

Formative Usability Testing

2024

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1.2. Chief Investigator and Investigation Site

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2. Glossary of Abbreviations

Acronym	Definition
ALAM	A Little About Me
ASD	Autism Spectrum Disorder
AV	Audio Visual
BCH	Birmingham Children's Hospital (Part of Birmingham Women's and Children's NHS Foundation Trust)
CI	Chief Investigator
CRF	Clinical Research Facility
HRC-DDR	HealthTech Research Centre in Devices, Digital and Robotics
IEC	International Electrotechnical Commission
MD-TEC	Medical Devices Testing and Evaluation Centre
NIHR	National Institute for Health and Care Research
PIS	Participant Information Sheet
REC	Research Ethics Committee
SAMD	Software As Medical Device
SME	Small to Medium Sized Enterprise
UHBNFT	University Hospitals Birmingham NHS Foundation Trust

3. Glossary of Tables and Figures

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4. Introduction

4.1.About HRC-DDR

The National Institute for Health and Care Research (NIHR) HealthTech Research Centre in Devices, Digital and Robotics (HRC-DDR) is funded by the NIHR to support UK Small to Medium sized Enterprises (SMEs) translate their technology into clinical practice. It is managed through University Hospitals Birmingham NHS Foundation Trust (UHBNFT). UHBNFT is one of the largest NHS Trusts in the UK with 2,700 beds and an annual turnover of more than £1.6bn.

The HRC-DDR is co-located within the Medical Devices Testing and Evaluation Centre (MD-TEC). Originally funded through the European Social Innovation Fund and collaborative academic partnerships, MD-TEC is a state-of-the-art testing and usability simulation suite that mirrors the clinical environment. The NIHR HRC-DDR/MD-TEC supports the testing and evaluation of medical technologies at every stage of development to ensure they are fit for purpose, improve patient care and ultimately add value to the healthcare portfolio. Human factors formative and summative usability testing is conducted to IEC: 62366 [1] and utilises the latest technology patient simulators and phantoms (a manikin that mimics human anatomy or function). The wider MD-TEC and HRC-DDR team also provides advice on design, development and regulatory approval of medical devices (inclusive of software as a medical device), grant application support and clinical investigation guidance.

4.2.Study Background

Approximately 550,000 children in the UK undergo a surgical procedure annually, with 1 in 160 children having been diagnosed with autism [2,3]. While many children often find visits to hospital daunting, neurodiverse children are twice as likely to experience anxiety and poorer outcomes [4].

Little Journey have developed a smartphone app which provides engaging, interactive, and child-friendly content designed to psychologically prepare neurodiverse children and support families before attending hospital appointments. It provides virtual tours of hospital rooms and age-tailored animations to describe the hospital-specific clinical pathway. The app also aims to reduce challenging behaviours (actions or attitudes that are difficult for others to accept or manage) and improve both patient and parent

experience and outcomes in hospital. Whilst not a software as medical device (SAMd), the app is supporting entry into the clinical pathway and would benefit from human factors testing to identify potential areas for improvement.

Little Journey are developing an additional module named 'A Little About Me' (ALAM). This module has several quizzes for children and their caregivers to complete before coming to hospital, including questions about their communication preferences, what's important to them, what they like and how they feel about being in hospital. Three of the quizzes are designed to be completed by children (Figures 4.1, 4.2 and 4.3), and two by their caregivers (Figures 4.4 and 4.5). It includes tools to understand patient needs, build rapport, learn about previous hospital experiences, anxiety levels and suggested beneficial adjustments. This is designed to support positive relationship-building between clinical staff and patients, enabling support to be provided for neurodiverse children and their parent/guardian/caregiver, thus improving the hospital experience for everyone involved.

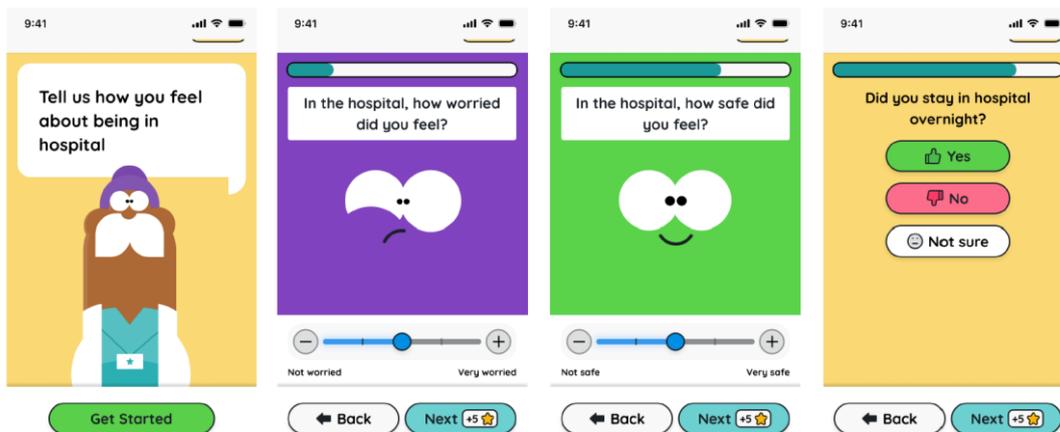


Figure 4.1. Child's Quiz: Going to Hospital.

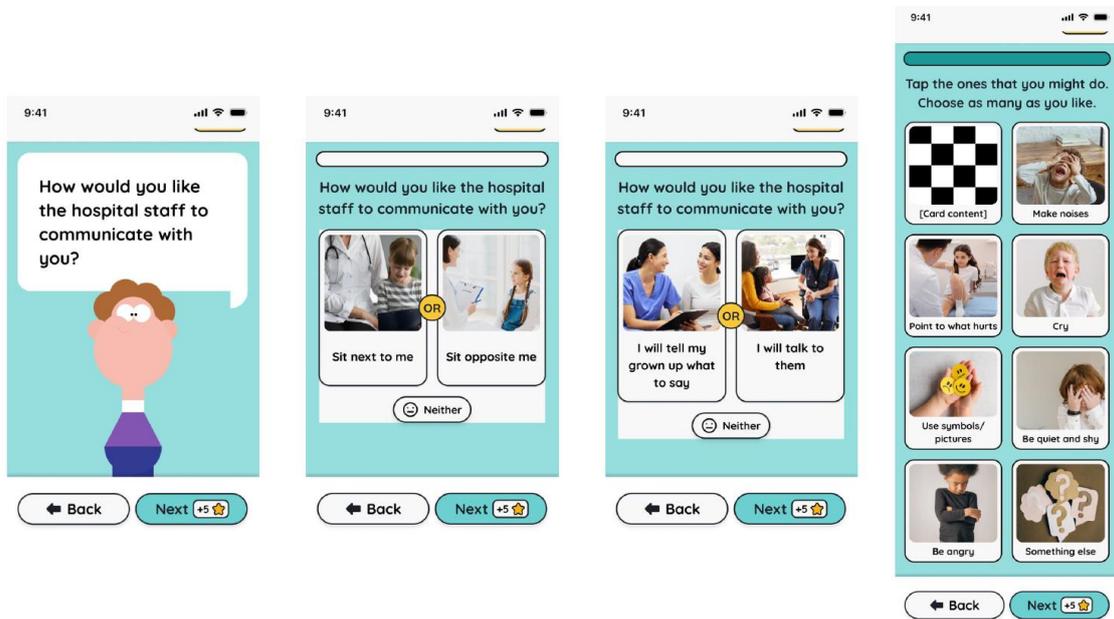


Figure 4.2. Child's Quiz: My communication style.

