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EPIC-CP pilot trial: a multi-centre, randomised controlled trial investigating the feasibility and acceptability of social prescribing for Australian children with cerebral palsy

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Complete List of Authors:	Ostojic, Katarina; University of New South Wales Medicine & Health, Population Child Health Clinical Research Group Karem, Isra; University of New South Wales Medicine & Health, Population Child Health Clinical Research Group Paget, Simon; Children's Hospital at Westmead; The University of Sydney Faculty of Medicine and Health, The Children's Hospital at Westmead Clinical School Berg, Alison; The Children's Hospital at Westmead Burnett, Heather; John Hunter Children's Hospital Scott, Timothy; Sydney Children's Hospital Randwick Martin, Tanya; University of Sydney Poche Centre for Indigenous Health, Sydney medical School Dee-Price, Betty-Jean; Flinders University, Southgate Institute for Health, Society and Equity Mcintyre, Sarah; The University of Sydney Sydney Medical School, Cerebral Palsy Alliance Research Institute Smithers Sheedy, Hayley; University of New South Wales, Population Child Health Clinical Research Group; The University of Sydney Sydney Medical School, Cerebral Palsy Alliance Research Institute Mimmo, Laurel; The Sydney Children's Hospitals Network Masi, Anne; University of New South Wales School of Clinical Medicine, Discipline of Psychiatry and Mental Health Scarcella, Michele; The Sydney Children's Hospitals Network Azmatullah, Sheikh; University of New South Wales, EPIC-CP Group Calderan, Jack; University of New South Wales, EPIC-CP Group Mohamed, Masyitah; University of New South Wales, EPIC-CP Group Olaso, Anne; University of New South Wales, EPIC-CP Group van Hoek, Matthew and Debbie ; University of New South Wales, EPIC-CP Group Woodbury, Mackenzie; University of New South Wales, EPIC-CP Group Wilkinson, Alunya; University of New South Wales, EPIC-CP Group Chambers, Georgina; University of New South Wales Centre for Big Data Research in Health, National Perinatal Epidemiology and Statistics Unit Zwi, Karen; University of New South Wales Medicine & Health, Population Child Health Clinical Research Group; The Sydney Children's Hospitals Network, Community Child Health Dale, Russell; University of Sydney Sydney Medical School, The Children's Hospital at Westmead Clinical School; Children's Hospital at Westmead

	Eapen, Valsamma; University of New South Wales School of Clinical Medicine, Discipline of Psychiatry and Mental Health Lingam, Raghu; University of New South Wales Medicine & Health, Population Child Health Clinical Research Group Strnadová, Iva ; University of New South Wales, School of Education, Faculty of Arts, Design and Architecture Woolfenden, Susan ; Sydney Local Health District, Community Paediatrics Research Group, Institute for Women, Children and Families; University of New South Wales Medicine & Health, Population Child Health Clinical Research Group
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Title: EPIC-CP pilot trial: a multi-centre, randomised controlled trial investigating the feasibility and acceptability of social prescribing for Australian children with cerebral palsy

Authors:
Katarina Ostojic[1], Isra Karem[1], Simon Paget[2,3], Alison Berg[3], Heather Burnett[4], Timothy Scott[5], Tanya Martin[6], Betty-Jean Dee-Price[7], Sarah McIntyre[8], Hayley Smithers-Sheedy[1,8], Laurel Mimmo[9], Anne Masi[10], Michele Scarcella[9], Sheikh Azmatullah[11], Jack Calderan[11], Masyitah Mohamed[11], Anne Olaso[11], Debbie van Hoek[11], Matthew van Hoek[11], Mackenzie Woodbury[11], Alunya Wilkinson[11], Georgina Chambers[12], Karen Zwi[1,9], Russell C Dale[2,3], Valsamma Eapen[10], Raghu Lingam[1], Iva Strnadová[13], Sue Woolfenden[1,13], & EPIC-CP Group[11]

Affiliations:

1. Population Child Health Clinical Research Group, Faculty of Medicine and Health, University of New South Wales, Sydney, Australia
2. The Children's Hospital at Westmead Clinical School, Faculty of Medicine and Health, University of Sydney, Sydney, Australia
3. The Children's Hospital at Westmead, Sydney, Australia
4. John Hunter Children's Hospital, Newcastle, Australia
5. Sydney Children's Hospital, Sydney, Australia
6. POCHE Centre for Indigenous Health, Faculty of Medicine and Health, University of Sydney, Sydney, Australia
7. Southgate Institute for Health, Society and Equity, Flinders University, South Australia, Australia
8. Cerebral Palsy Alliance Research Institute, Sydney Medical School, The University of Sydney, Sydney, Australia
9. Sydney Children's Hospitals Network, Sydney, Australia
10. Discipline of Psychiatry and Mental Health, School of Clinical Medicine, University of New South Wales, Sydney, NSW, Australia.
11. EPIC-CP Group, University of New South Wales, Sydney, Australia
12. National Perinatal Epidemiology and Statistics Unit, Centre for Big Data Research in Health & School of Clinical Medicine, University of New South Wales, Sydney Australia
13. School of Education, Faculty of Arts, Design and Architecture, University of New South Wales, Sydney, Australia
14. Community Paediatrics Research Group, Institute for Women, Children and Families, Sydney Local Health District, Sydney, New South Wales, Australia

Keywords: cerebral palsy; social determinants of health; paediatrics; social prescribing; health inequities; health services research

Abstract

Introduction: The social determinants of health contribute to poorer health outcomes for children with cerebral palsy and are barriers to families accessing health services. At an individual level, social determinants of health are experienced as unmet social needs, for example unsafe housing conditions. There is emerging evidence that clinical pathways for the systematic identification and referral to services for unmet social needs can support families to address these needs. These clinical pathways have not been implemented for children with cerebral palsy. The objectives are to investigate the feasibility and acceptability of two codesigned social needs clinical pathways for parents/caregivers of children with cerebral palsy- social prescribing (i.e., Community Linker plus resource pack) compared to resource pack only.

Methods and Analysis: This pilot randomised controlled trial will run at the three tertiary Paediatric Rehabilitation Services in New South Wales, Australia. A total of 120 participants will be recruited, with randomisation stratified by study sits. A screening tool will be used to identify families experiencing unmet social needs. Parents/caregivers who report one or more unmet social need and consent will be eligible. The active control group will receive a resource pack containing information on community services to support unmet social needs. The social prescribing intervention group will receive one-on-one Community Linker support, in addition to the resource pack. Feasibility of the research design and the clinical pathways will be evaluated using the number/proportion of parents/caregivers who complete screening, consent, engage with the intervention, and complete research measures. Acceptability will be evaluated using questionnaires and qualitative interviews.

Ethics and Dissemination: Human research ethics approval was granted by the Sydney Children's Hospitals Network Human Research Ethics Committee. Participants and stakeholders will receive updates and findings via regular communication channels including meetings, presentations, and publications.

Registration Details: Australia New Zealand Clinical Trials Registry 12622001459718

Strengths and limitations of this study

- This is the first study to evaluate the feasibility and acceptability of two codesigned clinical pathways for families of children with cerebral palsy experiencing unmet social needs.
- As feasibility is the primary outcome of interest, this study is not powered to investigate efficacy but will inform a potential future efficacy trial.
- Strengths of this study include the formative research to codesign the clinical pathway and research methodology inclusive research practices, partnership with research advisors with a lived experience of cerebral palsy, and mixed-methods approach to investigate feasibility and acceptability.

INTRODUCTION

Cerebral palsy (CP) is a lifelong condition and the most common cause of physical disability in childhood, with an estimated prevalence of 1.5 per 1000 live births in high-income countries[1] including Australia[2]. It is a diagnostic term describing a heterogenous group of permanent but not unchanging disorders of movement and/or posture, caused by a non-progressive lesion or anomaly to the immature brain.[2] Amongst individuals with cerebral palsy, the motor disorder/s (spastic, dyskinetic, ataxic, hypotonic) vary and severity of gross motor impairment can range from having a minimal to severe impact on gross motor function.[2] People living with cerebral palsy may also experience other comorbidities including intellectual disability (32.0%), epilepsy (33.5%), hearing- (12.8%), vision- (36.4%), and speech- (62.7%) impairment.[2] Many people with cerebral palsy need long-term, high-quality support from health and social-care services to enable management of their chronic health condition/s and promote optimal quality of life.[3]

There is evidence of health inequities in children with cerebral palsy.[4,5] In Australia, socioeconomic disadvantage at birth is associated with increased severity of cerebral palsy functional outcomes (more severe gross motor impairment, at least one moderate-severe comorbidity) at age 5 years.[4] Health inequities have their origins in the social determinants of health- the non-medical conditions in which people are born, grow, live, work, and age including food, transport, and housing.[6] There is increasing recognition of the importance of addressing the social determinants of health to improve health outcomes.[7] At a personal level, social determinants of health are experienced as unmet social needs (e.g., housing needs).[7,8]

A recent systematic review explored clinical pathways for the identification and referral of unmet social needs in children attending outpatient community and ambulatory healthcare services.[9] Interventions were described as being implemented in one of three ways: 1) Identification of unmet social needs with clinician training; 2) Identification of unmet social needs with targeted community resources; and 3) Identification of unmet social needs with Navigator/Link Worker support.[9] The review found positive outcomes, with all pathways leading to an increase in social needs identification and referrals, and reduction in social needs.[9] Notably, there was no superior pathway type; though, outcome measures were heterogeneous and not easily comparable.[9]

In the United Kingdom, a formalised scheme for health professionals to identify and refer patients to non-medical community services to target their unmet social needs, using a “Link Worker”, is referred to as “social prescribing”.[10] Individuals living with chronic physical health conditions and multimorbidity have been recognised as a key clinical cohort that may benefit from social prescribing.[11] To date, social prescribing has not been tested for children with disability, including cerebral palsy, in the Australian context.

This pilot clinical trial aims to address this critical research gap. It builds on our previous formative research involving people with a lived experience of cerebral palsy, their families, and health service providers to codesign a social prescribing pathway for children with cerebral palsy and their families in Australia.[12] The objectives of this pilot randomised controlled trial (RCT) are to assess the feasibility and acceptability of two codesigned social needs clinical pathways - social prescribing (i.e., Community Linker plus resource pack) compared to resource pack only- for parents/caregivers of children with cerebral palsy in tertiary Paediatric Rehabilitation clinic settings.

METHODS

Objectives and hypotheses

The primary objectives of this pilot RCT are to evaluate the feasibility and acceptability of implementation and delivery of the codesigned social needs pathways. Secondary objectives include assessment of fidelity and service model variations, to determine the short-term impacts of the intervention at 3- and 6-months post-enrolment, and to inform a future, definitive multicentre large-scale RCT.

We hypothesise that both the social prescribing intervention (Community Linker plus resource pack) and active control intervention (self-navigation using resource pack) will be feasible and acceptable, according to outcome measures described in sections below.

Study design

This is a multi-centre, unblinded, pilot RCT. The unmet social needs of parents/caregivers of children with cerebral palsy will be screened during their clinic appointment. Families who self-report experiencing unmet social on the screening tool and consent to the research study are randomised into arms, either 1) social prescribing intervention arm (Community Linker plus resource pack) or 2) active control arm (self-navigation using resource pack). The rationale for this design is that there is evidence to support both pathways (Community Linker; resource pack), and it is unethical to screen for unmet social needs and not provide a response. The trial design is outlined in Figure 1.

[INSERT FIGURE 1 HERE]

Setting

This study is conducted at the Rehabilitation Departments of the three tertiary paediatric hospitals in New South Wales, Australia: The Children's Hospital at Westmead, Sydney Children's Hospital Randwick, and John Hunter Children's Hospital. The Paediatric Rehabilitation Departments offer a comprehensive cerebral palsy clinical service staffed by a multi-disciplinary team including paediatric rehabilitation medicine physician, nurse, physiotherapist, occupational therapist, and social worker.

Study population

Participants in the RCT must meet the following criteria to be eligible for the study:

Inclusion criteria

1. Parent/caregiver of a child (aged 0-18 years) with a confirmed diagnosis of cerebral palsy who is patient of the Cerebral Palsy Service at one of the following tertiary Paediatric Rehabilitation Departments: Kids Rehab, the Children's Hospital at Westmead; Rehab2Kids, Sydney Children's Hospital; HNEkidsRehab, John Hunter Children's Hospital.
2. Parent/caregiver self-report at least one unmet social need from the following six items on the adapted WECARE screening tool: Childcare or schooling; Government benefits and vouchers; Housing; Food; Bills; Transport.
3. Reside in New South Wales or Australian Capital Territory.
4. Provide informed consent.

Exclusion Criteria

1. Parent/caregiver have no mechanism for contact (telephone or email).
2. Family already enrolled and assigned a research participant ID. In the instance where a parent/caregiver meets inclusion criteria and has multiple children with a diagnosis of cerebral

palsy (e.g., siblings with cerebral palsy or twins with cerebral palsy), the parent/caregiver will only be able to enrol once for their family.

Service provider participants (qualitative interviews/focus groups): Service providers working at the Rehabilitation Departments of the three NSW Children's Hospitals will be invited to take part in qualitative interviews/ focus groups to explore their perspectives of the pilot trial and implementation of social prescribing intervention (Community Linker plus resource pack) and active control intervention (self-navigation using resource pack).

Intervention

Active control (self-navigation with resource pack)

Participants randomised to the active control arm will be provided with a resource pack containing information on community services to support their unmet social needs. The resource pack was codesigned during the earlier formative research phase and piloted during iterative codesign processes.[12] The resource pack will be available in hard-copy and online. The online version of the resource pack will be available on a secure website accessible only to individuals provided the QR code to the webpage or direct weblink. The resource pack is an enhancement to usual care.

Social prescribing intervention arm (Community Linker plus resource pack)

Participants randomised to the social prescribing intervention arm will receive one-on-one Community Linker support, in addition to the resource pack (described above). The Community Linker provides one-on-one support based upon the needs of the family.

A Community Linker is a trained, non-medical staff member who assist parents/caregivers to connect with appropriate services and supports to address their unmet social needs. Community Linkers provide practical, hands-on support navigating services e.g., finding an appropriate local community service, making referrals to services, helping parents/caregivers complete forms, follow-up with services, booking appointments. Each study site will employ a Community Linker to be supervised by the Cerebral Palsy Service Manager and Cerebral Palsy Service Social Worker. Community Linkers will follow a codesigned documented standard operating procedure including specific training modules, which includes escalation procedures should concerns be disclosed that are beyond the scope of their role (e.g., mental health concerns, domestic violence, clinical concerns).

All participants in the intervention arm will have an intake appointment with the Community Linker at their service. Dependent on participant preference, the intake appointment may occur face-to-face at the Rehabilitation Department immediately after randomisation. Alternatively, it may occur via phone, videoconference, or in-person at a different time that suits the participant. All participants will have an intake appointment within one week of randomisation to the social prescribing arm. During the appointment, participants will discuss their unmet social needs with the Community Linker; the current supports and services they are accessing; what they need help with; and their goals for managing their unmet social needs. A personalised care plan will be made together with the parent/caregiver and their child/young person with cerebral palsy (as required). The parent/caregiver will be offered the opportunity to for their child/young person with cerebral palsy to engage with the Community Linker. Parents/caregivers will also elect their preferred mode (e.g., videoconference, phone call, email) and frequency of communication (e.g., once-a-week, once a fortnight) with the Community Linker which can be revised at any time as required. The Community Linker will provide support for a period of 3-months.

The frequency of engagement will depend on participants preferences and needs. However, the Community Linker will conduct minimum monthly check-ins for all participants.

