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PARTICIPANT INFORMATION SHEET AND CONSENT FORM
Parent/Guardian Participant

Study Title	EPIC-CP: a pilot clinical trial of social prescribing for children and young people with cerebral palsy and their parents/caregivers
Chief Investigator	**Professor Susan Woolfenden** Professor of Community Paediatrics, The University of Sydney Adjunct Professor, UNSW Sydney Honorary Staff Specialist, Sydney Children's Hospitals Network **Email:** susan.woolfenden@health.nsw.gov.au **Phone:** 02 9378 1361 or 0429889196
Site Principal Investigator	*[insert site principal investigator name]* *[insert site principal investigator position]* *[insert site principal investigator email]* *[insert site principal investigator phone number]*
Main Study Contact Person	**Dr Katarina Ostojic** Research Fellow, The University of Sydney Adjunct Associate Lecturer, UNSW Sydney **Email:** Katarina.ostojic@sydney.edu.au **Phone:** 0452-539-414

Introduction

This is an invitation for you to take part in a research study titled *"EPIC-CP: a pilot clinical trial of social prescribing for children and young people with cerebral palsy and their parents/caregivers".*

This study is being done at *[insert name of department, name of study site]* in conjunction with *[insert other study sites]*, The University of New South Wales, and The University of Sydney.

This information sheet tells you about the study. It explains the processes involved with taking part in the study. Knowing what is involved will help you decide if you want to take part in the study. 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 do not wish to take part, you do not have to.

What is the purpose of this study?

This study looks at ways to support parents/caregivers of children with cerebral palsy (CP) with the "*social determinants of health*". The social determinants of health are the everyday things in life that all families need to thrive including childcare and schooling; government benefits and vouchers; housing; food; money to pay bills; and transport.

Research from Australia has shown that many parents/caregivers of children with CP want help with these everyday things in life and have trouble finding the right supports and services for their family.

Studies from the United States of America with parents/caregivers of children (children who do not have a diagnosis of CP) have tested different programs to help families with the everyday things in life/their basic needs. These studies have found that providing families with a resource pack containing information about local supports and services can help them address problems they are having with their basic needs. These studies have also found that

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providing families with a resource pack and connecting parents/caregivers with a person called a “Community Linker” can help. The Community Linker provides 1:1 support to help families access supports and services for their basic needs.
These programs have not been done before with parents/caregivers of children with CP in Australia. Together with parents/caregivers of children with CP and their health care professionals, we have designed a resource pack and Community Linker program that aims to be suitable for the unique needs of families of children with CP. We are now testing these two programs (resource pack; resource pack plus Community Linker) in a pilot research study to see if parents/caregivers find them helpful and easy to use. Finding this out is important so we can provide programs to help parents/caregivers get the support they need for their everyday things in life/basic needs and in turn help support their family to thrive.

About 100 parents/caregivers are expected to take part in this pilot research study. This study is funded by research project grant from the Cerebral Palsy Alliance Research Foundation and Sydney Children’s Hospitals Foundation.

Why have I been invited to this study?

You are invited to take part in this study because you are the parent/caregiver of a child/young person with a diagnosis of CP who attends *[insert study site].* You are eligible to take part in this study because you reported wanting help with one or more everyday thing/basic need when completing a survey in the waiting room during your child’s recent appointment at *[insert study site]*.

Do I have to take part in this study?

Participation in any research project is voluntary. You do not have to take part in this study to receive help with your basic needs. If you do not want to take part in this study, or if you are not eligible, you can talk about your concerns with your child’s health care professionals at *[insert study site]* and they can provide you information about supports or services that may be able to help.

If you do not wish to take part, you do not have to. If you decide that you can take part and later change your mind, you are free to withdraw from the project at any stage. Your decision that you can or cannot take part, or that you can take part and then withdraw, will not affect your child’s routine care, relationship with professional staff, or relationship with *[insert study site]*

If you agree to take part, we will ask you to sign a consent form and give you a copy to keep.

What does participation in this study involve?

Sometimes we do not know which program is best for helping people to improve their health. To find out we need to compare different groups. This pilot study aims to test and compare two programs: 1) Resource pack, and 2) Resource pack plus Community Linker. Therefore, 50% of participants in this study will receive Program 1- Resource pack and 50% of participants will receive Program 2- Resource pack plus Community Linker.

If you decide to participate then you will be "randomised" into one of the groups described below. Randomisation 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 your health care professionals can choose what group you will be in. If you decide to take part in the study, you will need to provide consent and complete some short questionnaires. Then you will be told which program you are to get and be provided access to the program.

