‘SPACE CYP’ Pilot:

Social **P**rescribing **A**nd **C**ommunity r**E**sources for **C**hildren and **Y**oung **P**eople

Protocol v1.0 10/03/2022

IRAS Number:	309038
Sponsors Number:	R+D 10063 (PIF 2583)
Funders Number:	ARC REF OFC2021-24 GNCH FOUNDATION REF 7647
CPMS ID:	52488
Caldicott Application Number:	9556
ISRCTN:	42100

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Study Summary

Children and young people (CYP) have unmet health and social needs, especially those with neurodevelopmental impairment. These could be addressed through social prescribing (SP). SP is a key component of universal personalised care, supported in the NHS Long Term Plan. It involves link workers (LW) helping those with health and social care needs to engage with supportive community resources. Its current focus is on adults.

Aim:

To identify the components of effective SP for CYP, identifying lessons learned across two settings.

The two settings are:

1) Great North Children's Hospital (GNCH - new hospital pilot study)

2) Zone West (ZW - ongoing community study)

This protocol describes the arrangements for the GNCH pilot study, additional elements of fieldwork for an ongoing ZW study and the joint evaluation of social prescribing across the GNCH hospital setting and the community Zone West setting.

Study Design	Mixed-methods evaluation
Study Participants & Planned Sample Size	▪ Link Workers (n=4) ▪ Children and young people and their carers (n=60, 30 from each setting).
Follow-up Duration	Up to 6 months
Planned Study Period	▪ Start date: 31/03/2022 ▪ Duration: 20 months

Funding and Support in Kind

Financial support for the project is being provided by:

- Great North Children's Hospital Foundation
- Ways to Wellness
- NIHR ARC NENC

Study Flowchart

For the Zone West project, only the interviews and observations are in addition to current practice. The GNCH pilot is entirely new.

1. Background and Rationale

Many children growing up in the North of England face challenges due to deprivation[1]. Deprivation adversely affects long-term outcomes[2]. The COVID-19 pandemic heightened these pre-existing problems and added new ones of social isolation, mental health and disrupted service provision, leading to high levels of unmet need [3,4]. Against this backdrop, children with chronic complex healthcare problems (of which neurodisablity forms the largest group) have particularly high levels of unmet non-medical needs. More than half of families with a child with complex healthcare needs have financial difficulties, and a third express difficulty accessing non-medical services[5]. More support for these children and their families is urgently needed.

Social prescribing (SP) is a development currently being established in primary care networks, in which 'link workers' support those with health and social needs to find and engage with community resources to help their health and wellbeing[6]. SP is a key component of universal personalised care, supported through NHS England as part of the NHS Long Term Plan. There is emerging evidence from SP schemes in adults (including Ways to Wellness), of benefits to wellbeing and in some cases reductions in NHS costs [see https://www.kingsfund.org.uk/publications/social-prescribing]. SP schemes for CYP are emerging, e.g. Streetgames (who also oversee a CYP SP network). However, a recent systematic review found *no* published studies of SP for CYP [7]. Since then, Bertotti et al.[8] reported a 2-year evaluation of SP for young people (YP), demonstrating improved mental wellbeing, reduced use of NHS and social care, and evidence of a social return on investment well above the average for adult SP schemes. They recommend further "test and learn" approaches to SP for YP, and research into the specific skills required for LW supporting this group.

Our proposal addresses these recommendations whilst complementing the studies in Bertotti's report. The average age of participants in Bertotti's report was 16 years, whereas we investigate a younger group. We will evaluate the established community-based Zone West programme for primary school aged children. Furthermore, we will set up and evaluate an innovative scheme to support children with neurodisability and their families – an approach endorsed by respondents to our preparatory surveys and extensive stakeholder discussions. Both schemes will undertake outcomes evaluation separately as part of their internal working. This project addresses a mixed-methods evaluation of SP for CYP across settings, identifying components for best practice.

Some general principles of SP are clear. Schemes require understanding of and engagement with local community assets[9]. Participant engagement is enhanced by: good explanation of the scheme and potential benefits at referral; accessibility and quality of the resource; and a supportive LW[10]. Our project explores the challenges of SP for a younger, less independent group of children including those with disability, for whom acknowledging the support role but also the needs of the family, is key.