Sample size

The pilot trial will aim to obtain a minimum of 35 respondents in each trial arm at 3- and 6- month follow-up. Assuming a 30% loss to follow-up in line with previous research[13,14], a total sample size of 120 families will be recruited - 60 in each research arm.[15] Per Teare et al (2014) a total sample size of 120 parents/caregivers makes it possible to assess feasibility as the relevant primary outcome.[15] Randomization will be stratified by Rehabilitation Department/study site. Thus, at each study site, 20 parents/caregivers will be randomised to each research arm.

Within the prior formative research to codesign the interventions, quality improvement cycles were conducted at one study site piloting the screening tool and pathways.[12] During the 12-week testing period, 105 parents/caregivers of children with cerebral palsy completed the unmet social needs screening form. Based on this experience, we estimate a recruitment period of 3-months to enrol all participants in the study across three sites. The data from this pilot RCT will form sample size calculations for a potential future RCT of efficacy.

Qualitative data sample size: As this is inductive rather than deductive research a sample size calculation cannot be done. However, using purposeful sampling, the saturation point will most likely be reached after 10-20 interviews with parents/caregivers. We estimate that 5-10 service providers will take part in an interview/focus group per site, thus 15-30 service provider participants in total.

Screening and recruitment strategy

Parent/caregiver participants: All parents/caregivers of a child with cerebral palsy attending the participating Rehabilitation Departments will be asked to complete a paper-based unmet social needs screening form during their routine clinic visit (Supplementary File 1). The screening form includes information about the research study where parents/caregivers can indicate their interest (yes/no) in hearing more and provide contact details if applicable. All screening forms will be distributed and collected by the site Community Linker. Contact details of interested parents/caregivers will be provided to project staff responsible for enrolment.

If parents/caregivers screen positive on the tool (self-report one or more unmet social needs) but are not interested in knowing more about the study, they will be advised to discuss their concerns with their clinical team per routine care. If interested parents/caregivers are not eligible for the project, they will be told that they are ineligible for the research project and will be advised to discuss any concerns with their clinical team per routine care. If interested parents/caregivers are eligible for the project, they will be provided a participant information sheet and consent form (PISCF). The PISCF may be provided immediately during the family's attendance of the clinical appointment in paper form or sent via email, dependent of the family's preference and availability on the day.

Service provider participants: Service providers will be identified through department meetings and professional networking within the participating study sites. Interested service providers will be given a Service Provider PISCF either in hardcopy version or via recruitment email. They will be given time to think about the project and have the opportunity to ask any questions they may have about their participation in the study to the study coordinator.

Consent

Parent/Caregiver and young person participants: Parent/caregiver and young person PISCFs will provide information about the research, the risks/benefits, and its voluntary nature. The parent/caregiver PISCF will be provided to all interested parents/caregivers. Additionally, young people aged 8 years or older who can self-report (determined via parent/caregiver and young person report) will be provided a young person PISCF. If the young person has capacity to provide consent, they will be requested to co-consent along with their parent/caregiver in whatever form of communication suits their preference and needs (e.g., in writing, verbal consent, using augmented and alternative communication methods). The approved PISCF's will be translated into other languages based on data pertaining to limited English language proficiency and largest language groups attending the tertiary Paediatric Rehabilitation Departments.

It will be made clear to participants that they can stop participating in the study at any time without consequences to the care or services they receive. If the participant expresses that they are not interested in the study, no further contact will be made in relation to the study. Parents/caregivers will also be free to withdraw their consent if they change their minds at any point during the study. Participants can provide informed consent in several ways: signing the hardcopy of the PISCF at a face-to-face visit; signing the online REDCap consent form to be included in recruitment email[16]; providing verbal consent via phone call. Participants will be asked to complete a baseline questionnaire immediately after providing consent.

Service provider participants: the service provider PISCF will be distributed as paper-based copy or via recruitment email. The recruitment email will include a link directing potential service provider participants to the online version of the PISCF via the Redcap® data link. Service providers will be required to either sign the hard copy consent form and return to study coordinator or sign the online consent form hosted on RedCap.

Randomisation and intervention allocation

Participants will be randomised automatically by the REDCap platform[16], assigning 50% of participants to each group. Randomisation will be conducted by project staff. Randomisation will be stratified by Rehabilitation Department/study site. Across the entire project, 60 parents/caregivers will be randomised to the social prescribing intervention arm (n= 20 at each study site) and 60 parents/caregivers will be randomised to the active control arm (n=20 at each site). The project staff will notify participants of their intervention allocation via one of three methods (face-to-face; email; phone) dependent on their personal preference and corresponding to chosen method of consent as described above.

Outcome measures

Table 1 offers a summary of the outcome measures.

Pilot outcomes- feasibility and acceptability

Feasibility will be evaluated against the stop-go criteria for success of feasibility, as follows:

1. Recruitment rates: Recruitment will be successful if 80% of our target sample is met in the 3 months of recruitment.
2. Uptake of intervention: Will be considered successful if > 70% of families complete the intervention.
3. Follow-up of participants: Will be considered successful if > 70% of families complete all the study visits.

We will also evaluate feasibility and acceptability via:

- Process measures: non-identifiable data will be recorded on the proportion of families who: complete vs. decline the unmet social needs screening form; positive vs. negative unmet social needs screening; are interested vs. not interested in research participation consent vs. do not consent to research study.
- Community Linker logbook: each Community Linker will keep a logbook of their activities including type of social care navigation activities provided, e.g., advice regarding services, attending services with families, types of pf services, referrals made to services collected etc.
- Satisfaction and acceptability survey: At 3-month post-enrolment, all participants (social prescribing intervention; active control) will be asked to complete a bespoke questionnaire regarding their satisfaction and acceptability of their allocated intervention.
- Parent/caregiver qualitative interview: At 3-month post-enrolment, participants in the social prescribing group will be invited to complete a qualitative interview to explore their experiences, barriers, and enablers to social prescribing as perceived by parents/caregivers. The interviews will be conducted 1:1 with the project coordinator and will follow a semi-structured interview guide. Interviews will be conducted face-to-face, phone, or teleconference dependent on participants preference.
- Clinician qualitative interview/focus group: clinicians from participating study sites will be invited to take part in interview/focus group exploring the experiences, barriers, and enablers of social prescribing intervention and active control intervention as perceived by clinicians (conducted during trial implementation based on availability and preference of staff at sites).

Secondary outcomes- proposed impacts for future RCT

Secondary outcomes aim to determine short-term impacts of the intervention at 3- and 6- months post-enrolment. This will help inform sample size and outcome measures to be used in future, definitive multi-centre large-scale RCT. Per Table 1, outcomes will be assessed at baseline, 3-month follow-up, and 6-month follow-up including: unmet social needs (adapted WECARE tool)[17], parent/caregiver distress (K-6 Distress Scale – Self Administered)[18], Child/young person global health (PROMIS Parent Proxy Scale v1.0 - Global Health 7 (item 1; item 2)[19] or PROMIS Pediatric Scale v1.0 – Global Health 7 (item 1; item 2))[19], and Parent/caregiver global health (PROMIS Scale v1.2 - Global Health (item 1; item 2))[20], and service use captured on bespoke survey.

Furthermore, at baseline parent/caregivers will be asked to complete a demographic survey. A medical record review of children with CP will be completed for all participants to describe the characteristics of participating children/families and explore any potential association between outcome measures and clinical factors relating to the child with cerebral palsy and demographic factors related to the parent/caregiver.

Table 1. Summary of study outcome measures		
Outcome	**Methods and measures**	**Time**
Primary outcomes		
Feasibility of a social prescribing intervention (resource pack plus in-person Community Linker) and active control intervention (self-navigation with resource pack)	• Number/proportion of completed screens for identification of unmet social needs (screening) • Number/proportion of families interested in research study (screening) • Number/proportion of eligible clients who consent to participation in research project (baseline) • Number/proportion of social prescribing group participants to engage with in-person Community Linker (3-month follow-up) • Number/proportion of participants who complete 3-, and 6-month follow-up assessments (3-month follow-up; 6-month follow-up)	Ongoing throughout implementation
Acceptability and satisfaction with social prescribing intervention (resource pack plus in-person Community Linker) and active control intervention (self-navigation with resource pack)	Parent/caregiver satisfaction and acceptability collected via bespoke questionnaire.	3-month follow-up
Acceptability and experiences of social prescribing intervention (resource pack plus in-person Community Linker)	• Qualitative interviews with parent/caregiver on experiences, barriers, and enablers to social prescribing intervention. • Qualitative focus groups with health service providers at participating Paediatric Rehabilitation study sites on experience, Barrie's, and enablers to social prescribing intervention.	Parents/caregivers:3-month follow-up. Clinicians: conducted during trial implementation based on availability and preference of staff at sites)
Intervention fidelity- social prescribing intervention (resource pack plus in-person Community Linker)	Type of social prescribing activities provided, e.g., advice regarding services, attending services with families, types of referrals made to services collected using Community Linker logbook	Ongoing throughout implementation
Secondary outcomes		
Unmet social needs	Parent/caregiver self-report via an adapted version WECARE tool[17]	Screening, 3-month follow-up, 6-month follow-up

Parent/caregiver distress	Parent/caregiver self-report via K-6 Distress Scale – Self Administered[18]	Screening, 3-month follow-up, 6-month follow-up
Child/young person global health	Parent/caregiver proxy-report, to be used when the child is <8 years of age or when if the child/young person is unable to self-report, via PROMIS Parent Proxy Scale v1.0 - Global Health 7 (item 1; item 2) Or Child/young person self-report, to be used if the child/young person is ≥ 8 years of age and can self-report, via PROMIS Pediatric Scale v1.0 – Global Health 7 (item 1; item 2)[19]	Screening, 3-month follow-up, 6-month follow-up
Parent/caregiver global health	Parent/caregiver self-report via PROMIS Scale v1.2 - Global Health (item 1; item 2)[20]	Screening, 3-month follow-up, 6-month follow-up
Service use	Types of services parents/caregiver's report using for unmet social needs via bespoke survey	3-month follow-up

Data collection

All participants will be allocated a unique identifier code that will be used throughout the study. For enrolment and quantitative data collection, the study will prioritise electronic collection procedures. However, participants will be given the option to complete research questionnaires face-to-face, online via REDCap[16], or on the phone with the research staff. All quantitative data, irrespective of initial mode of data collection, will then be entered into a secure password-protected server-based database, REDCap.[16] Any hard copies of consent forms and de-identified questionnaires will be stored in a locked cabinet at each study site before being securely transferred to the study team at UNSW. When being stored at the study sites, hardcopy materials will be stored in a locked filing cabinet within a locked office, accessible only to the site project staff.

Qualitative interviews with families and qualitative focus groups with health service providers will be conducted face-to-face, via phone call, or videoconference dependent on participants preference. Interviews and focus groups will be transcribed verbatim, and all data management, storage, and analysis will be done at UNSW. All paper copy and taped data will be de-identified. Coded information will be stored in a locked filing cabinet, or on password protected digital media. As soon as interviews have been transcribed the audio tapes will be erased.

All paper data and questionnaires will be entered into a secure password-protected server-based database, REDCap hosted at UNSW, and stored for 15 years after the last date of data collection.[16] After 15 years, any paper data will be shredded, and the electronic data will be permanently erased, and backups destroyed.

Data analysis

Quantitative data analysis

Participant characteristics will be reported using descriptive statistics. The analysis will be according to randomised treatment allocation. The analysis of primary outcomes - feasibility and acceptability - will be based on descriptive statistics reported as percentage (95% confidence interval). Analysis of secondary outcomes will be purely exploratory and not powered to detect efficacy, thus we will not perform tests of significance. Secondary outcome measures will be described by intervention allocation using the t-test and non-parametric tests for continuous data and the chi-squared test for categorical data. If suitable, linear and logistic regression modelling will be conducted to test group differences adjusting for basic baseline (where the model allows), for example, gender, and other sociodemographic characteristics.

Qualitative data collection and analysis

Data collected from the semi-structured interviews and semi-structured focus groups will be coded according to common themes using a thematic analysis.[21] Researcher triangulation will be employed to further substantiate the emerging themes. Data collection and analysis will continue until no new themes or hypotheses emerge, that is a “saturation point” is reached. Initially all coding of the interviews and development of themes will be done by hand. This provides the opportunity to redefine and/or merge themes as analysis proceeds. When no new themes are emerging, data will be managed with the assistance of the qualitative software NVivo 11 software by the principal investigator. Transcription checks against tapes and notes taken, triangulation, feedback, will be employed to ensure rigour (e.g., all interviewees will receive a copy of their interview transcript to check). Comments after reading these will be fed back into the analysis.

Patient and public involvement

The social needs clinical pathways being evaluated in this pilot RCT were codesigned with people with a lived experience of CP, their families, and health care professionals in earlier formative research. [12] This study is overseen by two research advisory groups - one group of young adults with CP and one group of parents of a young person with CP. Research advisors meet with the project officer monthly and provide input into each phase of the study, i.e., project conception and planning, data collection and analysis, dissemination. They have been involved with the project since commencement of earlier formative research to codesign the program and will continue to work together for this pilot RCT.[12] Research advisors are paid $30 (AUD) per hour.

This project has a governance structure including several sub-committees: research operations committee, research advisory group, steering committee, and knowledge translation committee. Each committee meets consistently with the chief investigator and project officer to facilitate information exchange and cooperation between stakeholders.

For completing the study questionnaires at baseline, 3-month follow-up, and 6-month follow-up; parent/caregiver research participants will be reimbursed for their time with a $20 gift voucher for each data collection time-point.

Ethics and considerations

Ethics approval for this project was granted by the Sydney Children's Hospitals Network (SCHN) Human Research Ethics Committee (2022/ETH01688) in October 2022. Site-specific research governance approvals were granted for SCHN and John Hunter Children's Hospitals. This trial has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12622001459718)

Where a reportable clinical incident is identified through or during the data collections an incident report will be lodged in the Incident Investigation and Management System as per the NSW Health Clinical Incident Policy. During the research project, we may identify families where there is domestic violence, financial abuse, or imminent risk of homelessness. In this event, families will be referred directly to CP Service Social Worker. Referral to the CP Service Social Worker does not exclude the parent/caregiver from participation in the research project. They will receive support from the site CP Service Social Worker in addition to their allocated intervention. If child protection concerns are raised usual mandatory reporting guidelines will apply.

Participants are free to withdraw their consent at any time. Reasons for non-participation will be recorded, and the decision not to participate or to withdraw from the study will not affect the participant's relationship with study hospitals. In such case, the researchers will not collect additional information from the participant.

Dissemination and policy implications

Research findings will be shared with people living with CP, parents/caregivers and family members of people with CP, health professionals, social service professionals, policy makers, and academics via various outputs including a lay summary of research findings, a poster summarising research results displayed at study sites, peer-reviewed publications, conference presentations. These outputs will be developed in collaboration with all project members, including research advisors, to ensure the material is suitable and accessible to the relevant audience.

Authors contributions: KO, IK, and SW led the design of the study with input and guidance from SP, TM, BJDP, SM, HSS, LM, HB, TS, AB, AM, MS, JC, SA, MM, MW, AW, KZ, RD, VE, RL, IS, and EPIC-CP Group. KO, IK, and SW produced the draft manuscript and SP, HSS, RD, BJDP, SM, IS, RL, LM, AM, KZ, and VE contributed to the manuscript. All authors read and approved the final manuscript.

