PARENT PARTICIPANT FORMATION SHEET

V1.2 18.08.26

Title: SiblingGame Research Study

A randomised controlled trial of a digital 'serious game' designed to promote wellbeing in young siblings of children with learning disabilities

Chief Investigator: Professor Richard Hastings

You are invited to take part in a research study called 'SiblingGame'. Before you decide, it is important to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully.

This information sheet explains why the study is being done, what taking part involves and how the study will be carried out.

You are welcome to talk to others (e.g. family and friends) about the study before you decide whether to take part. Please ask us if there is anything that is not clear, or if you would like more information.

Short summary

Description of the SiblingGame Study

- This is a research study for children (siblings) between 6 and 10 years of age who have a brother or sister with a learning disability, and their parents / carers.
- We are doing research about an online 'serious' game that siblings play to help them work through their needs and experiences as a brother or sister of a child with learning disability.
- We would like to find out if playing this game can improve siblings' sense of wellbeing and help them in other ways and whether this game could be offered across the UK as a support resource for these siblings.
- In the study, some siblings will get to play the game and some will not play the game but will be offered access to the game at the end of the study.

What is a serious game?

A serious game is a game played to support a learning goal rather than pure fun. A serious game uses challenges, games and quizzes in this case to help siblings learn life skills and to handle real life situations

What taking part means

- You are invited to take part in the SiblingGame Study
- Taking part would involve both you and the sibling/s (brothers and sisters of your child with learning disability) within your family.

Your time commitment, (as a parent)

This is anticipated to be:

- up to an hour at the start of the study
- up to an hour each at 3-months, 7.5-months and 12-months after the start.

Your child (the sibling) and will also be asked questions at the start of the study and at 3-month and 12-months after the start.

In one half of families, siblings will be asked to play the game over the 12-month period.

A small number of parents and siblings will also be asked to participate in interviews about taking part in the research, and you or your child might be invited separately later to take part in an interview.

You may be recorded during the study if you give your consent to take part verbally. Interviews may also be recorded, but we will give you more information about that later if you or your child takes part in an interview.

If there is anything you need further clarification on after reading this information please contact us. Contact details are at the end of this overview and in the main document.

Reward/reimbursement/expenses

- We cannot pay you in cash to take part in this study, but you and the sibling taking part will receive vouchers as a thank you for the time you give in completing questionnaires.

Confidentiality/anonymity and data security

- Your data will be treated as anonymous and confidential.
- It will be stored securely at the University of Birmingham with restricted access, only permitted people carrying out the research will see your name or contact details.
- Any information that can identify you will be replaced with a participant study number.
- Study information will be kept securely at the University of Birmingham for 25 years (in line with data storage policy).

Results of the study

- A report of the research results will be published.
- The results will also be published on the University websites, in research publications and presented at scientific meetings.
- You will not be identified in any report, publication or presentation.

Who is funding the study?

The study is funded by the National Institute for Health and Care Research (NIHR).

Contact details

If you have any questions, you can contact Louise Rixon at the University of Birmingham. Email: siblinggame@contacts.bham.ac.uk

Further information

What is the study about?

This is a research study to see if an online 'serious' game can support young siblings who a have a brother or sister with a learning disability. A serious game is fun and engaging for children and has been designed to provide a safe and supportive place for children to work through their experiences as a sibling. The game we are researching has been designed with lots of input from siblings and already tested in the Netherlands and Norway.

We are looking for 60 families to take part in the research. Half of the families will be randomly selected (like flipping a coin) to have access to the serious game for the siblings in the family. The other half of families will not have access to the game during the study but will be offered free access afterwards.

Why is the study being done?

Siblings who have a brother or sister with a learning disability can face challenges in their daily lives, including reduced wellbeing and enhanced care responsibilities for their brother or sister. They can also find it difficult to tell other people about their needs.

There is a lack of support available for the siblings of children with learning disabilities in the UK which you may have experienced as a parent, and your child may have experienced as a sibling.

We would like to find out whether the serious game can support the siblings of children with learning disabilities, giving them a safe and secure space to explore and help work through their own experiences both alone and with a parent. We would like to understand whether this game could be offered across the UK as a resource for all young siblings including those who may have caring responsibilities for their brother or sister.

