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# Helping parents with mental health problems to parent young infants: a Randomised Controlled Trial of Parent-Infant Psychotherapy and counselling

**Submission date**
09/01/2006

**Recruitment status**
No longer recruiting

**Registration date**
08/03/2006

**Overall study status**
Completed

**Last Edited**
14/06/2016

**Condition category**
Mental and Behavioural Disorders

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
RG/1/010104792

# Study information

### Scientific Title
Helping parents with mental health problems to parent young infants: a Randomised Controlled Trial of Parent-Infant Psychotherapy and counselling

### Acronym
PIP RCT

### Study objectives
Current study hypotheses as of 24/10/2007:
Aim 1:
The first aim of the study is to demonstrate that Parent-Infant Psychotherapy (PIP), an intervention based on addressing issues of parent-infant relationships with the participation of the infant, is more beneficial to infant development and parent-infant relationship than services that are routinely available to parents with mental health problems and their babies.

Aim 2:
The second aim of the study is to demonstrate that PIP brings about changes in maternal mental state; particularly increasing maternal well-being to a degree that is comparable to interventions that are routinely available to this group.

Aim 3:
The third aim is to explore parents' experience of therapy in order to enlighten service providers about the aspects of these services that are valued by users. This part of the study is intended as a preliminary inquiry into the nature of the barriers that can prevent a significant proportion of mothers with psychological difficulties and relationship problems with their infants from approaching mental health services.

Aim 4:
Finally, the study intends to establish the background for attempts at testing hypotheses concerning the clinically most effective components of PIP.

Previous study hypotheses:
Aim 1:
The first aim of the study is to demonstrate that Parent-Infant Psychotherapy (PIP), an intervention based on addressing issues of parent-infant relationships with the participation of the infant, is more beneficial to infant development and parent-infant relationship than an intervention addressing the mothers mental health issues alone.

Aim 2:
The second aim of the study is to demonstrate that PIP brings about changes in maternal mental state; particularly increasing maternal well-being to a degree that is comparable to interventions specifically aimed at addressing maternal mental health problems alone.

Aim 3:
The third aim is to explore parents' experience of therapy (both PIP and counselling) in order to

enlighten service providers about the aspects of these services that are valued by users. This part of the study is intended as a preliminary inquiry into the nature of the barriers that can prevent a significant proportion of mothers with psychological difficulties and relationship problems with their infants from approaching mental health services.

Aim 4:
Finally, the study intends to establish the background for attempts at testing hypotheses concerning the clinically most effective components of PIP.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Camden and Islington Community Local Research Ethics Committee (REC), 25/05/2005, ref: 05 /Q0511/47). As of 24/10/2007 a substantial amendment was made to the trial design, and this was approved by the above REC on the 11/06/2007.

## Study design
Interventional study with random allocation to one of two treatment groups. Allocation is done by external advisor to the study. Longitudinal follow up at six and twelve months.

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
GP practice

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Probable psychiatric caseness as measured on the general health questionnaire

## Interventions
Current interventions as of 24/10/2007:
1. Treatment As Usual (TAU): this will be the package of care that is normally available to families in their local area. In general, TAU is provided through primary care workers such as GPs and health visitors. Some more specialised services are often available for parents with mental health problems. These include support from family support workers, enhanced health visiting, social worker or midwifery services (listening visits), one to one support from clinical psychologists (provided through local Child and Adolescent Mental Health Services [CAMHS] services), psychotherapists or counsellors, postnatal support groups, creches providing respite,

parenting education workshops, peer-supported groups, home visiting services, child psychiatry and family therapy. The level of input from each of these depends on the needs of the families and the local provision.

2. Parent-infant psychotherapy (experimental treatment): this treatment involves both mothers and infants attending the GP surgery or health centre or accessible community setting close to the GP practice. Clinicians involved in this treatment are psychotherapists with a psychodynamic orientation. The focus of the treatment is on the interactions between the parent and child during the session and how the parents understand their children's emotional needs as well as their own thoughts and feelings about their parenting role.

Simply stated, parent-infant psychotherapy focuses on the relationship through individual work with parent and with child and with the two of them together. These levels of work all occur with parent and child in the same room with one therapist. The aim is to help parents understand their children's development and emotional needs and in turn, to help children become more effective in engaging their parents' care and hence, to increase parents' pleasure in their parenting role. This is achieved by talking with the parent about their current experiences with the child, especially as observed during the sessions, and about parents' past childhood experiences as these will impact on their parenting of the particular child. The therapist also works directly with the child using age appropriate play in an effort to model effective behaviours for the parent and to help the child feel more engaged and emotionally cared for during the session. These direct efforts with the child are conceptually focused to make the parents' behaviours more predictable for the child, in an effort to facilitate more effective interactions between the two. The child's experience of this predictability is expressed through his/her more effective behaviours in engaging the parent's care-giving.

