

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	<input type="checkbox"/> Prospectively registered
Registration date 25/09/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/08/2022	Condition category 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Group designed randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

There are no secondary outcome measures.

Overall study start date

04/11/2015

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

It is hoped that a total of 64 participants will be reached, half of which receive the intervention, and half in the control groups.

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**

Malta

United Kingdom

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

Sponsor details

Tal-Qroqq
Msida
Malta
MSD

Sponsor type

University/education

ROR

Funder(s)

Funder type

University/education

Funder Name

University of Malta

Funder Name

HSBC - Malta

Results and Publications

Publication and dissemination plan

Plans to finalise PhD in 2020, after which I hope to publish this study, ideally in a high-impact peer reviewed journal, or a parenting journal. I hope to be able to publish more than one article, together with my tutors as co-authors. The study protocol, and a statistical analysis will be available on completion of the study.

Intention to publish date

31/12/2020

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
Thesis results			09/08/2022	No	No