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Pilot RCT of the use of VIG with preterm babies

Submission date
01/10/2014

Recruitment status
No longer recruiting

Registration date
23/10/2014

Overall study status
Completed

Last Edited
22/05/2017

Condition category
Pregnancy and Childbirth

[_] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Premature babies can have a number of developmental problems and infants born before 32 weeks gestation and suffering medical complications are the most likely to have long-term, developmental, psychological, emotional and behavioural difficulties. Many of these problems are the result of a nervous system that isnt working properly, or a lowered IQ . However, a variety of other factors, including parental sensitivity (a parents ability to understand their babies behaviour) may also have a part to play. Research has shown that some parents do have difficulties interacting with their preterm babies, particularly when they are feeling under stress and anxious. Although mothers of premature babies appeared to look at and talk more with their infants, they were more directive and controlling and smiled less, touched less and used significantly less emotional mirroring (copying the emotional responses of the baby). Similarly, premature infants were generally more passive, less responsive and playful, less contingently vocal (imitating their parents voice), and more fretful. A recent review has found that parenting interventions (for example, providing community support) can be successful in improving the relationship between mothers and preterm infants. This has identified the need for more cues-based parenting interventions to address ongoing problems with the relationship between parents and their preterm babies that are not addressed by existing methods of working. Video-interaction guidance (VIG), a method where participants are filmed doing a particular task and then watch it back, seems to be a good method of working with parents and full-term infants. Here, we are going to find out whether VIG works with parents and preterm infants.

Who can participate?
Parents with an infant born at 32 weeks or less gestation, who has received care on the neonatal unit (NICU).

What does the study involve?
Parents are allocated into one of two groups, a control group and an intervention group. Both receive the usual care from community staff. The intervention group also receive an additional 3 home visits from a practitioner trained in VIG. The VIG practitioner visits the families at a time that is convenient to them and the family is given an opportunity to talk about their experiences of having a baby born preterm, their perceptions of what their baby is like, and to identify their babys cues and signals on film. Video-film of parent-infant interaction is then undertaken on the NICU and edited to show best possible moments of interaction. At the first visit parents watch and discuss the film, and are encouraged to recognise moments of attunement (i.e. where an

infant was making eye-contact or touching the parent), and to discuss these with the VIG practitioner. Parents are subsequently filmed at home with their babies. The VIG practitioner again edits the film to show baby cues and positive moments of interaction and then shares them with the parents at the final visit.

What are the possible benefits and risks of participating?
We hope that participation in the study is an interesting and satisfying experience for all families, and that in the long-term, the study will produce an advance in knowledge about what works to help families who are experiencing problems.

Where is the study run from?
University Hospitals Coventry and Warwickshire Hospital. The research is being conducted by a team of researchers at Warwick Medical School, at the University of Warwick.

When is study starting and how long is it expected to run for?
January 2012 to December 2012.

Who is funding the study?
The Grace Fund (UK)

Who is the main contact?
Professor Jane Barlow
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Contact information

Type(s)
Scientific

Contact name
Prof Jane Barlow

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R&D Reference for UHCW NHS Trust: AU084111

Study information

Scientific Title
Using video interaction to support parents whose babies were born at 32 weeks or less gestation: Results of a Pilot RCT

Study objectives
To assess the potential of video interaction guidance in increasing parental sensitivity

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coventry and Warwickshire National Research Ethics Committee, 14/03/2011, ref. 11/H1211/6.

Study design
The study involved a pilot randomized controlled trial (RCT) in which eligible families were randomized to a Video Interactive Guidance (VIG) intervention or standard care control arm.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Improving parental sensitivity with their preterm babies

Interventions
Both the intervention and control groups received usual care from community health staff. The intervention group received an additional 3 home visits from a practitioner trained in VIG. The VIG practitioner visited the families at a time that was convenient to them and offered an opportunity for families to talk about their experiences of having a baby born preterm, their perceptions of what their baby was like, and to identify their babys cues and signals on film. Video-film of parent-infant interaction was undertaken on the NICU and edited to show best possible moments of interaction. At the first visit parents watched and discussed the film, and were encouraged to recognise moments of attunement (i.e. where an infant was making eye-

contact or touching the parent), and to discuss these with the VIG practitioner. Parents were subsequently filmed at home with their babies and the VIG practitioner again edited the film to show baby cues and positive moments of interaction that were then shared with parents at the subsequent visit.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Parent-infant interaction which was measured using a three-minute videoclip of parent-infant interaction that was coded using the CARE-Index.

This measure classifies infant and adult interaction on seven dimensions - three aspects of maternal behaviour (sensitivity; covert and overt hostility; unresponsiveness) and four aspects of infant behaviour (co-operation; compulsivity ; difficultness; and passivity). This scale is highly correlated with the infant Strange Situation assessment pattern of attachment. Scores range from 0 to 14, higher scores indicating better sensitivity and/or co-operation. Inter-rater reliability for the current study was 0.77 for Sensitivity and 0.81 for Co-operation for two coders who were blind to study group.

Secondary outcome measures
1. The Hospital Anxiety and Depression Scale - this is a 14-item validated self-rating scale that measures anxiety and depression in both hospital and community settings. Lower scores indicate improvement.
2. The Parenting Stress Inventory - this is a validated measure of both sources and levels of stress in parents of a new baby, and comprises a 23-item Likert scale with lower scores indicating less stress.
3. The Primary Care - Post Traumatic Stress Disorder - this is a 4-item screen that was designed for use in primary care and other medical settings. The screen includes an introductory sentence to cue respondents to traumatic events, and a positive response to 3 items indicates the need for further assessment with a structured interview for PTSD

Overall study start date
01/01/2012

Completion date
31/12/2012

Eligibility

Key inclusion criteria
Parents with an infant born at 32 weeks or less gestation, who had received care on the neonatal unit (NICU).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
47 parents participated, of whom some were couples. 31 dyads were randomised to the study, 16 in intervention group, 15 in control group.

Key exclusion criteria
Parents with twins or multiple births

Date of first enrolment
01/01/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Professor of Public Health in the Early Years
Coventry
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Sponsor information

Organisation
University of Warwick (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www2.warwick.ac.uk/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Charity

Funder Name
The Grace Fund (UK)

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	19/10/2016		Yes	No