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A randomized controlled trial of the intervention Video-feedback of Infant-Parent Interaction (VIPI) for infants under 2 years of age

Submission date
02/07/2014

Recruitment status
No longer recruiting

Registration date
04/08/2014

Overall study status
Completed

Last Edited
04/10/2023

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
We are carrying out a study of 200 families with interaction problems with their infants under the age of 2 years in Norway. Video feedback of Infant-Parent Interaction (VIPI) is a method which is widely practiced in primary healthcare in the Scandinavian countries, but no clinical study has been conducted of its effects on parent-child interaction. In this study, we want to compare the effects of VIPI with usual care on parent-child interaction.

Who can participate?
Families who are considered to have interaction problems with their infants who are less than 2 years of age.

What does the study involve?
The families are randomly allocated to one of two groups: VIPI or treatment-as-usual (TAU). Over a period of 2 years three trained research assistants will visit the families in their homes. During the visit, parents will complete questionnaires and will be videotaped when interacting with their infants for 30 minutes in a natural everyday situation like feeding, playing or nappy changing. These videotapes will later be assessed. We will assess the families before VIPI (T1), after VIPI (T2) and 6 months later. The TAU group in this study receives consultations from health nurses, social and child welfare workers, community psychologists, and practitioners.

What are the possible benefits and risks of participating?
For most parents there will expectedly be an immediate direct treatment benefit either from VIPI or TAU. There will be no risk to the participants.

Where is the study run from?
The VIPI study aims to recruit about 200 families from two major cities and six rural areas in Norway.

When is the study starting and how long is it expected to run for?
The study started in January 2011 and will last until December 2015.

Who is funding the study?
National Network of Infant Mental Health, Oslo (Norway).

Who is the main contact?
Professor Turid Suzanne Berg-Nielsen, tsbn@r-bup.no
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ISRCTN2014

Study information

Scientific Title
A longitudinal randomized controlled trial of the intervention Video-feedback of Infant-Parent Interaction (VIPI) for infants under 2 years of age

Acronym
VIPI

Study objectives
It is hypothesized that parents with moderate interaction problems with their infants will profit from the intervention (VIPI) compared to treatment as usual (TAU). Parents with either minor interaction problems or more serious problems will not benefit from VIPI than TAU.
It is hypothesized that maternal depressive symptoms will moderate the effect of VIPI, with more symptoms resulting in less effect.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Committee of Ethical Research in Mid-Norway, 02/10/2007, ref. 1.2007.2176

Primary study design
Interventional

Study design
Naturalistic multi-site longitudinal randomized controlled trial with a parallel-group, consecutively randomized single-blinded design with a 1-2-1-2 allocation ratio within each site

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psychiatry, developmental psychology

Interventions
Participants will be randomly allocated to one of two groups:
1. Video-feedback of Infant-Parent Interaction (VIPI)
2. Treatment as usual (TAU)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
An observational measure with standardized coding of parent-child interaction: The Emotional Availability Scales measured at baseline (T1), after 2 months (T2) and after 8 months (T3).

Key secondary outcome(s)
Ages & Stages Questionnaire social-emotional measuring parent-reported social-emotional development in infants measured at baseline (T1), after 2 months (T2) and after 8 months (T3).

Completion date
31/12/2015

Eligibility

Key inclusion criteria
Parents of infants under 2 years of age with interaction problems with their infant and sufficient proficiency in Norwegian to fill out questionnaires

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
112

Key exclusion criteria
Parents with:
1. Psychosis
2. Developmental delays
3. Ongoing substance abuse problems

Date of first enrolment
01/01/2011

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Norway

Study participating centre
RBUP
Oslo
Norway
0405

Sponsor information

Organisation
National Network of Infant Mental Health (Norway)

Funder(s)

Funder type
Other

Funder Name
National Network of Infant Mental Health, Oslo (Norway)

Results and Publications

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	video feedback of infant-parent interaction (VIPI) results	12/02/2015		Yes	No
Results article	1-year interactional results	18/06/2018	23/04/2019	Yes	No
Results article	Results in a low- to moderate-risk sample	14/09/2023	04/10/2023	Yes	No