Development and evaluation of a parenting intervention to promote motor development in infants born very preterm

Version 1.8
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Short title: Helping Our Premature infants ON to better motor skills (HOP-ON)

REC reference:

Trial Sponsor: University of Nottingham

Funding Source: Action Medical Research UK
STUDY PERSONNEL AND CONTACT DETAILS

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## SYNOPSIS

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th>Development and evaluation of a parenting intervention to promote motor development in infants born very preterm</th>
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<tbody>
<tr>
<td><strong>Acronym</strong></td>
<td>HOP-ON</td>
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<td><strong>Short title</strong></td>
<td>Helping Our Premature infants ON to better motor skills (HOP-ON)</td>
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<tr>
<td><strong>Chief Investigator</strong></td>
<td>Professor Cris Glazebrook</td>
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<tr>
<td><strong>Objectives</strong></td>
<td>Develop and evaluate a multimedia, computer based intervention to promote motor skills in very premature infants</td>
</tr>
<tr>
<td><strong>Study Configuration</strong></td>
<td>Multi-centre randomised controlled trial</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>Secondary care</td>
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<tr>
<td><strong>Sample size estimate</strong></td>
<td>Calculation to give 90% power to detect a 9.0-point difference in the Bayley III motor scales scores based on a mean of 101.5 (SD 18.1)</td>
</tr>
<tr>
<td><strong>Number of participants</strong></td>
<td>A minimum of 138 required, 69 in the intervention group and 69 in the control group. However, approx 180 recruited to allow for drop out.</td>
</tr>
<tr>
<td><strong>Eligibility criteria</strong></td>
<td>Infants born at 32 weeks or less gestation.</td>
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<tr>
<td><strong>Description of interventions</strong></td>
<td>CD-ROM or DVD and information booklet containing information on interacting with infant and motor development activities. Control group have interaction information only.</td>
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<tr>
<td><strong>Duration of study</strong></td>
<td>3 years</td>
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<tr>
<td><strong>Outcome measures</strong></td>
<td>Difference in Bayley III motor scales scores</td>
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<tr>
<td><strong>Statistical methods</strong></td>
<td>Analysis will be based on intention to treat basis. Multivariate analysis will be conducted</td>
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ABBREVIATIONS

AE Adverse Event
CI Chief Investigator overall
CRF Case Report Form
DAP Data Analysis Plan
DCD Developmental Co-ordination Disorder
DMC Data Monitoring Committee
GCP Good Clinical Practice
ICF Informed Consent Form
NHS National Health Service
PI Principal Investigator at a local centre
PIS Participant Information Sheet
REC Research Ethics Committee
R&D Research and Development department
SEN Special Educational Needs
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STUDY BACKGROUND INFORMATION AND RATIONALE

Very preterm children, born at less than 32 week gestation, are at significantly increased risk for impaired motor development compared with their term peers. This results in a high prevalence of survivors with persistent mild neuromotor dysfunction and poor motor skills [1, 2]. Deficits in motor planning, sensory-motor integration, speed and quality of movement, gross motor skills such as balance and ball skills, and fine motor skills such as manual dexterity and visuo-spatial abilities have been widely documented. These are evident in infancy [3, 4] and persist through childhood and adolescence [5-9]. Very preterm birth is therefore associated with a high risk of developmental coordination disorder (DCD) later in life [8], even among those children who have IQ in the normal range and are free of neuro-sensory disability [10, 11]. Motor difficulties are associated with cognitive deficits, inattention, social and emotional problems and learning difficulties [2, 7, 8, 12], which have a profound impact upon a child’s integration and performance in school. The high prevalence of motor impairment in very preterm children may therefore contribute to the poor academic attainment and high prevalence of special educational needs (SEN) observed in this population [13, 14].