Conversely, parents are helped to develop more effective ways to engage the child that are contingently responsive in age appropriate ways to a child's emotional needs. In this intensive focus on the interactions between the two, we hope that both child and parent become more predictable to each other. This treatment is manualised with full descriptions of the early, middle and ending phase of the intervention and includes criteria for adherence. Therapists' performance is monitored through regular videotaping during training and therapists are trained to adhere to the criteria in the model. In the trial, videotaping of therapy sessions will only take place on specific random sessions.

The treatment takes place usually over a twenty-six week period (six months) with an average of 10 sessions total and an average of a session every two weeks.

Previous interventions:
1. Parental counselling (standard treatment): counsellors associated with general practices adhere to the standards of the British Association of Counselling and Psychotherapy and possess a counselling or psychotherapy qualification from a UK accrediting body. All are members of United Kingdom Council for Psychotherapy (UKCP) or British Confederation of Psychotherapists (BCP). The participating practices all have one or more counsellors working mostly on a part-time basis in the practice. Their orientation is psychodynamic or humanistic. These counselling sessions focus on mothers' presenting problems, past history and relationship difficulties including though not exclusive to those with their child. Importantly, during these sessions, the child is not present and the relationship between the mother and child is not the exclusive focus. On average, parents attend such counselling sessions over a six-month period with an average of 10 to 12 sessions. While these sessions are not taped or video recorded, counsellors routinely

keep detailed process notes. This treatment is not manualised but counsellors will complete a process report checklist, the periodical rating scale. These ratings will be used to describe the therapists' standard mode of working with families and mothers' response to treatment.

2. Parent-infant psychotherapy (experimental treatment): this treatment involves both mothers and infants attending the GP surgery or health centre or accessible community setting close to the GP practice. Clinicians involved in this treatment are psychotherapists with a psychodynamic orientation. The focus of the treatment is on the interactions between the parent and child during the session and how the parents understand their children's emotional needs as well as their own thoughts and feelings about their parenting role.

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The treatment takes place usually over a twenty-six week period (six months) with an average of 10 sessions total and an average of a session every two weeks. As stated above, this is equivalent to the average dose or total session amount in the counselling intervention.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Infant well-being, including developmental level and health status

### Secondary outcome measures

1. Quality of the parent-child interaction
2. Maternal well-being, including mental health, parenting stress and life outcomes
3. Parental experience of the therapeutic intervention

### Overall study start date
25/05/2005

### Completion date
01/06/2010

## Eligibility

### Key inclusion criteria
1. Independently identified by their General Practitioner (GP), health visitor, or another professional as requiring counselling or other mental health services
2. The child is less than 12 months of age
3. Mothers meet probable psychiatric case criteria based on the general health questionnaire (greater than 4/5) (to be assessed by research team)
4. Mothers meet at least one of the following indicators of social exclusion:
4.1. Low income household (eligibility for income support)
4.2. Long term unemployment (greater than 2 years)
4.3. Temporary or overcrowded accommodation (more than two persons per room)
4.4. Single or unpartnered
4.5. Presence of chronic physical illness or disability
4.6. Early childhood history of foster or institutional care
4.7. Social isolation associated with recent relocation
4.8. Less than 20 years of age
4.9. Previous diagnosis of non-psychotic psychiatric illness

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
80 parent and infant dyads

### Key exclusion criteria
1. Non-English speaking families
2. Current psychosis
3. Substance abuse disorders or chronic drug dependence
4. Intelligence Quotient (IQ) below 70
5. Infants with any sensory or motor disability that prevents their participation in a standard developmental assessment (e.g. blindness, hearing impairment, cerebral palsy)

**Date of first enrolment**
25/05/2005

**Date of final enrolment**
01/06/2010

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**University College London**
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# Sponsor information

**Organisation**
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**Sponsor type**
University/education

**Website**
http://www.ucl.ac.uk

**ROR**
https://ror.org/02jx3x895

# Funder(s)

**Funder type**
Government

**Funder Name**
Big Lottery Fund (ref: RG/1/010104792)

**Alternative Name(s)**
BIG

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/03/2016 | | Yes | No |