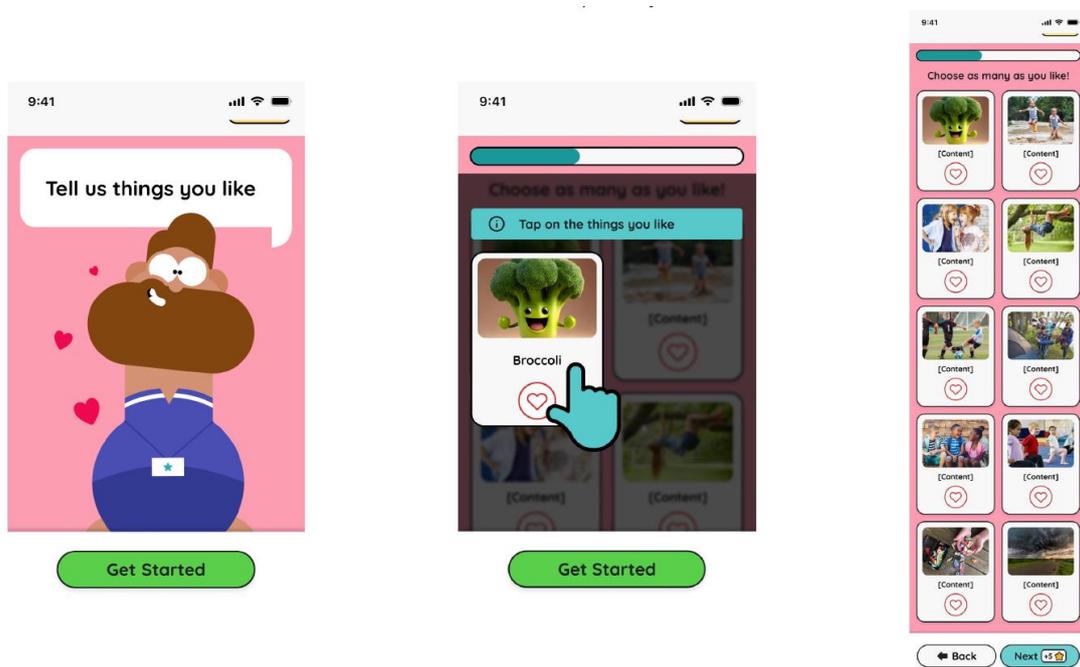


Figure 4.3. Child's Quiz: My likes.

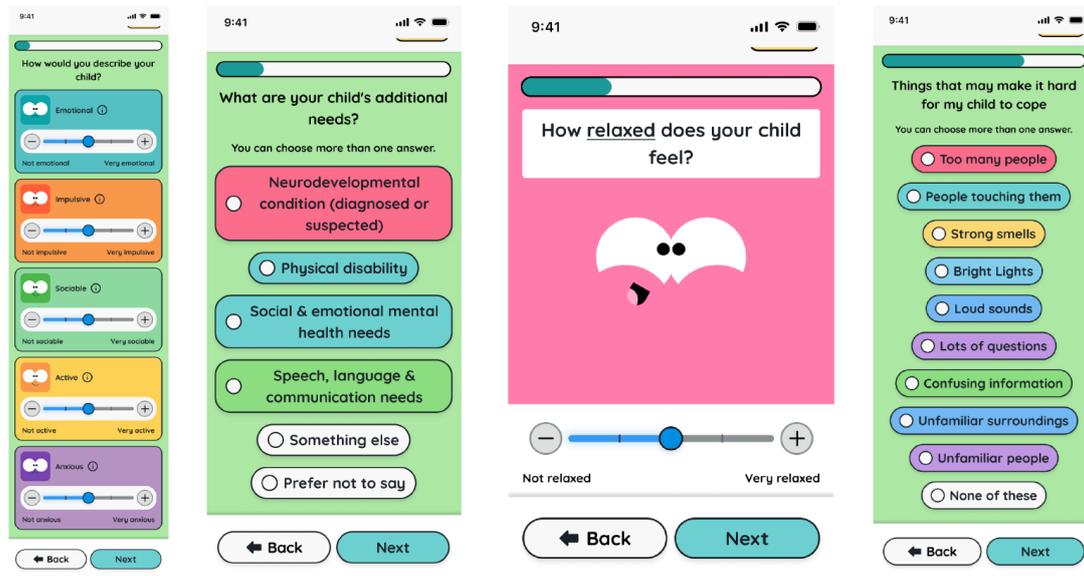


Figure 4.4. Parent's Quiz: Supporting your child.

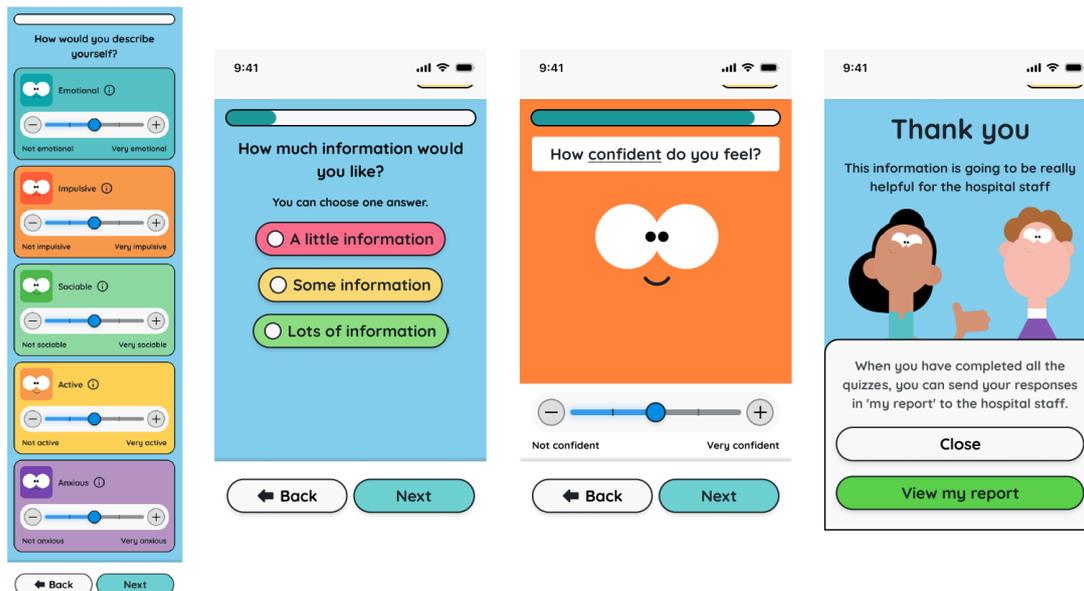


Figure 4.5. Parent's Quiz: Supporting you.

The aim of this study was to assess the usability of the Little Journey app with 7 children aged between 3-12 years with a diagnosis of autism spectrum disorder (ASD) and their parents/guardians/caregivers.

4.3. Test Objectives

The objectives of this usability study were to evaluate and assess usability and acceptability of the Little Journey app by parents/guardians/caregivers and children aged between 3-12 years old who have a diagnosis of ASD. Participants were registered patients at Birmingham Children's Hospital (BCH) and their parents/guardians/caregivers. Patients and their parents/guardians/caregivers were asked to complete a set of tasks in the app using a task list (Appendix 1) followed by a semi-structured interview.

5. Executive Summary

The NIHR HRC-DDR conducted a formative usability study between 22nd October and 31st December 2024 in the NIHR Clinical Research Facility (CRF) at BCH. Seven participants including six 7–12-year-olds and one 3–6-year-old took part in the study along with their parent/guardian/caregiver. Key aspects evaluated were the usability and acceptability of navigating the hospital tours and completing the quizzes in the Little Journey app.

Overall, the participants gave positive feedback on the Little Journey app and the unmet need was noted by the parent participants as they felt it would improve the hospital experience for children with ASD and their families. The feedback around the tours and character descriptions were mostly positive and particularly helpful if a child was preparing to come into hospital for the specific procedure shown. Feedback on the quizzes was positive and the participants expressed they felt the information gathered would be particularly helpful for hospital staff to not only better understand the needs of the child, but of the parent/guardian/caregiver too. Five children and all parent/guardian/caregiver participants thought the app was appropriate and usable for children with ASD, however, some children may need additional support from the parent/guardian/caregiver.

Several recommendations and suggestions for potential improvements were made. These included additional tours, amendments to the character descriptions and refinements to the wording of some of the questions asked in the quizzes to make them clearer.

6. Methods

6.1. Study Approvals

This study was reviewed and approved by the London Camberwell St Giles Research Ethics Committee (REC) (Ref: 24/PR/0962 August 2024). Local research and development approval was obtained from Birmingham Children’s Hospital prior to study commencement.

6.2. Participants

Patients were screened and recruited as per the study protocol. The inclusion criteria used can be seen below in Table 6.1.

Inclusion Criteria
Child’s diagnosis of autism spectrum disorder (ASD)
Child aged between 3-12 years old
Child is a registered patient at Birmingham Children’s Hospital attending hospital as part of their care
Child and parent/guardian/legal representative (caregiver) willing and able to participate in study, including child’s cognitive ability to use the app
Child and parent/guardian/legal representative’s (caregiver) ability to understand written English and provide verbal feedback in English

Table 6.1. The Inclusion Criteria.

