Protocol

JIA (Juvenile Idiopathic Arthritis) Toolbox Feasibility Study

JIA Toolbox Feasibility Study

18/12/2024 Version 2

IRAS number: 336429

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

KEY STUDY CONTACTS

Chief Investigator	Ursula Ankeny (Design Researcher at SHU), u.ankeny@shu.ac.uk 07762323084
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Funder(s)	Medical Research Council (MRC IAA 2023 Call)
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Co-Investigator	Catherine Dunbar (Occupational Therapist at SCH), c.dunbar@nhs.net
Co-Investigator	Dr Joe Langley (Principal Research Fellow at SHU), j.langley@shu.ac.uk, 07760882488
Co-Investigator	Nick Dulake (Researcher and product designer at SHU) n.dulake@shu.ac.uk
Advisor	Richard Beesley (Director of Juvenile Arthritis Research (JAR) charity)

STUDY SUMMARY

Study Title	JIA Toolbox Feasibility Study
Internal ref. no. (or short title)	JIA Toolbox Feasibility Study
Study Participants	Children with JIA (aged 7-16), their parents and their teachers
Planned Size of Sample (if applicable)	N=25
Planned Study Period	9 months (08.04.24 – 31.07.25)
Research Question/Aim(s)	What are the potential impacts of using 'JIA Toolbox' for: - Children and Young People (CYP) with Juvenile Idiopathic Arthritic (JIA) in terms of improving overall condition management by enabling independence and improved functional ability? - Parents of CYP with JIA in terms of enabling improved condition management? - Healthcare Professionals (HCP's) working in JIA management in terms of improving physio adherence? - and teachers of children with JIA in terms of improving communication around the condition in the classroom?

The Research Team and expertise:

CI: Ursula Ankeny – Design Researcher and Product Designer. Expertise in co-designing technological healthcare solutions and delivering multiple healthcare research projects.
CO-I: Daniel Hawley – Consultant Paediatric Rheumatologist. Expertise in treating and managing Juvenile Idiopathic Arthritis and delivering healthcare research projects.
CO-I: Catherine Dunbar – Specialist Paediatric Rheumatology Occupational Therapist. Expertise in working with children with JIA on their occupational needs and therefore areas of difficulty that are unmet by current products and delivering healthcare research projects.
CO-I: Nick Dulake – Industrial Designer and design researcher. Expertise in designing and prototyping products for industry, including electronic, sensor and textile-based solutions, and delivering a variety of health related research projects.
CO-I: Joe Langley – Principal Research Fellow. Expertise in design and co-design as methods of applied Research and Knowledge Mobilisation in the field of Health and Wellbeing.

The team is highly experienced in:

- Translational research,
- Patient focused research,
- Co-designing solutions,
- Developing products, services and interventions that promote dignity and enhance quality of life,
- And commercialisation of solutions – example 'head-up' neck collar (designed, developed and currently on the market) and recently awarded global 'Made With Patients' award.

Protocol

1.0 Lay Summary

This is a 12-month feasibility study to test the effectiveness and viability of a group of 3 assistive devices to help improve independence and functional ability for children and young people (CYP) with Juvenile Idiopathic Arthritis (JIA). These devices have been extensively co-designed with CYP with JIA, their parents, healthcare professionals and teachers, ensuring they provide solutions to priority unmet needs within the JIA community. The devices have already undergone a successful proof-of-concept study. This feasibility project aims to assess the effectiveness and viability of the devices in a real-world setting over a longer time-frame and with a larger cohort.

2.0 Background

This study aims to assess the potential impacts of 'JIA Toolbox', (Appendix1) – three novel prototypes that collectively aim to improve the independence and functional ability of Children and Young People (CYP) with Juvenile Idiopathic Arthritis (JIA).

'JIA Toolbox' addresses key unmet needs identified by stakeholders during previous work. Each prototype (Appendix1) addresses a specific unmet need:

UNMET NEED: Joint pain that prevents CYP from doing activities they love.
PROTOTYPE 1 SOLUTION: a wearable pain management device that heats and vibrates to help distract the brain from pain based on the idea of gate theory.