2. Theoretical Framework

The social determinants of health have long been known – for example, the relationship between serious adverse life events and depression [11]; and between poverty and life expectancy as described in the Marmot Review and follow-on report [12]. The effect is evident right from early childhood: for example, children and young people from deprived backgrounds are more likely than average to attend Accident and Emergency departments, and to be admitted to hospital [13]. There is a strong association between developmental disabilities and socio-economic disadvantage [14]. All these examples highlight the negative effects of deprivation and adverse events on health; conversely, positive social influences can mitigate against these effects.

Social capital describes "the extent and nature of our connections with others and the collective attitudes and behaviours between people that support a well-functioning, close-knit society"[15]. Social capital is important for well-being at the level of the individual and the wider community. Achieving health and well-being at the level of the individual clearly requires inputs tailored to the individual's needs and preferences – this underpins the principles of personalised care. Social prescribing is a key component of universal personalised care and is supported in the community through NHS England as part of the NHS Long Term Plan [16].

The salutogenic model of health[17] provides a potentially useful framework within which to consider what might be key components of good link worker practice. This model views health as a continuum rather than as a dichotomous state in relation to disease; and focusses on promoting factors which may support the individual in achieving improved health wherever they are on the continuum. The model incorporates the view that an individual's "sense of coherence" (essentially a reflection of personal resilience) influences their health[18]. Unfortunately, this presents a limitation for the current study in that sense of coherence may not be measurable in a number of participants.

Husk et al.[10] undertook a realist review which aimed to clarify what processes are involved in effective social prescribing interventions for adults in a community setting. They identified three key stages – enrolment, engagement and adherence. Enrolment by the participant is underpinned by a belief that the social prescribing process will be beneficial, and by the referral being presented in an acceptable way. Engagement in prescribed activities is more likely if these are accessible to the participant and if transit to the first session is supported. Adherence with the program is more likely if the activity leader is skilled; adherence may also be affected by a change in the participant's medical condition.

Tierney et al[19]. also undertook a realist review, focussing on the role of the link worker in primary care and using a "context-mechanism-outcome" approach to provide a testable programme theory to explain how social prescribing works and in what conditions. Two key concepts arose – "buy-in" to the service, and establishing and maintaining good relationships between the link worker and other stakeholders including healthcare professionals, patients and the voluntary sector. Buy-in required support from key stakeholders; clear information about the nature of the service; and confidence in the capability of the individuals employed as link workers. Potential outcomes included improved wellbeing and reduced use of GP services. They then drew upon the existing theories around social capital and "Patient activation" (which relates to the "sense of coherence" mentioned above). Their theoretical framework is an appropriate starting point for our study but is likely to require modification in light of the participant group under study. The additional factors of relevance in our study are the age group (children), and for the hospital pilot (in addition to this setting), the presence of neurodisability. These factors raise additional challenges related to the relative lack of

independence/autonomy of the group under study; physical challenges such as restricted mobility; communication challenges related to the age and/or underlying condition of the young person; and negotiating the hospital setting which in the first instance will likely be unfamiliar to the link worker.

3. Research Question/Aims

To identify the components of effective social prescribing (SP) for children and young people (CYP) and their families, identifying lessons learned across two settings.

3.1 Objectives

1. **Describe, understand and explain social prescribing for CYP across the two settings** We evaluate SP for CYP across two settings – one existing service, Zone West (ZW) and one newly established, Great North Children's Hospital (GNCH) - to identify effective components of practice to guide recommendations for training and service delivery.

2. **Identify, understand and explain effective link worker behaviours, and barriers and facilitators to service engagement** This analysis will inform development of a more broadly applicable model for SP service provision for CYP and their families.

3. **Identify, understand and explain how regional and national policy can support and improve SP for CYP and their families.**
   We will ensure lessons learned are applied as widely as possible. We have a large and experienced steering group including representation from local CCGs, Newcastle City Council SEND board, NECS and NHS Improvement who will advise on how the policy environment is shaping support for CYP, and how to support wider adoption of the approach.

3.2 Outcome

We intend that our study will lead to a greater understanding of how to provide optimal social prescribing services supporting children and young people and their families, across different settings and circumstances. This will include a description of effective link worker behaviours as well as broader aspects of service provision. We intend to disseminate these findings. Our intention is that the findings would be used to optimise service provision including components such as link worker training, and to inform regional and national policy on SP for CYP.

