta Health Centre
Constitution Street
Mosta
Malta
MST 9059

Study participating centre
Floriana Health Centre
F.S. Fenech Street
Floriana
Malta
FRN 1211

Study participating centre
Paola Health Centre
Antoine De Paule Square
Paola
Malta
PLA 1266

Study participating centre
Rabat Health Centre
Civic Centre
St. Kataldu Street
Rabat
Malta
RBT 1528

Study participating centre
Qormi Health Centre
Victory Road
Qormi
United Kingdom
QRM 2503

Sponsor information

Organisation
University of Malta

ROR
https://ror.org/03a62bv60

Funder(s)

Funder type
University/education

Funder Name
University of Malta

Funder Name
HSBC - Malta

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the fact that the participants gave consent only to have data shared with the investigator and her team. Means and standard deviations for each measure will be included in the publication of the results.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		14/12/2020	14/12/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Thesis results			09/08/2022	No	No