REC approved recruitment flyers (Appendix 2) were circulated to staff groups within BCH electronically and hard copies of the recruitment flyer were also displayed within BCH. Potential patients were also screened through clinic lists (e.g. pre-admissions) and support departments (e.g. play). Eligible patients and interested parents/guardians/caregivers were sent a letter (Appendix 3) along with the age-appropriate Participant Information Sheet (PIS) for the child (Appendix 4 & 5) and parent/guardian/caregiver (Appendix 6).

Participants had at least 48 hours to consider the information in the child and parent PIS before being contacted by a member of the research team to see if they remained interested in taking part in the study.

Participants were scheduled into the study once interested parent/guardian/caregiver confirmed that they had read the PIS, agreed they met the eligibility criteria, and confirmed that the child has an ASD diagnosis. Parents/guardians/caregivers were instructed to bring confirmation of eligibility in the form of a paediatrician letter/report confirming ASD diagnosis to the study visit. Participation in the study consisted of a single visit to the hospital with one Parent/guardian/caregiver. Participant LJ006 had to return to the hospital due to technical issues on the first visit.

The participants varied in age, as summarised in Table 6.2.

Participant ID	Participant
LJ001	Child 7-12 years
LJP01	Parent
LJ002	Child 7-12 years
LJP02	Parent
LJ003	Child 7-12 years
LJP03	Parent
LJ004	Child 7-12 years
LJP04	Parent
LJ005	Child 3-6 years
LJP05	Parent
LJ006	Child 7-12 years
LJP06	Parent
LJ007	Child 7-12 years
LJP07	Parent

Table 6.2. Age/relationship of participants.

6.3.Tasks and Test Scenario

The test conditions were designed to realistically represent conditions of the app’s use. The room was arranged so that individuals could interact with the app in a quiet space without any distractions.

On arrival, eligibility was confirmed by the Chief Investigator (CI) or a delegated member of the research team and recorded on the Eligibility Form for the child (Appendix 7) and parent/guardian/caregiver (Appendix 8). Child participants aged 6 years and above were asked to give assent (Appendix 9 & 10) and the research team received consent from the parents/guardians/caregivers (Appendix 11 & 12). Four

participants consented to take part in the study but declined to be filmed (LJ001, LJ003, LJ004, LJ005) however, their activity on the app was recorded via the iPhone screen recording function. Participants were briefed on the purpose and organisation of the usability session and then encouraged through a task list to simulate use of the app with support from the research team if needed (appendix 1).

The participants subsequently engaged in a short semi-structured interview to provide their feedback on the Little Journey app (Appendix 13, 14 & 15).

7. Results

7.1.Overall Interaction

The device used and time taken for participants to interact with the app is displayed in Table 7.1.

Participant ID	Time (HH:MM:SS)	Device
LJ001, LJP01	00:19:40	iPhone
LJ002, LJP02	00:19:37	iPhone
LJ003, LJP03	00:15:00	iPhone
LJ004, LJP04	00:16:20	iPhone
LJ005, LJP05	00:23:25	iPhone
LJ006, LJP06	00:32:20	iPhone
LJ007, LJP07	00:20:12	Android

Table 7.1. Device used and Participants' app interaction time.

The shortest interaction time was 15 minutes (LJ003), and the longest interaction time was 32 minutes (LJ006). The average time to complete the task list was calculated at 20 minutes 56 seconds and the median time was 19 minutes 40 seconds.

One child participant, aged between 3-6 years, did not give verbal feedback during the study session but did partake in non-verbal feedback using a printed happy/neutral/sad face to choose from when answering (LJ005). All child participants used the faces to give feedback.

7.1.1. Child Feedback

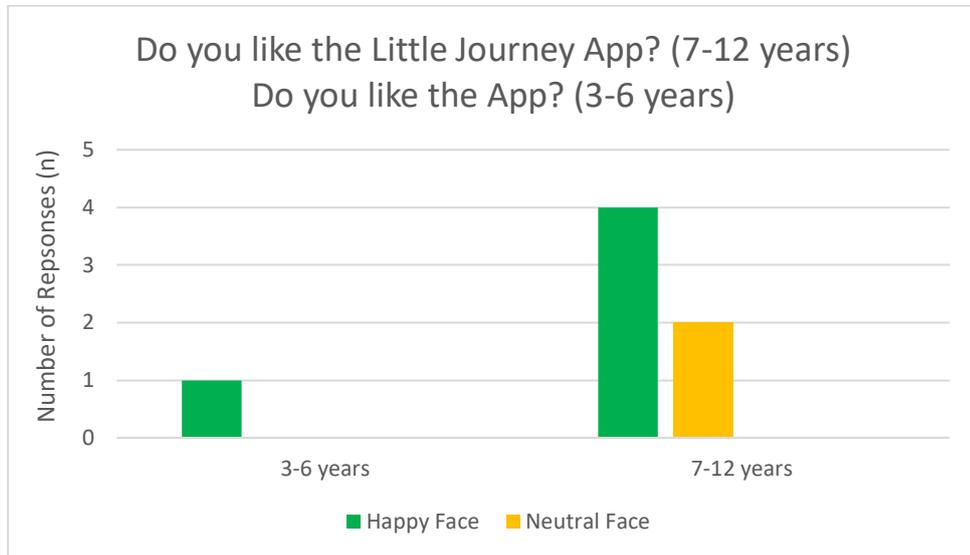


Figure 7.1.1. Child Response: App.

The child participants' initial impressions of the app were positive with no participants selecting the red, unhappy face. When asked if they liked the Little Journey App (Figure 7.1.1), five participants selected a happy face (LJ001, LJ002, LJ003, LJ005, LJ006) and two participants selected a neutral face (LJ004, LJ007). Participants found the app easy to use (LJ001, LJ002, LJ004, LJ006, LJ007), 'very functional' (LJ002) and 'better than other apps' (LJ001). One participant said the app 'was alright' (LJ007) and another 'liked the faces' (LJ004). One participant commented they liked being shown the hospital (LJ004) and three participants liked being asked what they liked (LJ003, LJ004, LJ007).

Some participants would like to see more games (LJ006, LJ007), 'more fun' (LJ006) and 'football or Lego' games (LJ007).

7.1.2. Parent Feedback

The parent participants' initial impressions of the app were positive describing it as 'amazing' (LJP01), 'good' (LJP03, LJP04, LJP07), 'colourful' (LJP01, LJP06), 'engaging' (LJP01, LJP06) and 'user friendly' (LJP02,

LJP03, LJP05, LJP07). When asked what they liked about the app, one participant said *‘everything, and feel passionate that you are doing it because of my experiences with (child’s name). I am sure [their] experiences will continue as [they] have just been discharged from one clinic and is now going to another clinic, and [they] will continue to do runners, hiding, screaming swear words at nurses and not letting them near [them], biting dad if [they] need to be held, it’s not nice’* (LJP01). Another participant said *‘I like that they can express how they want to be communicated to, giving them the value of your opinion matters’* (LJP05). One participant said, *‘the app will really help build an idea of each individual child’* (LJP07). Another participant said, *‘It would be interesting to try the exercises and relaxation to see what advice it offers, that could be such a treasure trove of information for parents and kids, could be used for anywhere in the NHS, dentists, GPs its very, very useful’* (LJP02).

Some participants made recommendations for the app such as:

- *‘More interactive and animated things for the children’s section’* and *‘more game quizzes’* (LJP07).
- *‘Multiple languages’* (LJP02)

7.2.Tour and Character Usability/Acceptability

7.2.1. Child Feedback

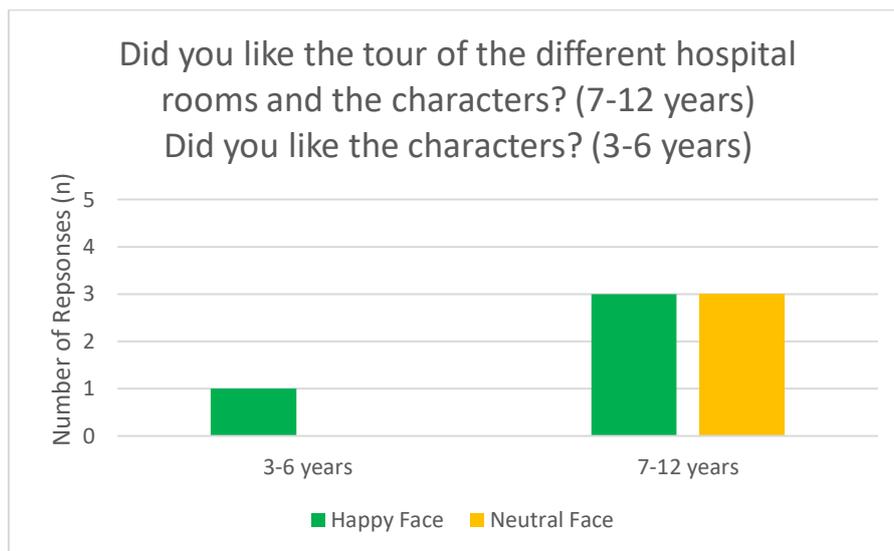


Figure 7.2.1. Child Response: Tours & Characters.