4. Study Design and Setting

4.1 Study Design

A mixed-methods evaluation.

4.2 Participants & Setting

Link workers (n=4) and children and young people and their families/carers (n=60; 30 per site) will be recruited. This is a multicentre study.

Hospital-based site*:* This new pilot service will situate the identification, referral and initial assessment in a hospital setting and will target those with high levels of unmet need who are embedded in secondary/tertiary care.

Community-based site: Newcastle's ZW project is an existing service, supporting children aged 7-11 years with concerns raised from education, health and/or social care (see https://www.northeastwellbeing.co.uk/zone-west/). Research governance approvals are in place for the existing service and evaluation (IRAS ID 266176) – this application simply includes the addition of qualitative observations and interviews of participants and their families in that study.

4.3 Intervention

Link Workers (LW) at the Community site and the Hospital site will establish peoples' individual profiles of need, identify and support clients to engage with relevant services, reviewing progress at 3 and 6 months.

In practice, this will mean (both sites):

- Person identified as potentially eligible
- Consent for referral to LW (through standardised pathway) and study participation
- LW meets participant, builds relationship, records demographic data; documents profile of need (guided by parents as proxy where necessary). For the hospital-based project, related needs of close family members will be similarly captured.
- LW identifies and discusses relevant resources with participant.
- Participant accesses resources, with support if needed.
- LW follows up with tailored support (e.g. contact every 2-4 weeks as necessary) and reviews at 3 and 6m

The TIDIER[20] checklist below summarises the key features of the intervention in each setting.

Name	GNCH pilot	Zone West
Why	Children with neurodisability and their families have high levels of unmet need. SP is a plausible solution to addressing this.	ZW identifies primary school age children with needs in the dimensions of education, health and/or social care and assigns a LW to help address needs.
What Materials	Support star (Triangle) will be used by LW to gather information about domains and levels of need, at baseline and follow up. This will form the basis of a conversation about unmet needs in a range of domains. LW will receive training in its use.	A bespoke questionnaire forms the basis of a conversation about unmet needs in a range of domains.
What Procedures	Unmet needs will be mapped, and participants referred to (and supported to attend if need be) community services to address this need	Unmet needs will be mapped, and participants referred to (and supported to attend if need be) community services to address this need
Who Provided	Link workers – with relevant life experience, personal qualities and values to be able to undertake the work. Training includes: Social Prescribing - elearning for healthcare (e-lfh.org.uk) Plus some shadowing with link workers/hospital team. Optional training to fill in gaps in experience: Level 2/3 Information, Advice and Guidance; Level 2 Counselling; Life Coaching; Active Inclusion (welfare benefits); Motivational Interviewing; City of sanctuary (refugee and asylum)	Link workers – with relevant life experience, personal qualities and values to be able to undertake the work. Training: ZW LWs receive induction and training from existing LWs, which includes a period of shadowing existing LWs in schools
How Provided	Individual, face to face session at baseline. Ongoing follow up by telephone/virtual means, with face to face reviews at 3 and 6 months.	1:1 and group work.
Where	Children identified during inpatient hospital stay, where baseline assessments will occur. Engagement with LW (up to 6m) and community services within the North of Tyne and	Community-based, West end of Newcastle (Children who are patients at one of three GP practices and attend one of four primary schools)

	Gateshead ICP (indefinite) continues after discharge from hospital.	
When & How Much	The amount of intervention will be tailored to need, but LW intervention will be time limited to 6 months for practical reasons. During this time LW will make contact with participants at least once a month – but more regular contact may be required where there are high levels of need.	The link worker will identify key areas of need individualized for the child. They will then design a programme to match them with the appropriate assets within the community. The frequency of visits from the link worker will be determined by the link worker and the child/family.
Tailoring	This is a personalised intervention, adapted to address unmet need	This is a personalised intervention, adapted to address unmet need
Modifications	If recruitment through inpatients is slow we will also recruit through outpatients.	If recruitment is slow we could expand the number of GP surgeries
How Well (Adherence)	We will document LW contacts and whether participants accessed community resources to which they were referred, and where relevant, how long for. In-depth interviews will also explore adherence	We will document LW contacts and whether participants accessed community resources to which they were referred, and where relevant, how long for. In-depth interviews will also explore adherence.