Children with DCD are less physically fit and significantly more likely to be overweight or obese than their term peers [15]. Cairney and colleagues also found lower participation in physical activity amongst children with DCD and greater rates of obesity amongst boys with the condition [16]. This is a particular concern for preterm infants who are at risk of excess adiposity [17, 18]. Preterm infants, especially those that are small for gestational age have reduced lean body mass, when compared to infants with birth weight appropriate for their gestational age [19]. Many of these infants have experienced rapid “catch up growth” during early infancy and our ongoing research exploring maternal beliefs about infant feeding seems to suggest that mothers are anxious for smaller infants to gain weight and feed them accordingly. This additional weight tends to be fat rather than lean mass resulting in low muscle mass which impairs glucose metabolism and thus potentially increases the risk of later cardiovascular disease [19].

Early experience can, however, moderate outcomes for very preterm infants [20]. A recent meta-analysis reported a significant effect of interventions involving parents on motor outcomes at 12 months of age [21]. The vast majority of interventions included in these reviews were general programmes designed to enhance global neuro-developmental outcomes. The authors of a more targeted intervention designed to improve motor performance and involve caregivers in implementing the intervention for
their infants reported significantly enhanced motor outcomes in preterm infants [22]. Indeed, the authors of a review of intervention studies conclude that specific developmental training in which parents learn how to promote their infant’s development maximises the effect on motor outcomes [23]. Recent reports also conclude that the efficacy of parenting interventions for very preterm infants may be optimised in programmes commenced post-discharge [13, 24], particularly for enhancing motor outcomes [25], when parents have greater opportunity to interact with their infants.

Our previous research suggests that mothers may experience difficulties interacting with their very preterm infants [24]. Mothers typically perceive their preterm infants as too sleepy or fragile for play in the early months after discharge [26] and are reluctant to rouse sleeping infants resulting in long periods asleep in the supine position. Opportunities for play in the prone position are associated with better motor outcomes [27]. Majnemer has argued that stereotyping of premature infants, combined with their biological vulnerability, means that preterm infants are particularly disadvantaged by environmental barriers to motor development [28]. For example, one study found mothers responded more negatively to babies labelled as premature perceiving the infants as weaker physically, they also chose less developmentally appropriate play programs [29]. Mothers who rated their babies as more vulnerable and engaged in more prematurity stereotyping at five months had infants who achieved lower scores on the Mental Scale of the Bayley Scales of Infant Development at 32 months old [29]. These mothers also showed less patience and were less supportive of their infants while interacting with them at nine months of age [30]. Perceptions of vulnerability have been shown to predict poorer infant developmental outcomes [31]. Research to date therefore suggests interventions to address negative perceptions and parental confidence are needed to reduce barriers to motor development and that such interventions need to occur early. Most parenting interventions have focused on mothers but there is evidence that paternal engagement is also an important predictor of child development [32] in low birth weigh, pre-term infants [33]. The proposed intervention will therefore aim to include fathers where possible.

**Rationale for developing computer-based multimedia intervention to promote motor skills in preterm infants:** Computer access has increased rapidly in the UK and, by 2007, 70% of households owned a home computer and 61% of homes had an internet link [34]. Additional access through the work place and public areas such as libraries and schools means that web-based information is a feasible method of health promotion for mothers of young children. One of the key strengths of multimedia
information is that its interactive function can be used to promote a sense of control. Feedback to the user can improve feelings of competence in relation to the targeted behaviour. Interactive multimedia has proved to be an effective and engaging method of patient education in clinical settings and is associated with greater improvements in knowledge compared to non-interactive information provision [35]. Evidence from randomised-controlled trials suggests that computer-based information can both increase knowledge and influence behaviour. For example, a computer delivered intervention with children and young people with asthma was associated with better knowledge, improved perceived control of asthma compared to written information and improved clinical outcomes at 6 months follow-up [36]. Primary care patients prescribed Skinsafe, a multimedia intervention, had better knowledge about early signs of melanoma and were more likely to be regularly checking their skin compared to controls [37]. The Sharing My Infants Learning Experiences (SMILES) program was developed to promote parental interactions with preterm infants [38] by illustrating aspects of effective parent–infant interaction using photos, interactive question and answers and video clips. It also aimed to address barriers to interaction identified in our previous research [26], such as maternal uncertainty and low expectations of preterm infants. The pilot study found mothers of very premature infants who were given the SMILES program were more confident about interacting with their infants compared with controls (mean 28.4 vs 17.14, Cohen’s d = 2.05) and perceived their infant as being more capable during social interactions (27.0 vs 22.14, Cohen’s d = 0.74) [38].