The child participants' impressions of the tour and characters were mostly positive. When asked about the tour of the different hospital rooms and the characters (Figure 7.2.1), four participants selected a happy face (LJ003, LJ004, LJ005, LJ006), three participants selected a neutral face (LJ001, LJ002, LJ007) and no participants selected the unhappy face. Some participants found the tours and characters to be 'ok' (LJ001) and 'not too exciting, not too boring' (LJ002) while another gave them a 'big yes' (LJ003) and 'liked the playroom' (LJ003). One participant found the 'videos were talking too fast' (LJ004) and another liked the characters describing them as funny but did not like the hospital rooms and said they 'need to be more cartoonish' (LJ007). This participant would like to see more animated characters and rooms and would prefer to design their own character (LJ007).

7.2.2. Parent Feedback

Participants described the tours as 'brilliant' (LJP01), 'child friendly' (LJP06), 'informative' (LJP06), 'so useful' (LJP07) and 'much nicer than watching a YouTube video of someone going into the scanner' (LJP01). One participant said 'I wish something like this existed before as (child's name) has had three MRI's and [they] didn't really understand what was happening at the time. It would help a lot of children having a visual step by step' (LJP07). A participant said, 'explaining MRI and what that does is helpful and tells us what to expect and will help (child's name) ... [they] don't like the unknown and wouldn't worry about it as much' (LJP03). Another participant added '[they] may not understand what an MRI is but I'm sure [they] understood the message of the tour' (LJP05). All but one parent participant thought the tour of the hospital rooms and character descriptions would be helpful for their child (LJP04).

Other participants found the app 'good but didn't cover every path' (LJP05) and 'not easy to navigate' (LJP04). One participant said 'for (child's name) things have to be literal; (child's name) needs to see an actual observation monitor and an actual hospital gown... I don't think it's realistic enough for children who rely on matter of fact' (LJP04). One participant noted that their child wasn't particularly interested in the character descriptions due to the child not expecting to go into hospital (LJP06). One participant noted there was no MRI scanner noise on the character description (see 04:30 – 04:40 on video), 'having had one it is quite a thunderous noise' (LJP02). Another participant noted their child missed the description on the first tour and went onto the MRI tour, however because they did not know what an MRI machine is, they went to exit the

tour (see 03:40 – 03:58 on video) even though parent tried to direct them back (LJP01). A participant also noted that their child accidentally turned the device onto silent via a side button while watching a character description but there was no notification of this (see 05:20 – 06:00 on video) (LJP02). Another participant commented *‘when you are watching videos it says press person to start, they talk then another person comes up, nothing happened and it doesn’t tell you to do anything, I pressed the screen and nothing happened until I pressed the person’* (LJP04) (see 06:00 – 06:40 on video).

Some participants made recommendations for the video tours and character descriptions such as:

- Child *‘got a little distracted on the longer ones’* in reference to the character descriptions and *‘having a second click to refocus (child’s name) would help’* (LJP02).
- More tours (LJP01, LJP07) such as *‘Endoscopy’* (LJP01) and *‘a treatment room or what to expect during a blood test’* (LJP07).
- *‘Having a little flag come up if you accidentally hit silent and turn mute on’* (LJP02)
- *‘Videos to be more self-explanatory, what to click’, ‘may seem simple but could be better explained to say what to do rather than just stare at the screen’* (LJP04).
- *‘Photos so [they] know exactly what [they’re] looking at, the actual room and actual MRI scanner so [they] know ahead of time and can be okay with it’* (LJP03).

7.2.3. Observations

Two participants had sound disappear during character descriptions (LJ001, LJ002) (see 04:00 – 04:25 on video). All participants who went on the MRI character description of what the MRI looks and sounds like did not have the scanner noise (see 04:30 – 04:40 on video). One participant had a different experience on the app (see 06:50 – 11:41 on video) (LJ006) which resulted in the following:

- Non-animated tours.
- No option/delay of ‘Next Room’ buttons, only ‘Exit Room’ buttons which confused participant on where to go.
- ‘Touch me to start’ button was on ceiling of tour and plays with view of floor and not the character or scanner.

- Child paused tour and said 'I exited'.

7.3. Quiz Usability/Acceptability

7.3.1. Child Feedback

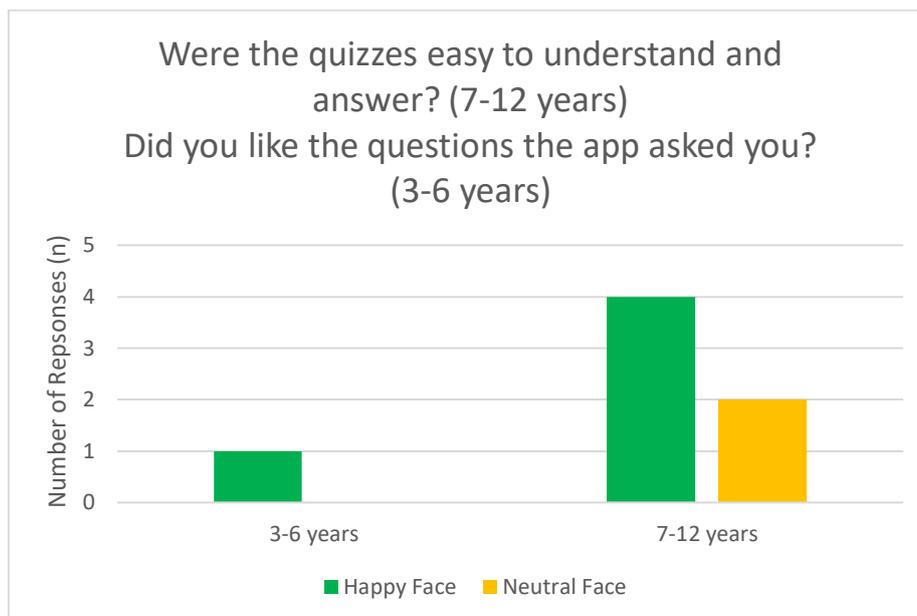


Figure 7.3.1. Child Response: Quizzes.

The child participants' initial impressions of the quizzes were positive. When asked about the questions in the quiz (Figure 7.3.1), five participants selected a happy face (LJ001, LJ004, LJ005, LJ006, LJ007) and two participants selected a neutral face (LJ002, LJ003). Most participants found the quizzes easy to understand and answer (LJ001, LJ002, LJ004, LJ006, LJ007) and 'liked the options' (LJ007), however one participant found the words hard to understand (LJ003) and another commented 'it really makes you think, you can't really remember a lot' (LJ002). The parent of this participant thought this comment related to the question asking about previous hospital visits (LJP02). Some participants particularly liked the 'my likes' quiz (LJ003, LJ004, LJ007). One participant would like to see more games and personality quizzes (LJ007). One participant commented it was 'hard to find parent quiz' and would like this improved (LJ003).

7.3.2. Parent Feedback

Parent participants' impressions of the quizzes and questions asked were positive. Participants described the quizzes and questions asked as 'good' (LJP01, LJP02, LJP03, LJP04, LJP07), 'suitable' (LJP01), 'appropriate' (LJP01), 'thought out' (LJP01), 'easy' (LJP03, LJP04, LJP06, LJP07), 'very straightforward and understandable' (LJP02), 'valid and relevant' (LJP05) and 'crucial' (LJP05). Participants liked that the quizzes asked how the parent was feeling as well as the child (LJP03, LJP05) and parents could give their input (LJP07). Participants also liked the question 'what should staff not do' embedded in the parent quiz as shown below in figure 7.3.2 (LJP03, LJP04). One participant said this is 'important for people to know how to cope with (child's name) and not to overwhelm [them] or touch [them], to know that before we go in would really work for us...putting it across before we go, saves the awkwardness for (child's name)' (LJP04).