The schedule of events is in the Appendix and details the assessments specific to each setting. For Zone West, the only change to the current service is the addition of observations and qualitative interviews. More details about the assessments are given below in section 5.

5. Methods of Data Collection and Data Analysis

5.1 Data Collection

Three interrelated approaches will be used:

1. Qualitative data to understand features of optimal service

1a. In-depth interviews with families

In-depth interviews with families (parents, and children including siblings where appropriate/possible) will be undertaken. We will use purposive sampling to explore experiences of families/children (n=15 per site) with differing needs and backgrounds, to start to establish what works, for whom, when and how.

We will encourage them to bring photos of meaningful moments during community engagement sessions to aid in expression of what they found beneficial as well as what they found challenging (photo elicitation methods). O'Donovan, (Co-I) has experience of using photovoice methodology[21-23] and the approach is particularly valuable for eliciting the experiences of people with disability[24,25] In a photo elicitation study, cameras are given to individuals in order to capture photographic images around a central theme which is of concern. These photographs are then used to facilitate interview-style discussions to explore the theme further. The photographs and findings from the discussions are then shared with the wider community stakeholders, often in the form of a workshop[26]. The reason for choosing photo elicitation as a method is that we are interested in understanding the potentially unanticipated perspectives of carers. Unlike more traditional methods of enquiry (e.g. research led structured interviews), the aim of photovoice is to centre the framing of a topic directly around the perspectives of the study participants and elicit what is important to them from a first-hand perspective[27].

Commencing after the baseline assessment, families will be trained in the photo elicitation method. They will be instructed to capture images related to their experiences. We will hold discussions at 3 and 6 months with the participants, where we will undertake an in-depth discussion with the photographs as prompts/starting points.

Discussions will be framed around the 'SHOWED' mnemonic; a commonly deployed method in photovoice studies[28], which consists of five questions;

1. What do you **S**ee here?
2. What is really **H**appening here?
3. How does this relate to **O**ur lives?
4. **W**hy does this condition **E**xist?
5. What can we **D**o about it?

Individual interviews with the participants will be conducted until data saturation.

1b. Qualitative Observation

Qualitative observation of interactions between link workers and children/families, and of engagement with services (n=15-30 per site), using audio recordings where consent is provided, to identify components of good practice.

1c. Short, informal debriefs

Short, informal debriefs with the LW every two weeks to understand service issues.

We anticipate a mixture of face to face and virtual (telephone or Teams) interviews, factoring in flexibility in relation to potential developments with the COVID-19 pandemic and also convenience and resources available to families. A topic guide, developed by the research team including parent advisors, will be used to guide the interviews but will not be restrictive.

2. Quantitative process data to understand pathways and throughput.

We will use routinely collected data on the number of referrals, uptake rate, continued engagement rate and numbers declining or deemed inappropriate for referral; demographics; number and nature of community groups referred to and engagement with these; time spent by LW per person and nature of work

3. Quantitative pre- and post-intervention data.

Baseline data collection including demographics and contact details for families will be collected in both settings, and forms part of standard care for link worker interventions.

Pre and post intervention data will be collected at each setting, covering the domains of:

- Profile of needs
- Quality of life and wellbeing
- Specific data relevant to the population under study.

Specifically, we will cover:

3a. GNCH site - Pre- and post-intervention data (i.e. at baseline, end of intervention and at 6m)

i) ***The Support Star will be used by the link worker as part of the assessment of needs. This does not form part of usual NHS care but is the method by which a link worker will gather information to guide the intervention and to record progress.*** The Support Star was designed for young people facing serious illness, with both young person and parent/carer versions available)

ii) ***The following questionnaires will be administered by the research team and are not part of routine data collection by link workers, but are gathered for the purposes of this study***

- Wellbeing (Outcomes Rating scales including age <5y with proxy scoring) – takes <1 min[29]
- Quality of life (EQ-5D for adults; CHU-9D for children including proxy version) – takes<5 min

- Warwick-Edinburgh Mental Wellbeing Scale (parents) – takes <5 min
- Three questions to gauge financial strain on the family [30] – takes <1 min
  The three financial strain questions are:-
  - How often they or their household puts off buying something they need
  - How much difficulty they or their household had paying bills in the last 12 months
  - At the end of each month over the past 12 months, did they or their household end up with more than enough money left over, some money left over, just enough to make ends meet, or not enough to make ends meet

3b. Zone West site – form part of the routine ZW care

See schedule of events in Appendix, where these are covered for completeness but they form part of the routine ZW care and are covered by existing research governance approvals.