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Group 1: Resource pack
If you are randomised to Group 1 you will be given a resource pack with information about supports and services that can help you get the support for everyday things in life/basic needs. The resource pack is available in hard-copy and online. We will provide you a hard-copy version and/or link to the online resource pack.

Group 2: Resource pack plus Community Linker
If you are randomised to Group 2 you will be given a resource pack and be connected to a person called a Community Linker.
Resource pack: The resource pack contained information about supports and services that can help you get the support for everyday things in life/basic needs. The resource pack is available in hard-copy and online. We will provide you a hard-copy version and/or link to the online resource pack.
Community Linker: A Community Linker is a project staff member employed by *[insert study site].* The Community Linker will provide 1:1 support to help you connect with supports and services to address your concerns with the everyday things/basic needs. This person can provide practical support to help your family with these needs. For example, help you find the right service for your family, connect with services, complete forms etc. The Community Linker does not provide any therapy services, but they can help you to connect to other services that might help.
After you have enrolled in the study and been randomised to this group, the Community Linker will contact you to schedule a time for an intake appointment where you can discuss what help you need and the best ways to communicate moving forward. They will communicate with you via methods most suitable for you (e.g., face-to-face, telephone, email, or videoconferencing). The Community Linker will be available to support you for up to 3-months or until you do not require further support.

No matter which group you are randomised to, you can still contact your health care professionals at *[insert study site]* and they will refer you to the Social Worker who can provide help.

If I say yes, what is involved?

If you agree to take part, we will ask you to sign the consent form below; OR sign the online consent; OR provide verbal consent over the telephone to research project staff.
Your child can also co-sign the consent form if they wish. We also have an information sheet for young people that explains the research study.

After you provide consent to take part in this research, we will ask you to complete some surveys at three (3) separate time-points: i) Enrolment; ii) 3-months after you enrol in the study; iii) 6-months after you enrol in the study.

- *Enrolment:* Complete a survey about you, your child, your support needs, and what services you are using. This will take about 20 minutes. You can choose to do it online, by paper, over the phone, or in-person. We can provide an interpreter to assist.
- *3-months after you enrol in the study:* Complete a similar survey in 3-months' time. This will ask questions about you, your child, your support needs, what services you are using, and your thoughts about the research group you received. This will take about 30 minutes. We can provide an interpreter to assist.
  If you were randomised to Group 2, we will also invite you to take part in a research interview to tell us about your experiences using the resource pack and working with the Community Linker. We will contact you at another time to discuss this process before the research is complete.

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- *6-months after you enrol in the study:* Complete a similar survey in 6-months' time. This will ask questions about you, your child, your support needs, and what services you are using. This will take about 20 minutes. We can provide an interpreter to assist.

At each time point, we also ask two short questions about your child's overall health. These questions take a few minutes to answer. If your child is aged 8 years or older and can answer these questions (on their own or with support), we invite them to answer these short questions about their overall health. Alternatively, if your child is younger, cannot answer the questions, or does not want to answer the questions, that is okay. You can answer the questions on their behalf.

We will also collect data from about you and your child with CP from your child's medical records at *[insert hospital study site]*. This reduces the number of questions we need to ask you. The data we collect from the hospital includes:

- Information about you and your child such as country of birth, date of birth, gender, language spoken at home, postcode
- Information about your child CP sub-type and their medical condition.
- Information about the types of services you or your child has seen at the hospital and referrals that have been made

Any information we collect that can identify you or your child will remain confidential.

The total time you are involved with this project will be 6 months, but you can choose to withdraw at any time.

Reimbursement

For completing the study surveys at baseline, 3-month follow-up, and 6-month follow-up; you will be reimbursed for your time with a $20 gift voucher for Coles or Woolworth for each time. Therefore, if you complete the study surveys at all three time points, you will be offered a total of $60 in gift vouchers for Coles or Woolworths.

What are the possible risks and disadvantages of taking part?

There is very little risk to you, however if you become upset or distressed because of taking part in this research project, the research team will arrange for counselling or other appropriate help. Any counselling or help will be provided by qualified staff who are not members of the research team. This will be provided free of charge.

What are the possible benefits of taking part?

The assistance you receive from the resource pack and/or Community Linker may support you get the help you need for the everyday things in life/basic needs. This research aims to understand how best to provide support for parents/caregivers experiencing problems with their basic needs (social determinants of health) and to improve how parents/caregivers access supports and services for these needs. However, it may or may not directly benefit you or your child.