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Figure caption:

Figure 1: study diagram

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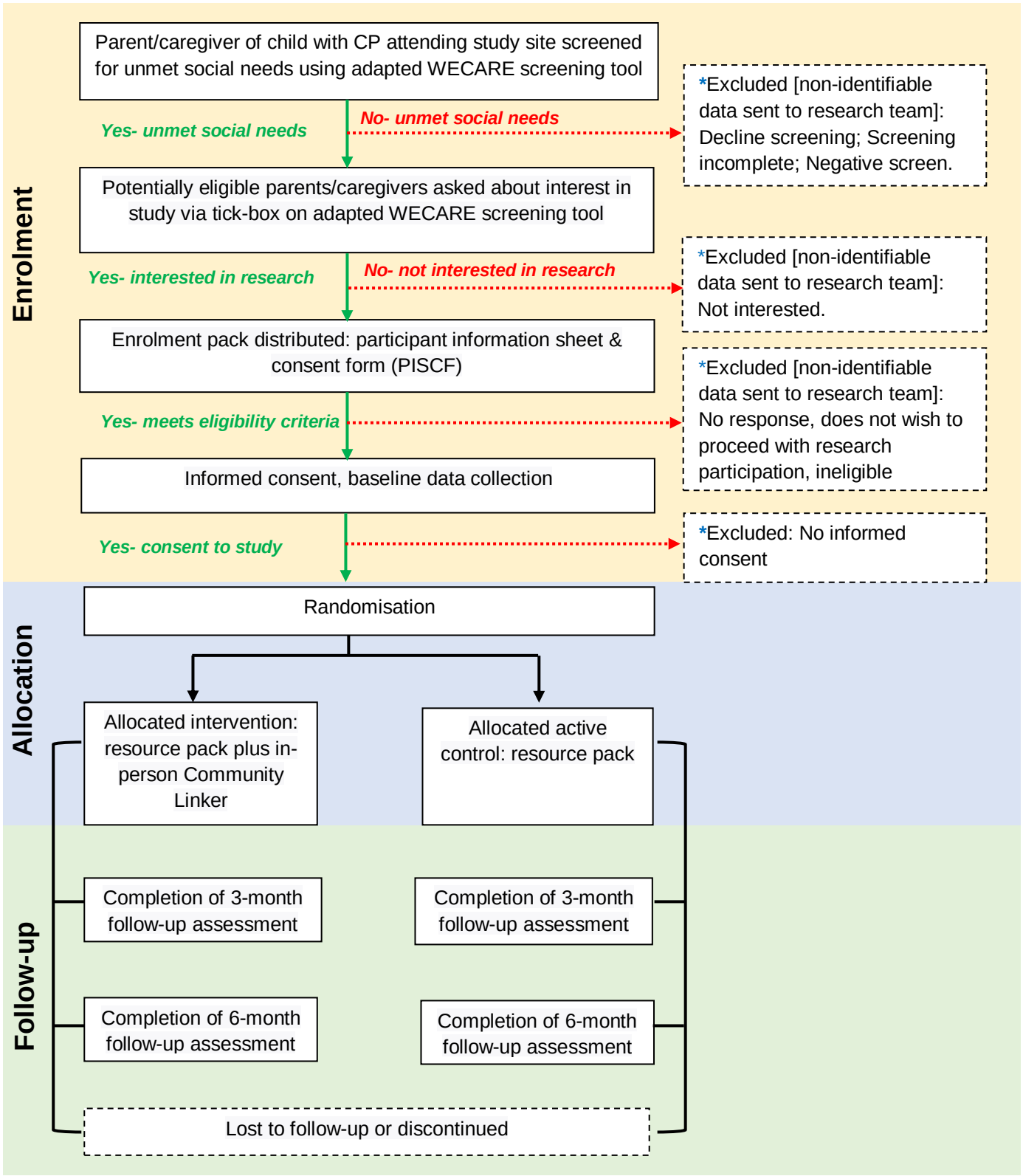

Figure 1: study diagram

**Any parents/caregivers who identify unmet social needs but decide to not participate in the research study at any time point during enrolment (i.e., tick "no" to research interest in screening form, do not wish to enrol after being provided PISCF etc) will be offered the resource pack and advised to discuss their concerns with their child's clinical team per routine care.*

BMJ Open

EPIC-CP pilot trial study protocol: a multi-centre, randomised controlled trial investigating the feasibility and acceptability of social prescribing for Australian children with cerebral palsy

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Complete List of Authors:	Ostojic, Katarina; The University of Sydney Faculty of Medicine and Health, Community Paediatrics Research Group, Central Clinical School; University of New South Wales Medicine & Health, Population Child Health Clinical Research Group Karem, Isra; University of New South Wales Medicine & Health, Population Child Health Clinical Research Group Paget, Simon; Children's Hospital at Westmead; The University of Sydney Faculty of Medicine and Health, The Children's Hospital at Westmead Clinical School Berg, Alison; The Children's Hospital at Westmead Burnett, Heather; John Hunter Children's Hospital Scott, Timothy; Sydney Children's Hospital Randwick Martin, Tanya; University of Sydney Poche Centre for Indigenous Health, Sydney medical School Dee-Price, Betty-Jean; Flinders University, Southgate Institute for Health, Society and Equity Mcintyre, Sarah; The University of Sydney Sydney Medical School, Cerebral Palsy Alliance Research Institute Smithers Sheedy, Hayley; University of New South Wales, Population Child Health Clinical Research Group; The University of Sydney Sydney Medical School, Cerebral Palsy Alliance Research Institute Mimmo, Laurel; The Sydney Children's Hospitals Network Masi, Anne; University of New South Wales School of Clinical Medicine, Discipline of Psychiatry and Mental Health Scarcella, Michele; The Sydney Children's Hospitals Network Azmatullah, Sheikh; University of New South Wales, EPIC-CP Group Calderan, Jack; University of New South Wales, EPIC-CP Group Mohamed, Masyitah; University of New South Wales, EPIC-CP Group Olaso, Anne; University of New South Wales, EPIC-CP Group van Hoek, Matthew and Debbie ; University of New South Wales, EPIC-CP Group Woodbury, Mackenzie; University of New South Wales, EPIC-CP Group Wilkinson, Alunya; University of New South Wales, EPIC-CP Group Chambers, Georgina; University of New South Wales Centre for Big Data Research in Health, National Perinatal Epidemiology and Statistics Unit Zwi, Karen; University of New South Wales Medicine & Health, Population Child Health Clinical Research Group; The Sydney Children's Hospitals Network, Community Child Health

	Dale, Russell; University of Sydney Sydney Medical School, The Children's Hospital at Westmead Clinical School; Children's Hospital at Westmead Eapen, Valsamma; University of New South Wales School of Clinical Medicine, Discipline of Psychiatry and Mental Health Lingam, Raghu; University of New South Wales Medicine & Health, Population Child Health Clinical Research Group Strnadová, Iva ; University of New South Wales, School of Education, Faculty of Arts, Design and Architecture Woolfenden, Susan ; Sydney Local Health District, Sydney Institute for Women, Children and their Families; The University of Sydney Faculty of Medicine and Health, Community Paediatrics Research Group, Central Clinical School Group, EPIC-CP; University of New South Wales, EPIC-CP Group
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Title: EPIC-CP pilot trial study protocol: a multi-centre, randomised controlled trial investigating the feasibility and acceptability of social prescribing for Australian children with cerebral palsy

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Authors:
Katarina Ostojic[1,2], Isra Karem[2], Simon Paget[3,4], Alison Berg[4], Heather Burnett[5], Timothy Scott[6], Tanya Martin[7], Betty-Jean Dee-Price[7], Sarah McIntyre[9], Hayley Smithers-Sheedy[2,9], Laurel Mimmo[10], Anne Masi[11], Michele Scarcella[10], Sheikh Azmatullah[12], Jack Calderan[12], Masyitah Mohamed[12], Anne Olaso[12], Debbie van Hoek[12], Matthew van Hoek[12], Mackenzie Woodbury[12], Alunya Wilkinson[12], Georgina Chambers[13], Karen Zwi[2,10], Russell C Dale[3,4], Valsamma Eapen[11], Raghu Lingam[2], Iva Strnadová[14], Sue Woolfenden[1,2,15], & EPIC-CP Group[12]

Affiliations:

1. Community Paediatrics Research Group, Central Clinical School, Sydney Medical School, Faculty of Medicine and Health, The University of Sydney, Sydney, Australia
2. Population Child Health Clinical Research Group, Faculty of Medicine and Health, University of New South Wales, Sydney, Australia
3. The Children's Hospital at Westmead Clinical School, Faculty of Medicine and Health, University of Sydney, Sydney, Australia
4. The Children's Hospital at Westmead, Sydney, Australia
5. John Hunter Children's Hospital, Newcastle, Australia
6. Sydney Children's Hospital, Sydney, Australia
7. POCHE Centre for Indigenous Health, Faculty of Medicine and Health, University of Sydney, Sydney, Australia
8. Southgate Institute for Health, Society and Equity, Flinders University, South Australia, Australia
9. Cerebral Palsy Alliance Research Institute, Sydney Medical School, The University of Sydney, Sydney, Australia
10. Sydney Children's Hospitals Network, Sydney, Australia
11. Discipline of Psychiatry and Mental Health, School of Clinical Medicine, University of New South Wales, Sydney, NSW, Australia.
12. EPIC-CP Group, University of New South Wales, Sydney, Australia
13. National Perinatal Epidemiology and Statistics Unit, Centre for Big Data Research in Health & School of Clinical Medicine, University of New South Wales, Sydney Australia
14. School of Education, Faculty of Arts, Design and Architecture, University of New South Wales, Sydney, Australia
15. Sydney Institute for Women, Children and their Families, Sydney Local Health District, Sydney, Australia

Keywords: cerebral palsy; social determinants of health; paediatrics; social prescribing; health inequities; health services research

Abstract

Introduction: The social determinants of health contribute to poorer health outcomes for children with cerebral palsy and are barriers to families accessing health services. At an individual level, social determinants of health are experienced as unmet social needs, for example unsafe housing conditions. There is emerging evidence that clinical pathways for the systematic identification and referral to services for unmet social needs can support families to address these needs. These clinical pathways have not been implemented for children with cerebral palsy. The objectives are to investigate the feasibility and acceptability of two codesigned social needs clinical pathways for parents/caregivers of children with cerebral palsy- social prescribing (i.e., Community Linker plus resource pack) compared to resource pack only.

Methods and Analysis: This pilot randomised controlled trial will run at the three tertiary Paediatric Rehabilitation Services in New South Wales, Australia. A total of 120 participants will be recruited, with randomisation stratified by study site. A screening tool will be used to identify families experiencing unmet social needs. Parents/caregivers who report one or more unmet social need and consent will be eligible. The active control group will receive a resource pack containing information on community services to support unmet social needs. The social prescribing intervention group will receive one-on-one Community Linker support, in addition to the resource pack. The screening tool, intervention, logic model, and resource pack were co-designed with patient families and their healthcare workers. Feasibility of the research design and the clinical pathways will be evaluated using the number/proportion of parents/caregivers who complete screening, consent, engage with the intervention, and complete research measures. Acceptability will be evaluated using questionnaires and qualitative interviews.

Ethics and Dissemination: Human research ethics approval was granted by the Sydney Children's Hospitals Network Human Research Ethics Committee. Participants and stakeholders will receive updates and findings via regular communication channels including meetings, presentations, and publications.

Registration Details: Australia New Zealand Clinical Trials Registry 12622001459718

Strengths and limitations of this study

- This is the first study to evaluate the feasibility and acceptability of two codesigned clinical pathways for families of children with cerebral palsy experiencing unmet social needs.
- As feasibility is the primary outcome of interest, this study is not powered to investigate efficacy but will inform a potential future efficacy trial.
- Strengths of this study include the formative research to codesign the clinical pathway and research methodology inclusive research practices, partnership with research advisors with a lived experience of cerebral palsy, and mixed-methods approach to investigate feasibility and acceptability.

INTRODUCTION

Cerebral palsy (CP) is a lifelong condition and the most common cause of physical disability in childhood, with an estimated prevalence of 1.5 per 1000 live births in high-income countries(1) including Australia.(2) It is a diagnostic term describing a heterogenous group of permanent but not unchanging disorders of movement and/or posture, caused by a non-progressive lesion or anomaly to the immature brain.(2) Amongst individuals with cerebral palsy, the motor disorder/s (spastic, dyskinetic, ataxic, hypotonic) vary and severity of gross motor impairment can range from having a minimal to severe impact on gross motor function.[(2)] People living with cerebral palsy may also experience other comorbidities including intellectual disability (32.0%), epilepsy (33.5%), hearing- (12.8%), vision- (36.4%), and speech- (62.7%) impairment.(2) Many people with cerebral palsy need long-term, high-quality support from health and social-care services to enable management of their chronic health condition/s and promote optimal quality of life.(3)

There is evidence of health inequities in children with cerebral palsy.(4, 5) In Australia, socioeconomic disadvantage at birth is associated with increased severity of cerebral palsy functional outcomes (more severe gross motor impairment, at least one moderate-severe comorbidity) at age 5 years.(4) Health inequities have their origins in the social determinants of health- the non-medical conditions in which people are born, grow, live, work, and age including food, transport, and housing.(6) There is increasing recognition of the importance of addressing the social determinants of health to improve health outcomes.(7) At a personal level, social determinants of health are experienced as unmet social needs (e.g., housing needs).(7, 8)

A recent systematic review explored clinical pathways for the identification and referral of unmet social needs in children attending outpatient community and ambulatory healthcare services.(9) Interventions were described as being implemented in one of three ways: 1) Identification of unmet social needs with clinician training; 2) Identification of unmet social needs with targeted community resources; and 3) Identification of unmet social needs with Navigator/Link Worker support.(9) The review found positive outcomes, with all pathways leading to an increase in social needs identification and referrals, and reduction in social needs.(9) Notably, there was no superior pathway type; though, outcome measures were heterogeneous and not easily comparable.(9)

In the United Kingdom, a formalised scheme for health professionals to identify and refer patients to non-medical community services to target their unmet social needs, using a “Link Worker”, is referred to as “social prescribing”.(10) Individuals living with chronic physical health conditions and multimorbidity have been recognised as a key clinical cohort that may benefit from social prescribing.(11) There is also small scale data on a “Key Worker” in the UK, with their involvement associated with better outcomes for families, and minor reductions in children unmet needs. Their role however, is broader than that of a “Link Worker”, with less focus on systematic screening.(12) To date, social prescribing has not been tested for children with disability, including cerebral palsy, in the Australian context.

This pilot clinical trial aims to address this critical research gap. It builds on our previous formative research involving people with a lived experience of cerebral palsy, their families, and health service providers to codesign a social prescribing pathway for children with cerebral palsy and their families in Australia.(13) The objectives of this pilot randomised controlled trial (RCT) are to assess the feasibility and acceptability of two codesigned social needs clinical pathways - social prescribing (i.e., Community Linker plus resource pack) compared to resource pack only- for parents/caregivers of children with cerebral palsy in tertiary Paediatric Rehabilitation clinic settings.

METHODS

Objectives and hypotheses

The primary objectives of this pilot RCT are to evaluate the feasibility and acceptability of implementation and delivery of the codesigned social needs pathways. Secondary objectives include assessment of fidelity and service model variations, to determine the short-term impacts of the intervention at 3- and 6-months post-enrolment, and to inform a future, definitive multicentre large-scale RCT.

We hypothesise that both the social prescribing intervention (Community Linker plus resource pack) and active control intervention (self-navigation using resource pack) will be feasible and acceptable, according to outcome measures described in sections below.

Co-design of intervention and trial with parents and young people

The intervention was co-designed using a modified Hawkins et al.(14) framework. It involved families of children with CP, and their healthcare providers. This was to ensure the intervention was responsive to the needs of its end-users and was tailored for implementation in the local health setting. A protocol of this codesign approach has been published(15) and the findings of the codesign research phase is currently under review, reporting against the GRIPP guideline.

Study design

This is a multi-centre, unblinded, pilot RCT which will take place from April 2023 until December 2024. The unmet social needs of parents/caregivers of children with cerebral palsy will be screened during their clinic appointment. Families who self-report experiencing unmet social on the screening tool and consent to the research study are randomised into arms, either 1) social prescribing intervention arm (Community Linker plus resource pack) or 2) active control arm (self-navigation using resource pack). The rationale for this design is that there is evidence to support both pathways (Community Linker; resource pack), and it is unethical to screen for unmet social needs and not provide a response. The trial design is outlined in Figure 1.