Data collected as part of the Zone West project will be stored securely on existing secure server (online case management system "Penelope" covered by existing research governance approvals. The ZW team will provide the research team with necessary demographic information regarding participants to be observed and interviewed; and will provide anonymised summaries for process evaluation and pre-post evaluation data.

Data collected as part of the GNCH pilot will be manually entered via a web-based form into a secure Management Information System (MIS) hosted by Ways to Wellness, in line with their usual practice for social prescribing clients. The MIS is provided by the company Vital Service (vital-service.io) which uses a Linux-based operating system. All of the data is hosted and stays on UK based servers. To access the system, a unique login and password are required (login is over a 256-bit HTTPS connection). LW will use this MIS to record the baseline demographic data and Support Star assessments as well as other notes regarding their interaction with participants (e.g. services referred to; follow up contacts etc.). The research team will be given read only access to the records for clients in this study and also "edit" access to an assessment section in which they can upload completed questionnaires and notes related to the research. Each application on the server has its own separate location within the server's file system, its own databases, and separate access credentials for files and each database. The access control functionality within WtoW MIS ensures only authorised users can see the data they need to see, and no more. A software firewall is part of the wider server infrastructure on the server. WtoW also restricts access following multiple failed login attempts and has 2FA authentication provided by SMS enabled. (This means that the user has a specific username and password and must also authenticate each login with a code sent via text). A secure password reset system is in place through Vital Service. There is daily backup of the service with 7-day retention which is encrypted.

5.2 Data Analysis

Descriptive statistics will summarise quantitative data on rates of eligibility, consent, recruitment and retention; summary statistics will be included for assessment and outcome measures; the setting-specific outcomes will be summarised for each setting separately to further understand each pilot but are not the main focus of the current application.

Interviews and observations, following participant's consent, will be recorded verbatim, transcribed (by an approved external organisation e.g. UK Transcription) and anonymised for analysis. Observation and informal debriefs will involve the production of contemporaneous anonymised fieldnotes. Photos will be collected. All qualitative analyses will be conducted according to the standard procedures of rigorous qualitative analysis. We will use procedures from first-generation grounded theory (coding, constant comparison, memoing), from analytic induction (deviant case analysis) and constructionist grounded theory (mapping). We will undertake independent coding and cross checking and a proportion of data will be analysed collectively in data clinics (with core research team) and workshops with stakeholders where people share and exchange interpretations of key issues emerging from the data. Qualitative interview and observation data (both sites) will be stored on a secure server on Newcastle University's system, with password protected access to the research team.

6. Sample and Recruitment

6.1 Eligibility Criteria

6.1.1 Inclusion Criteria

GNCH Pilot	**Zone West**
The child has complex chronic needs related to neurodisability (e.g. cerebral palsy; epilepsy)	Concerns regarding education/health/social situation: **Education** ▪ Academic performance below expectation on bi-annual data capture ▪ Significant concern about behaviour and/or attendance (school registers) ▪ Concern from multi professional group **Social** ▪ Identified within a family engaging in an early help assessment but no early help plan in place ▪ Multi professional concern but not meeting the threshold for referral to Social Care ▪ Deemed appropriate by a referral from the community hub **Health** ▪ Poorly controlled long term health conditions ▪ Expressions of emotional distress such as behavioural or mood disorders

Children who are hospital in-patients, and their families - Admitted under any paediatric team (not just neurology/neurodisability) Living in area falling within North of Tyne/Gateshead ICP region	In the catchment area of 3 GP practices (CRUDDAS Park, Holmside, West Road) and attending one of the following schools in the West End of Newcastle (St Johns, St Pauls, Wingrove, Stocksfield, Bridgewater, Broadwood)
Age: infant/child of any age (<16)	Age 7-10 years (cohort 1)
Willing to consent to both the intervention and the evaluation	