UNMET NEED: CYP don't engage with their physio as they find it boring and frustrating due to perceived lack of progress. This therefore creates ongoing strained and frustrated relationships with parents and HCP's.
PROTOTYPE 2 SOLUTION: a motivational physiotherapy tool that incrementally lights up in response to the stretches helping CYP visualise and 'see' progress.

UNMET NEED: CYP often need help in the classroom but are too embarrassed to put their hand up as they don't want everyone to know about their condition. This can lead to feelings of disbelief from the teacher and a strained relationship between pupil and teacher.
PROTOTYPE 3 SOLUTION: a communication wearable for school that silently vibrates to alert the teacher to difficulty enabling better communication and combatting feelings of disbelief.

Our previous proof-of-concept study received positive feedback, prompting the drive to refine the prototypes and continue with a feasibility study. Our work aims to improve outcomes for CYP with JIA by empowering and equipping them: to self-manage confidently and independently, to harness their wider support network when necessary and to embed positive health behaviours from a young age.
1,000-1,500 CYP are diagnosed with JIA every year [2]. It affects CYP's lives, "impacting on relationships, school, physical and individual domains" [4] due to "chronic or recurrent pain and disability" [3]. Widespread lack of understanding often makes CYP with JIA feel isolated, e.g. "There will always be a teacher who responds to me being tired, with: 'I also get tired, but still got to do stuff'" [6]. There are products designed to support CYP with JIA but they have limitations and our previous work shows they are not sensitive to user needs. 'JIA Toolbox' has been developed using a co-design approach with CYP, parents/guardians, HCPs and teachers to ensure that it meets key stakeholder needs and is therefore more likely to be adopted by patients and clinical services.

A major priority for health services is helping people with long-term conditions (LTC's), including arthritis, as highlighted in the 2030 Agenda for Sustainable Development. LTC's such as JIA can be life-limiting with emotionally and physically debilitating effects. Longer term, JIA can restrict access to employment, putting increased pressure on the economy and healthcare resources. Developing self-management skills from a young age is crucial to managing chronic illness. Equipping CYP to become confident in managing their own condition is particularly important as CYP transition from children's to adults' services.

COVID-19 highlighted the importance of effective self-management as healthcare resources were diverted to support COVID-19. This withdrawal of, or limited access to, key support can have a negative impact on the physical and mental wellbeing of CYP with LTC's. The development of self-management tools such as 'JIA Toolbox' is key to help relieve pressure on healthcare professionals and alleviate concerns of patients. The wider, informal stakeholder support networks surrounding each patient such as teachers are also

an integral part of condition management. However, they remain an under used resource. In part, this is due to the lack of appropriate resources (tools, knowledge, information, power) to support CYP in seeking help from such people and in part, due to a lack of appropriate resources (tools, knowledge, information, empathy) that enable these people to provide relevant kinds of support. The tools in 'JIA Toolbox' aim to fill this gap. This is novel, relevant and potentially transferrable to other chronic conditions.

Existing studies describing the experience of living with JIA [3-6] tend to focus exclusively on one stakeholder's experience or on the physical symptoms, neglecting both the wider life impact and insights of other stakeholders. This study will therefore provide contemporary data on CYPs experiences of living with JIA to inform future research.

3.0 Clinical need

Juvenile Idiopathic Arthritis (JIA) is a paediatric long-term condition affecting approximately 15,000 children and young people (CYP) in the UK, with 1,000-1,5000 new diagnoses each year. It causes ongoing joint inflammation, pain and stiffness, making everyday activities difficult. It affects every aspect of CYP's lives, impacting on physical, social, emotional and education development, with widespread lack of understanding often making CYP with JIA feel isolated. There are products designed to support CYP with JIA but they have limitations and our previous work (a survey and co-design process conducted in 2018) shows they are not sensitive to user needs. Our survey highlighted that CYP with JIA find these products difficult to use as most therapeutic aids are targeted towards an adult population. The few that are aimed at children were seen as patronising and stigmatising. These products also often neglect to take into account the wider stakeholder network such as parents, teachers and healthcare professionals, and therefore neglects to support them in helping CYP with JIA.