[INSERT FIGURE 1 HERE]

Setting

This study is conducted at the Rehabilitation Departments of the three tertiary paediatric hospitals in New South Wales, Australia: The Children's Hospital at Westmead, Sydney Children's Hospital Randwick, and John Hunter Children's Hospital. The Paediatric Rehabilitation Departments offer a comprehensive cerebral palsy clinical service staffed by a multi-disciplinary team including paediatric rehabilitation medicine physician, nurse, physiotherapist, occupational therapist, and social worker.

Study population

Participants in the RCT must meet the following criteria to be eligible for the study:

Inclusion criteria

1. Parent/caregiver of a child (aged 0-18 years) with a confirmed diagnosis of cerebral palsy who is patient of the Cerebral Palsy Service at one of the following tertiary Paediatric Rehabilitation Departments: Kids Rehab, the Children's Hospital at Westmead; Rehab2Kids, Sydney Children's Hospital; HNEkidsRehab, John Hunter Children's Hospital.

2. Parent/caregiver self-report at least one unmet social need from the following six items on the adapted WECARE screening tool: Childcare or schooling; Government benefits and vouchers; Housing; Food; Bills; Transport.
3. Reside in New South Wales or Australian Capital Territory.
4. Provide informed consent.

Exclusion Criteria

1. Parent/caregiver have no mechanism for contact (telephone or email).
2. Family already enrolled and assigned a research participant ID. In the in stance where a parent/caregiver meets inclusion criteria and has multiple children with a diagnosis of cerebral palsy (e.g., siblings with cerebral palsy or twins with cerebral palsy), the parent/caregiver will only be able to enrol once for their family.

Service provider participants (qualitative interviews/focus groups): Service providers working at the Rehabilitation Departments of the three NSW Children's Hospitals will be invited to take part in qualitative interviews/ focus groups to explore their perspectives of the pilot trial and implementation of social prescribing intervention (Community Linker plus resource pack) and active control intervention (self-navigation using resource pack).

Intervention

The intervention was co-designed with over 200 participants through a rigorous codesign research phase described in detail in separate publications. Research participants co-developed the program logic model and prototype of the intervention. Following an intensive qualitative needs assessment, participants codeveloped the intervention including tool for standardised screening of unmet social needs, Community Linker role and scope of practice, and resource pack. This process was piloted in research action cycles, with continuous refinement until a consensus was achieved. The finalised logic model is shown in figure 2.

[INSERT FIGURE 2 HERE]

Active control (self-navigation with resource pack)

Participants randomised to the active control arm will be provided with a resource pack containing information on community services to support their unmet social needs. The resource pack was codesigned during the earlier formative research phase and piloted during iterative codesign processes.(13) The resource pack will be available in hard-copy and online. The online version of the resource pack will be available on a secure website accessible only to individuals provided the QR code to the webpage or direct weblink. The resource pack is an enhancement to usual care, which may involve clinicians recommending these services for unmet needs as part of their care

Social prescribing intervention arm (Community Linker plus resource pack)

Participants randomised to the social prescribing intervention arm will receive one-on-one Community Linker support, in addition to the resource pack (described above). The Community Linker provides one-on-one support based upon the needs of the family, as an extension to usual care, in addition to the resource pack.

A Community Linker is a trained, non-medical staff member who assist parents/caregivers to connect with appropriate services and supports to address their unmet social needs. Community Linkers provide

practical, hands-on support navigating services e.g., finding an appropriate local community service, making referrals to services, helping parents/caregivers complete forms, follow-up with services, booking appointments, assisting in gathering support letters and submitting paperwork for funding under the National Disability Insurance Scheme. The Community Linker position description including their title, qualifications, and key roles and responsibilities was codesigned with end-users during the previous phase of research. Each study site will employ a Community Linker to be supervised by the Cerebral Palsy Service Manager and Cerebral Palsy Service Social Worker. Community Linkers will follow a codesigned documented standard operating procedure including specific training modules, which includes escalation procedures should concerns be disclosed that are beyond the scope of their role (e.g., mental health concerns, domestic violence, clinical concerns).

All participants in the intervention arm will have an intake appointment with the Community Linker at their service. Dependent on participant preference, the intake appointment may occur face-to-face at the Rehabilitation Department immediately after randomisation. Alternatively, it may occur via phone, videoconference, or in-person at a different time that suits the participant. All participants will have an intake appointment within one week of randomisation to the social prescribing arm. During the appointment, participants will discuss their unmet social needs with the Community Linker; the current supports and services they are accessing; what they need help with; and their goals for managing their unmet social needs. A personalised care plan will be made together with the parent/caregiver and their child/young person with cerebral palsy (as required). The parent/caregiver will be offered the opportunity to for their child/young person with cerebral palsy to engage with the Community Linker. Parents/caregivers will also elect their preferred mode (e.g., videoconference, phone call, email) and frequency of communication (e.g., once-a-week, once a fortnight) with the Community Linker which can be revised at any time as required. The Community Linker will provide support for a period of 3-months. The frequency of engagement will depend on participants preferences and needs. However, the Community Linker will conduct minimum monthly check-ins for all participants.

Sample size

The pilot trial will aim to obtain a minimum of 35 respondents in each trial arm at 3- and 6- month follow-up. Assuming a 30% loss to follow-up in line with previous research(16, 17), a total sample size of 120 families will be recruited - 60 in each research arm.(18) Per Teare et al (2014) a total sample size of 120 parents/caregivers makes it possible to assess feasibility as the relevant primary outcome.[15] Randomization will be stratified by Rehabilitation Department/study site. Thus, at each study site, 20 parents/caregivers will be randomised to each research arm.

Within the prior formative research to codesign the interventions, quality improvement cycles were conducted at one study site piloting the screening tool and pathways.(13) During the 12-week testing period, 105 parents/caregivers of children with cerebral palsy completed the unmet social needs screening form. Based on this experience, we estimate a recruitment period of 3-months to enrol all participants in the study across three sites. The data from this pilot RCT will form sample size calculations for a potential future RCT of efficacy.

Qualitative data sample size: As this is inductive rather than deductive research a sample size calculation cannot be done. However, using purposeful sampling, the saturation point will most likely be reached after 10-20 interviews with parents/caregivers. We estimate that 5-10 service providers will take part in an interview/focus group per site, thus 15-30 service provider participants in total.

Screening and recruitment strategy

Parent/caregiver participants: All parents/caregivers of a child with cerebral palsy attending the participating Rehabilitation Departments will be asked to complete a paper-based unmet social needs screening form during their routine clinic visit (Supplementary File 1). The screening form includes information about the research study where parents/caregivers can indicate their interest (yes/no) in hearing more and provide contact details if applicable. All screening forms will be distributed and collected by the site Community Linker. Contact details of interested parents/caregivers will be provided to project staff responsible for enrolment.

If parents/caregivers screen positive on the tool (self-report one or more unmet social needs) but are not interested in knowing more about the study, they will be advised to discuss their concerns with their clinical team per routine care. If interested parents/caregivers are not eligible for the project, they will be told that they are ineligible for the research project and will be advised to discuss any concerns with their clinical team per routine care. If interested parents/caregivers are eligible for the project, they will be provided a participant information sheet and consent form (PISCF). The PISCF may be provided immediately by the Community Linker during the family's attendance of the clinical appointment in paper form or a REDCap link sent via email, dependent of the family's preference and availability on the day.

Service provider participants: Service providers will be identified through department meetings and professional networking within the participating study sites. Interested service providers will be given a Service Provider PISCF either in hardcopy version or via recruitment email. They will be given time to think about the project and have the opportunity to ask any questions they may have about their participation in the study to the study coordinator.

Consent

Parent/Caregiver and young person participants: Parent/caregiver and young person PISCFs will provide information about the research, the risks/benefits, and its voluntary nature. The parent/caregiver PISCF will be provided to all interested parents/caregivers (Supplementary File 2). Additionally, young people aged 8 years or older who can self-report (determined via parent/caregiver and young person report) will be provided a young person PISCF. If the young person has capacity to provide consent, they will be requested to co-consent along with their parent/caregiver in whatever form of communication suits their preference and needs (e.g., in writing, verbal consent, using augmented and alternative communication methods). The approved PISCF's will be translated into other languages based on data pertaining to limited English language proficiency and largest language groups attending the tertiary Paediatric Rehabilitation Departments.

It will be made clear to participants that they can stop participating in the study at any time without consequences to the care or services they receive. If the participant expresses that they are not interested in the study, no further contact will be made in relation to the study. Parents/caregivers will also be free to withdraw their consent if they change their minds at any point during the study. Participants can provide informed consent in several ways: signing the hardcopy of the PISCF at a face-to-face visit; signing the online REDCap consent form to be included in recruitment email(19); providing verbal consent via phone call. Participants will be asked to complete a baseline questionnaire immediately after providing consent.

Service provider participants: the service provider PISCF will be distributed as paper-based copy or via recruitment email. The recruitment email will include a link directing potential service provider

participants to the online version of the PISCF via the Redcap® data link. Service providers will be required to either sign the hard copy consent form and return to study coordinator or sign the online consent form hosted on RedCap.

Randomisation and intervention allocation

Participants will be randomised automatically by the REDCap platform(19), assigning 50% of participants to each group. Randomisation will be conducted by project staff. Randomisation will be stratified by Rehabilitation Department/study site. Across the entire project, 60 parents/caregivers will be randomised to the social prescribing intervention arm (n= 20 at each study site) and 60 parents/caregivers will be randomised to the active control arm (n=20 at each site). The project staff will notify participants of their intervention allocation via one of three methods (face-to-face; email; phone) dependent on their personal preference and corresponding to chosen method of consent as described above.

Outcome measures

Table 1 offers a summary of the outcome measures.

Pilot outcomes- feasibility and acceptability

Feasibility will be evaluated against the stop-go criteria for success of feasibility, as follows:

1. Recruitment rates: Recruitment will be successful if 80% of our target sample is met in the 3 months of recruitment.
2. Uptake of intervention: Will be considered successful if > 70% of families complete the intervention.
3. Follow-up of participants: Will be considered successful if > 70% of families complete all the study visits.

We will also evaluate feasibility and acceptability via:

- Process measures: non-identifiable data will be recorded on the proportion of families who: complete vs. decline the unmet social needs screening form; positive vs. negative unmet social needs screening; are interested vs. not interested in research participation consent vs. do not consent to research study.
- Community Linker logbook: each Community Linker will keep a logbook of their activities including type of social care navigation activities provided, e.g., advice regarding services, attending services with families, types of pf services, referrals made to services collected etc.
- Satisfaction and acceptability survey: At 3-month post-enrolment, all participants (social prescribing intervention; active control) will be asked to complete a bespoke questionnaire regarding their satisfaction and acceptability of their allocated intervention.
- Parent/caregiver qualitative interview: At 3-month post-enrolment, participants in the social prescribing group will be invited to complete a qualitative interview to explore their experiences, barriers, and enablers to social prescribing as perceived by parents/caregivers. The interviews will be conducted 1:1 with the project coordinator and will follow a semi-structured interview guide. Interviews will be conducted face-to-face, phone, or teleconference dependent on participants preference.
- Clinician qualitative interview/focus group: clinicians from participating study sites will be invited to take part in interview/focus group exploring the experiences, barriers, and enablers of social prescribing intervention and active control intervention as perceived by clinicians (conducted during trial implementation based on availability and preference of staff at sites).

Secondary outcomes- proposed impacts for future RCT

Secondary outcomes aim to determine short-term impacts of the intervention at 3- and 6- months post-enrolment. This will help inform sample size and outcome measures to be used in future, definitive multi-centre large-scale RCT. Per Table 1, outcomes will be assessed at baseline, 3-month follow-up, and 6-month follow-up including:

- unmet social needs (adapted WECARE tool)(20),
- parent/caregiver distress (K-6 Distress Scale – Self Administered)(21),
- Child/young person global health (PROMIS Parent Proxy Scale v1.0 – Global Health 7 (item 1; item 2)(22) or PROMIS Pediatric Scale v1.0 – Global Health 7 (item 1; item 2))(22), and
- Parent/caregiver global health (PROMIS Scale v1.2 – Global Health (item 1; item 2))(23), and
- Service use captured on bespoke survey.

Furthermore, at baseline parent/caregivers will be asked to complete a demographic survey. A medical record review of children with CP will be completed for all participants to describe the characteristics of participating children/families and explore any potential association between outcome measures and clinical factors relating to te child with cerebral palsy and demographic factors related to the parent/caregiver.

Table 1. Summary of study outcome measures		
Outcome	**Methods and measures**	**Time**
Primary outcomes		
Feasibility of a social prescribing intervention (resource pack plus in-person Community Linker) and active control intervention (self-navigation with resource pack)	• Number/proportion of completed screens for identification of unmet social needs (screening) • Number/proportion of families interested in research study (screening) • Number/proportion of eligible clients who consent to participation in research project (baseline) • Number/proportion of social prescribing group participants who engage with in-person Community Linker (3-month follow-up) • Number/proportion of participants who complete 3-, and 6-month follow-up assessments (3-month follow-up; 6-month follow-up)	Ongoing throughout implementation
Acceptability and satisfaction with social prescribing intervention (resource pack plus in-person Community Linker) and active control intervention (self-navigation with resource pack)	Parent/caregiver satisfaction and acceptability collected via bespoke questionnaire.	3-month follow-up
Acceptability and experiences of social prescribing intervention (resource pack plus in-person Community Linker)	• Qualitative interviews with parent/caregiver on experiences, barriers, and enablers to social prescribing intervention. • Qualitative focus groups with health service providers at participating Paediatric Rehabilitation study sites on experience, Barrie's, and enablers to social prescribing intervention.	Parents/caregivers:3-month follow-up. Clinicians: conducted during trial implementation based on availability and preference of staff at sites)
Intervention fidelity- social prescribing intervention (resource pack plus in-person Community Linker)	Type of social prescribing activities provided, e.g., advice regarding services, attending services with families, types of referrals made to services collected using Community Linker logbook	Ongoing throughout implementation
Secondary outcomes		
Unmet social needs	Parent/caregiver self-report via an adapted version WECARE tool(20)	Screening, 3-month follow-up, 6-month follow-up

Parent/caregiver distress	Parent/caregiver self-report via K-6 Distress Scale – Self Administered(21)	Screening, 3-month follow-up, 6-month follow-up
Child/young person global health	Parent/caregiver proxy-report, to be used when the child is <8 years of age or when if the child/young person is unable to self-report via PROMIS Parent Proxy Scale v1.0 - Global Health 7 (item 1; item 2) Or Child/young person self-report, to be used if the child/young person is ≥ 8 years of age and can self-report, via PROMIS Pediatric Scale v1.0 – Global Health 7 (item 1; item 2)(22)	Screening, 3-month follow-up, 6-month follow-up
Parent/caregiver global health	Parent/caregiver self-report via PROMIS Scale v1.2 - Global Health (item 1; item 2)(23)	Screening, 3-month follow-up, 6-month follow-up
Service use	Types of services parents/caregiver's report using for unmet social needs via bespoke survey	3-month follow-up

Data collection

All participants will be allocated a unique identifier code that will be used throughout the study. For enrolment and quantitative data collection, the study will prioritise electronic collection procedures. However, participants will be given the option to complete research questionnaires face-to-face, online via REDCap(19), or on the phone with the research staff. All quantitative data, irrespective of initial mode of data collection, will then be entered into a secure password-protected server-based database, REDCap.(19) Any hard copies of consent forms and de-identified questionnaires will be stored in a locked cabinet at each study site before being securely transferred to the study team at UNSW. When being stored at the study sites, hardcopy materials will be stored in a locked filing cabinet within a locked office, accessible only to the site project staff.