STUDY AIM AND PURPOSE

PURPOSE

PRIMARY AIM AND OUTCOMES

This study aims to develop and evaluate a multimedia, computer-based intervention to promote motor skills in very preterm infants. Scores on the Bayley III motor scale and Alberta Infant Motor Scale will be the primary outcome measure. Secondary outcomes are Bayley’s (III) fine and gross motor subscale scores, parental perceptions of infant capability, parental confidence, infant quality of movement, infant growth and parenting stress.
SECONDARY AIM AND OUTCOMES

To develop and validate a short tool to assess quality of movement, which can be used to compliment the Bayley Scales of Infant Development, which is a validated scale. The secondary aim will be the research outcome of a PhD study for a member of the research team (Anita Hughes).

STUDY DESIGN

The study is a quantitative experimental design which will utilise a randomised controlled trial to enable the HOP-ON intervention to be evaluated. The participants will be randomisation into either the intervention group or the control group. The randomisation will be done via sealed envelopes which will be picked when expression of interest forms are returned. The participants in the intervention group will receive the HOP-ON CD-ROM if they have a computer or a DVD and information booklet pack, which contains the SMILES information, and the control group participants will receive the SMILES CD-ROM if they have a computer or a DVD and information booklet pack. All parents will be given an evaluation form to complete at the end of the trial, to evaluate participation. Those who consent, may be contacted for follow-up studies.

STUDY MANAGEMENT

The data will be collected by one of the research team and stored by the research team securely at the University of Nottingham during the data collection period, and then by the chief investigator, or their nominated replacement for seven years following the last publication. During the study the research team will meet monthly.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

The study will be conducted over three years, however, the study will require the participants to be involved for a period of approximately 18 months.

End of the Study

The study will end Spring 2013.
SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

The study will involve the parents and their infants. The parents of infants who were born at 32 weeks gestational age or less, admitted to neonatal units in Derby, Nottingham or Leicester and have either recently been discharged, or an anticipated discharge date in the next 2 weeks will be invited to participate in the study.

Posters will be displayed in the five neonatal units involved in the study. At each site members of the participant’s usual care team will be informed of the study, and will provide the initial information about the study to the potential participants. The information will contain details about the study and contact details for the research team for more information if they are interested in participating. An expression of interest form will be available with a stamped addressed envelope for the participant to inform the research team of their interest.

If needed, the usual hospital interpreter and translator services will be available to assist with discussion of the trial, the participant information sheets, and consent forms, but the consent forms and information sheets will not be available printed in other languages in the first instance. It will be explained to the potential participant that entry into the study is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time, but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Inclusion criteria

Parent/s aged between 16-60 years of age, who have a preterm infant - born at 32 weeks gestation or less.
Preterm infants born 32 weeks of gestation or less, and progressing well enough to have either been recently discharged from hospital, or being discharged from hospital within the next two weeks.
Both parent and infant inclusion criteria must be met for inclusion in the study.
Exclusion criteria

Parent/s of infants who are still receiving hospital care at 3 months adjusted age, and their premature infants who are still receiving hospital care at 3 months adjusted age. Parent/s of multiple births, where the number of infants is greater than two (three of more infants).

To avoid excessive travel costs, infants born outside the defined catchment area will be excluded from the study. There are no other exclusion criteria.

Expected duration of participant participation

Study participants will be participating in the study for approximately 18 months.

Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigators. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

All participants will provide written informed consent. The initial Consent Form will be signed and dated by the participant and researcher before the parent and infant enter the study. The Investigator will, if required, explain the details of the study and Participant Information Sheet, and expression of interest forms will be available on all units. The Investigator will ensure that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the potential participant has concerning study participation.

Initial informed consent will be collected from each participant before they undergo any interventions (including physical examination and history taking) related to the study. One copy of this will be kept by the participant, and one will be kept by the Investigator.
Should there be any subsequent amendment to the final protocol, which might affect a participant’s participation in the study, continuing consent will be obtained using an amended Consent Form which will be signed by the participant.