What will happen if I take part?

1. **Step 1 – Are you interested and eligible to take part?**

You have already responded to our advertisement about the study and asked us to arrange a time to talk to you about the study. This information sheet has been sent to you because you have identified that you and your family are potentially eligible for and interested in this research.

Your family will be able to take part in the research if:

- Your family includes at least one child with learning disabilities (of any age – your child with learning disability could be an adult)

- You have at least one other child (a sibling of the child with the learning disability) aged 6-10 years-old who is willing to take part in the research
- The sibling has sufficient English language ability to play the game
- At least one parent/carer also is willing to complete research questionnaires about the sibling, the child with learning disabilities and the family
- We can only include families in the research where you are happy to provide informed consent for both you and your child (the sibling) to take part in the study
- You need to be living in England, Scotland, Wales or Northern Ireland at the start of the study

You will not be able to take part in the research if:

- The sibling is experiencing current significant mental health difficulties (e.g., they are receiving treatment from a child and adolescent mental health team)
- The sibling is already taking part in an intervention designed to support siblings in the same ways the serious game does. We can talk this through with you.
- You live outside of the UK at the start of the study, or you do not give us your clear consent/agreement to take part in the research

2. Step 2 – Checking eligibility - telephone or online call

A researcher will contact you (at a time you have said is convenient, by telephone or online). If we are unable to reach you initially, we will attempt to contact you on further occasions. We may send text messages, leave voice mails and send emails to help us get in touch with you.

During the call, the researcher will describe the study and go through the information sheet with you. You will be able to ask questions about the research. If you then want some more time to consider whether you want to take part in the research, we will arrange another time to speak to you again to check that your family is eligible to take part.

If you want to take part in the research, the researcher will explain the eligibility checking process and ask if you are happy to go ahead with this check. If you decided not to go ahead or do not give consent for the eligibility-check to take place, the researcher will end the call, and we will destroy information held about you. If you do agree, the researcher will ask some questions about you and your children (both your child with a learning disability and siblings) to check that your family is eligible to take part in the study. Part of this check will include completing the Vineland Adaptive Behavior Assessment with the researcher – this is so that we can describe clearly that all the families in the research include a child with learning disability. Once all the eligibility questions have been completed, the researcher will check the information with the research team and get back to you to confirm whether your family is eligible to take part in the research.

What if my family is not eligible to take part?

If you are not eligible to take part in the study, we will explain the reasons for this. Sometimes, there might be reasons why you are not eligible to take part now, but where you might be eligible to take part at later (e.g., the sibling is not quite old enough). If this is the case, with your permission we will keep your personal information (name and contact details) so that we can contact you later to see if you would still like to take part in the research. If your family is not eligible, we will destroy information already collected about you and your family.

3. Step 3 - Consent to take part in the research study

If your family is eligible to take part in the research and you would still like to do so you will need to complete consent forms. Consent forms can be made available in languages other than English. We will ask you to provide consent for both you and any participating siblings. This includes providing consent to view the sibling's game progress and engagement via a game dashboard.

You have some options for completing the consent form:

- You can be provided with a link to complete the consent online, or
- You can provide verbal consent over the telephone or an online call (Zoom/MS Teams) with the researcher. If you provide verbal consent, we will need to record the meeting where you agree to take part in the study. The researcher will then email confirmation that you have given verbal consent.
- You can also receive the consent form in the post for you to complete and return to the study team.
- Signed consent and assent forms are scanned on receipt, and physical (paper) copies are destroyed. Scanned copies are stored on the University of Birmingham secure servers.

Do I have to take part in the research?

No, taking part is entirely voluntary. It is up to you to decide whether, or not, to take part. If you decide to take part, you will need to complete consent forms for you and the sibling. You will also be free to stop taking part at any time and without giving a reason.

If you decide that you would prefer not to be in the study, we may ask you why you have decided not to take part (as this could be useful for us to know for the study), but you don't have to answer this question if you don't want to.

