**APPENDIX LIST**





Orkin J, *et al. BMJ Open* 2021; 11:e046706. doi: 10.1136/bmjopen-2020-046706

**APPENDIX A:** Timing of clinic visits and clinic members in neonatal follow up (NFU) clinics per site

| Site | Timing of clinic visits (corrected age) | NFU clinic members |
|---|---|---|
| The Hospital for Sick Children, Toronto | • 6 week telephone visit for neurology, premature and PPHN patients.<br>• 4 months<br>• 8 months*<br>• 12 months<br>• 18 months<br>• 36 months<br><br>*Cardiac visits start at 8 months. | • Neonatologists<br>• Nurse practitioner<br>• Occupational therapists<br>• Physiotherapists<br>• Speech-language pathologists<br>• Psychometrists<br>• Psychologist |
| Sunnybrook Health Sciences Centre, Toronto | • Post-discharge<br>• 4-6 weeks<br>• 4 months<br>• 8 months<br>• 12 months<br>• 18 months<br>• 36 months<br>• Kindergarten<br>• School | • Neonatologists and developmental paediatricians<br>• Registered nurse<br>• Occupational therapists<br>• Physiotherapist<br>• Speech-language pathologist |
| Mount Sinai Hospital, Toronto | • 3.5 months<br>• 8 months<br>• 12 months<br>• 18 months<br>• 36 months | • Neonatologists<br>• Nurse practitioner<br>• Occupational therapists<br>• Physiotherapist<br>• Speech language pathologist<br>• Psychologist |
| Montreal Children's Hospital, Montreal | • Post-discharge phone call<br>• 4 months<br>• 9 months<br>• 18 months<br>• 36 months<br>• Preschool<br>• Subsequent visit and extra visits possible, on clinical basis. | • Pediatricians<br>• Neonatologist<br>• Nurses<br>• *Occupational therapist, Physiotherapist, Psychologist, Speech & language therapist, Audiologist, Social worker, Clinical nutritionist<br><br>*Services on consultation for developmental surveillance and short interventions |
| BC Women's Hospital, British Columbia | • 4 months<br>• 8 months<br>• 18 months<br>• 3 years<br>• 4.5 years | • Neonatologists<br>• Nurses<br>• Occupational therapists<br>• Physiotherapists<br>• Speech and language therapists<br>• Psychologists |



Orkin J, *et al. BMJ Open* 2021; 11:e046706. doi: 10.1136/bmjopen-2020-046706

| | | |
|---|---|---|
| Children's Hospital of Eastern Ontario and The Ottawa Hospital, Ottawa | • 4 months<br>• 10 months<br>• 18 months<br>• 4 years<br><br>Additional visits may be booked if concerns are identified | • Neonatologists<br>• Pediatrician and developmental pediatrician<br>• Neonatal nurse practitioner<br>• Registered nurse<br>• Physiotherapist<br>• Psychologist |



Orkin J, *et al. BMJ Open* 2021; 11:e046706. doi: 10.1136/bmjopen-2020-046706

**APPENDIX B:** Overview of ACT sessions and curriculum

| Session | ACT Core Processes | Objectives | Key Activities |
|---|---|---|---|
| **Pre-session (20 min)** | 1. Values | 1. Build rapport<br>2. Briefly describe what to expect in sessions<br>3. Answer any questions and let them know other family members can attend | - Complete pre-session worksheet |
| **Session 1: Welcome to the Matrix (1 hour)** | 1. Values<br>2. Present moment<br>3. Committed action | 1. Participate in values authorship, an exercise with an aim at focusing on life domains that are uniquely important to each person<br>2. Connect more deeply with what is most important to us<br>3. Show up fully for our lives and for the important people in our lives<br>4. Live the qualities that are most important to each of us<br>5. Bringing awareness to our behaviour | - The Matrix<br>- Mindfulness exercise: What's important about being here?<br>- Planning a bold move<br>- Sharing appreciations of the session |
| **Session 2: Just noticing (1 hour)** | 1. Defusion<br>2. Present moment<br>3. Acceptance | 1. Bring awareness to the thoughts, feelings, sensations, and memories<br>2. Noticing what our actions are in service of<br>3. Noticing the short and long term costs and benefits of 'toward' and 'away' moves<br>4. Bringing awareness to an interaction with someone that is about appreciation rather than problem solving | - Mindfulness exercise: Setting intention<br>- Check-in on bold moves<br>- Functional analysis of the Matrix<br>- The sweet spot exercise<br>- Just notice<br>- Sharing appreciations of the session |
| **Session 3: Watching your thoughts (1 hour)** | 1. Defusion<br>2. Acceptance<br>3. Present moment | 1. Loosening rigid repertoires of behaviour in the presence of painful private experiences, such as difficult thoughts, feelings, sensations, and memories | - Thought exercise (e.g., thought factory)<br>- Fish and hooks worksheet<br>- Mindfulness exercise<br>- Noticing hooks and response to hooks<br>- "Hooky" words exercise |