If my child is unable to cope, PLEASE can hospital staff NOT

- Get angry
- Touch them
- Crowd them
- Look at them
- Ask them direct questions
- Make loud noise

Figure 7.3.2 Question example: 'what should staff not do'.

One participant said 'I like the multiple-choice questions, rather than having to write an answer. Options are helpful to help choose what they want' (LJP07) and the 'what do you like questions are very useful to help build rapport' (LJP07). This participant also noted that the quizzes have given them ideas to consider

and explore based on the way their child answered the questions (LJP07). Another participant said, *'if doctors and nurses paid attention to the answers it would completely change their experience in hospital'* (LJP01). One participant said, *'I particularly liked the communication, getting to know your child, how they communicate is so beneficial for their experience'* (LJP02).

One participant said, *'the questions were good but a lot of the times I did give the middle option'* (LJP07). Another participant said *'some of the questions for (child's name) were a tiny bit wordy, because [they] were going too fast [they] might have forgotten what the question was asking'* (LJP02). Some participants found the questions asked to be vague and/or needed to explain them to their child (LJP01, LJP04, LJP07) for example, the how happy do you/your child feel questions (LJP01, LJP07). One participant said *'some questions could be tweaked to be more specific, the "how do you feel" questions, it would give the hospital good feedback and help pinpoint any need for improvement. It will help get the perfect plan in place for each child'* (LJP07). Participants who have support needs themselves may also be unsure of the questions (LJP01, LJP02, LJP06). One participant noted their child wanted to select more than one answer and said *'(child's name) wanted to pick two answers and it was either or, sometimes [they] don't want to move around and others [they] want to sit still sometimes, so could be both'* (LJP03) and would like to see this improved in future. Some participants could not locate the child quiz (LJP06) (see 20:30 – 22:25 on video) and/or the parent quiz (LJP04) (see 22:27 – 23:40 on video). One participant said, *'It was frustrating that I could not find the quizzes'* (LJP06), and another said, *'I couldn't find the quiz that needs to be not in the kids section, being a parental quiz I was looking for parental section'* (LJP04); participants would like to see this improved in future. A participant did not like the slider answers and felt this could be improved noting *'(child's name) struggled with slider, there was two ways of moving slider, sometimes it moved sometimes it didn't, asked (child's name) to try using the minus and plus button which [they] were more satisfied with'* (LJP01) (see 23:40 – 25:20 on video). This participant also noted *'when using slider in parent app it took big jumps, I'm not sure if that affected any other questions'* (LJP01).

Some participants made recommendations for the quizzes such as:

- A free text option to add extra information/specifics (LJP03, LJP07)

- More words of praise at the end of the quizzes *'remarks of well done, you did a great job... will get them more interested, that would be a plus'* (LJP05).
- *'On the likes and dislikes, maybe fewer answers on a page, four icons and then scroll down a big list is daunting, maybe have a more button as it can be a little overwhelming'* (LJP02).

7.4.App Usability/Acceptability for Children with ASD

7.4.1. Child Feedback

Most child participants thought that other children with ASD would like to use the app before coming to hospital (LJ001, LJ002, LJ003, LJ004, LJ006). One participant commented it *'depends on the child but I liked it'* (LJ007), they also pointed out children who are blind and/or deaf may not but did not elaborate.

Some child participants thought others with ASD would like it because it is *'easy'* (LJ001, LJ002), *'explains things'* (LJ003), so *'they know what to expect'* (LJ004), is *'not bombarding you with questions and takes it quite slowly'* (LJ002), would *'make them calm by showing them around and giving them tours and quizzes'* (LJ001) and would *'make them concentrate and feel more relaxed'* (LJ001). One participant thought others would like it but wasn't sure why (LJ006).

7.4.2. Parent Feedback

All participants thought the app was appropriate and usable for children with ASD however, some participants thought the level of support the child would need from the parent would depend on their individual needs (LJP01, LJP02, LJP05). Some participants found the colours (LJP01, LJP06) and animations (LJP05) were particularly appropriate for children with ASD, although one participant said, *'the cartoons are good for kids but not from an information giving point of view. As for the waiting room, I know they can't take a picture of every single waiting room but that's not really what a waiting room is like in real life that's a cartoon, more important for what a real hospital waiting room looks like, if not, it's setting them up for something they won't have'* (LJP04). One participant said *'It would calm anxiety in a child with autism who doesn't know what to expect'* and *'It allows autistic children to take it in in their own time beforehand'* (LJP07).

8. Conclusions

In conclusion, the overall response to the Little Journey app was extremely positive with participants showing keen interest in using the app. The app was found to be engaging, helpful and child friendly. Parent participants expressed they felt that touring the hospital rooms and communicating their additional needs/preferences as well as their child’s via the quizzes, would be effective in preparing and supporting children with ASD and their families before attending hospital. Overall feedback suggests use of the app would improve patient and caregiver experience and support healthcare staff to deliver personalised care and improve outcomes.

The participants made several suggestions for possible improvements to the Little Journey app (Table 8.1).

1	Additional games & quizzes
2	Language options
3	Adjust pace of character descriptions
4	Option to create own character
5	Add MRI scanner noise
6	Add flag/notification if device is on silent during character description
7	Add instruction labels to all characters
8	Add ‘clicks’ during character descriptions to keep child engaged
9	Additional tours/pathways
10	An option to see an actual photo of room/equipment/item
11	Make quizzes more accessible/easier to find
12	Simplify and/or reword questions around feelings
13	Improve slider
14	Add free text option at the end of quizzes
15	Add more words of praise at the end of the child quizzes
16	Add a ‘see more’ option to reduce list of answer on my likes quiz
17	Add option to select more than one answer for all questions

Table 8.1. Recommendations and suggestions.

9. References

1. International Standard (2015) – IEC 62366-1 (Application of usability engineering to medical devices)
2. Narayanan H, Raistrick C, Pierce J.M. T, Shelton C (2022) - *Carbon footprint of inhalational and total intravenous anaesthesia for paediatric anaesthesia: a modelling study*. Paediatric Anaesthesia.
3. Tinybeans (2022) – *The LEGO Foundation Just Invested \$20M to Support Neurodivergent Children*
4. Little Journey – Primary Research (unpublished).

10. Appendix 1 Task List

Little Journey – Usability Study Task List

- Using the smartphone provided, please can you use the Little Journey app to complete the following tasks.
 - We are not testing your ability to do this; we are testing the app to see how user friendly and interactive this is with real parents/guardians, legal representatives and their children.
 - If you have any difficulties this is not a problem, let one of the research team know.
 - You are welcome to take a break at any time.
1. Log into app, selecting the following options:
 - a. Hospital: Gloucestershire Royal Hospital and Cheltenham General Hospital
 - b. Pathway: MRI Pathway at GRH
 - c. Select recommended character (animal or human)
 2. View 'Take a tour'
 - a. Select 'MRI awake'
 - b. View at least two different rooms of the tour, including:
 - i. Entrance
 - ii. Waiting Room
 - iii. Play Room
 - iv. Scanner Room
 - v. Home Time
 3. Complete 2 quizzes (for children). The below are available for you to choose from:
 - a. Going to hospital
 - b. My communication style
 - c. My likes
 4. Complete 1 parent quiz, either:
 - a. Supporting your child
 - b. Supporting you

11. Appendix 2 Recruitment Flyer

NIHR | HealthTech Research Centre
Devices, digital and robotics



Opportunity to test a new app!

Feedback needed on a new app designed to support children with autism coming to hospital!

The NIHR HealthTech Research Centre in Devices, Digital and Robotics (HRC-DDR) & Birmingham Children's Hospital are assisting the development of an app designed to support children and families coming to hospital.

You and your child may be eligible if your child:



- Is aged between 3-12 years old.
- Has an Autism Spectrum Disorder diagnosis.
- Is registered as a patient at Birmingham Children's Hospital.
- Has the ability to understand written English and provide verbal feedback

Participation in this study involves:

- A **single visit** to Birmingham Children's Hospital.
- You and your child participating in a **1 hour** usability session.
- You and your child using the app (using a phone provided) and giving your feedback!
- Reasonable travel expenses and a **£50 Love2Shop Voucher** will be provided if enrolled.



Interested? Contact us!