In addition, at the 12 month visit, the researcher will discuss and then provide a continuation of consent form.

**STUDY REGIMEN**

It is anticipated that recruitment will take place from November 2010 onwards until the appropriate sample size is obtained. Due to the longitudinal nature of the study it may be necessary to recruit over the target sample size to ensure an adequate sample size at the end of the trial. Once participants have consented they will be provided with a questionnaire to establish some baseline data and enable some basic demographic data to be collected prior to discharge from hospital. If the infant has already been discharged from hospital, then information may be sent out via the clinical team. Participants are also being asked for consent to access the infant’s medical notes, to allow for additional data regarding any tests conducted regarding the infant’s health and development. On discharge from hospital participants will be sent a pack which contains either the HOP-ON CD-ROM if they have a computer, or a DVD and information booklet with the SMILES information, or the SMILES CD-ROM if they have a computer, or a DVD and information booklet. The packs will include a letter for their Health Visitor and their GP to inform them of their participation. The CD-ROM, DVD and information booklets contain suggestions for parents to help their premature infant learn specific motor skills and interact with their infant, which may help to reduce stereotyping of premature babies. The CD-ROM, DVD and information booklet will contain clear instructions from trained professionals, and highlight appropriate everyday types of activities for each stage of their infant’s motor development. The activities on the HOP-ON element of the CD-ROM, DVD and information booklet have been designed by physiotherapists, to promote movement that is appropriate to the infant’s stage of development, and would not require any special equipment. One specific example would be skin to skin hand over hand (parents hand facilitating baby to touch key body areas, hand to hand, hand to foot, foot to foot for example) tactile exploration of body, face and texture in a fully supported (by parent) posture. The SMILES CD-ROM/DVD has been used and validated by members of the researcher team in an earlier study, and contains information and suggestions of interactions with premature infants.
At three months (age adjusted) questionnaires will be sent out to the parent for completion, along with a stamped addressed envelope for return. Then at one year (age adjusted) researchers will visit the parents to conduct a motor assessment, and a researcher lead questionnaire will be completed. The University of Nottingham fieldwork guidelines will be followed by the researchers for home visits. At the visit, the researchers will conduct motor assessments of the infant (Bayley’s III; Alberta Infant Motor Scale; and newly developed scale). The researchers will be trained to conduct the motor assessments. To ensure valid assessment it is anticipated that this with be video recorded. To do this consent will be re-visited regarding the recording of the motor assessment of the infant. However, if the parent does not consent for videoing it would not affect their inclusion in the study. If they consent for the recording then they will be informed that their infant’s dignity will be respected during the recording of the video, and these would be anonymised where possible, by not including names, and allocating a study code. Parents will be offered a copy of the recording, which will allow them to assess how the infant’s dignity is being respected, and to demonstrate that no names were used. If the parent consented for use of the recording for educational purposes, they will be reminded that this is optional and that they still have the option to withdraw consent for use of the recording for this purpose.

Prior to contacting the parent, the infant’s medical record would be checked to ensure that the infant is still alive before any questionnaires are sent out. In addition, as the 3 month questionnaire contains a stress index, if the scores revealed any concerns, the mother would be contacted and the appropriate support discussed. i.e. contact GP, Health Visitor, specialist support. This would again be the response if any concerns were raised at the 12 month visit.

The recording will also be stored securely in accordance with the University of Nottingham guidance for storage of source data. At the end of the visit an evaluation questionnaire will be given to parents along with details of the HOP-ON website which will provide details on activities for their infants up to the age of 3 years. If in the initial consent form the participants have agreed to be contacted for future follow-up, then consent regarding retaining address for this will be sought at this time.

**TIMEFRAME:**
November 2010: Start recruitment from three NHS Trust, who in total have five neonatal units
January 2011 onwards: At three months adjusted age for the infant, the parents will be sent a questionnaire pack containing health questions, the interacting with my premature infant questionnaire and the parenting stress index.

November 2011 onwards: At 12 months adjusted age: parents will be contacted and a visit arranged to complete parent questionnaires, and to assess the infant’s motor skills. This assessment of motor skills will be filmed to allow for the quality of the data to be assessed and the developed motor scale to be validated. Consent for the video recording will be obtained, but having the assessment video is not an essential element to participating in the study, so is completely voluntary.