4. Step 4 - Before the study begins (this is called the Baseline)

We will ask you to complete some questionnaires:

- Background information about your family including ages, gender, ethnicity, disabilities/special educational needs, family socioeconomic circumstances, family size and structure, languages spoken at home and education.
- Research questionnaires that ask about the siblings' quality of life, mental health and the quality of sibling relationships; your child with learning disability's mental health; your well-being and quality of life and the different services your family accesses for support.

These questionnaires can be completed by you online, over the telephone with the researcher, or the questionnaires can be posted to you. We will ask you which of these methods you prefer when you complete the consent form. These questionnaires may take up to about 30 minutes to complete. Some of these questionnaires are available in languages other than English.

We will also meet with the sibling(s) in the family who are taking part in the research. Although you will give your consent for siblings to take part, when we meet with siblings, we will double check that they agree to taking part in the research. If they do not give their agreement to take part, we will discuss the options with you. We may suggest asking again on another day and going through the sibling information sheet with them again. If your child does not give their agreement to taking part in the SiblingGame Study, we will not be able to continue with the data collection as your family would not be eligible to continue.

Ideally, the meeting with the sibling will be online with a researcher, but we can arrange a face-to-face visit if you or the sibling would prefer. We will ask the sibling questions about their well-being and feelings of self-worth, and their relationship with their brother/sister with learning disability. These questionnaires have all been developed for and tested with children aged 6-10 years. This meeting with the researcher may take up to 60 minutes and we request that you are present in the same room when we talk to the sibling.

5. Step 5 - Randomisation

Once you and the sibling have completed the baseline data collection process, we will carry out the randomisation where a computer decides at random if your family will be given access to the sibling serious game straightaway or be given access at the end of the research study. We will email or telephone you to let you know whether your family will get access to the sibling serious game straightaway.

What will happen if my family is randomised to get the sibling serious game?

1. You will receive an email and a link for the sibling to sign up to the game. They can choose the username to use throughout.
2. You will receive a parent guide including information and tips on how to support the siblings playing the game. This information is in writing and there are also video versions.
3. Siblings are free to work their way through the game, at their own pace, completing each level of the game before moving onto the next.

The serious game was first developed in the Netherlands as an easily accessible support intervention for young siblings. The original game, based on a book, was developed in co-creation with siblings. The accessible game helps siblings to work through thoughts and feelings about their brother or sister in a playful way and is free for families to use. Children make their way through the 8 levels, reflecting on their own thoughts and feelings, playing mini games and completing printable worksheets. The game includes videos of other siblings talking about their brothers and sisters. The game is played by your child and there are no external links to other siblings. The game is owned and hosted by Vrije Universiteit (Free University) Amsterdam; the University of Birmingham research team uses an English language version which is only for the SiblingGame study. If your family is randomised to get the game, the data from your child playing the game will be logged on a dashboard. This will include information about when, how much and what levels they played and does not include any personal information other than their username.

What will happen if my family is randomised to not get the sibling serious game?

You will carry on as usual, but you will still be a part of the research. We will ask all families to take part in completing study questionnaires again (see below). At the end of the study (after one year), we will offer your family free access to the sibling serious game for all the siblings that take part. The siblings will not have to play the game.

The 3-month. 7.5-month and 12-month follow ups

Every family in the study will be asked to complete questionnaires again 3-months, 7.5-months and 12-months after they completed baseline. At 3 months and 12 months, we will ask you and the sibling to complete all the same questionnaires again. At 7.5 months, we will just ask you to complete two questionnaires.

- When it is time for you to complete these questionnaires, we will contact you to send an online survey link or make an appointment to speak to you online/on the telephone or to visit you (again, you decide).

- We will also contact you to make a time for a researcher to meet with the sibling again online or in person.
- If you have not been able to complete the questionnaires, we may need to email and/or phone to remind you.

Interviews

As a part of the research, we also want to talk to 12 parents and 12 siblings to explore experiences of taking part in the research and the playing of the game (for those families who have been given access to it). All interviews would need to take place in an online meeting with a researcher. We will want to talk to siblings around 3 months after your family started the study and parents at about 7.5 months after starting the study. If you might be interested in you or your sibling child taking part in an interview, you can tell us now. We would send you information about interviews later so that you can decide then to agree or not to take part in an interview. You do not have to take in an interview just because you are taking part in the main research study. You do not have to take part in an interview just because you say now that you would like to receive the interview information later.

