

Pilot RCT of the use of VIG with preterm babies

Submission date 01/10/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/10/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/05/2017	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English Summary

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 isn't working properly, or a lowered IQ. However, a variety of other factors, including parental sensitivity (a parent's ability to understand their baby's 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 baby's 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

Contact details

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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 hypothesis

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

Condition

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 baby's 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

Overall study end date

31/12/2012

Eligibility

Participant 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.

Participant exclusion criteria

Parents with twins or multiple births

Recruitment start date

01/01/2012

Recruitment end date

31/12/2012

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Professor of Public Health in the Early Years

Coventry

United Kingdom

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Sponsor information**Organisation**

University of Warwick (UK)

Sponsor details

c/o Professor Jane Barlow

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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