Key stakeholder groups (CYP with JIA, their parents, healthcare professionals and teachers) were active participants throughout our previous work, through co-design workshops and surveys. The key highlighted clinical need was assistance with self-management.

This is broken down into the following specific unmet needs:

- Pain-management. Improved pain management would enable CYP to do more of the things they love, by providing a solution that they can use independently as and when is needed, positively impacting their wellbeing.
- Physiotherapy adherence as currently CYP often do not do clinician-recommended exercises. Improved compliance with recommended physiotherapy interventions may reduce pain in the long-term and improve mobility.
- Communication between the pupil and teacher. Improving this communication would provide CYP with a way to discreetly access necessary support without facing stigma, improving their concentration by removing anxiety around accessing help

As a result, 'JIA Toolbox' was co-designed and developed to fulfil these needs and previously tested on a cohort of n=10 CYP with JIA during a proof-of-concept study. The results from

the proof-of-concept study were successful with 80% of participants finding one or more of the prototypes beneficial for their condition management.

The aim of this study is therefore to further refine the prototypes based on participant feedback and then test their effectiveness and viability over a longer time frame (3 months) with a larger cohort (n=25) in improving overall condition management in terms of improved independence and functional ability. The data collected will therefore be: experiences of living with JIA both with and without 'JIA Toolbox' and prototype use patterns to build up a strong evidence based on the effectiveness and viability of these devices, enabling a good point from which to leverage further funding.

4.0 Study Objectives and Purpose

This is a feasibility study assessing the effectiveness and viability of Juvenile Idiopathic Arthritis (JIA)Toolbox in improving overall condition management by improving Children and Young People's (CYP's) independence and functional ability.

Each prototype was developed to address an unmet need and therefore has a specific aim:

- Prototype 1: A wearable device that aims to promote pain self-management skills;
- Prototype 2: A motivational tool that aims to improve physiotherapy engagement;
- Prototype 3: A wearable device that aims to promote discrete communication between CYP and teachers and other stakeholders.

The primary objective of this study is to explore the potential impact of 'JIA Toolbox' in addressing the unmet needs identified by stakeholders by conducting a feasibility study to explore the usage of the three prototypes and their impact on CYP's independence and functional ability.

The secondary objective is to collect contemporary data on CYP's experiences of living with JIA to inform future research and innovation.

5.0 Study Design

CYP aged 7-16 years with JIA, parents/guardians and HCPs based at Sheffield Children's Hospital (SCH) and/or a part of Juvenile Arthritis Research (JAR) charity will participate throughout this study.

The components of 'JIA Toolbox' are illustrated in Appendix1. The potential impact of these devices will be assessed by comparing baseline qualitative data about living with JIA, with data collected when the devices are in use. Post-intervention interviews with participants will capture practical usability issues and the potential impact of 'JIA Toolbox' on CYP's wider life, like social impact, to frame possible outcome measures for future evaluation.

The study design is shown in Appendix 2. It will consist of:

WP4
4.1 Recruitment of participants n=25 (CYP aged 7-16) and their parents/guardian from SCH or JAR
4.2 Consenting processes

WP5
5.1 Prototype testing by clinical engineering
5.2 Virtual training session on data collection processes for participants (1 hour)
5.3 Baseline data collection period (2 weeks)
5.4 In person training session on prototypes (1- 1.5 hours)
5.5 Intervention period using prototypes (3 months)
5.6 'JIA Toolbox' returned to SCH
5.7 post-intervention data collection period (2 weeks)
5.8 End of intervention interview (1 hour 1:1 with researcher)

WP6
6.1 Analyse qualitative data with healthcare professionals who are a part of the research team