6.1.2 Exclusion Criteria

GNCH Pilot	**Zone West**
Child considered too medically unwell for SP intervention to be appropriate at this time	Children on a child protection plan or already have an early help plan in place Under regular review with mental health services.
Index case aged 16 or over	Age <7 or >10y
Does not have a condition leading to neurodisability	Children with significant communication difficulties, unable to access assets
Out of region	Out of region
Not willing to give consent to take part	Families who do not wish to engage

If the potential participant is already involved in a research study, and taking part in our study would interfere with the findings of one or both studies, then we would not recruit them. If they are taking part in, or have taken part in, another research study which does not conflict with the current study, we would be happy for them to take part in this one provided they would not be, or feel, overburdened by research commitments.

6.2 Sampling

It is anticipated that at a minimum of 30 (and up to 50) families will be enrolled in the study from each site; this will depend on caseload complexity and will be reviewed regularly.

6.2.1 Size of Sample

The sample size was chosen pragmatically, based on anticipated capacity of each service.

6.2.2 Sampling Technique

Within the sample described above, we will use purposive sampling to undertake in-depth interviews and observations exploring experiences of families/children (n=15 per site) with differing needs and backgrounds, to start to establish what works, for whom, when and how.

6.3 Recruitment

6.3.1 Sample Identification

GNCH pilot: Potential participants will be identified by ward staff who are part of the existing care team (and using written criteria to help with identification), and provided with information about the link worker service and study (flyer).

Zone West: The child and family will be identified by the GP at one of three surgeries (which will act as PICs) and will be provided with information about the project. If they consent, their information will be shared with the school and the SEND/inclusion lead teacher at the child's school will approach the family to explain further the intervention and outline what is involved. If the family are happy to proceed at this point, the details will be given to the link worker to arrange the consent and enrolment.

6.3.2 Consent

GNCH Pilot: Potential participants will be given an information sheet about the study and have the opportunity to discuss the study with a member of the team, and ask questions. Most participants will require parental consent, but will have the opportunity to provide assent where appropriate.

Written informed consent to take part will be obtained prior to any study procedures taking place.

Zone West: Consent for ZW will be taken at the first visit by the link worker for inclusion in the project and in the evaluation of the intervention. For all children consent will be taken from their parent or person with parental responsibility. Consent will be obtained to access local GP and hospital medical records and educational data. Consent to take part in this additional evaluation (current study) could be provided at the same time as consent for entry to ZW, or shortly after recruitment to ZW. Hence North East Wellbeing is the site for this project, as this organisation is the Charity which hosts the Zone West project; and the ZW link workers take the consent and undertake the intervention.

7. Ethical and Regulatory Considerations

7.1 Assessment and Management of Risk

Ethical considerations for research involving CYP are stringent: however, it is appropriate to evaluate schemes for children rather than infer outcomes from adults.

LWs will need to find a balance between the focus on CYP and the needs of the family.

Participation in the study is optional: parents will consent to the link worker referral on behalf of their child and provide written informed consent regarding participation.

Given the personal nature of topics which may be discussed (e.g. financial, social and emotional pressures; and health), a key issue is patient/participant confidentiality, which will be respected. Guidance regarding ethics of photovoice studies will be followed (Wang et al., Health Education and Behaviour 2001: DOI 10.1177/109019810102800504).

Information governance and safe data storage are essential in line with GDPR requirements. The live ZW project already has appropriate systems in place. Ways to Wellness is adapting a current information management system for use by LW in the hospital setting. This will be separate from NHS records. Pseudonymised data (from observations and interviews) and anonymised demographic data will be available to the study team and stored on a secure server at Newcastle University for analysis.

NHS research governance procedures including IRAS research ethics application for the hospital scheme will be followed. IRAS and Newcastle University approvals are already in place for the Zone West scheme, but an amendment will encompass the process evaluation components of this study. The researcher undertaking the interviews will require a research passport. DBS checks will be undertaken for those undertaking patient-interfacing work. GCP training and regular supervision meetings will be in place for the RA and LWs (who work to standard policies). Lone working policies will be followed. A steering group will oversee the project.

Finally, there is an emotional labour component to the LW role; peer support will be timetabled.

It will be stated in the information sheet that information disclosed in interviews or observations will be confidential unless it indicates a potential risk to self or others, in which case relevant authorities will be informed.