Qualitative interviews with families and qualitative focus groups with health service providers will be conducted face-to-face, via phone call, or videoconference dependent on participants preference. These will focus on participant's thoughts on and experiences engaging with the intervention, and clinicians' views on how well the intervention integrated within the clinics. Interviews and focus groups will be transcribed verbatim, and all data management, storage, and analysis will be done at UNSW. All paper copy and taped data will be de-identified. Coded information will be stored in a locked filing cabinet, or on password protected digital media. As soon as interviews have been transcribed the audio tapes will be erased.

All paper data and questionnaires will be entered into a secure password-protected server-based database, REDCap hosted at UNSW, and stored for 15 years after the last date of data collection.(19) After 15 years, any paper data will be shredded, and the electronic data will be permanently erased, and backups destroyed.

Data analysis

Quantitative data analysis

Participant characteristics will be reported using descriptive statistics. The analysis will be according to randomised treatment allocation. The analysis of primary outcomes – feasibility and acceptability – will be based on descriptive statistics reported as percentage (95% confidence interval). Analysis of secondary outcomes will be purely exploratory and not powered to detect efficacy, thus we will not perform tests of significance. Secondary outcome measures will be described by intervention allocation using the t-test and non-parametric tests for continuous data and the chi-squared test for categorical data. If suitable, linear and logistic regression modelling will be conducted to test group differences adjusting for basic baseline (where the model allows), for example, gender, and other sociodemographic characteristics.

Qualitative data collection and analysis

Data collected from the semi-structured interviews and semi-structured focus groups will be coded according to common themes using a thematic analysis.(24) Researcher triangulation will be employed to further substantiate the emerging themes. Data collection and analysis will continue until no new themes or hypotheses emerge, that is a "saturation point" is reached. Initially all coding of the interviews and development of themes will be done by hand. This provides the opportunity to redefine and/or merge themes as analysis proceeds. When no new themes are emerging, data will be managed with the assistance of the qualitative software Nvivo 11 software by the principal investigator. Transcription checks against tapes and notes taken, triangulation, feedback, will be employed to ensure rigour (e.g., all interviewees will receive a copy of their interview transcript to check). Comments after reading these will be fed back into the analysis.

Patient and public involvement

The social needs clinical pathways being evaluated in this pilot RCT were codesigned with people with a lived experience of CP, their families, and health care professionals in earlier formative research. (13) Outcomes to be assessed in this pilot RCT were included as part of the co-design process. This study is overseen by two research advisory groups - one group of young adults with CP and one group of parents of a young person with CP. Research advisors meet with the project officer monthly and provide input into each phase of the study, i.e., project conception and planning, data collection and analysis, dissemination. They have been involved with the project since commencement of earlier formative research to codesign the program and will continue to work together for this pilot RCT.[12] Research advisors are paid $30 (AUD) per hour.

This project has a governance structure including several sub-committees: research operations committee, research advisory group, steering committee, and knowledge translation committee. Each committee meets consistently with the chief investigator and project officer to facilitate information exchange and cooperation between stakeholders.

For completing the study questionnaires at baseline, 3-month follow-up, and 6-month follow-up; parent/caregiver research participants will be reimbursed for their time with a $20 gift voucher for each data collection time-point.

Ethics and considerations

Ethics approval for this project was granted by the Sydney Children's Hospitals Network (SCHN) Human Research Ethics Committee (2022/ETH01688) in October 2022. Site-specific research governance approvals were granted for SCHN and John Hunter Children's Hospitals. This trial has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12622001459718)

Where a reportable clinical incident is identified through or during the data collections an incident report will be lodged in the Incident Investigation and Management System as per the NSW Health Clinical Incident Policy. During the research project, we may identify families where there is domestic violence, financial abuse, or imminent risk of homelessness. In this event, families will be referred directly to CP Service Social Worker. Referral to the CP Service Social Worker does not exclude the parent/caregiver from participation in the research project. They will receive support from the site CP Service Social Worker in addition to their allocated intervention. If child protection concerns are raised usual mandatory reporting guidelines will apply.

Participants are free to withdraw their consent at any time. Reasons for non-participation will be recorded, and the decision not to participate or to withdraw from the study will not affect the participant's relationship with study hospitals. In such case, the researchers will not collect additional information from the participant.

Dissemination and policy implications

Research findings will be shared with people living with CP, parents/caregivers, and family members of people with CP, health professionals, social service professionals, policy makers, and academics via various outputs including a lay summary of research findings, a poster summarising research results displayed at study sites, peer-reviewed publications, conference presentations. These outputs will be developed in collaboration with all project members, including research advisors, to ensure the material is suitable and accessible to the relevant audience.

Authors contributions: KO, IK, and SW led the design of the study with input and guidance from SP, TM, BJDP, SM, HSS, LM, HB, TS, AB, AM, MS, JC, SA, MM, MW, AW, KZ, RD, VE, RL, IS, and EPIC-CP Group. KO, IK, and SW produced the draft manuscript and SP, HSS, RD, BJDP, SM, IS, RL, LM, AM, KZ, and VE contributed to the manuscript. All authors read and approved the final manuscript.

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Competing interest statement: The views expressed are those of the author(s) and not necessarily those of the funding partners. NSW Health has no direct role in study design; data collection, analysis, and interpretation, or writing of final reports, presentations, or publications.

WORD COUNT: 4297 (including in text citations)

Figure caption:

Figure 1: study diagram
Figure 2: finalised logic model

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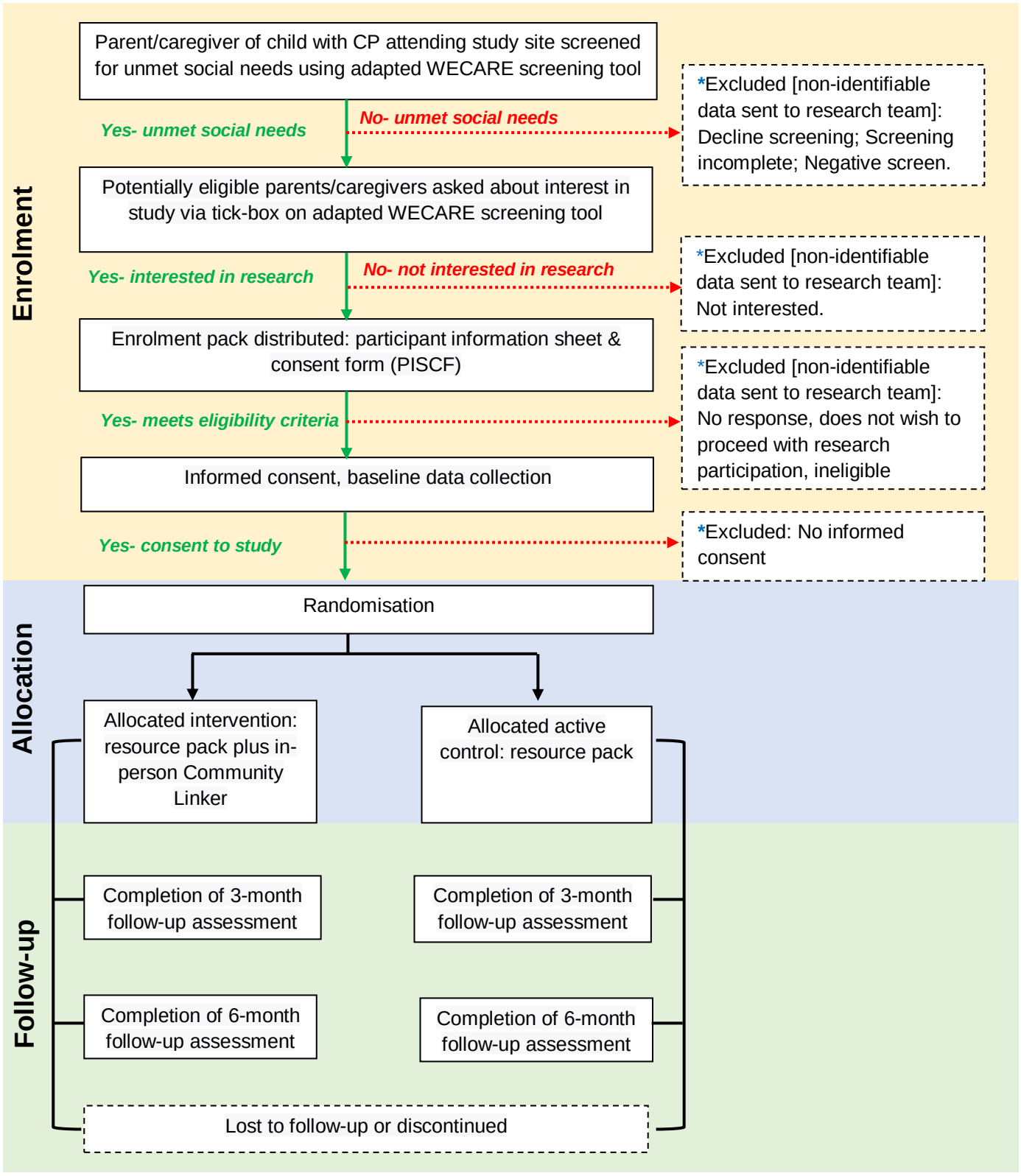

Figure 1: study diagram

**Any parents/caregivers who identify unmet social needs but decide to not participate in the research study at any time point during enrolment (i.e., tick "no" to research interest in screening form, do not wish to enrol after being provided PISCF etc) will be offered the resource pack and advised to discuss their concerns with their child's clinical team per routine care.*

LOGIC MODEL: EPIC-CP program for children with cerebral palsy and their families

Context

Knowledge:

- Community Linker (CL) has extensive knowledge of the social services and supports across health and community.
- CL has sound knowledge of paediatrics, disability/chronic and complex health conditions, social determinants of health, and psychosocial functioning.

Skills:

- CL is not a therapeutic role- provides practical, hands-on support to families to help them link with and navigate to services.
- CL has strong communication skills, empathetic, able to work closely with families.
- CL receives training via various formalised training modules from NSW Health and non-government organisations.

Supervision:

- CL works within the CP clinical service within each Paediatric Hospital.
- CL employed in NSW Health as an "Allied Health Assistant" position.
- CL has day-to-day direct supervision from CP Service Manager.
- Weekly reporting to EPIC-CP research project team.
- CL working closely with/alongside CP Service Social Worker.

Activities

- Standardised *identification* of *unmet social needs via* survey of adapted WECARE tool.
- Standardised *self-referral* pathway of families when completing the paper-based screening form and indicating interest in the social prescribing study.
- Standardised *intake* of children/families with Community Linker (CL)- initial consultation to identify priorities and develop individualised family plan.
- Standardised *referral pathway to key community services* (Family Connect and Support, NDIS Partners in Community) via CL, utilised as required per family.
- The CL will have *minimum monthly engagement* with parent/caregiver via text/phone/email etc. based on family preference.
- Cases requiring more *complex care or involving mandatory reporting* will be referred to the CP Service Social Worker.
- Per routine care, *standardised referral pathway to CP Service Social Worker* for families not eligible for research or requiring more intensive support.

KPIs, outputs, process measures

KPIs

- All families of children with CP are routinely screened for unmet social needs when attending CP service/clinic.
- Frequency of engagement with CL per personalised family plan (minimum once-a-month check-in).

Process measures:

- # of families with/without unmet social needs.
- # of families who self-referral to social prescribing pathway.
- # families who complete unmet social needs screening tool but decline research participation.
- # families who decline completing unmet social needs screening tool.
- Frequency and type of engagement with CL (via logbook).
- # referrals to CP Service Social Worker.
- # referrals to Family Connect Support Case Management.

Outputs

- Adapted WECARE screening tool for unmet social needs- adapted for families of children with CP attending Rehab Department.
- Library of generic e-resources of services available to support unmet social needs.
- Generating and maintaining library of local resources and contacts appropriate for each study site/local region.

Outcome/ Goals

Primary outcome/goals: Standardised identification and then reduction of unmet social needs (identified via adapted WECARE survey) following program (3- month duration).

Secondary outcomes:

- Increase in social supports/services families engage with.
- Improvement in child/young person and parent/caregiver quality of life.
- Reduction in parent/caregiver distress.
- Reduction in non-attendance of outpatient appointments.

[insert study site logo]

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

[insert study site logo]

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.

[insert study site logo]

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.

[insert study site logo]

- *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

[insert study site logo]

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.

[insert study site logo]

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.*

[insert study site logo]

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**
_____	_____	_____

[insert study site logo]

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**
_____	_____	_____

Table 1 GRIPP2 long form

From: GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research

Section and topic	Item	Reported on page No
Section 1: Abstract of paper		
1a: Aim	Report the aim of the study	Page 2 Line 8–11
1b: Methods	Describe the methods used by which patients and the public were involved	Page 2, line 18–19
1c: Results	Report the impacts and outcomes of PPI in the study	NA
1d:Conclusions	Summarise the main conclusions of the study	NA
1e: Keywords	Include PPI, "patient and public involvement," or alternative terms as keywords	NA
Section 2: Background to paper		
2a: Definition	Report the definition of PPI used in the study and how it links to comparable studies	NA
2b: Theoretical underpinnings	Report the theoretical rationale and any theoretical influences relating to PPI in the study	Page 4 Line 13–16
2c: Concepts and theory development	Report any conceptual or theoretical models, or influences, used in the study	Page 4 ine 24–26
Section 3: Aims of paper		
3: Aim	Report the aim of the study	Page 3 Line 41–47
Section 4: Methods of paper		
4a: Design	Provide a clear description of methods by which patients and the public were involved	Page 4 Line 13–18
4b: People involved	Provide a description of patients, carers, and the public involved with the PPI activity in the study	Page 4 Line 14–15
4c: Stages of involvement	Report on how PPI is used at different stages of the study	NA

Section and topic	Item	Reported on page No
4d: Level or nature of involvement	Report the level or nature of PPI used at various stages of the study	Page 5 Line 20–26
Section 5: Capture or measurement of PPI impact		
5a: Qualitative evidence of impact	If applicable, report the methods used to qualitatively explore the impact of PPI in the study	NA
5b: Quantitative evidence of impact	If applicable, report the methods used to quantitatively measure or assess the impact of PPI	NA
5c: Robustness of measure	If applicable, report the rigour of the method used to capture or measure the impact of PPI	NA
Section 6: Economic assessment		
6: Economic assessment	If applicable, report the method used for an economic assessment of PPI	NA
Section 7: Study results		
7a: Outcomes of PPI	Report the results of PPI in the study, including both positive and negative outcomes	NA
7b: Impacts of PPI	Report the positive and negative impacts that PPI has had on the research, the individuals involved (including patients and researchers), and wider impacts	NA
7c: Context of PPI	Report the influence of any contextual factors that enabled or hindered the process or impact of PPI	NA
7d: Process of PPI	Report the influence of any process factors, that enabled or hindered the impact of PPI	NA
7ei: Theory development	Report any conceptual or theoretical development in PPI that have emerged	NA
7eii: Theory development	Report evaluation of theoretical models, if any	NA
7f: Measurement	If applicable, report all aspects of instrument development and testing (eg, validity, reliability, feasibility, acceptability, responsiveness, interpretability, appropriateness, precision)	NA
7 g: Economic assessment	Report any information on the costs or benefit of PPI	NA
Section 8: Discussion and conclusions		
8a: Outcomes	Comment on how PPI influenced the study overall. Describe positive and negative effects	Page 13 Line 2–20
8b: Impacts	Comment on the different impacts of PPI identified in this study and how they contribute to new knowledge	NA
8c: Definition	Comment on the definition of PPI used (reported in the Background section) and whether or not you would suggest any changes	NA
8d: Theoretical underpinnings	Comment on any way your study adds to the theoretical development of PPI	NA
8e: Context	Comment on how context factors influenced PPI in the study	NA