The end of study is defined as the date of the last interview of the last participant.
As 'JIA Toolbox' consists of therapeutic self-management tools, participants will decide when to use the prototypes during the 3-month intervention period. As such, there should be no added burden to the participants in using these products, as they are designed to assist with condition management rather than hinder. There will be two training sessions, one on how to use the data collection packs (examples shown in appendix 3) and one on how to use the prototypes. This will ensure that the participants are clear on what they should do, minimising any potential risks in interacting with the prototypes. There will be regular weekly check ins to ensure participants are happy with the study and to troubleshoot any issues raised. The 3-month intervention period where the participants are using the devices will take place over August, September and October, giving CYP 1 month to get used to the devices prior to using them in a school context. From the previous proof-of-concept study, it was highlighted that the devices were beneficial in building CYP-teacher relationship near the beginning of the school year. Post-intervention interviews will be conducted at the end of the study to ensure all experiences are equally captured and to give participants the opportunity to highlight anything they feel needs additional clarification.

The study design has had input from YOUR RHEUM which is a group of CYP (11-24) with diagnosed rheumatic conditions, and JAR which is a group of CYP (7-25) with Juvenile Arthritis. Both groups regularly input on CYP rheumatology research. They have a strong track-record in advising on and shaping rheumatology research and represent a 'Gold Standard' approach to PPI involvement. These groups have been involved in shaping the study design and participant facing materials such as the data collection packs to ensure they are appropriate and will be effective. They have also commented on the prototypes themselves, feeling that they fulfill key unmet needs within the JIA population. Daniel Hawley and Catherine Dunbar are both healthcare professionals who work within

rheumatology and come into regular contact with CYP with JIA. They are both members of the project team and have been involved in planning the study design, utilising their extensive knowledge of the condition to ensure it is appropriate and capturing useful data. This project is being funded by Medical Research Council and as such, had to go through a rigorous application process.

6.0 Participant Recruitment

The study will recruit from SCH Rheumatology service. Daniel Hawley (DH) or CD will initially approach potential participants using a recruitment flyer (shown in appendix 2) for context (also available through SCH Rheumatology Facebook group). Interested participants will be screened by clinical members of the study team and given a participant information sheet (shown in appendix 5,6,7,8). Following this, they will give verbal consent for Ursula Ankeny (Principal Investigator) to call them for any queries. A consent form (shown in appendix 9, 10 and 11) will then be emailed to be signed and sent back.

The study will also recruit from JAR charity. They have a group of members who have agreed to be contacted about research opportunities. The process would involve me sending the recruitment poster to JAR which they would circulate among their members. JAR would then send an email with a form to fill in to register interest. This form would ask for details around the child's age (to check eligibility) and other inclusion criteria as well as their contact details which by submitting the form they would agree to be shared with UA. That list would then be sent to UA, who would then call each interested participant and if they would like to take part UA would then send through the Participant information sheets. After reading the PIS, if they would like to join the study UA will then send them the consent form for them to sign and return. UA has spoken with the director of JAR, Richard Beesley who is happy with this approach.

The process for recruiting and consenting teachers hinges upon which CYP have consented to be involved, as it is their teacher(s) that will need to be recruited. Once interested CYP and their parent/guardian have been consented. UA or CD will approach the CYP's school/ teacher with a recruitment flyer for context. If interested, they will be given a participant information sheet. If they wish to proceed, a call will be arranged with the study lead UA for any queries. A consent form will then be emailed to be signed and sent back. If their teachers do not want to participate, this will still be useful data as it speaks to adoption of the intended prototypes. However, it is expected that at least 50% of CYP's teachers will engage with the study as the prototypes are designed to assist them in their role, in terms of helping and communicating with CYP. Based on the proof-of-concept study 100% of CYP's teacher's engaged, and we therefore expect similar engagement.