- Email: bwc.clinicalresearchfacility@nhs.net
- Telephone: 0121 333 9550

By contacting us, you are consenting to having your email, telephone and name recorded for the purpose of this study.
Little Journey - Usability Study, IRAS 341609, V2.0 18/07/2024

12. Appendix 3 Cover Letter

Birmingham Women's and Children's NHS Foundation Trust
NIHR Clinical Research Facility
Birmingham Children's Hospital
Steelhouse Lane
Birmingham
B4 6NH

Date: XX/XX/2024

RE: Little Journey – Usability Study

Dear Parent/Guardian/Legal Representative,

You and your child have been invited to take part in research being undertaken at Birmingham Children's Hospital. The research study is sponsored by Little Journey and is being conducted by a research team including staff from Birmingham Children's Hospital and the National Institute of Health and Care Research (NIHR) HealthTech Research Centre in devices, digital and robotics (HRC-DDR) at University Hospitals Birmingham NHS Foundation Trust.

Please find two participant information sheets enclosed, one for your child and one for yourself. If there are any details in the information sheets that are not clear, then please contact the research team using the details provided.

If you are interested in participating, please contact us at Birmingham Children's Hospital using the contact details provided below:

Little Journey Study Team
Email: bwc.clinicalresearchfacility@nhs.net
Telephone: 0121 333 9550

Thank you for considering taking part.

Yours sincerely,

Lucy Cooper

Advanced Nurse Practitioner
Chief Investigator

13. Appendix 4 Participant Information Sheet – Children 3-6 Years

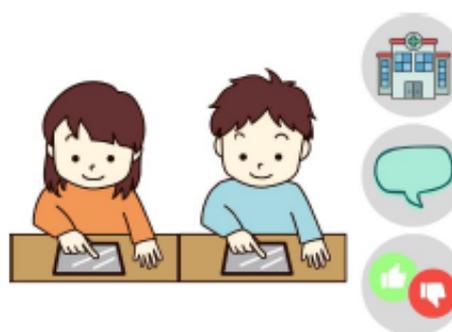
Participant Information Sheet – Children 3-6 years

Little Journey Usability Study



You have been asked to look at an app. This app will help children coming to hospital.

You will use the app with someone who looks after you.



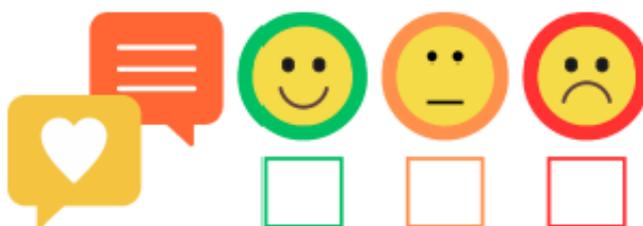
You will look at some hospital rooms on the app and answer some questions.



We will record your voice so we know what you think about the app.

We will also video record you if that's okay.

At the end, you can tell us if you like the app and why!



14. Appendix 5 Participant Information Sheet – Children 7-12 Years

Participant Information Sheet (PIS) - Children 7-12 years



Little Journey – Usability Study

We are asking for your help with a research project at Birmingham Children's Hospital. Please read this information which will help you decide if you would like to help.

What is research?

Research helps us learn new things from people. This includes asking questions to get new information.

Why is this research being done?

An app has been made to help children feel more prepared and relaxed coming to hospital. We want to make sure the smartphone app can be used by lots of different children.

In this research, you will use the app and then answer some questions about it. Someone in the research team will give you a phone to use. We would like to know whether you like the app, and what could be changed to make it better!



Who are the research team?

If you would like to help with the research, there will be a researcher to show you how to use the app and ask you questions about it afterwards. They will keep your information safe and not tell anyone that you have helped with the study.

Why have I been asked to help?

You have been asked to help because you have been to Birmingham Children's Hospital before to have a test or to see a doctor.

What will happen if I take part?

1. You and someone who looks after you will come to Birmingham Children's Hospital for about one hour. We will ask if you are happy to take part in this research.
2. If you are happy to take part, you will be asked if we can film you using the app. This filming will show us whether the app is easy to use. You do not need to be filmed to take part, but we will need to record your voice so we can write down what you've said.
3. We will show you and the person who looks after you how to use the app. We will then ask you to use the app. The app will ask about how you would like hospital staff to communicate (speak) with you. We will also ask what's important to you when you come to hospital.
4. The research team will ask you whether you like the app, and what you think could make it better!

Will the study upset me?

The app will talk about hospitals and a test that happens to some children in hospital. This may or may not be a test you have had before. We will not be talking about your care in hospital.

We don't think that this will upset you. Someone who looks after you will be with you all the time. If you want to take a break or stop taking part at any point, please tell us or tell the person who looks after you.

Will the study help me?

The study will not change how you are looked after in the hospital. What you think is very important and will help to make the app better for other children coming to hospital in the future.

Do I have to take part?

No, if you do not want to take part in the study, that's okay! If you change your mind during the study that's also okay, please tell the person who looks after you, or tell someone in the research team.

What should I do now?



You have time to talk to your family and ask any questions you have. Someone who looks after you can contact us to ask us your questions.

If you would like to take part, someone who looks after you will arrange a time for you to meet with us.

When we see you, you have the chance to ask us questions before you take part. We will ask the person who looks after you to fill in a few forms to say that you are happy to take part.

If you want to, you can also fill in a form to say that you want to help with the research.

Thank you for reading this information!

15. Appendix 6 Participant Information Sheet – Parent

Participant Information Sheet (PIS)

Little Journey – Usability Study

You and your child have been invited to take part in research being undertaken at Birmingham Children's Hospital. The research study is sponsored by Little Journey. Before you make a decision about you and your child taking part, we would like to explain why the study is taking place and what it will involve. If there are aspects of the information sheet that are not clear then please contact the research team using the details provided.

What is the purpose of the study?

Little Journey are a company based in England who are developing solutions to reduce anxiety in children and improve hospital experiences, based on the founder's experience as an anaesthetic doctor. Little Journey has developed an app which provides engaging, interactive and age-appropriate content designed to prepare and support children and their families coming to hospital. Additionally, Little Journey would like to collect further information from children and parents/guardians/legal representatives before coming to hospital which will support clinicians in addressing individual's needs and concerns. The Little Journey app aims to reduce anxiety in children and parents before hospital procedures and to improve children's and parent's/guardian's/legal representative's experience of healthcare.

It is important that the Little Journey app is usable and accessible for everyone. Feedback collected through this research is needed from children with an autism diagnosis, and their families, to further improve the app. This research is being conducted by the NIHR HealthTech Research Centre in Devices, Digital and Robotics (HRC-DDR) Team from University Hospitals Birmingham NHS Foundation Trust, and Birmingham Women's and Children's Hospital NHS Foundation Trust, who are working with Little Journey to support the app's development and improvement. More information about Little Journey can be found here: www.littlejourney.health/

Is my child eligible to take part?

Your child must meet all of the below eligibility criteria to participate in this study.

Eligibility Criteria
A diagnosis of Autism Spectrum Disorder (ASD)
Aged between 3-12 years old
Registered patient at Birmingham Children's Hospital attending hospital as part of their care
Willing and able to participate in study, including the cognitive ability to use the app
Ability to understand written English and provide verbal feedback in English

Am I eligible to take part?

You are eligible to participate as a parent/ guardian/ legal representative if your child meets the above eligibility criteria. As their parent/guardian/legal representative, you must also be willing and able to participate in the study, and able to understand written English and provide verbal feedback in English.

What will happen if me and my child take part?

After you have had sufficient time to read this information leaflet and think about it, you may contact us, or we will contact you to discuss the study further and answer any questions you may have. If you agree to take part in the study and confirm that your child has received a diagnosis of autism spectrum disorder, you both will be invited to the Clinical Research Facility in Birmingham Children's Hospital. We will ask to see a copy of your child's autism diagnosis (letter/report) to check they are suitable to take part. The study involves a single visit which is anticipated to take approximately 1 hour.

A member of the research team will speak to you about the study, answer any questions, confirm that your child is eligible, and check that you and your child still want to take part. If so, you and your child will both be enrolled in the study. The study explanation and consent process is anticipated to take approximately 20 minutes. We will also ask you if you would like a summary of the study findings, and for contact details for who to send these to in the future.

