

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

|                                        |                                                               |                                                      |
|----------------------------------------|---------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>11/09/2017   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>25/09/2017 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>09/08/2022       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                               | <input checked="" type="checkbox"/> Results          |
|                                        |                                                               | <input type="checkbox"/> 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  
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## 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 trial 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

**Primary study design**

Interventional

**Study design**

Group designed randomised controlled trial

**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 avoid 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? |
|--------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Basic results</a>  |         | 14/12/2020   | 14/12/2020 | No             | No              |
| <a href="#">Thesis results</a> |         |              | 09/08/2022 | No             | No              |