Families who participate in the study will receive a £50 'thank you' voucher recognising their time and involvement. The participation gift will be mentioned in the participant information sheet, once the participants have expressed an initial interest in WP4, after seeing the flyer. Teachers will not receive financial renumeration due to the fact that the prototype

pertaining to them is designed to assist duties that fall within the remit of their role in terms of helping and communicating with CYP.

Recruitment flyers, participant information sheets, consent and assent forms are shown in Appendix (5,6,7,8,9,10 and 11).

6.1 Selection of Participants

Inclusion Criteria

- Aged 7- 16 years (minimum age is 7 to ensure participants can adequately engage with the prototypes and describe their experience)
- Diagnosis of JIA
- Currently experiencing JIA symptoms
- Currently managed within SCH Rheumatology Service
- Fluent in verbal and written English
- Access to a computer with an internet connection to facilitate virtual co-design workshops due to the COVID-19 pandemic

Exclusion Criteria

- Aged <7 years or >16 years
- Non-fluent in verbal and written English
- Diagnosis of autistic spectrum disorder (ASD)
- Children with medically unexplained pain, pain amplification syndromes or other pain disorder
- Co-existing joint or muscle disorder other than JIA

We have excluded CYP with ASD because it can affect sensory processing including the interpretation of pain and may also affect how CYP are able to communicate. We have excluded CYP with other pain disorders because this would likely behave and respond differently to pain associated with JIA. We have excluded CYP with any co-existing joint or muscle disorder other than JIA because these may behave or respond differently to symptoms associated with JIA.

7.0 Data handling and record keeping

The use of personal addresses, emails and telephone numbers will be used to send potential participants information on the study, these will not be seen or used outside of the clinical care team until participants have consented and given the researcher their preferred method of contact.

All research data will be collected confidentially and as per Appendix 15: data sharing agreement, identifiable data will be stored on encrypted NHS servers. All identifiable data will be password protected to ensure maximum security, which only the research team will have access to. The data will then be anonymised and transferred to q:/ Drive on the

Sheffield Hallam University server which will only be accessible by the SHU research team. It will be transferred from nhs.net account to nhs.net account to ensure sufficient security is maintained. The Q drive is SHU's Research Store service and provides shared storage for currently active research projects. Data is backed up automatically on a daily basis and can be fully recovered in the case of accidents. All backups are securely kept on two remote locations for a period of 90 days. Access to all folders is restricted to researchers, students and external partners working on the project. Password-protection will be used on all data files to ensure only the research team have access.

Participants will consent to the use of photography video recording for the study, they will be made aware that no images taken will be used for dissemination or publicity without their further consent.

8.0 Access to source data

The sponsor will permit monitoring and audits by the relevant authorities, including the Health Research Authority and Research Ethics Committee. The investigator will also allow monitoring and audits by these bodies and the sponsor, and they will provide direct access to source data and documents.

9.0 Statistical Analysis

As this is a qualitative feasibility study, a sample size of 25 is adequate according to Lancaster et al as supported by NIHR when estimating a parameter within a study. This study is testing the effectiveness and viability of 'JIA Toolbox', we are looking at the practicalities of using these prototypes in real contexts and seeking clues as to the potential real-life impacts, by way of specifying further product design refinements and as a way of understanding how a future pilot evaluation study might be practically designed and which outcome measures would be relevant to service users, HCPs and device manufacturers.

At the conclusion of this study, the STOP/GO criteria for continuing onto a larger study will be:

- green light if 50% report a positive change in their condition management,
- amber light requiring potential changes if 30% report a positive change and,
- red light if only 10% report a positive change.

10.0 Safety Assessment

The study will be monitored and audited in accordance with the Monitoring Standard Operating Procedures of the Directorate of Research & Innovation at Sheffield Children's NHS Foundation Trust. All study related documents will be available on request for monitoring and audits by the Sponsor, the Health Research Authority and the relevant Research Ethics Committee.

