



Information statement and consent form

Participant Information Sheet/Consent Form Interventional Study – *Dance Teacher consent form*

Title	Dance PaRticipation for Extremely prEterm children with Motor Impairment at prEschool age: a feasibility study
Short Title	Dance PREEMIE- feasibility study
Protocol Number	
Project Sponsor	The University of Melbourne
Coordinating Principal Investigator	A/Professor Alicia Spittle
Associate Investigator(s)	Kate Cameron, A/Professor Jeanie Cheong, A/Professor Jennifer McGinley, Dr Kim Allison
Location	Murdoch Children's Research Institute



Part 1 What does my participation involve?

1 Introduction

This is an invitation for you to take part in this research project, as you have expressed interest in the Dance PREEMIE study. Dance PREEMIE is a feasibility study trying to find out if preschool age children, who were born early or low birthweight and have difficulty with their motor skills, can be successfully involved in community dance classes.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the commitment and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the training session and follow-up interview that are described
- Consent to a member of the research team observing one or more of your dance classes.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Children born at less than 28 weeks gestational age or less than 1000g are at risk of movement difficulties as they reach preschool and primary school age. Movement difficulties can include things like poor balance, difficulty with activities such as throwing and catching or difficulty with day-to-day tasks such as getting dressed. The Dance PREEMIE study aims to help children with their movement skills while they are still at preschool age, prior to starting school. Children will be given the opportunity to attend a dance class in their local area, with a dance teacher that has been provided with extra training. We want to know if the Dance PREEMIE intervention is feasible for premature children and their families. Specifically, we want to know if parents felt that their children could attend the classes and found them to be enjoyable. If the Dance PREEMIE intervention is successful, we hope to offer it to more preterm children and their families.

The results of this research will be used by Kate Cameron to obtain a PhD.

Investigator Kate Cameron is supported by an Australian Government Research Training Program Scholarship to coordinate the study.

3 What does participation in this research involve?

After you expressed interest in the study, a member of the research team will have contacted you to provide an overview of the study and time commitment required. You been given this detailed participant information sheet and consent form and given time to read through the information.

Once you have consented to be involved in the project, a participating child will be offered to attend your dance class. If you and the child's family agree on this arrangement, you will be asked to participate in the following:

Training session

You will be asked to attend a training session at Murdoch Children's Research Institute. This session will take place during the school holidays (either before Term 4 2019 or before Term 1 of 2020). The training session will focus on topics such as strategies for teaching children with motor difficulties, and opportunities will be provided for you to share your experiences with other dance teachers. The session will be taken by a qualified physiotherapist, and you will be provided with an information package to take home. You will be asked to fill out a brief questionnaire at the beginning and at the end of the information session.

Enrolling the participating child into your dance class

Once a child has been matched to your dance class, we ask that you enrol them as you would any other child. It is the responsibility of you and your dance school to obtain relevant information, such as emergency contacts and relevant medical conditions, from the family. To maintain confidentiality, we require that you do not discuss the participating child's involvement in the Dance PREEMIE study or any of the child's personal details gained through your dance school's enrolment process, except with the owner of the dance school (if this is not you), members of the research team or the child's family.

Teaching your preschool class

Once the participating child has started their dance class, you will be asked to incorporate the strategies discussed in the training session into your dance class to the best of your ability. These strategies should not affect the style of dance, or the syllabus that you teach. More detailed information on this topic will be provided during the training session. We do not require that you prioritise the participating child in any way while teaching your class. The participating child will be enrolled for at least 8 weeks. If the term is longer than 8 weeks, the child can attend for the remainder of the term. Before and after this 8-week period, the child will have an assessment of their motor skills. We ask that you keep track of class attendance for the participating child and inform the research team of how many classes the child attended. During the 8-week period, a member of the research team will come and observe your dance class twice. The purpose of this is to gather information on the differences between the dance classes involved in the study, and how you implement teaching strategies during your class.

Telephone Interview

At the end of the term, we will ask you participate in a brief telephone interview (maximum 30 minutes) to discuss what you thought about the trial. This conversation will be recorded. We are interested to hear about the dance teacher's perspective; what was easy, what was hard, what worked well etc. You will also be asked to complete a final online questionnaire (ten minutes).

What to expect from participating children

Children involved in this study will have been deemed safe to participate in moderate to high intensity physical activity before they enrol in your dance class. More details on what to expect from participating children will be covered in the training session. If you wish to discuss this further before consenting, please contact Kate Cameron at k.cameron@student.unimelb.edu.au

Participating children:

- May be smaller than other children their own age
- May become tired or fatigued faster than other children
- May take longer to learn a new movement compared to other children
- May have difficulty following instructions as quickly as other children

Costs and reimbursement

On the day of the training session, you will be provided with free parking, and the session will be fully catered. Travel costs to and from the education session will not be reimbursed.

The fees of the child to attend the dance school will be paid for by the study directly to the dance school, as for any other student. The dance teacher will not receive any additional financial reimbursement for including a participating child in their class.