| | | | |
|---|---|---|---|
| | | 2. Practice creating distance from one's thoughts<br>3. Learning how to observe experiences rather than being the experience | - Sharing appreciations of the session |
| **Session 4: Staying your course (1 hour)** | 1. Self as context<br>2. Present moment<br>3. Values<br>4. Defusion<br>5. Acceptance<br>6. Committed Action | 1. Reflecting on the experience of the sessions<br>2. Participate in values authorship<br>3. Clarifying values and awareness on how close you are to 'living' them; reflect without judgment or needless defense | - Review of past sessions<br>- Bullseye exercise<br>- Mountain meditation or sky and weather<br>- Object exercise<br>- Note to future self |

**APPENDIX C:** Model consent form for participants



Orkin J, *et al. BMJ Open* 2021; 11:e046706. doi: 10.1136/bmjopen-2020-046706

# Consent to Participate in a Research Study

**Study Title:**

Coached, Coordinated, Enhanced Neonatal Transition (CCENT): A multi-centre pragmatic randomized controlled trial

**Principal Investigators:**

| | | |
|---|---|---|
| Dr. Julia Orkin | Hospital for Sick Children | 416-813-7654 x201150 |
| Dr. Eyal Cohen | Hospital for Sick Children | 416-813-7654 x202626 |
| Dr. Paige Church | Sunnybrook Health Sciences Centre | 416-480-6100 x87789 |
| Dr. Nathalie Major | Children's Hospital Eastern Ontario | 613-737-7600 x2664 |

**Clinical Lead Investigator:**

| | | |
|---|---|---|
| Dr. Linh Ly | Hospital for Sick Children | 416-813-7654 x2997 |

**Research Contact:**

| | | |
|---|---|---|
| Arpita Parmar | Hospital for Sick Children | 416-813-7654 x305780 |
| Kayla Esser | Hospital for Sick Children | 416-813-7654 x309026 |

**Study Sponsor:**

This research is funded by the Canadian Institute of Health Research, under the Strategy for Patient Oriented Research (SPOR).

**Conflict of Interest:**

There are no conflicts of interest to declare related to this study.

**Introduction**

You are invited to participate in a research study because your child is a patient in the Neonatal Intensive Care Unit (NICU). This consent form describes the research study and what it means to participate. This consent form may have words that you do not understand. Please ask the study staff to explain anything that you do not understand. Please take as much time as you need to think about your decision to participate or not and ask any questions you have. If it is helpful to you, you are encouraged to discuss the study with family, friends, your personal physician, other health professionals, or any members of your community that you trust. All participation is voluntary, and you are not under any obligation to participate.

**Why is this study being done?**

Infants and parents in the Neonatal Intensive Care Unit (NICU) experience significant stress, including worrying about their child's health, separation from each other, possible painful procedures, and prolonged hospitalization. Support available in the NICU consists of your baby's bedside nurse, medical team, various specialists caring for your baby, and social workers. In addition to the standard supports that are available in the NICU, families and care providers have identified certain medical and social needs that go beyond the care available in the NICU. The purpose of this study is to evaluate a neonatal follow-up model that offers additional support for children and their family during their NICU admission as well as their transition home. In this study, some families will be randomly assigned a dedicated "key worker" (nurse navigator) who will play a supportive role for you and your family during the transition out of the hospital. The results of this study, including your feedback, will be used to improve future care for children in the NICU and their families.