Further information is provided in the ***risk assessment form***

11.0 Ethical Considerations

1. Risk of unintended distress
Discussion with participants about JIA will be treated sensitively. Interviews may lead to minor distress. To minimise this risk, participants will be informed they do not have to complete any questions or take part in any activities that make them uncomfortable and reminded that they have the right to withdraw at any point and will still receive their thank you voucher. If a participant becomes distressed, the session will be ended sensitively but quickly. Any participant who has shown evidence of distress will be discussed with the study clinicians (DH/CD). The rheumatology team has a clinical psychologist who could be involved if significant distress is felt to have occurred, although it is not anticipated this will be needed.

2. Burden of time
Involvement is optional and participants will receive a 'thank you' voucher. The use of the prototypes is designed to fit around day-to-day activities and to assist rather than be a burden. Difficulty in using the products will be minimised through training and weekly check ins where the project team can trouble shoot any queries.

3. Concern that they can't withdraw
Before each part of the study, participants, parents and guardians will be informed that this is a voluntary research study and they are free to withdraw at any point and it will not affect their future healthcare.

4. Risk of unintentionally worsening symptoms
The prototypes are designed to help improve symptoms and are based upon proven therapies and known and tested technologies that are routinely used in other products on the market, therefore this risk is minimal. Based on the proof-of-concept study, the prototypes were seen as beneficial to symptom manage and did not make any participants symptoms worse.

5. Using the prototypes
The prototypes are electronic devices and as such could potentially pose a risk to participants. Firstly, in the previous proof-of-concept study there were no safety issues with the devices. Secondly, the devices for this study will be manufactured by CPI, who have an extensive track record of creating safe, efficient and high quality health tech devices. Thirdly, before using the prototypes, a 1 hour training session will be set up with CI Ursula Ankeny to ensure the participants feel confident in using them. The prototypes themselves will use known and tested technologies that are routinely used in other products on the market and therefore the risk of danger is minimal. For prototype 1 which uses a carbon fibre heating element, there will be sensors incorporated into the device which will stop the device if needed to ensure it does not overheat.

12.0 Justification of finance and resources

UA time (1 day a week over 18 months (£16,362): Although PI, UA is the only person who can do this work as it builds on the previous background work of which she has sole and extensive knowledge (specifically relating to the underpinning research, design and development of the prototypes and experience in developing innovations for the JIA population).

Sheffield Hallam University in kind contribution:

- Dr Joe Langley (CO-I): Advising on ethics/research approvals, design aspects, PPIE sessions and general applicable queries as the project develops.
- Nick Dulake (CO-I): Consulting on prototype improvements, design and prototype assistance, technical assistance and ongoing advising of related aspects.

Sheffield Children's Hospital in kind contribution:

- Dr Daniel Hawley (CO-I): Project planning, review of patient information sheets, identification and recruitment of patient participants.
- Catherine Dunbar (CO-I): Review of patient information sheets, identification and recruitment of patient participants.

PPIE sessions with YOUR RHEUM (£1,200) and JAR (Juvenile Arthritis Charity) (£2000): To advise and steer the research at an early stage by CYP with JIA and their families, and input on study design and participant facing materials where appropriate to ensure maximum engagement from the participants involved.

'Thank you' vouchers (£50 per participant (30) = £1500): for participant time to acknowledge participant contribution to encourage engagement.

Technical equipment (£3000): For design and development of the prototypes in line with improvements from proof-of-concept study. Sufficient development and trialling will ensure the systems work well and will be used and engaged with correctly.

Prototype production – Primary manufacturer (£50,000) & heat panel manufacturer (£2,500) : An integral part of the study. The prototypes must be manufactured to a high standard to ensure they work reliably and are robust.

Dissemination and conference fees (£2000): To attend applicable conferences such as Paediatric Rheumatology conference, European rheumatology conference, design4health, European health design conference. This will enable widespread dissemination of the findings (ensuring IP protection is maintained), increasing impact of the research project.

13.0 Reporting and dissemination

The findings from the proposed study will be compiled and reported to the Rheumatology team at Sheffield Children's Hospital. They will also be published in peer-reviewed papers and journals such as the Design4Health journal.