4 What do I have to do?

During this study you will be asked to:

- Attend a full-day training session at the Murdoch Children's Research Institute
- Enrol a participating child in your dance class for a minimum of 8 weeks
- Maintain the confidentiality of the child enrolled in your class
- Use the strategies discussed in the training session to the best of your ability
- Consent to a member of the research team observing two of your dance classes
- Participate in a follow-up phone call at the end of the term
- Provide the research team with the attendance record of the participating child

5 Other relevant information about the research project

We plan to recruit 10 preschool aged children and up to 10 dance teachers. If this study is successful, we hope to do another research project involving more children and dance schools.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the Murdoch Children's Research Institute or the research team.

7 What are the alternatives to participation?

You do not have to take part in this research project.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research, however possible benefits may include;

- The enrolment of a new student in your preschool dance class (children who enjoy the class are encouraged to stay)
- A free training session on teaching movement to children that is up-to-date and based on the latest evidence. This session will be run by a qualified physiotherapist. In addition, you will receive a certificate of participation for your involvement in Dance PREEMIE.

9 What are the possible risks and disadvantages of taking part?

We do not anticipate any risks from participation in this study. Attending the training session at MCRI may impose an inconvenience.

10 What will happen to the information you collect about me and my dance class?

We will store all information in securely locked filing cabinets and password protected computers. We will not disclose personal information to anyone outside the study team without your permission (with the exception of the Royal Children's Hospital Ethics Committee or if required by law).

11 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw, as we will have to find a replacement dance class for the participating child. If you do decide to withdraw from the research project, we will ask you to participate in a follow-up phone call to discuss the study. However, this is optional. If you decide to withdraw fully from the project, the researchers will keep any information gathered as part of the study.

12 What happens when the research project ends?

The Dance PREEMIE intervention ends after the participating child has completed 8 dance classes and you have attended the follow-up telephone interview. After the project is finished, the participating child may choose to continue with the dance class, if that is what you (dance teacher) and the participating child's family wish. When the project is completed a summary of the findings will be sent to you.

Part 2 How is the research project being conducted?

13 What will happen to information about me?

By signing the consent form you consent to the relevant research project staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential except as required by law and will only be used for the purpose of this research project. Only the researchers involved with this project and the Royal Children's Hospital ethics committee can have access to this information. We can disclose the information only with your permission except as required by law.

It is anticipated that the results of this research project will be published and or presented in a variety of forums. In any publication and/or presentation, we will report information about the whole group of participants and information will be provided in such a way that you cannot be identified, except with your permission.

The information will be re-identifiable. This means that we will remove your names and give the information a special code number. Only the research team can match your names to your code numbers, if it is necessary to do so.

All information will be stored securely in locked filing cabinets at the Murdoch Children's Research Institute and once all analyses have been performed, the data will be securely archived. Electronic information will also be stored on a password-protected computer database at the Murdoch Children's Research Institute for 7 years after the youngest child in the study turns 18, after which time it may be destroyed. Only the project researchers will have access to the data.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information.

15 Complaints and compensation

The A/Prof Alicia Spittle Chief Investigator will be available throughout the study if you have any questions, and is happy to take concerns at any time. Her contact details are: (03) 9035 5340 This project has been approved by the ethics department at the Royal Children's Hospital. You can contact the Director of Research Ethics & Governance at The Royal Children's Hospital Melbourne if you:

- have any concerns or complaints about the project
- are worried about your rights as a research participant
- would like to speak to someone independent of the project.

The Director can be contacted by telephone on (03) 9345 5044.

In the very unlikely even that you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate treatment. If you're eligible for Medicare, you can receive any medical

treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

16 Who is organising and funding the research?

This research project is being conducted by the Victorian Infant Collaborative Study, and will be supported by an Australian Government Research Training Project Scholarship.

17 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the Royal Children's Hospital.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

18 Further information and who to contact

If you want any further information concerning this project, or if you have any problems which may relate to your involvement in the project, please contact A/Prof Alicia Spittle Chief Investigator on (03) 9035 5340.

Consent Form - *Adult providing own consent*

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Short Title	Dance PREEMIE- feasibility study
Protocol Number	
Project Sponsor	The University of Melbourne
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Location	Murdoch Children's Research Institute

Consent Agreement

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project.

I understand that I will be given a signed copy of this document to keep.

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____ Signature _____ Date _____
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Declaration by Study coordinator/Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____ Signature _____ Date _____
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† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

Title Dance PaRticipation for Extremely prEterm children with Motor Impairment at prEschool age-feasibility study

Short Title Dance PREEMIE- feasibility study

Protocol Number

Project Sponsor The University of Melbourne

Coordinating Principal Investigator A/Professor Alicia Spittle

Associate Investigator(s) Kate Cameron, A/Professor Jeanie Cheong, A/Professor Jennifer McGinley, Dr Kim Allison

Location Murdoch Children's Research Institute

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Murdoch Children's Research Institute.

Name of Participant (please print) _____
Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

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Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____
Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.