Section and topic	Item	Reported on page No
8f: Process	Comment on how process factors influenced PPI in the study	NA
8 g: Measurement and capture of PPI impact	If applicable, comment on how well PPI impact was evaluated or measured in the study	NA
8 h: Economic assessment	If applicable, discuss any aspects of the economic cost or benefit of PPI, particularly any suggestions for future economic modelling.	NA
8i: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so that others can learn from this study	NA

PPI patient and public involvement

Back to article page ›

Research Involvement and Engagement

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Contact us

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1, Line 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 12, Line 22
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	Page 1, Line 4
Funding	4	Sources and types of financial, material, and other support	Page 13, Line 6
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 1
	5b	Name and contact information for the trial sponsor	Page 13, lines 6-7
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 3
	6b	Explanation for choice of comparators	Page 5, line 12-18
Objectives	7	Specific objectives or hypotheses	Page 4, lines 2-11
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 4, lines 14-21
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 4, lines 24-29
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 4-5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 5
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 7-10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	NA

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 7, lines 43-48
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	NA
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page 7, line 28-31
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 7, lines 28-36
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 7, lines 30-31
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 1, Page13
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 9-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 11, lines 1-22
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 11, lines 24-46
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	NA
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 12, line 20-23
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 7, lines 2-20
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 11, lines 5-22
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 13, lines 9-11
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 12, lines 39-45
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	NA
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

EPIC-CP pilot trial study protocol: a multi-centre, randomised controlled trial investigating the feasibility and acceptability of social prescribing for Australian children with cerebral palsy

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Complete List of Authors:	Ostojic, Katarina; The University of Sydney Faculty of Medicine and Health, Community Paediatrics Research Group, Central Clinical School; University of New South Wales Medicine & Health, Population Child Health Clinical Research Group Karem, Isra; University of New South Wales Medicine & Health, Population Child Health Clinical Research Group Paget, Simon; Children's Hospital at Westmead; The University of Sydney Faculty of Medicine and Health, The Children's Hospital at Westmead Clinical School Berg, Alison; The Children's Hospital at Westmead Burnett, Heather; John Hunter Children's Hospital Scott, Timothy; Sydney Children's Hospital Randwick Martin, Tanya; University of Sydney Poche Centre for Indigenous Health, Sydney medical School Dee-Price, Betty-Jean; Flinders University, Southgate Institute for Health, Society and Equity Mcintyre, Sarah; The University of Sydney Sydney Medical School, Cerebral Palsy Alliance Research Institute Smithers Sheedy, Hayley; University of New South Wales, Population Child Health Clinical Research Group; The University of Sydney Sydney Medical School, Cerebral Palsy Alliance Research Institute Mimmo, Laurel; The Sydney Children's Hospitals Network Masi, Anne; University of New South Wales School of Clinical Medicine, Discipline of Psychiatry and Mental Health Scarcella, Michele; The Sydney Children's Hospitals Network Azmatullah, Sheikh; University of New South Wales, EPIC-CP Group Calderan, Jack; University of New South Wales, EPIC-CP Group Mohamed, Masyitah; University of New South Wales, EPIC-CP Group Olaso, Anne; University of New South Wales, EPIC-CP Group van Hoek, Matthew and Debbie ; University of New South Wales, EPIC-CP Group Woodbury, Mackenzie; University of New South Wales, EPIC-CP Group Wilkinson, Alunya; University of New South Wales, EPIC-CP Group Chambers, Georgina; University of New South Wales Centre for Big Data Research in Health, National Perinatal Epidemiology and Statistics Unit Zwi, Karen; University of New South Wales Medicine & Health, Population Child Health Clinical Research Group; The Sydney Children's Hospitals Network, Community Child Health

	Dale, Russell; University of Sydney Sydney Medical School, The Children's Hospital at Westmead Clinical School; Children's Hospital at Westmead Eapen, Valsamma; University of New South Wales School of Clinical Medicine, Discipline of Psychiatry and Mental Health Lingam, Raghu; University of New South Wales Medicine & Health, Population Child Health Clinical Research Group Strnadová, Iva ; University of New South Wales, School of Education, Faculty of Arts, Design and Architecture Woolfenden, Susan ; Sydney Local Health District, Sydney Institute for Women, Children and their Families; The University of Sydney Faculty of Medicine and Health, Community Paediatrics Research Group, Central Clinical School Group, EPIC-CP; University of New South Wales, EPIC-CP Group
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Paediatrics, Patient-centred medicine
Keywords:	PAEDIATRICS, Health Equity, Health Services Accessibility

Title: EPIC-CP pilot trial study protocol: a multi-centre, randomised controlled trial investigating the feasibility and acceptability of social prescribing for Australian children with cerebral palsy

Date and Version: 29/April/2024, Version 3

Authors:
Katarina Ostojic[1,2], Isra Karem[2], Simon Paget[3,4], Alison Berg[4], Heather Burnett[5], Timothy Scott[6], Tanya Martin[7], Betty-Jean Dee-Price[7], Sarah McIntyre[9], Hayley Smithers-Sheedy[2,9], Laurel Mimmo[10], Anne Masi[11], Michele Scarcella[10], Sheikh Azmatullah[12], Jack Calderan[12], Masyitah Mohamed[12], Anne Olaso[12], Debbie van Hoek[12], Matthew van Hoek[12], Mackenzie Woodbury[12], Alunya Wilkinson[12], Georgina Chambers[13], Karen Zwi[2,10], Russell C Dale[3,4], Valsamma Eapen[11], Raghu Lingam[2], Iva Strnadová[14], Sue Woolfenden[1,2,15], & EPIC-CP Group[12]

Affiliations:

1. Community Paediatrics Research Group, Central Clinical School, Sydney Medical School, Faculty of Medicine and Health, The University of Sydney, Sydney, Australia
2. Population Child Health Clinical Research Group, Faculty of Medicine and Health, University of New South Wales, Sydney, Australia
3. The Children's Hospital at Westmead Clinical School, Faculty of Medicine and Health, University of Sydney, Sydney, Australia
4. The Children's Hospital at Westmead, Sydney, Australia
5. John Hunter Children's Hospital, Newcastle, Australia
6. Sydney Children's Hospital, Sydney, Australia
7. POCHE Centre for Indigenous Health, Faculty of Medicine and Health, University of Sydney, Sydney, Australia
8. Southgate Institute for Health, Society and Equity, Flinders University, South Australia, Australia
9. Cerebral Palsy Alliance Research Institute, Sydney Medical School, The University of Sydney, Sydney, Australia
10. Sydney Children's Hospitals Network, Sydney, Australia
11. Discipline of Psychiatry and Mental Health, School of Clinical Medicine, University of New South Wales, Sydney, NSW, Australia.
12. EPIC-CP Group, University of New South Wales, Sydney, Australia
13. National Perinatal Epidemiology and Statistics Unit, Centre for Big Data Research in Health & School of Clinical Medicine, University of New South Wales, Sydney Australia
14. School of Education, Faculty of Arts, Design and Architecture, University of New South Wales, Sydney, Australia
15. Sydney Institute for Women, Children and their Families, Sydney Local Health District, Sydney, Australia

Corresponding author: Katarina Ostojic, katarina.ostojic@sydney.edu.au

Keywords: cerebral palsy; social determinants of health; paediatrics; social prescribing; health inequities; health services research

Abstract

Introduction: The social determinants of health contribute to poorer health outcomes for children with cerebral palsy and are barriers to families accessing health services. At an individual level, social determinants of health are experienced as unmet social needs, for example unsafe housing conditions. There is emerging evidence that clinical pathways for the systematic identification and referral to services for unmet social needs can support families to address these needs. These clinical pathways have not been implemented for children with cerebral palsy. The objectives are to investigate the feasibility and acceptability of two co-designed social needs clinical pathways for parents/caregivers of children with cerebral palsy- social prescribing (i.e., Community Linker plus resource pack) compared to resource pack only.

Methods and Analysis: This pilot randomised controlled trial will run at the three tertiary Paediatric Rehabilitation Services in New South Wales, Australia. A total of 120 participants will be recruited, with randomisation stratified by study site. A survey tool will be used to identify families experiencing unmet social needs. Parents/caregivers who report one or more unmet social need/s and consent will be eligible. The active control group will receive a resource pack containing information on community services to support unmet social needs. The social prescribing intervention group will receive one-on-one Community Linker support, in addition to the resource pack. The survey tool, intervention, logic model, and resource pack were co-designed with patient families and their healthcare workers. Feasibility of the research design and the clinical pathways will be evaluated using the number/proportion of parents/caregivers who complete survey tool, consent, engage with the intervention, and complete research measures. Acceptability will be evaluated using questionnaires and qualitative interviews.

Ethics and Dissemination: Human research ethics approval was granted by the Sydney Children's Hospitals Network Human Research Ethics Committee. Participants and stakeholders will receive updates and findings via regular communication channels including meetings, presentations, and publications.

Registration Details: Australia New Zealand Clinical Trials Registry 12622001459718

Strengths and limitations of this study

- This is the first study to evaluate the feasibility and acceptability of two co-designed clinical pathways for families of children with cerebral palsy experiencing unmet social needs.
- As feasibility is the primary outcome of interest, this study is not powered to investigate efficacy but will inform a potential future efficacy trial.
- Strengths of this study include the formative research to co-design the clinical pathway and research methodology, inclusive research practices, partnership with research advisors with a lived experience of cerebral palsy, and mixed-methods approach to investigate feasibility and acceptability.

INTRODUCTION

Cerebral palsy (CP) is a lifelong condition and the most common cause of physical disability in childhood, with an estimated prevalence of 1.5 per 1000 live births in high-income countries(1) including Australia.(2) It is a diagnostic term describing a heterogenous group of permanent but not unchanging disorders of movement and/or posture, caused by a non-progressive lesion or anomaly to the immature brain.(2) Amongst individuals with cerebral palsy, the motor disorder/s (spastic, dyskinetic, ataxic, hypotonic) vary and severity of gross motor impairment can range from having a minimal to severe impact on gross motor function.[(2)] People living with cerebral palsy may also experience other comorbidities including intellectual disability (32.0%), epilepsy (33.5%), hearing- (12.8%), vision- (36.4%), and speech- (62.7%) impairment.(2) Many people with cerebral palsy need long-term, high-quality support from health and social-care services to enable management of their chronic health condition/s and promote optimal quality of life.(3)

There is evidence of health inequities in children with cerebral palsy.(4, 5) In Australia, socioeconomic disadvantage at birth is associated with increased severity of cerebral palsy functional outcomes (more severe gross motor impairment, at least one moderate-severe comorbidity) at age 5 years.(4) Health inequities have their origins in the social determinants of health- the non-medical conditions in which people are born, grow, live, work, and age including food, transport, and housing.(6) There is increasing recognition of the importance of addressing the social determinants of health to improve health outcomes.(7) At a personal level, social determinants of health are experienced as unmet social needs (e.g., housing needs).(7, 8)

A recent systematic review explored clinical pathways for the identification and referral of unmet social needs in children attending outpatient community and ambulatory healthcare services.(9) Interventions were described as being implemented in one of three ways: 1) Identification of unmet social needs with clinician training; 2) Identification of unmet social needs with targeted community resources; and 3) Identification of unmet social needs with Navigator/Link Worker support.(9) The review found positive outcomes, with all pathways leading to an increase in social needs identification and referrals, and reduction in social needs.(9) Notably, there was no superior pathway type; though, outcome measures were heterogeneous and not easily comparable.(9)

In the United Kingdom, a formalised scheme for health professionals to identify and refer patients to non-medical community services to target their unmet social needs, using a “Link Worker”, is referred to as “social prescribing”.(10) Individuals living with chronic physical health conditions and multimorbidity have been recognised as a key clinical cohort that may benefit from social prescribing.(11) There is also small scale data on a “Key Worker” in the UK, with their involvement associated with better outcomes for families, and minor reductions in children unmet needs. Their role however, is broader than that of a “Link Worker”, with less focus on systematic screening.(12) To date, social prescribing has not been tested for children with disability, including cerebral palsy, in the Australian context.

This pilot clinical trial aims to address this critical research gap. It builds on our previous formative research involving people with a lived experience of cerebral palsy, their families, and health service providers to co-design a social prescribing pathway for children with cerebral palsy and their families in Australia.(13) The objectives of this pilot randomised controlled trial (RCT) are to assess the feasibility and acceptability of two co-designed social needs clinical pathways - social prescribing (i.e., Community Linker plus resource pack) compared to resource pack only- for parents/caregivers of children with cerebral palsy in tertiary Paediatric Rehabilitation clinic settings.

METHODS

Objectives and hypotheses

The primary objectives of this pilot RCT are to evaluate the feasibility and acceptability of implementation and delivery of the co-designed social needs pathways. Secondary objectives include assessment of fidelity and service model variations, to determine the short-term impacts of the intervention at 3- and 6-months post-enrolment, and to inform a future, definitive multicentre large-scale RCT.

We hypothesise that both the social prescribing intervention (Community Linker plus resource pack) and active control intervention (self-navigation using resource pack) will be feasible and acceptable, according to outcome measures described in sections below.

Co-design of intervention and trial with parents and young people

The intervention was co-designed using a modified Hawkins et al.(14) framework. It involved families of children with CP, and their healthcare providers. This was to ensure the intervention was responsive to the needs of its end-users and was tailored for implementation in the local health setting. A protocol of this co-design approach has been published(13) and the findings of the co-design research phase is currently under review, reporting against the GRIPP guideline.

Study design

This is a multi-centre, unblinded, pilot RCT which will take place from April 2023 until December 2024. The unmet social needs of parents/caregivers of children with cerebral palsy will be screened during their clinic appointment. Families who self-report experiencing unmet social needs on the survey tool and consent to the research study are randomised into arms, either 1) social prescribing intervention arm (Community Linker plus resource pack) or 2) active control arm (self-navigation using resource pack). The rationale for this design is that there is evidence to support both pathways (Community Linker; resource pack), and it is unethical to screen for unmet social needs and not provide a response. The trial design is outlined in Figure 1.

[INSERT FIGURE 1 HERE]

Setting

This study is conducted at the Rehabilitation Departments of the three tertiary paediatric hospitals in New South Wales, Australia: The Children's Hospital at Westmead, Sydney Children's Hospital Randwick, and John Hunter Children's Hospital. The Paediatric Rehabilitation Departments offer a comprehensive cerebral palsy clinical service staffed by a multi-disciplinary team including paediatric rehabilitation medicine physician, nurse, physiotherapist, occupational therapist, and social worker.

Study population

Participants in the RCT must meet the following criteria to be eligible for the study:

Inclusion criteria

1. Parent/caregiver of a child (aged 0-18 years) with a confirmed diagnosis of cerebral palsy who is patient of the Cerebral Palsy Service at one of the following tertiary Paediatric Rehabilitation Departments: Kids Rehab, the Children's Hospital at Westmead; Rehab2Kids, Sydney Children's Hospital; HNEkidsRehab, John Hunter Children's Hospital.

2. Parent/caregiver self-report at least one unmet social need from the following six items on the adapted WECARE survey tool: Childcare or schooling; Government benefits and vouchers; Housing; Food; Bills; Transport.
3. Reside in New South Wales or Australian Capital Territory.
4. Provide informed consent.

Exclusion Criteria

1. Parent/caregiver have no mechanism for contact (telephone or email).
2. Family already enrolled and assigned a research participant ID. In the instance where a parent/caregiver meets inclusion criteria and has multiple children with a diagnosis of cerebral palsy (e.g., siblings with cerebral palsy or twins with cerebral palsy), the parent/caregiver will only be able to enrol once for their family.