What will happen to information about me and my child?

By signing the consent form, you consent to the research team collecting and using personal information about you and your child for the research project. Your privacy and your child's

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privacy and confidentiality will be protected at all times. Their information will only be used for the purpose of this research study, and it will only be disclosed with your permission, except as required by law. For example, researchers are required to report if a participant is believed to be at risk of harm.

In order to protect your privacy and your child's privacy, the study team will remove any information that may be used to identify them from any study documents, and instead of their name appearing on the documents, they will be identified by a specific study code number that applies only to them. Only this code number will be used on any research-related information collected about you/your child for this study, so that their identity as part of the study will be kept completely private.

If you take part in an interview, the audio recordings of the interviews will be erased as soon as they have been transcribed. Field notes will be scanned and stored electronically, and hard copies destroyed after 15 years. Any electronic data will be kept on a password protected computer at the Population Child Health Group at the University of New South Wales. The project manager and principle investigator will have access to the stored and locked data.

Only select researchers involved in this study will have access to your details. All information will be stored on a secure drive at [insert study site] or on secure web application called REDCap. This REDCap system is managed by the University of New South Wales. All information collected during the screening process and study that can identify your child will be treated confidential in accordance with Australian privacy laws. Confidential data will be stored for a period of 15 years from the time of the study is completed. This information will only be accessible to study investigators. After 15 years, computer files will be deleted, and paper files will be shredded.
If you withdraw yourself from the study, we will not collect any more information. We would like to keep the information we have already collected about you/ your child to help us ensure that the results of the research project can be measured properly. Please let us know if you do not want us to do this.

How will the results of the study be distributed?

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, information will be provided in such a way that you cannot be identified, except with your explicit permission.

You can indicate on the consent form if you wish to receive a lay summary of the study findings.

Who should I contact if I have any questions?

If you have any questions or want more information about this study before or during participation, you can contact **Dr. Katarina Ostojic** on **0452-539- 414** or email her at Katarina.ostojic@sydney.edu.au

Who do I contact if I have concerns about the study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been approved by the Sydney Children's Hospitals Network (SCHN) HREC **(approval number: 2022/ETH01688)**. If you have any concerns or complaints about any aspect of the project or the way it is being conducted, you may contact the Executive Officer of the SCHN HREC on (02) 9845 1253 or SCHN-Ethics@health.nsw.gov.au.

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The conduct of this research is at the *[insert site name].* Any person with concerns or complaints about the conduct of this research may also contact the [details of the Research Governance Officer of the health district will be provided following SSA application]

Thank you for taking the time to consider this research.
If you wish to take part in it, please sign the attached consent form.
This participant information sheet is for you to keep. *We will also give you a copy of the signed consent form.*

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CONSENT FORM
Parent/Guardian Participant

Study Title	EPIC-CP: a pilot clinical trial of social prescribing for children and young people with cerebral palsy and their parents/caregivers
Chief Investigator	**Professor Susan Woolfenden** Professor of Community Paediatrics, The University of Sydney Adjunct Associate Professor, UNSW Sydney Honorary Staff Specialist, Sydney Children's Hospitals Network **Email:** susan.woolfenden@health.nsw.gov.au **Phone:** 02 9378 1361 or 0429889196
Site Principal Investigator	*[insert site principal investigator name]* *[insert site principal investigator position]* *[insert site principal investigator email]* *[insert site principal investigator phone number]*
Main Study Contact Person	**Dr Katarina Ostojic** Research Fellow, The University of Sydney Adjunct Associate Lecturer, UNSW Sydney **Email:** Katarina.ostojic@sydney.edu.au **Phone:** 0452-539-414

Declaration by Parent / Guardian

☐ I have read the Parent / Guardian 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 project described in the Parent / Guardian Information Sheet.

☐ 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 them at any time during the project without affecting the future health care of my child.

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

☐ I wish to receive a lay summary of the study findings via email/ post address:

Parent/caregiver

Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____

Your contact details will be used to arrange for you to take part in the study and to tell you about the findings afterwards.

Email address: _____

Best contact number (mobile preferred): _____

Young person: if your child would like to, they can co-sign this consent form

Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____

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Complete the following section only if the participant is unable to read or requires an oral translation:

- The informed consent form was accurately explained to, and apparently understood by, the participant, and
- Informed consent was freely given by the participant

Signature of interpreter	**Please PRINT name**	**Date**
_____	_____	_____