A member of the research team will show you and your child how to use the app. You and your child will then have opportunity to use the app, completing a set of tasks, on a phone that will be provided by the research team. This will include answering some questions about how your child would like hospital staff to communicate with them, what your child likes to do in their free time, and how you would like to be supported by the hospital. This will take approximately 25 minutes. You will be asked if you are happy for this part of the study to be filmed. This filming will focus on the interaction with the app and show whether the app is easy to use. You and your child's face will be included in the video, however this will not provide any details which will allow anyone to link the video to who you are. We will audio record the task session to capture any questions or feedback that you have, and record the screen so we can see how you used the app.

After you and your child have used the app, a member of the research team will ask your child some questions related to the ease of use and accessibility of the app to gather their feedback. We will also ask you some similar questions to collect your feedback. This will take approximately 15 minutes and will be audio recorded to capture all your feedback.

After the study day, your verbal feedback will be written down by a member of the research team. The audio recording will then be deleted. Your feedback will be written into a report using your study number, not you or your child's name. The video footage will not link you to your study number, so your feedback cannot be linked to your video footage.

What will happen with the results of the study?

Your feedback is important. The strengths and weaknesses of the app and any feedback/ recommendations you and your child have will be written into a report by the NIHR HRC-DDR team. This report, alongside edited video footage, will be provided to Little Journey and help to support the future development of the Little Journey app. Your names and any personal details will not be given to Little Journey. Instead, your child will be given a study number which any feedback will be attributed to.

Little Journey, based in England, is the sponsor and data controller for this study. University Hospitals Birmingham will act as the "data processor" for this study. This means that University Hospitals Birmingham, on behalf of Little Journey, is responsible for defining what data is collected, how it is stored and used. The video recording, and audio recording where consent has been provided, may be used by Little Journey for conference presentations, educational presentations or courses.

Any personal identifiable data will be kept securely at Birmingham Children's Hospital for 6 months after the end of the study. The anonymous research data, which will have no information to directly link back to you as a participant, will be kept for 10 years after the study has finished so we can check the results.

What are the benefits of taking part?

The study will not change how your child is looked after in hospital and will therefore have no direct benefits at this time. Your feedback may lead to design changes that improve the ease of use and accessibility of the Little Journey app. This may lead to reduced pre-hospital anxiety in parents and children and improved hospital experiences in the future.

If you and your child consent to take part in the study you will be given a £50 Love2Shop voucher to thank you for your time.

What are the possible disadvantages of taking part in the study?

The app will detail a fictional simulated hospital procedure that is not specific to your child's medical care and may or may not be a previous or upcoming procedure. The information presented in the app is tailored for children and uses animated characters to discuss the non-invasive procedure. You are required to be present for the duration of their participation in addition to paediatric research trained staff. We therefore believe that there is a low risk that this may upset your child.

You and your child will be able to take a break, or stop taking part, at any point of the study. Overall, the risks to you and your child are very low.

What if I have any concerns or if something goes wrong?

If you have a concern about any aspect of this study, you should first ask to speak to a member of the research team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting Birmingham Children Hospitals' Patient Advice and Liaison Service (PALS) via one of the following methods (opening hours are Monday - Friday 8.30am - 4.30pm):

- Telephone: 0121 333 8403
- Email: bwc.pals@nhs.net

A 24-hour answerphone service is available. More information is available here: <https://bwc.nhs.uk/patient-advice-and-liaison-service-pals/>

The risks associated with the study are low, however we will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of British Healthcare Industry (ABHI). We will pay compensation where the injury probably resulted from the app being tested as part of the trial protocol.

Any payment would be without legal commitment. (Please ask if you wish more information on this). We would not be bound by these guidelines to pay compensation where the injury resulted from a procedure outside the trial protocol or where the protocol wasn't followed. The study is insured with Travelers Insurance Company Ltd.

Who is organising the study?

The study is being organised by the NIHR HealthTech Research Centre in Devices, Digital and Robotics (HRC-DDR), a team hosted by University Hospitals Birmingham NHS Foundation Trust (UHB). The study protocol, this information sheet, and other study documents have been developed by the research team with support from patient and public representative volunteers. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Camberwell St Giles Research Ethics Committee (REC).

This study has been funded by Small Business Research Initiative (SBRI).

Expenses

Reasonable travel expenses will be provided with evidence. Please let us know if you would like travel expenses to be provided when scheduling your visit. If you are enrolled in the study we will provide a £50 Love2Shop voucher as a thank you for your time.

How do I take part?

If you would like to take part in this study, please email bwc.clinicalresearchfacility@nhs.net or call 0121 333 9550 and ask to speak to the Little Journey study team. We will ask a few questions to confirm if you can be included in the study, including checking that your child has received a letter/report confirming an autism diagnosis. By emailing or phoning us to register your interest, you are consenting to having your name, email address and phone number stored by Birmingham Children's Hospital for this research purpose only. Confirmation of your eligibility and informed consent to take part in the study will take place at the start of your study visit. This includes a member of the research team seeing a copy of your child's autism diagnosis (letter/report).

You and your child do not have to take part. However, if you decide to take part you will be asked to sign a consent form on behalf of yourself and your child to confirm that you have understood what the study involves and that you would like to take part. Your child will be asked to complete an assent form where appropriate. You will be given a copy of the consent form to keep. You can change your mind and withdraw from the study at any time, without giving us any reason.

Research Team Contact

Little Journey Study Team

Email: bwc.clinicalresearchfacility@nhs.net

Telephone: 0121 333 9550

Address: Clinical Research Facility, Birmingham Children's Hospital, Birmingham B4 6NH.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name and your child's name, age, confirmation of previous hospital experience and ASD diagnosis. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to HealthTechDDR@uhb.nhs.uk
- by ringing us on 0121 371 8537.

For more information

Some general information about research is available online. Sources include the NHS website, clinical trials, and medical research – getting involved.

<http://www.nhs.uk/conditions/Clinical-trials/pages/gettinginvolvedinresearch.aspx>

Thank you for considering taking part in this research study.

16. Appendix 7 Eligibility Form – Children 3-12 years



Little Journey – Usability Study Eligibility Form – Children 3-12 years

Inclusion Criteria	
	Please tick/ cross
A diagnosis of Autism Spectrum Disorder (ASD)	
Aged between 3-12 years old	
Age of child in years:	
Registered patient at Birmingham Children’s Hospital attending hospital as part of their care	
Willing and able to participate in study, including the cognitive ability to use the app	
Ability to understand written English and provide verbal feedback	

Final Eligibility Check (Please Circle)		
Are all inclusion criteria ticked?	Yes <i>Can participate</i>	No <i>Can not participate</i>

Date Completed:	
Name of research team member confirming eligibility:	
Signature:	

17. Appendix 8 Eligibility Form – Parent/Guardian/Legal Representative



Little Journey – Usability Study Eligibility Form – Parent/Guardian/Legal Representative

Inclusion Criteria	
	Please tick/ cross
A child with a diagnosis of Autism Spectrum Disorder (ASD)	
A child aged between 3-12 years old	
A child who is registered as a patient at Birmingham Children’s Hospital attending hospital as part of their care	
A child that is willing and able to participate in study, including the cognitive ability to use the app	
A child with the ability to understand written English and provide verbal feedback	
Willing and able to participate in the study	
Willing and able to understand written English and provide verbal feedback	

Final Eligibility Check (Please Circle)		
Are all inclusion criteria ticked?	Yes <i>Can participate</i>	No <i>Can not participate</i>

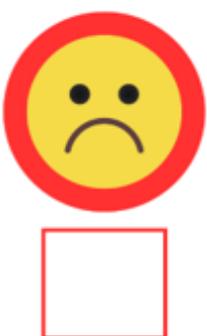
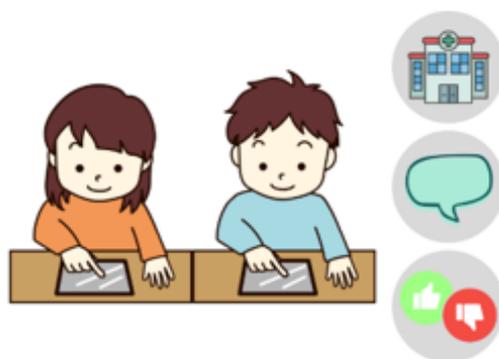
Date Completed:	
Name of research team member confirming eligibility:	
Signature:	

18. Appendix 9 Child Assent Form 6 Years

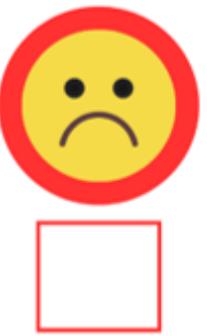
Child Assent Form – 6 years Little Journey – Usability Study

Name of person taking assent	
Date Completed	
Signature of person taking assent	

1. Would you like to take part?



2. Would you like to be filmed?

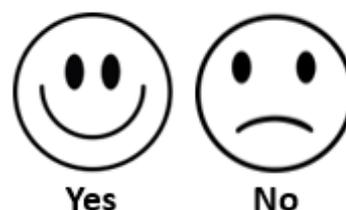


19. Appendix 10 Child Assent Form 7-12 Years

Child Assent Form – 7-12 years Little Journey – Usability Study

Name of person receiving assent	
Date Completed	
Signature of person receiving assent	

Please tick, mark or colour the boxes below:



Would you like to take part in this research?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------



Can we record you with cameras while you are using the app?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------



Can we record your voice when we ask you questions?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

Please write your name in the box below.