What are the possible benefits of taking part?

The sibling serious game is new to the UK, and we do not know yet if it will directly benefit siblings and their families. By taking part in this study, you will be helping to answer whether the game might be beneficial for the siblings of children with a learning disability. The results of this study may benefit siblings, and their families in the future.

What are the possible disadvantages and risks of taking part?

You (and the sibling) will be asked to fill out questionnaires before the study begins and then several times later. These questionnaires may take time to complete, and we ask that you do complete them. The questionnaires include positive things but will also ask you and the participating sibling to reflect on challenges you may both face. We do not think that taking part in this study will pose any risk to parent carers or siblings. However, the questionnaires may make you both think about upsetting events so you may feel uncomfortable or upset when answering the questions. If this is the case, you can access extra support by contacting one of these helplines:

Mencap – 0808 808 111, www.mencap.org.uk

Contact – 0808 808 3555, www.contact.org.uk

Sibs – www.sibs.org.uk

Should you have any concerns, please contact the research team using the contact information at the end of this information sheet.

Online safety for children

The sibling serious game is played online. Information about keeping your child safe online can be found on the following websites. If your family is randomised to get access to the game, we will remind you about sources of advice about keeping your children safe online.

NSPCC online safety for children - www.nspcc.org.uk/keeping-children-safe/online-safety/

Internet Matters - www.internetmatters.org

What will happen if I don't want to carry on being part of the study?

Taking part in this study is voluntary. You can leave the study at any time, without giving a reason, and without this affecting you or your child in any way. If you initially consent to take part in the research and then decide to leave the study, you may be asked which aspect of the study you would like to leave. These aspects could be:

- To leave the study – this means you, and your child, have decided to completely leave the study and no longer participate in any aspect, or
- To partially or fully leave from any further data collection (questionnaires, interviews) – this might mean your child (the sibling) may continue to play the game, but we will not ask you to complete any further questionnaires or take part in any interviews, or
- Your child no longer wants to play the game or take part in follow up data collection, but you are happy to continue to be involved in the study.

If you decide not to carry on, or to partially withdraw, we will:

- Talk to you about the options, so that we are clear what you want to do
- Complete a 'withdrawal' form, on your behalf, based on the information you have provided. We will send you a copy of this form for your records.

What happens to your data if you choose to withdraw:

- Your data can be withdrawn from the study on your request up to the point that we begin to analyse the data. At this point we cannot remove anonymised data from the study.
- We expect that we will not be able to remove your data from the research after1 month following completion of your final questionnaire.

Safety reporting – what you need to know.

We have a duty to keep your information secure and confidential. However, we are required to disclose information which suggests that you or a child may be at risk of harm. The reason for this is requirements to safeguard and protect a adults and children.

If we become aware that an adult or child is at significant risk of harm, we may also share this information.

When sharing information, we will only do this when we genuinely believe there is a risk of harm. We may share this information with the local authority in your area or other statutory services who are meant to provide help.

Our research team at the University of Birmingham (Study Manager, Dr Louise Rixon and Research Associate, Emma Taylor) are Disclosure and Barring Service (DBS) checked. Dr Katie Cebula, at the University of Edinburgh (interview lead) is a member of the Protecting Vulnerable Groups (PVG) scheme in Scotland. The PVG scheme, managed by Disclosure Scotland, is a mandatory membership system for anyone doing regulated work with children or protected adults in Scotland, (this is the same as the DBS in England and Wales and Access NI in Northern Ireland).

Is there payment for taking part in the study?

While we cannot pay you in cash to be in the study we can give you vouchers as a thank you for giving your time to complete questionnaires (and participate in interviews, if applicable). Parents will receive a high street shopping voucher when they complete the questionnaires when the study begins (baseline), at 3-months, 7.5-months and 12-months (£30 at baseline, £30 at 3-month follow up, £10 at 7.5 months, and £50 at 12-month follow up – a possible total of £140), to say *thank you* for your time. We will also send you vouchers for the sibling each time that siblings complete the questionnaires. This will be £20 at each of the three time points (possible total for siblings of £60).

Parents and siblings taking part in interviews would be given an additional £20 shopping voucher to say thank you for their time. Information about these vouchers will be shared with you later if you consent to being invited to be a part of the interviews.