7.2 Research Ethics Committee (REC) and Other Regulatory Review & Reports

Before the start of the study, a favourable opinion will be sought from a REC for the study protocol, informed consent forms and other relevant documents e.g. advertisements.

Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.

All correspondence with the REC will be retained.

It is the Chief Investigator's responsibility to produce the annual reports as required.

The Chief Investigator will notify the REC of the end of the study.

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.

If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

7.2.1 Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

7.2.2 Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amendments also need to be notified to the HRA and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

The amendment history will be tracked to identify the most recent protocol version.

7.3 Peer Review

The GNCH pilot proposal was reviewed by the GNCH Foundation board prior to allocation of funding.

The Zone West proposal was reviewed by funders and already has ethics approval.

The proposal for joint evaluation of the SP projects was reviewed by independent academics as part of the ARC funding decision. The ARC decision to fund was made using:

- Scores from external and internal peer review.
- Ratings from the ARC Implementation Advisory Group and Public Advisory Network which reflected the potential for impact and community engagement.

A further design review of funded projects was provided by the ARC Enabling Methodologies Theme.

7.4 Patient & Public Involvement

To inform the Hospital-based work, consultation was undertaken with YPAGNE and Bridges school. Online surveys were also used to seek views of parents of children with disability regarding link worker provision. There was a high reported level of need and strong support for the proposal; parents described priorities and desired features of the service.

To inform the Community-based work, Newcastle's West End Community Family Hub is represented on the ZW steering group. A consultation/listening phase involving 100 children, parents and teachers from the West End Schools Trust shaped the ZW pilot's focus on primary school age children.

Research Governance: We have parent representatives that will sit on the steering committee. One of the LWs has experience leading parent self-help groups and working in the third sector; both have experience of PICE work in other NIHR projects. They will advise on aspects of the engagement workshops.

Ongoing assistance and advice: Engagement workshops (30 participants in total, 3 workshops) will seek feedback from parents and children (n=15) and other stakeholders (community leaders, teachers and hospital staff [n=15]) as the project evolves. YPAGNE will provide ongoing feedback to the project, supported through the GNCH Foundation.

7.5 Protocol Compliance

Accidental protocol deviations can happen at any time. They must be adequately documented and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

7.6 Data Protection & Patient Confidentiality

All investigators and study site staff must comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Only personal data necessary for the study will be collected.

Ways to Wellness will develop a data management information system to store necessary data securely for the hospital pilot. Access to personal identifying data will be limited to those who need it for undertaking the intervention and/or the evaluation (e.g. to contact participants to arrange appointments). Link workers undertaking the intervention will store their notes within this system as described above in section 5; researchers will be given read-only access to this data but will have write access to upload documents. Zone West already have a secure electronic data case management system in place. Paper data collected by LWs is stored in a secure locked filing cabinet in a code-locked room at Healthworks Newcastle and is all anonymised. Any email communication regarding participants will be through secure nhs.net email accounts.

Audio recordings that are collected during the study will be transcribed as soon as reasonably possible afterwards. They will be sent only to UK based services with strict data

privacy policies, which comply with GDPR; and who have ISO 27001 certification. They will then be pseudonymised. We will use a unique patient study number to link participants to pseudonymised study data stored on secure password protected university systems. Essentially, all participant data that is generated for analysis for the research will be labelled with a participant study number, not with the participant name, and all identifiers unnecessary for the analysis (e.g. address) will be removed in generating the research data files. Only appropriate members of the research team will have access to the research data files. Members of the research team accessing the data will have undertaken GCP and GDPR training. The data that is extracted to university servers for analysis will be labelled with the unique participant identification code. The Chief Investigator will keep a list linking the participant names to their study numbers – an electronic copy (kept separately from the study data as a password-protected document) and a hard copy kept in a locked cabinet. Appropriately qualified members of the Trust R+D Department/representatives of the sponsor may inspect data as part of their audit and monitoring processes

In the unlikely event of a breach in GDPR the relevant supervisory authorities will be made aware of the breach within 72 hours, where feasible. If the breach is likely to affect an individual personally, that individual will be informed without undue delay. If they feel it appropriate, they will be able to make a formal complaint through the NHS Complaints Procedure. If the breach is a result of negligence then participants may have grounds for compensation.