**How many participants will be in this study?**

It is anticipated that about 250 families will take part in this study, from research sites located at seven hospitals across Canada. Approximately 70 families will be enrolled at SickKids.

**How long will the study take?**

This length of the study for participants is 18 months and the results will be known in 2022-2023.

**What will happen in this research study?**

If you decide to participate, you will be "randomized" into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have an equal chance of being placed in either group. Neither you, nor the research staff can choose what group you will be in. You will be told which group you are in.

Both groups will receive the standard of care through the neonatal follow-up clinic and will be seen at routine times, which includes follow-up appointments at 6 weeks, 4 months, 12 months, and 18 months corrected age.

<u>Group 1: Parental Coaching and Care Coordination in addition to Standard of Care</u>

If you are randomized to this group, you and your family will be assigned a dedicated key worker, whose role is to offer support and coaching to parents. The key worker's role involves three main components: 1) parental coaching within a mindfulness framework, which involves structured group mindfulness sessions, 2) care coordination, which includes supporting providers in clear communication when



Orkin J, *et al. BMJ Open* 2021; 11:e046706. doi: 10.1136/bmjopen-2020-046706

coordinating between acute care, primary care, neonatal follow-up, home and community as well as supporting you in system and resource navigation, and 3) education and anticipatory guidance, which involves providing parents and families with proactive education targeting normal challenges in caring for a child who required care in the NICU.

Four coaching sessions (+ an introductory session) will be offered to the parental caregivers in this group, each will be approximately 1 hour. The sessions will follow an Acceptance and Commitment Therapy and mindfulness framework. These sessions will be offered to families throughout their stay in the NICU, but can be completed virtually if necessary. The key worker will provide support to families during NICU admission, as well as during the transition out of hospital up until 12 months corrected age. This support will come in the form of 6 weekly phone calls post-discharge from the NICU, followed by 10 monthly phone calls (months 2-12 post-discharge). Additional resources may be sent to you by e-mail if you provide your e-mail to the key worker. All caregivers in the child's family are encouraged to participate.

Group 2: Standard of Care

If you are randomized to this group, your child will receive the standard treatment as directed by their care team. The standard of care involves routine neonatal follow-up appointments at 6-weeks, 4-months, 12-months and 18-months corrected age.

**What are the study procedures?**

As a participant in this study, researchers will be collecting information about you and your child. This information will be carefully stored in a secure study database. Information will be collected in the following way:

1. Questionnaires

Participants in both groups will be asked to complete questionnaires about yourself and your child. The questionnaires will ask questions relating to your level of stress and depression, your feelings of empowerment, your overall health and wellbeing, your experience with service delivery (i.e., coordination among providers and families), family use relating to your child's medical needs, and your child's overall health and wellbeing. The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

There is a chance that during the study you may be identified as experiencing significant depression or anxiety through your responses to the depression questionnaire. The research staff facilitating the surveys will be trained to identify participants with these concerns and will facilitate a referral to the clinical team or identify local services that will provide support. In the event that a safety concern is identified, you will be asked permission to contact your family doctor or primary care provider and you will be asked to make an appointment. If you do not consent for your family doctor or primary care provider to be contacted we will respect your decision, however clinic staff (i.e. social work) will be notified. In the case of an emergency situation emergency services would be contacted instead.

Each questionnaire has a different timeline for completion. Some questionnaires are completed at all five time-points while others might only be completed once. The approximate additional time commitment at each follow-up date is as follows: baseline (60 minutes), 6-weeks (15 minutes), 4-months (30 minutes), 12-months (60 minutes) and 18-months (10 minutes). These questionnaires can be done in person while at your clinic visit, over the phone or online, depending on the method that is most convenient for you. If you choose to complete the surveys online, you will be asked to provide an email address where the survey links can be sent.