Who is organising and funding the study?

The study is being led by University of Birmingham and involves team members from the University of Edinburgh, the University of Glasgow, the Sibs charity, VU Amsterdam, and Cambridgeshire County Council. The study is funded by the National Institute for Health and Care Research (NIHR).

Who has reviewed the study?

- This study has been reviewed by a Research Ethics Committee at the University of Birmingham.
- We have partnered with Sibs, the sibling charity, to develop both sibling and parent advisory groups. We have a young adult siblings researcher group who will also work with us throughout the research study. The study is overseen by a Study Management Group involving all the research partners and an independent Study Steering Committee.
- This study has been assessed as medium risk. By consenting to participate in the research, you are confirming you understand that should any harm be sustained due to your participation (that was not caused by negligence of the research team), the University of Birmingham cannot offer compensation.

What will happen to the results of the study?

- A report of the research results will be completed and sent to the funding body NIHR. The results will be published on the University websites, in research publications and presented at scientific meetings. You will not be identified in any report, publication or presentation.

Contact details

What if I have any questions about the study?

- If you have any questions, you can contact **Louise Rixon** at the **University of Birmingham.**
  Email: siblinggame@contacts.bham.ac.uk

What if I would like to make a complaint?

- If you would like to make a complaint or provide feedback, we would ask you to speak to a member of the research team in the first instance. However, if you would like to speak to someone who is not part of the research team, please address your complaint to the person below, who is entirely independent of this trial: ***To be advised by University of Birmingham***

- If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer at the University of Birmingham: ***To be advised by University of Birmingham***

- If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the **Information Commissioner's Office (ICO) www.ico.org.uk or 0303 123 1113.**

<u>This section tells you about your information and data that will be collected about you for the research. We also tell you about data protection and confidentiality. Please take the time to read it carefully.</u>

We will be collecting personal and sensitive information from you so it is important that you know that we will follow the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018 to protect your data.

What personal information are you collecting?

When you agree to take part in the research, you will be assigned a unique participant study number. This participant study number will be assigned to your data that is collected during this study to protect your anonymity. People who do not need to know who you are will <u>not</u> be able to see your personal information such as your name or contact details.

The University of Birmingham will need to collect the following personal information from you for the research:

1. Your first name and surname,
2. The name of the child taking part "the sibling",
3. Your telephone number,
4. Your email address,
5. Your home address
6. Your device's IP address (your device's unique address when connected to a network) will be automatically collected when completing the questionnaires online to ensure network and information security. However, the IP address is not linked to individuals, and we will not link your device's IP address to other data which we are collecting. We will not analyse the data unless we have specific reason to look at an IP address. The personal data collected will be kept separate from any data about you.

Only specific research team members at the University of Birmingham who are responsible for collecting personal and sensitive data, will have access to these data.

Who will have access to my data and how will my data be protected?

This study is being run by the University of Birmingham so your information will be held by them as they are the 'data controllers' and the' data processors'. The University of Birmingham decides how and why your personal data are processed.

- Your information and data will be stored securely at the University of Birmingham with restricted access. They have policies and procedures in place to keep your data safe.

- Only permitted people carrying out the research will see your name or contact details. Any information that can identify you (directly and indirectly) will be removed from the research data and will be replaced with your participant study number. The key linking your identity to this participant study number will be stored securely and separately to the research data to safeguard your identity.

- Study information will be kept securely in line with policy at University of Birmingham for 25 years.

- Your name, address or other identifiable information will not be shared.

- Electronic consent and assent forms will be stored securely on University secure servers; paper copies are securely destroyed after scanning.

What are my choices about how my information is used by The University of Birmingham?

We might not always be able to remove, change or delete the data if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this. If we have collected any information that could potentially identify you such as your name, address, phone number or email address, you can request that we destroy this within 28 days of you telling us that you no longer want to continue in the study.

To find out more information, you can:

- Contact a member of the research team – contact details are on page 11.

- Ask for a copy of the University of Birmingham Research Privacy Notice which is found here: Your Privacy - University of Birmingham or you can email **dataprotection@contacts.bham.ac.uk** and request a copy.