Service provider participants (qualitative interviews/focus groups): Service providers working at the Rehabilitation Departments of the three NSW Children's Hospitals will be invited to take part in qualitative interviews/ focus groups to explore their perspectives of the pilot trial and implementation of social prescribing intervention (Community Linker plus resource pack) and active control intervention (self-navigation using resource pack).

Intervention

The intervention was co-designed with over 200 participants through a rigorous co-design research phase described in detail in separate publications (13, 15-17). Research participants co-developed the program logic model and prototype of the intervention. Following an intensive qualitative needs assessment, participants co-developed the intervention including a survey tool for the standardised identification of unmet social needs, Community Linker role and scope of practice, and resource pack. This process was piloted in research action cycles, with continuous refinement until a consensus was achieved. The finalised logic model is shown in figure 2.

[INSERT FIGURE 2 HERE]

Active control (self-navigation with resource pack)

Participants randomised to the active control arm will be provided a resource pack containing information on community services to support their unmet social needs. The resource pack was co-designed during the earlier formative research phase and piloted during iterative co-design processes(13). The resource pack will be available in hard-copy and online. The online version of the resource pack will be available on a secure website accessible only to individuals provided the QR code to the webpage or direct weblink. The resource pack is an enhancement to usual care, which may involve clinicians recommending these services for unmet needs as part of their care.

Social prescribing intervention arm (Community Linker plus resource pack)

Participants randomised to the social prescribing intervention arm will receive one-on-one Community Linker support, in addition to the resource pack (described above). The Community Linker provides one-on-one support based upon the needs of the family, as an extension to usual care, in addition to the resource pack.

A Community Linker is a trained, non-medical staff member who assists parents/caregivers to connect with appropriate services and supports to address their unmet social needs. Community Linkers provide

practical, hands-on support navigating services e.g., finding an appropriate local community service, making referrals to services, helping parents/caregivers complete forms, follow-up with services, booking appointments, assisting in gathering support letters and submitting paperwork for funding under the National Disability Insurance Scheme. The Community Linker position description including their title, qualifications, and key roles and responsibilities was co-designed with end-users during the previous phase of research. Each study site will employ a Community Linker to be supervised by the Cerebral Palsy Service Manager and Cerebral Palsy Service Social Worker. Community Linkers will follow a co-designed documented standard operating procedure including specific training modules, which includes escalation procedures should concerns be disclosed that are beyond the scope of their role (e.g., mental health concerns, domestic violence, clinical concerns).

All participants in the intervention arm will have an intake appointment with the Community Linker at their service. Dependent on participant preference, the intake appointment may occur face-to-face at the Rehabilitation Department immediately after randomisation. Alternatively, it may occur via phone, videoconference, or in-person at a different time that suits the participant. All participants will have an intake appointment within one week of randomisation to the social prescribing arm. During the appointment, participants will discuss their unmet social needs with the Community Linker; the current supports and services they are accessing; what they need help with; and their goals for managing their unmet social needs. A personalised care plan will be made together with the parent/caregiver and their child/young person with cerebral palsy (as required). The parent/caregiver will be offered the opportunity to for their child/young person with cerebral palsy to engage with the Community Linker. Parents/caregivers will also elect their preferred mode (e.g., videoconference, phone call, email) and frequency of communication (e.g., once-a-week, once a fortnight) with the Community Linker which can be revised at any time as required. The Community Linker will provide support for a period of 3-months. The frequency of engagement will depend on participants preferences and needs. However, the Community Linker will conduct minimum monthly check-ins for all participants.

Sample size

The pilot trial will aim to obtain a minimum of 35 respondents in each trial arm at 3- and 6- month follow-up. Assuming a 30% loss to follow-up in line with previous research (18, 19), a total sample size of 120 families will be recruited - 60 in each research arm.(20) Per Teare et al (2014) a total sample size of 120 parents/caregivers makes it possible to assess feasibility as the relevant primary outcome.[15] Randomization will be stratified by Rehabilitation Department/study site. Thus, at each study site, 20 parents/caregivers will be randomised to each research arm.

Within the prior formative research to co-design the interventions, quality improvement cycles were conducted at one study site piloting the survey tool and pathways.(13) During the 12-week testing period, 105 parents/caregivers of children with cerebral palsy completed the unmet social needs survey tool. Based on this experience, we estimate a recruitment period of 3-months to enrol all participants in the study across three sites. The data from this pilot RCT will form sample size calculations for a potential future RCT of efficacy.

Qualitative data sample size: As this is inductive rather than deductive research a sample size calculation cannot be done. However, using purposeful sampling, the saturation point will most likely be reached after 10-20 interviews with parents/caregivers. We estimate that 5-10 service providers will take part in an interview/focus group per site, thus 15-30 service provider participants in total.

Screening and recruitment strategy

Parent/caregiver participants: All parents/caregivers of a child with cerebral palsy attending the participating Rehabilitation Departments will be asked to complete a paper-based survey tool for standardised identification of unmet social needs during their routine clinic visit (Supplementary File 1). The survey tool includes information about the research study where parents/caregivers can indicate their interest (yes/no) in hearing more and provide contact details if applicable. All survey tools will be distributed and collected by the site Community Linker and project staff. Contact details of interested parents/caregivers will be provided to project staff responsible for enrolment.

If parents/caregivers screen positive on the tool (self-report one or more unmet social needs) but are not interested in knowing more about the study, they will be advised to discuss their concerns with their clinical team per routine care. If interested parents/caregivers are not eligible for the project, they will be told that they are ineligible for the research project and will be advised to discuss any concerns with their clinical team per routine care. If interested parents/caregivers are eligible for the project, they will be provided a participant information sheet and consent form (PISCF). The PISCF may be provided immediately by the Community Linker/project staff during the family's attendance of the clinical appointment in paper form or a REDCap link sent via email, dependent of the family's preference and availability on the day.

Service provider participants: Service providers will be identified through department meetings and professional networking within the participating study sites. Interested service providers will be given a Service Provider PISCF either in hardcopy version or via recruitment email. They will be given time to think about the project and have the opportunity to ask any questions they may have about their participation in the study to the study coordinator.

Consent

Parent/Caregiver and young person participants: Parent/caregiver and young person PISCFs will provide information about the research, the risks/benefits, and its voluntary nature. The parent/caregiver PISCF will be provided to all interested parents/caregivers (Supplementary File 2). Additionally, young people aged 8 years or older who can self-report (determined via parent/caregiver and young person report) will be provided a young person PISCF. If the young person has capacity to provide consent, they will be requested to co-consent along with their parent/caregiver in whatever form of communication suits their preference and needs (e.g., in writing, verbal consent, using augmented and alternative communication methods). The approved PISCF's will be translated into other languages based on data pertaining to limited English language proficiency and largest language groups attending the tertiary Paediatric Rehabilitation Departments.

It will be made clear to participants that they can stop participating in the study at any time without consequences to the care or services they receive. If the participant expresses that they are not interested in the study, no further contact will be made in relation to the study. Parents/caregivers will also be free to withdraw their consent if they change their minds at any point during the study. Participants can provide informed consent in several ways: signing the hardcopy of the PISCF at a face-to-face visit; signing the online REDCap consent form to be included in recruitment email(21); providing verbal consent via phone call. Participants will be asked to complete a baseline questionnaire immediately after providing consent.

Service provider participants: The service provider PISCF will be distributed as paper-based copy or via recruitment email. The recruitment email will include a link directing potential service provider

participants to the online version of the PISCF via the REDcap® data link. Service providers will be required to either sign the hard copy consent form and return to study coordinator or sign the online consent form hosted on REDCap.

Randomisation and intervention allocation

Participants will be randomised automatically by the REDCap platform(21), assigning 50% of participants to each group. Randomisation will be conducted by project staff. Randomisation will be stratified by Rehabilitation Department/study site. Across the entire project, 60 parents/caregivers will be randomised to the social prescribing intervention arm (n= 20 at each study site) and 60 parents/caregivers will be randomised to the active control arm (n=20 at each site). The project staff will notify participants of their intervention allocation via one of three methods (face-to-face; email; phone) dependent on their personal preference and corresponding to chosen method of consent as described above.

Outcome measures

Table 1 offers a summary of the outcome measures.

Pilot outcomes- feasibility and acceptability

Feasibility will be evaluated against the stop-go criteria for success of feasibility, as follows:

1. Recruitment rates: Recruitment will be successful if 80% of our target sample is met in the 3 months of recruitment.
2. Uptake of intervention: Will be considered successful if > 70% of families complete the intervention.
3. Follow-up of participants: Will be considered successful if > 70% of families complete all the study visits.

We will also evaluate feasibility and acceptability via:

- Process measures: non-identifiable data will be recorded on the proportion of families who: complete vs. decline the unmet social needs survey tool; positive vs. negative unmet social needs screening; are interested vs. not interested in research participation consent vs. do not consent to research study.
- Community Linker logbook: each Community Linker will keep a logbook of their activities including type of social care navigation activities provided, e.g., advice regarding services, attending services with families, types of pf services, referrals made to services collected etc.
- Satisfaction and acceptability survey: At 3-month post-enrolment, all participants (social prescribing intervention; active control) will be asked to complete a bespoke questionnaire regarding their satisfaction and acceptability of their allocated intervention.
- Parent/caregiver qualitative interview: At 3-month post-enrolment, participants in the social prescribing group will be invited to complete a qualitative interview to explore their experiences, barriers, and enablers to social prescribing as perceived by parents/caregivers. The interviews will be conducted 1:1 with the project coordinator and will follow a semi-structured interview guide. Interviews will be conducted face-to-face, phone, or teleconference dependent on participants preference.
- Clinician qualitative interview/focus group: clinicians from participating study sites will be invited to take part in interview/focus group exploring the experiences, barriers, and enablers of social prescribing intervention and active control intervention as perceived by clinicians (conducted during trial implementation based on availability and preference of staff at sites).

Secondary outcomes- proposed impacts for future RCT

Secondary outcomes aim to determine short-term impacts of the intervention at 3- and 6- months post-enrolment. This will help inform sample size and outcome measures to be used in future, definitive multi-centre large-scale RCT. Per Table 1, outcomes will be assessed at baseline, 3-month follow-up, and 6-month follow-up including:

- Unmet social needs (adapted WECARE survey tool)(22),
- Parent/caregiver distress (K-6 Distress Scale – Self Administered)(23),
- Child/young person global health (PROMIS Parent Proxy Scale v1.0 – Global Health 7 (item 1; item 2)(24) or PROMIS Pediatric Scale v1.0 – Global Health 7 (item 1; item 2))(24), and
- Parent/caregiver global health (PROMIS Scale v1.2 – Global Health (item 1; item 2))(25), and
- Service use captured on bespoke survey.

Furthermore, at baseline parent/caregivers will be asked to complete a demographic survey. A medical record review of children with CP will be completed for all participants to describe the characteristics of participating children/families and explore any potential association between outcome measures and clinical factors relating to the child with cerebral palsy and demographic factors related to the parent/caregiver. The feasibility and acceptability, and secondary outcome measures will be reviewed and findings will be integrated into an update program logic model to inform future, definitive multi-centre large-scale RCT.

Table 1. Summary of study outcome measures		
Outcome	**Methods and measures**	**Time**
Primary outcomes		
Feasibility of a social prescribing intervention (resource pack plus in-person Community Linker) and active control intervention (self-navigation with resource pack)	• Number/proportion of completed survey tools for identification of unmet social needs (screening) • Number/proportion of families interested in research study (screening) • Number/proportion of eligible clients who consent to participation in research project (baseline) • Number/proportion of social prescribing group participants who engage with in-person Community Linker (3-month follow-up) • Number/proportion of participants who complete 3-, and 6-month follow-up assessments (3-month follow-up; 6-month follow-up)	Ongoing throughout implementation
Acceptability and satisfaction with social prescribing intervention (resource pack plus in-person Community Linker) and active control intervention (self-navigation with resource pack)	Parent/caregiver satisfaction and acceptability collected via bespoke questionnaire.	3-month follow-up
Acceptability and experiences of social prescribing intervention (resource pack plus in-person Community Linker)	• Qualitative interviews with parent/caregiver on experiences, barriers, and enablers to social prescribing intervention. • Qualitative focus groups with health service providers at participating Paediatric Rehabilitation study sites on experience, Barrie's, and enablers to social prescribing intervention.	Parents/caregivers:3-month follow-up. Clinicians: conducted during trial implementation based on availability and preference of staff at sites)
Intervention fidelity- social prescribing intervention (resource pack plus in-person Community Linker)	Type of social prescribing activities provided, e.g., advice regarding services, attending services with families, types of referrals made to services collected using Community Linker logbook	Ongoing throughout implementation
Secondary outcomes		
Unmet social needs	Parent/caregiver self-report via an adapted version WECARE survey tool(22)	Screening, 3-month follow-up, 6-month follow-up

Parent/caregiver distress	Parent/caregiver self-report via K-6 Distress Scale – Self Administered(23)	Screening, 3-month follow-up, 6-month follow-up
Child/young person global health	Parent/caregiver proxy-report, to be used when the child is <8 years of age or when if the child/young person is unable to self-report, via PROMIS Parent Proxy Scale v1.0 - Global Health 7 (item 1; item 2) Or Child/young person self-report, to be used if the child/young person is ≥ 8 years of age and can self-report, via PROMIS Pediatric Scale v1.0 – Global Health 7 (item 1; item 2)(24)	Screening, 3-month follow-up, 6-month follow-up
Parent/caregiver global health	Parent/caregiver self-report via PROMIS Scale v1.2 - Global Health (item 1; item 2)(25)	Screening, 3-month follow-up, 6-month follow-up
Service use	Types of services parents/caregiver's report using for unmet social needs via bespoke questionnaire	3-month follow-up

Data collection

All participants will be allocated a unique identifier code that will be used throughout the study. For enrolment and quantitative data collection, the study will prioritise electronic collection procedures. However, participants will be given the option to complete research questionnaires face-to-face, online via REDCap(21), or on the phone with the research staff. All quantitative data, irrespective of initial mode of data collection, will then be entered into a secure password-protected server-based database, REDCap.(21) Any hard copies of consent forms and de-identified questionnaires will be stored in a locked cabinet at each study site before being securely transferred to the study team at UNSW. When being stored at the study sites, hardcopy materials will be stored in a locked filing cabinet within a locked office, accessible only to the site project staff.

Qualitative interviews with families and qualitative focus groups with health service providers will be conducted face-to-face, via phone call, or videoconference dependent on participants preference. These will focus on participant's thoughts on and experiences engaging with the intervention, and clinicians' views on how well the intervention integrated within the clinics. Interviews and focus groups will be transcribed verbatim, and all data management, storage, and analysis will be done at UNSW. All paper copy and taped data will be de-identified. Coded information will be stored in a locked filing cabinet, or on password protected digital media. As soon as interviews have been transcribed the audio tapes will be erased.

All paper data and questionnaires will be entered into a secure password-protected server-based database, REDCap hosted at UNSW, and stored for 15 years after the last date of data collection.(21) After 15 years, any paper data will be shredded, and the electronic data will be permanently erased, and backups destroyed.

Data analysis

Quantitative data analysis

Participant characteristics will be reported using descriptive statistics. The analysis will be according to randomised treatment allocation. The analysis of primary outcomes – feasibility and acceptability – will be based on descriptive statistics reported as percentage (95% confidence interval). Analysis of secondary outcomes will be purely exploratory and not powered to detect efficacy, thus we will not perform tests of significance. Secondary outcome measures will be described by intervention allocation using the t-test and non-parametric tests for continuous data and the chi-squared test for categorical data. If suitable, linear and logistic regression modelling will be conducted to test group differences adjusting for basic baseline (where the model allows), for example, gender, and other sociodemographic characteristics.