2. Direct Assessment

The study staff will administer one assessment, called the Nursing Child Assessment Satellite Training Parent-Child Interaction Teaching Scale, at your child's 12-month follow-up appointment. This involves you teaching your child something new (you can select from a list of possible activities that you think your child would enjoy and be interested in). This interaction will take approximately 10 minutes, and it will be recorded so that it can be scored at a later date. The recording will be de-identified, and stored in a secure, locked location, separate from the study data.

3. Qualitative Interview

At the end of the study, study participants may be invited to participate in a one-on-one interview in order for us to learn more about your experience with the key worker. This will take approximately 45 minutes to complete. The interview will be conducted on the telephone. Interviews will be audio-recorded and will be transcribed and analyzed by the research team. The transcription will be done by members of the research team. Your name or any other identifying information will not be included during the recording, except your voice. The audio recording will be checked by the interviewer/transcriber to ensure no identifying information is transcribed. All audio recordings will be stored on a password protected computer at the Hospital for Sick Children and the transcribed file will be identified by a study ID number.

4. Health Record

As a participant in this study, researchers will collect information about your child's health, clinic visits, tests, and service use from the Neonatal Intensive Care Units records. At the baseline, 4-month, and 12-month corrected age appointments, clinical data relating to your child's growth, development, and medical needs will be collected.

Your child's health card number (OHIP) will be used to link the information to data held at the Institute for Clinical Evaluative Sciences (ICES) in order to provide a complete picture of your child's use of health services. This data will not contain any information that could directly identify you (i.e. name, address, telephone number) and will be pooled with other study data.

This study will collect information from a clinical assessment that is routinely done as part of neonatal follow-up care. The Bayley Scales of Infant and Toddler Development is a developmental assessment that is done routinely as part of neonatal care at the 18-month follow-up appointment and takes approximately 90 minutes to complete. Scores from this assessment will be collected for our analysis. Authorized study staff will access your child's medical record up until the 18-months corrected age follow-up appointment to collect information from this clinical assessment.

**What are the risks, harms or discomforts of the study?**

We do not expect that you or your child will experience any harm by taking part in this study. Some of the questionnaires ask sensitive questions, which may cause emotional distress. You may choose not to answer these questions. There is an additional time commitment associated with the study procedures. The approximate additional time commitment to complete the assessments at each follow-up appointment is as follows: baseline (60 minutes), 6-weeks (15 minutes), 4-months (30 minutes), 12-months (60 minutes) and 18-months (10 minutes). For participants randomized to the intervention group, there is an additional time commitment of the coaching sessions with the key worker, and subsequent phone calls.



Orkin J, *et al. BMJ Open* 2021; 11:e046706. doi: 10.1136/bmjopen-2020-046706

There is a potential for a breach of privacy, however we will take steps to minimize that risk by storing all of the research data in a password-protected database and by storing personally identifying information in a separate place from the study data. There is a potential risk of loss of your confidentiality for the interviews because even though your name will not be part of the audio recording, your voice may still be identifiable as your voice. All audio recordings will be destroyed after transcription and the transcribed file will not contain your name or any identifying information.

Participants in Group 1 (the intervention arm) may have their Acceptance and Commitment Therapy sessions recorded for quality improvement purposes. These recordings will be assessed by a study team member to assess the facilitator's competence in delivering the intervention. These recordings will not be transcribed and participants will not be assessed/analyzed.

**Are there benefits from being in the study?**

If you agree to take part in this study, the experimental intervention may or may not be of direct benefit to you. This study incorporates a parental coaching and care coordination intervention, which aims to provide families with knowledge, and support them in the role of navigating the healthcare system and in the care of their child. The benefits associated with this may include improved parental stress and well-being, improved family empowerment, improved infant attachment, better coordination of care, more efficient health care utilization, improved service delivery and timely referrals to appropriate health services.

The study may lead to an improved parental support model, which hopes to change the focus of neonatal follow up across Canada to one that involves ongoing parental support and takes into account factors that are important for families as well as those related to the health of the child. The care coordination may be associated with a more efficient use of healthcare resources and lead to cost-savings for families and the healthcare system.

**What other choices are there?**

You do not have to take part in this study in order to receive treatment or care. If you choose not take part in this study, your child will receive standard treatment as directed by his/her doctor.