We will retain participant contact details for 3 years so we can contact participants about future relevant research with their consent.

In line with sponsor guidelines, all research data will be securely stored (as described above) for 10 years after the last sample is collected to allow adequate time for review, reappraisal or further research, and to allow any queries or concerns about the data, conduct of conclusions of the study to be resolved. Any paper documentation, including the master file will be archived in line with Newcastle Upon Tyne NHS Foundation Trust policy in secure storage provided offsite.

As CI, Dr Basu will be the custodian of research data generated for this study.

7.7 Indemnity

Insurance/indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research lies with the NHS.

Insurance/indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research lies with Newcastle University.

Insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research lies with the NHS for participants recruited through the NHS.

Compensation (as per information sheet): "In the very unlikely event that something does go wrong causing harm and this is due to someone's negligence then you may have grounds for compensation against Newcastle upon Tyne Hospitals NHS Foundation Trust. You may however have to pay your legal costs. The normal National Health Service complaints mechanism will still be available to you".

7.8 Access to the Final Study Dataset

All study investigators will have access to the final study dataset. Anonymised data may be used for later secondary analysis – consent for this is reflected in the patient documentation.

8. Dissemination Policy

8.1 Dissemination Policy

On completion of the study, the data will be analysed and tabulated and a Final Study Report prepared for submission to the funders. We also intend to publish the findings. Funding support will be acknowledged within the publications.

We will provide a lay summary of results for participants and hold a dissemination event.

The study protocol and full study report will be made publicly available through the Open Science Framework. Given the participant group under study and the complex confidentiality issues combined with the rarity of some of the conditions, it may not be possible to achieve anonymization of patient data – if not, we will not be able to make a participant level data set publicly available.

Complex statistical analysis code will not be generated within this study and therefore will not be shared.

8.2 Authorship Eligibility Guidelines & Any Use of Professional Writers

ICMJE authorship guidelines will be followed regarding manuscripts submitted for publication.

We will not be using professional/ghost writing services in generating outputs from this research.

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10. Appendices

10.1 Appendix 1- Required documentation for participating sites

- CVs of the research team
- Flyers
- PIS and consent forms on headed paper
- Copies of questionnaires to administer
- Topic guide for interview

10.2 Appendix 2 – Schedule of Procedures

10.2.1 Appendix 2.1 - Schedule of Procedures (GNCH Project)

Procedures	**Visits**						
	Screening	**Baseline visit (LW)**	**Assess**	**Follow up contacts and engagement with services**	**3 month assess**	**Follow up contacts and engagement with services**	**6 Month assess**
Informed consent	x						
Demographics- done by LW		x					
History-taking (guided by Support Star) – done by LW		x			x		x
Wellbeing assessment - Outcomes Rating scales (proxy for age <5y) Warwick-Edinburgh Mental Wellbeing scale (parents)			x				x
Quality of life assessment - EQ-5D for adults - CHU-9D for children including proxy			x				x
Financial strain Qs			x				x
LW Telephone				Every 2-4 weeks		Every 2-4 weeks	

with X calls for support/assess progress				depending on need		depending on need	
Observations by RA of LW sessions (15 total)		x			x		x
Observations by RA of engagements with services (15 total)				x			
In-depth Interview (15 participants)							x

Observations by RA – in red as no additional burden to participant.

10.2.2 Appendix 2.2 - Schedule of Procedures (ZW Project)

Additional procedures to usual protocol for ZW are shown in bold and shaded in green the others are covered by existing approvals.

Procedures	**Visits**			
	Screening	**Baseline visit (LW)**	**Follow up and engagement with services**	**End of intervention**
Informed consent	x			
Demographics questionnaire		x		
Early Help Plan assessment Data re school attendance, behaviour and attainment		x		
Assessments – Strengths and Difficulties questionnaire PedsQL Asset-specific measures (selected after targeted needs are identified)		x		x
Endpoint/Feedback questionnaire				x
Observations by RA of LW sessions/engagement with services (n=15 of each)			x	
In-depth interview (n=15)				x

Observations by RA – in red as no additional burden to participant.

10.3 Appendix 3 - Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

Any protocol amendments will be logged here whenever a new version of the protocol is produced.

Protocol amendments will be submitted to the Sponsor for approval prior to submission to the REC.