Spring 2013 onwards: A summary of the findings will be sent out to participants, and if they consented, information regarding any potential follow-up study.

STATISTICS

Methods

A member of the research team will conduct the statistical analysis, by entering the data into Statistical Package for the Social Sciences (SPSS) v16. Multivariate analysis will be conducted to ascertain predictive variables. The comments from the questionnaires will be transcribed, and coded to elicit any relevant themes.

Sample size and justification

The target sample size is 69 infants in each group, which will give the 90% power to detect a 9.0-point difference in Bayley III motor scales scores based a mean of 101.5 (SD 18.1) reported in very premature infants in an Australian sample [42]. However, approximately 180 will be recruited to allow for drop out.

ADVERSE EVENTS

The occurrence of adverse as a result of participation within this study is not expected and no adverse event data will be collected.

ETHICAL AND REGULATORY ASPECTS

There are several ethical issues that must be considered in relation to the study. Parents who have had a very premature infant are at a potentially vulnerable time. Participants
will only be approached by a member of the care team, and only when the infant is progressing well and will be being discharged from hospital within the next two weeks. No undue pressure or coersion to participate will be placed on potential participants.

Another possible ethical issue would be whether during discussions with a parent a child protection issue becomes apparent, if this is the case then it would need to be discussed with the family’s health visitor. For both of these issues parents would be made aware of this procedure at the start of the meeting.
ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), and the respective National Health Service (NHS) Research & Development (R&D) department. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent or assent and parent / guardian informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant or other legally authorised representative shall both sign and date the Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled.

If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).
DATA PROTECTION

All trial staff and investigators will endeavour to protect the rights of the trial’s participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The CRF will only collect the minimum required information for the purposes of the trial. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the trial staff and investigators and relevant regulatory authorities (see above). Computer held data including the trial database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).

Information about the trial in the participant’s medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham has taken out an insurance policy to provide indemnity in the event of a successful litigious claim for proven non-negligent harm.

STUDY CONDUCT

Study conduct will be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria); accountability of study materials.

The Study Coordinator, or where required, a nominated designee of the Sponsor, shall carry out a site systems audit at least yearly and an audit report shall be made.
STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Study Coordinator, or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

RECORD RETENTION AND ARCHIVING

In accordance with the University of Nottingham’s Research Code of Conduct, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE TRIAL BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.
PUBLICATION AND DISSEMINATION POLICY

A report will be written up and submitted to Action Medical Research UK at the end of the study, and findings will be written up for submission to academic journals and relevant conferences. In addition a thesis will be submitted to the University of Nottingham which will be available for loan. All participants will be provided with a summary of the findings of the study.

USER AND PUBLIC INVOLVEMENT

Users are invited to the research meetings and have had input into the content of research documents.

STUDY FINANCES

Funding source

Funding for the study is being provided by Action Medical Research UK and The Henry Smith Charity.

Participant stipends and payments

Participants will not be paid to participate in the study, and it is unlikely that any out of pocket expenses would be incurred by the participant.
SIGNATURE PAGES

Signatories to Protocol:

**Chief Investigator:**  Professor Cris Glazebrook

Signature:______________________________

Date: __________

**Co-Investigator:**  Dr Sarah Redsell

Signature:______________________________

Date: __________

**Co-Investigator:**  Dr Samantha Johnson

Signature:______________________________

Date: __________

**Co-Investigator:**  Dr Charlotte Beer

Signature:______________________________

Date: __________
Co-Investigator: Dr Helen Budge

Signature:__________________________________

Date: ___________

Co-Investigator: Sarah Westwater-Wood

Signature:__________________________________

Date: ___________

Co-Investigator: Dr Heather Wharrad

Signature:__________________________________

Date: ___________

Co-Investigator/PhD Student: Anita Hughes

Signature:__________________________________

Date: ___________
REFERENCES


and evaluation of a multimedia educational intervention for parents of premature infants. Archives of Disease in Childhood, 93(2 Meeting Abstracts): eap39-