**What are the optional parts to this study?**

Future researchers at the Women and Children's Health Research Institute (WCHRI) at the University of Alberta may want to use data from this study for new research. You have the option of allowing your study data to be re-used by approved researchers. Any of your personal information (i.e. your name, address, telephone number) that can identify you will be removed before files are shared with other researchers. Researchers that wish to use study data must 1) have their new study approved by an ethics board, and 2) sign an agreement ensuring your confidentiality and restricting data use to only the approved study.

I agree to the secondary use of my data to answer future related research questions (optional):

| | |
|---|---|
| I agree for my study data to facilitate future related research. I understand that my study data may be made available to other researchers, but my identity will be protected, and my confidentiality will be preserved. | _____ Initials |

I do NOT agree for my study data to facilitate future related research. I do NOT want my study data to be made available to other researchers. _____ Initials

**Can I choose to leave the study?**

It is your choice to take part in this study, participation is voluntary. You can change your mind at any time during the research study. The study team may ask why you are withdrawing for reporting purposes, but you do not need to give a reason to withdraw from the study if you do not want to. Withdrawal from the study will not have any effect on the care you or your child will receive at SickKids. If you decide to leave the study, you can contact the Principal Investigator or a member of the study team to let them know. If you choose to leave this study you can decide whether all your data that has been collected is kept and used for the research or deleted.

**Will I be paid and/or reimbursed if I join this study?**

As a token of our appreciation, you will receive a $10 gift card to either Tim Hortons, Starbucks or Walmart upon completion of the questionnaires at each appointment, with an additional $10 at 12 months, the NCAST visit, and the qualitative interview. In total, you may receive eight $10 gift cards over the course of the 18-month study. Gift cards will be provided to participants in both study groups.

**How will my privacy be protected?**

We will respect your privacy. No information about you or your child will be given to anyone outside of the study team or be published without your permission, unless required by law.

The SickKids study staff (study investigators, coordinators, and nurses) will collect personal health information about you and your child. This includes things learned from the study procedures described in this consent form and/or information from your child's medical records. They will only collect the information they need for the study. The study will collect personal information that could identify you or your child, such as child's full date of birth, expected date of delivery, discharge date, your name, telephone number, address, and email address.

All personal health information or personal information collected about you will be "de-identified" by replacing your identifiable information (i.e., name) with a "study number". The SickKids study staff are in control of the study code key, which is needed to connect your personal health information/personal information to you. The link between the study number and your identity will be safeguarded and only accessible to the study staff at SickKids. SickKids guidelines include the following:

- All information that identifies you, both paper copy and electronic information, will be kept confidential and stored and locked in a secure place that only the study staff will be able to access.
- Electronic files will be stored securely on hospital or institutional networks or securely on any portable electronic devices.
- No information identifying you will be allowed off site in any form without your consent. Examples include your hospital or clinic charts, copies of any part of your charts, or notes made from your charts.

The following people may come to the hospital to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Representatives of the SickKids Research Ethics Board and/or Research Quality and Risk Management team.

This study is part of a Canada wide, collaborative research network called CHILD-BRIGHT, involving investigators and collaborators from many Canadian healthcare institutions. Representatives at the CHILD-BRIGHT Data Coordinating Centre (DCC) at the Women & Children's Health Research Institute (WCHRI) will have access to your de-identified study data in order to perform system management functions and data analysis. If you wish to complete the study questionnaires online, your email address will be entered into WCHRI's REDCap system so that automated questionnaire reminders can be sent to you. Your email address will be only used for the purpose of facilitating questionnaire completion. WCHRI's REDCap installation is housed in a secure data centre at the University of Alberta Hospital that is behind the Faculty's firewall. Data will remain on REDCap until all data management and statistical analysis activity has been completed. We anticipate this will be within one year of the last participant's last study related contact with the research team.

The video-recording of the parent-child interaction assessment will be kept separate from the study data and stored in a secure, locked location. The videotapes will be viewed and scored by an individual who is trained in NCAST interpretation. You and your child's faces will be seen by the person assessing the video but they will NOT receive any personal identifying information about you. All study data including the video-recordings will be kept for 10 years as per CIHR guidelines. A health custodian will be consulted to ensure that this information is properly destroyed.