--

20. Appendix 11 Volunteer Informed consent form – Child Participation

Informed Consent Form – Child Participation Little Journey – Usability Study

White and blue boxes to be completed by participant	Grey boxes to be completed by researcher			
Participant identification number of parent/ guardian/ legal representative	U			
Child's participant identification number	U			
Name of child				
Name of researcher taking consent:				
Designation of researcher taking consent:				
<p>I confirm that I have read the information sheet dated 19/08/2024 (version 3.0) for the above study. My child and I have had the opportunity to consider the information, ask questions and had these answered satisfactorily.</p>				
				<i>initials</i> <input style="width: 40px; height: 30px;" type="text"/>
<p>I understand that the participation of my child is voluntary and they are free to withdraw at any time without giving any reason, without their legal rights being affected.</p>				
				<i>initials</i> <input style="width: 40px; height: 30px;" type="text"/>
<p>I agree that my child can take part in the above study.</p>				
				<i>initials</i> <input style="width: 40px; height: 30px;" type="text"/>
<p>I agree to my child being audio recorded during the task section of this study. I understand that this footage will be provided to Little Journey and can be used for the following:</p> <ul style="list-style-type: none"> - Production of usability testing reports - Conference presentations, educational presentations or courses 				
				<i>initials</i> <input style="width: 40px; height: 30px;" type="text"/>
<p>I agree to my child being audio recorded during the interview section of this study. I understand that this audio recording will not be made available to Little Journey.</p>				
				<i>Initials</i> <input style="width: 40px; height: 30px;" type="text"/>
<p>(optional) I agree to my child being video recorded for the task section of this study. I understand that this video footage will be provided to Little Journey and can be used for the following:</p> <ul style="list-style-type: none"> - Production of usability testing reports - Conference presentations, educational presentations or courses 				
				<i>initials</i> <input style="width: 40px; height: 30px;" type="text"/>

Name of child (BLOCK CAPITALS)		
Name of parent/guardian/legal representative	Date	Signature
Person taking consent (BLOCK CAPITALS)	Date	Signature

21. Appendix 12 Volunteer Informed consent form – Parent Participation

Informed Consent Form – Participation of Parent/ Guardian/ Legal Representative Little Journey – Usability Study

White and blue boxes to be completed by participant	Grey boxes to be completed by researcher
Participant Identification Number	LJ
Name of participant	
Name of researcher	
Designation of researcher taking consent	
I confirm that I have read the information sheet dated 19/08/2024 (version 3.0) for the above study. I have had the opportunity to consider the information, ask questions and had these answered satisfactorily.	<i>initials</i> <input style="width: 40px; height: 30px;" type="text"/>
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.	<i>initials</i> <input style="width: 40px; height: 30px;" type="text"/>
I agree to take part in the above study.	<i>initials</i> <input style="width: 40px; height: 30px;" type="text"/>
I agree to being audio recorded during the task section of this study. I understand that this footage will be provided to Little Journey and can be used for the following:	<i>initials</i> <input style="width: 40px; height: 30px;" type="text"/>
<ul style="list-style-type: none"> - Production of usability testing reports - Conference presentations, educational presentations or courses 	
(optional) I agree to being video recorded for the task section of this study. I understand that this video footage will be provided to Little Journey and can be used for the following:	<i>initials</i> <input style="width: 40px; height: 30px;" type="text"/>
<ul style="list-style-type: none"> - Production of usability testing reports - Conference presentations, educational presentations or courses 	
I agree to being audio recorded during the interview section of this study. I understand that this audio recording will not be made available to Little Journey.	<i>initials</i> <input style="width: 40px; height: 30px;" type="text"/>

The research team will write a brief summary of the outcome of the study which will be available for the participants. If you would like to receive the summary, please provide contact details (address or email) in the below box.

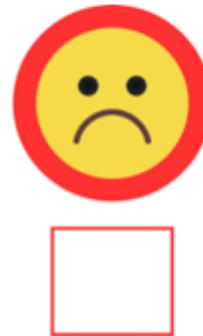
Name of parent/guardian/legal representative	Date	Signature
Person taking consent (BLOCK CAPITALS)	Date	Signature

22. Appendix 13 Child semi-structured interview 3-6 Years

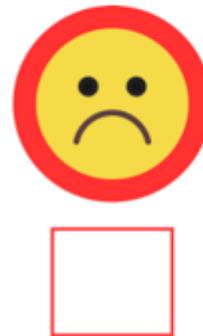
Little Journey – Usability Study Semi-Structured Interview (3-6 years)

Name of Interviewer:	
Date Completed:	

1. Did you like the app?



2. Did you like the characters?



3. Did you understand what the characters were talking about?



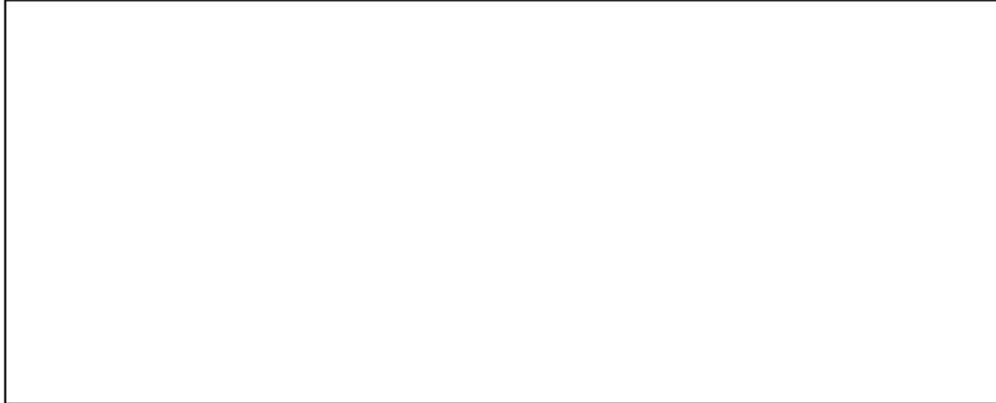
4. What was fun about the app?

5. Was anything hard to use in the app?

6. Did you like the questions the app asked you?



7. Would anything make the app better?



Thank you for your time in answering these questions and taking part in the usability study.

23. Appendix 14 Child semi-structured interview 7-12 Years

Little Journey – Usability Study Semi-Structured Interview (7-12 years)

Name of Interviewer:	
Date Completed:	

1. Did you like the Little Journey app?



Comments:

2. Did you like the tour of the different hospital rooms and the characters?



Comments:

3. What did you like about the app?

4. Was anything difficult to use in the app?



Comments:

5. Were the quizzes easy to understand and answer?



Comments:

6. Do you think other children with autism would like to use the app before coming to hospital?

7. What would make the app better?

Thank you for your time in answering these questions and helping us with this study.

24. Appendix 15 Parent semi-structured interview

Little Journey – Usability Study – Parent/ Guardian/ Legal Representative Semi-Structured Interview

Name of Interviewer:	
Date Completed:	

1. What did you think of the Little Journey app? Did you find it interactive and user friendly for you and your child?

2. Do you think the tour of the hospital room and character's descriptions would be helpful for your child?

3. Do you think the app is appropriate and usable for children with autism?

4. What did you like about the app?

5. What didn't you like about the app?

6. What did you think of the questions you were asked in the quiz? How did you find the quiz to complete?

7. Is there anything that would make the app better?

Thank you for your time in answering these questions and participating in the usability study.