Qualitative data collection and analysis

Data collected from the semi-structured interviews and semi-structured focus groups will be coded according to common themes using a thematic analysis.(26) Researcher triangulation will be employed to further substantiate the emerging themes. Data collection and analysis will continue until no new themes or hypotheses emerge, that is a "saturation point" is reached. Initially all coding of the interviews and development of themes will be done by hand. This provides the opportunity to redefine and/or merge themes as analysis proceeds. When no new themes are emerging, data will be managed with the assistance of the qualitative software Nvivo 11 software by the principal investigator. Transcription checks against tapes and notes taken, triangulation, feedback, will be employed to ensure rigour (e.g., all interviewees will receive a copy of their interview transcript to check). Comments after reading these will be fed back into the analysis.

Patient and public involvement

The social needs clinical pathways being evaluated in this pilot RCT were co-designed with people with a lived experience of CP, their families, and health care professionals in earlier formative research. (13) Outcomes to be assessed in this pilot RCT were included as part of the co-design process. This study is overseen by two research advisory groups - one group of young adults with CP and one group of parents of a young person with CP. Research advisors meet with the project officer monthly and provide input into each phase of the study, i.e., project conception and planning, data collection and analysis, dissemination. They have been involved with the project since commencement of earlier formative research to co-design the program and will continue to work together for this pilot RCT.[12] Research advisors are paid $30 (AUD) per hour.

This project has a governance structure including several sub-committees: research operations committee, research advisory group, steering committee, and knowledge translation committee. Each committee meets consistently with the chief investigator and project officer to facilitate information exchange and cooperation between stakeholders.

For completing the study questionnaires at baseline, 3-month follow-up, and 6-month follow-up; parent/caregiver research participants will be reimbursed for their time with a $20 gift voucher for each data collection time-point.

Ethics and considerations

Ethics approval for this project was granted by the Sydney Children's Hospitals Network (SCHN) Human Research Ethics Committee (2022/ETH01688) in October 2022. Site-specific research governance approvals were granted for SCHN and John Hunter Children's Hospitals. This trial has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12622001459718)

Where a reportable clinical incident is identified through or during the data collections an incident report will be lodged in the Incident Investigation and Management System as per the NSW Health Clinical Incident Policy. During the research project, we may identify families where there is domestic violence, financial abuse, or imminent risk of homelessness. In this event, families will be referred directly to CP Service Social Worker. Referral to the CP Service Social Worker does not exclude the parent/caregiver from participation in the research project. They will receive support from the site CP Service Social Worker in addition to their allocated intervention. If child protection concerns are raised usual mandatory reporting guidelines will apply.

Participants are free to withdraw their consent at any time. Reasons for non-participation will be recorded, and the decision not to participate or to withdraw from the study will not affect the participant's relationship with study hospitals. In such case, the researchers will not collect additional information from the participant.

Dissemination and policy implications

Research findings will be shared with people living with CP, parents/caregivers, and family members of people with CP, health professionals, social service professionals, policy makers, and academics via various outputs including a lay summary of research findings, a poster summarising research results displayed at study sites, peer-reviewed publications, conference presentations. These outputs will be developed in collaboration with all project members, including research advisors, to ensure the material is suitable and accessible to the relevant audience.

Authors contributions: KO, IK, and SW led the design of the study with input and guidance from SP, TM, BJDP, SM, HSS, LM, HB, TS, AB, AM, MS, JC, SA, MM, MW, AW, KZ, RD, VE, RL, IS, AO, DH, MH, GC and EPIC-CP Group. KO, IK, and SW produced the draft manuscript and SP, HSS, RD, BJDP, SM, IS, RL, LM, AM, KZ, and VE contributed to the manuscript. All authors read and approved the final manuscript.

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Competing interest statement: The views expressed are those of the author(s) and not necessarily those of the funding partners. NSW Health has no direct role in study design; data collection, analysis, and interpretation, or writing of final reports, presentations, or publications.

WORD COUNT: 4,351 (including in text citations)

Figure caption:

Figure 1: study diagram
Figure 2: finalised logic model

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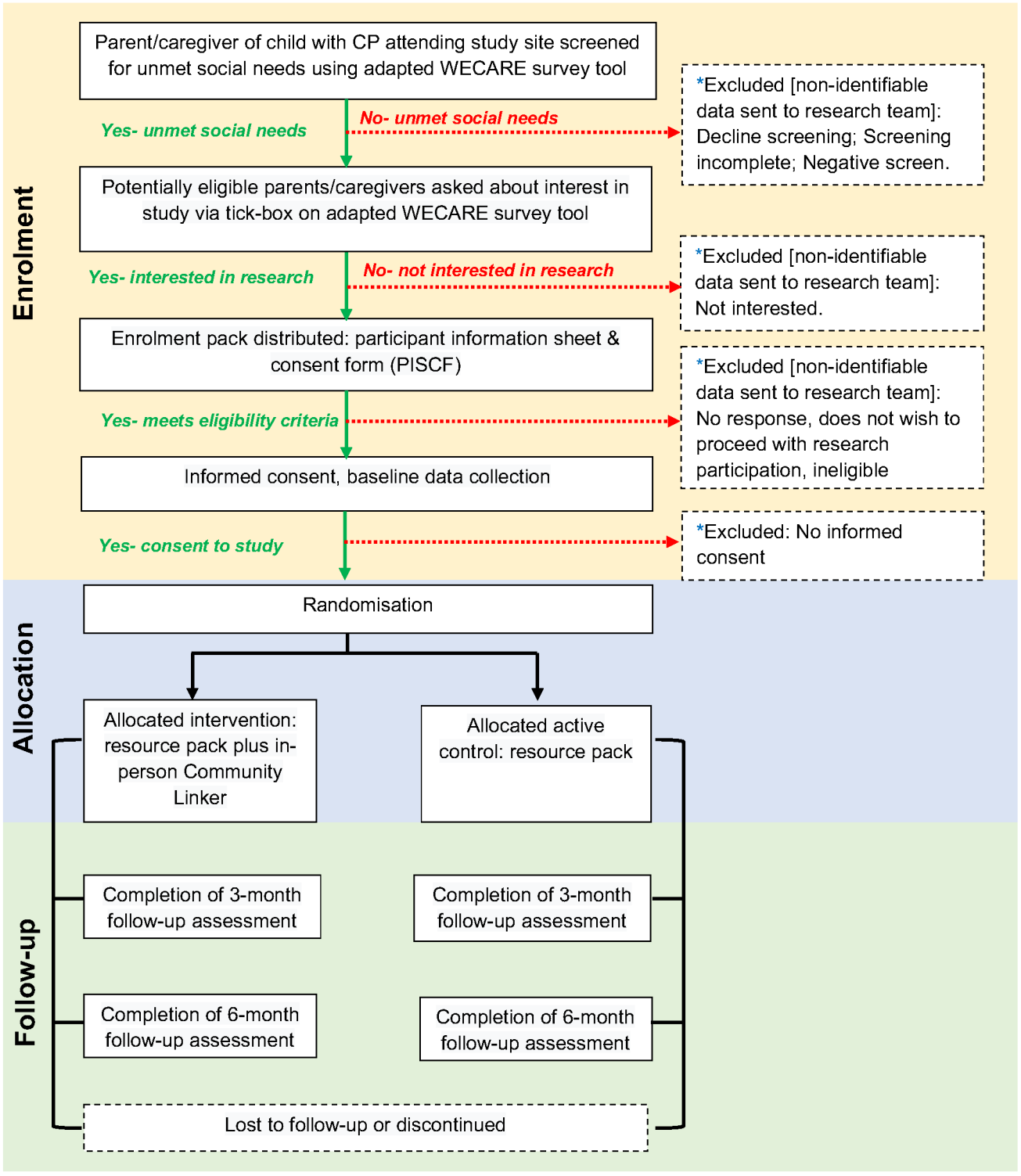

Figure 1: study diagram

**Any parents/caregivers who identify unmet social needs but decide to not participate in the research study at any time point during enrolment (i.e., tick "no" to research interest in screening form, do not wish to enrol after being provided PISCF etc) will be offered the resource pack and advised to discuss their concerns with their child's clinical team per routine care.*

LOGIC MODEL: EPIC-CP program for children with cerebral palsy and their families

Context

Knowledge:

- Community Linker (CL) has extensive knowledge of the social services and supports across health and community.
- CL has sound knowledge of paediatrics, disability/chronic and complex health conditions, social determinants of health, and psychosocial functioning.

Skills:

- CL is not a therapeutic role- provides practical, hands-on support to families to help them link with and navigate to services.
- CL has strong communication skills, empathetic, able to work closely with families.
- CL receives training via various formalised training modules from NSW Health and non-government organisations.

Supervision:

- CL works within the CP clinical service within each Paediatric Hospital.
- CL employed in NSW Health as an "Allied Health Assistant" position.
- CL has day-to-day direct supervision from CP Service Manager.
- Weekly reporting to EPIC-CP research project team.
- CL working closely with/alongside CP Service Social Worker.

Activities

- Standardised *identification* of *unmet social needs via* survey of adapted WECARE tool.
- Standardised *self-referral* pathway of families when completing the paper-based survey tool and indicating interest in the social prescribing study.
- Standardised *intake* of children/families with Community Linker (CL)- initial consultation to identify priorities and develop individualised family plan.
- Standardised *referral pathway to key community services* (Family Connect and Support, NDIS Partners in Community) via CL, utilised as required per family.
- The CL will have *minimum monthly engagement* with parent/caregiver via text/phone/email etc. based on family preference.
- Cases requiring more *complex care or involving mandatory reporting* will be referred to the CP Service Social Worker.
- Per routine care, *standardised referral pathway to CP Service Social Worker* for families not eligible for research or requiring more intensive support.

KPIs, outputs, process measures

KPIs

- All families of children with CP are routinely screened for unmet social needs when attending CP service/clinic.
- Frequency of engagement with CL per personalised family plan (minimum once-a-month check-in).

Process measures:

- # of families with/without unmet social needs.
- # of families who self-referral to social prescribing pathway.
- # families who complete unmet social needs screening tool but decline research participation.
- # families who decline completing unmet social needs survey tool.
- Frequency and type of engagement with CL (via logbook).
- # referrals to CP Service Social Worker.
- # referrals to Family Connect Support Case Management.

Outputs

- Adapted WECARE survey tool for unmet social needs- adapted for families of children with CP attending Rehab Department.
- Library of generic e-resources of services available to support unmet social needs.
- Generating and maintaining library of local resources and contacts appropriate for each study site/local region.

Outcome/ Goals

Primary outcome/goals: Standardised identification and then reduction of unmet social needs (identified via adapted WECARE survey) following program (3- month duration).

Secondary outcomes:

- Increase in social supports/services families engage with.
- Improvement in child/young person and parent/caregiver quality of life.
- Reduction in parent/caregiver distress.
- Reduction in non-attendance of outpatient appointments.

[insert study site logo]

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

[insert study site logo]

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.

[insert study site logo]

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.

[insert study site logo]

- *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

[insert study site logo]

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.

[insert study site logo]

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.*

[insert study site logo]

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**
_____	_____	_____

[insert study site logo]

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**
_____	_____	_____

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1, Line 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 12, Line 22
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	Page 1, Line 4
Funding	4	Sources and types of financial, material, and other support	Page 13, Line 6
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 1
	5b	Name and contact information for the trial sponsor	Page 13, lines 6-7
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 3
	6b	Explanation for choice of comparators	Page 5, line 12-18
Objectives	7	Specific objectives or hypotheses	Page 4, lines 2-11
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 4, lines 14-21
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 4, lines 24-29
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 4-5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 5
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 7-10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	NA

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 7, lines 43-48
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	NA
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page 7, line 28-31
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 7, lines 28-36
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 7, lines 30-31
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 1, Page13
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 9-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 11, lines 1-22
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 11, lines 24-46
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	NA
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 12, line 20-23
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 7, lines 2-20
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 11, lines 5-22
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 13, lines 9-11
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 12, lines 39-45
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	NA
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Table 1 GRIPP2 long form

From: GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research

Section and topic	Item	Reported on page No
Section 1: Abstract of paper		
1a: Aim	Report the aim of the study	Page 2 Line 8–11
1b: Methods	Describe the methods used by which patients and the public were involved	Page 2, line 18–19
1c: Results	Report the impacts and outcomes of PPI in the study	NA
1d:Conclusions	Summarise the main conclusions of the study	NA
1e: Keywords	Include PPI, "patient and public involvement," or alternative terms as keywords	NA
Section 2: Background to paper		
2a: Definition	Report the definition of PPI used in the study and how it links to comparable studies	NA
2b: Theoretical underpinnings	Report the theoretical rationale and any theoretical influences relating to PPI in the study	Page 4 Line 13–16
2c: Concepts and theory development	Report any conceptual or theoretical models, or influences, used in the study	Page 4 ine 24–26
Section 3: Aims of paper		
3: Aim	Report the aim of the study	Page 3 Line 41–47
Section 4: Methods of paper		
4a: Design	Provide a clear description of methods by which patients and the public were involved	Page 4 Line 13–18
4b: People involved	Provide a description of patients, carers, and the public involved with the PPI activity in the study	Page 4 Line 14–15
4c: Stages of involvement	Report on how PPI is used at different stages of the study	NA

Section and topic	Item	Reported on page No
4d: Level or nature of involvement	Report the level or nature of PPI used at various stages of the study	Page 5 Line 20–26
Section 5: Capture or measurement of PPI impact		
5a: Qualitative evidence of impact	If applicable, report the methods used to qualitatively explore the impact of PPI in the study	NA
5b: Quantitative evidence of impact	If applicable, report the methods used to quantitatively measure or assess the impact of PPI	NA
5c: Robustness of measure	If applicable, report the rigour of the method used to capture or measure the impact of PPI	NA
Section 6: Economic assessment		
6: Economic assessment	If applicable, report the method used for an economic assessment of PPI	NA
Section 7: Study results		
7a: Outcomes of PPI	Report the results of PPI in the study, including both positive and negative outcomes	NA
7b: Impacts of PPI	Report the positive and negative impacts that PPI has had on the research, the individuals involved (including patients and researchers), and wider impacts	NA
7c: Context of PPI	Report the influence of any contextual factors that enabled or hindered the process or impact of PPI	NA
7d: Process of PPI	Report the influence of any process factors, that enabled or hindered the impact of PPI	NA
7ei: Theory development	Report any conceptual or theoretical development in PPI that have emerged	NA
7eii: Theory development	Report evaluation of theoretical models, if any	NA
7f: Measurement	If applicable, report all aspects of instrument development and testing (eg, validity, reliability, feasibility, acceptability, responsiveness, interpretability, appropriateness, precision)	NA
7 g: Economic assessment	Report any information on the costs or benefit of PPI	NA
Section 8: Discussion and conclusions		
8a: Outcomes	Comment on how PPI influenced the study overall. Describe positive and negative effects	Page 13 Line 2–20
8b: Impacts	Comment on the different impacts of PPI identified in this study and how they contribute to new knowledge	NA
8c: Definition	Comment on the definition of PPI used (reported in the Background section) and whether or not you would suggest any changes	NA
8d: Theoretical underpinnings	Comment on any way your study adds to the theoretical development of PPI	NA
8e: Context	Comment on how context factors influenced PPI in the study	NA

Section and topic	Item	Reported on page No
8f: Process	Comment on how process factors influenced PPI in the study	NA
8 g: Measurement and capture of PPI impact	If applicable, comment on how well PPI impact was evaluated or measured in the study	NA
8 h: Economic assessment	If applicable, discuss any aspects of the economic cost or benefit of PPI, particularly any suggestions for future economic modelling.	NA
8i: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so that others can learn from this study	NA

PPI patient and public involvement

Back to article page ›

Research Involvement and Engagement

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