The audio-recording from the telephone interview will be stored on a password protected computer at the Hospital for Sick Children. All audio recordings will be destroyed after transcription and the transcribed file will not contain your name or any identifying information.

For intervention participants who consent, the audio recordings of the Acceptance and Commitment Therapy sessions will be uploaded to the SickKids Research Institute Secure File Transfer Portal and deleted off the recording device right after. After the facilitator's competence is assessed, the recordings will be deleted off the file transfer portal. These recordings will not be transcribed and participants will not be assessed/analyzed.

The study staff will keep any personal health information about you in a secure and confidential location for 7 years and then destroy it according to SickKids policy.

When the results of this study are published, your identity will not be disclosed. You have the right to be informed of the results of this study once the entire study is complete.

Because of the importance of being able to track your child's care across institutions, your child's OHIP number will be encrypted before it is linked to ICES to track your child's use of health services. The encryption process ensures that your child cannot be identified. ICES is a prescribed entity under the Personal Health Information Protection Act (PHIPA) and follows policies and procedures for privacy protection and data security as approved by Ontario's Privacy Commissioner.

**Will information about this study be available online?**

A description of this clinical trial will be available on the CHILD-BRIGHT website (https://child-bright.ca/ccent). This website will not include information that can identify you. You can search this website at any time.

**What are my rights when participating in a research study?**

You have the right to receive all information that could help you make a decision about participating in this study. You also have the right to ask questions about this study at any time and to have them answered to your satisfaction. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form, you do not give up any of your legal rights against the study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

**Will I receive study results?**

Research results will be shared through journal publications and academic conferences. When the results of this study are shared, your identity will not be disclosed. You have the right to be informed of the results of this study once the entire study is complete.

You have the right to be informed of the results of this study once the entire study is complete.
If you would like to be informed of the results of this study, please contact the study doctor. In addition, the results of this study will be available on the clinical trial registry (https://clinicaltrials.gov/, NCT0335024).

**Who can I call if I have questions about the study?**

If you have any questions during your participation in this research study you can contact the Study Doctor, Dr. Julia Orkin at 416-813-7654 x201150 or the research team members listed at the beginning of this consent form.

**Research Ethics Board Contact Information**

The study protocol and consent form have been reviewed by the SickKids Research Ethics Board (REB). If you have any questions regarding your rights as a research participant, you may contact the Office of the Research Ethics Board at 416-813-8279 during business hours.

# Consent to Participate in a Research Study

**Study Title:** Coached, Coordinated, Enhanced Neonatal Transition (CCENT): A multi-centre pragmatic randomized controlled trial

**By signing this research consent form, I understand and confirm that:**

1) All of my questions have been answered.
2) I understand the information within this informed consent form.
3) I allow access to my/my child's medical records and as explained in this consent form.
4) I do not give up any of my or my child's legal rights by signing this consent form.
5) I have been told I will be given a signed and dated copy of this consent form.
6) I agree to allow the person for whom I am responsible to take part in this study.

I consent on behalf of _____ (name of child) to participate in this study.

| _____ | _____ | _____ |
|---|---|---|
| Printed Name of Parent/Guardian | Parent/Guardian Signature | Date (DD/MMM/YYYY) |
| _____ | _____ | _____ |
| Printed Name & Role of person who the Consent Discussion | Signature of person who obtained the consent | Date (DD/MMM/YYYY) |

Optional:
□ I would like to hear the results of the study when they are available.
Please email me at: _____

**For Intervention Participants Only:**
The Acceptance and Commitment Therapy sessions may be audio recorded for quality improvement purposes to ensure competence of the facilitator. All recordings are confidential and will be stored on password protected computers until they are reviewed by a study team member subsequently destroyed. The audio recordings will not be analyzed as research data that will be reported elsewhere.

| | | |
|---|---|---|
| I consent to have the Acceptance and Commitment Therapy sessions audio recorded for quality improvement purposes | Parent/Guardian Initial: _____ | Parent/Guardian Initial: _____ |