The findings will also be presented at national and international conferences including Paediatric Rheumatology conference, European rheumatology conference, design4health, European health design conference. This will enable widespread dissemination of the findings increasing impact of the research project.

Results from the study will be used to inform further funding applications to progress the prototypes further in collaboration with Sheffield Children's Hospital. The study team includes members with specialist experience in medical technologies and senior clinicians in the field of JIA, ensuring appropriate experience and contacts for wide dissemination of results among the clinical and scientific communities

14.0 Impact

The proposed study aims to make a positive contribution to the field of JIA by improving the independence and functional ability of CYP with JIA through 'JIA Toolbox'. CYP with JIA live with chronic or recurrent pain which severely impacts their day-to-day life, particularly in terms of daily physical tasks, relationships, school and social activities, as well as their emotional wellbeing and self-confidence. CYP with JIA often feel isolated and different, as shown in a 2012 study of children's experience of living with arthritis "the worst thing was that my disease was invisible", often facing widespread lack of understanding from crucial stakeholders. Current products are difficult to use as most therapeutic aids are targeted towards an adult population. The few that are aimed at children come across as patronising and stigmatising, findings that were underlined in our previous work.

'JIA Toolbox' is a multifaceted intervention that has received widespread initial praise from stakeholders as it specifically addresses their unmet needs. On an individual level, 'JIA Toolbox' has the potential to significantly improve CYP's pain self-management skills, increase engagement with and adherence of physio regimes and improve communication with stakeholders. This would afford CYP with greater confidence and functional ability to participate across all spheres of their lives, across social, physical and educational domains, positively impacting their emotional wellbeing and wider life engagement.

Within an educational context, 'JIA Toolbox' will help to increase awareness of the condition without stigmatising CYP. It will also provide them with a way to discreetly access necessary support, improving their concentration by removing anxiety around accessing help.

Within a healthcare context, it will help to encourage self-management of the condition from a young age, promoting positive behaviour, which is particularly important during the post COVID-19 climate as well as during the transition process when CYP move to adult services. In addition, it is expected that 'JIA Toolbox' will improve compliance with recommended physiotherapy interventions which are often ignored despite the clinicians' recommendation. The socio-economic impact on wider healthcare organisations such as the NHS, is improved compliance with treatment as well as encouraging self-management. This

can then help reduce the financial and time burden from repeated, potentially avoidable appointments, which ties in to the current organisations' focus.

A major priority for health services is helping people with long-term conditions (LTC's), including arthritis, as highlighted in the 2030 Agenda for Sustainable Development. LTC's such as JIA can be life-limiting with emotionally and physically debilitating effects. Longer term, JIA can restrict access to employment, putting increased pressure on the economy and healthcare resources. Developing self-management skills from a young age is crucial to managing chronic illness. Equipping children and young people to become confident in managing their own condition is particularly important as children and young people transition from children's to adults' services.

Existing studies describing the experience of living with JIA tend to focus exclusively on one stakeholder's experience or on the physical symptoms, neglecting both the wider life impact and insights of other stakeholders. This study will therefore provide contemporary data on children and young people's experiences of living with JIA to inform future research. As such, the expected outcomes of this research include deeper understanding around:
1: contemporary data on the impact of JIA on the daily lives of children and young people with JIA and their parents/caregivers
2: preliminary data assessing the potential impact of 'JIA Toolbox' in real-world settings

15.0 Outcomes

There are two overall outputs from this project:

1. **Output:** Co-designed prototypes. The co-designed approach helps to ensure 'JIA Toolbox' will be useful, acceptable and of real benefit to the JIA community, improving chances of commercial success.

2. **Output:** In depth data (symptom experience and prototype use patterns) from a larger cohort n=25 over a longer period (3 months). The feasibility study context enables early discovery of barriers to adoption and therefore can be addressed and rectified. It also helps builds up a strong evidence base on the effectiveness and viability of these devices, enabling a good standpoint from which to leverage further funding.