## **PARTICIPANT INFORMATION SHEET FOR PARENTS and CARERS**

**Title: Informing the design of a home-based online pain-management support system (HOPSS) for parents, carers and children with cancer-related pain**

You are being invited to take part in a research study because your child has cancer with pain now or has had it in the past.

Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully. Feel free to talk to others about the study if you wish. Please ask if there is anything that is not clear or if you would like more information. My contact information is at the end of this document.

**What is the purpose of the research?**

Pain is among the most frequently reported symptoms of cancer or its treatment in children.  Home-based cancer-care has been shown to improve the physical and mental health for some children.  However, some parents or carers experience challenges when monitoring, assessing, and managing pain during home care.

Efforts have been made to support pain assessment and management at home using digital resources, for example websites and smart device applications (APPs).  A resource for cancer pain has not been developed in the United Kingdom.

The aim of this study is to design a digital resource to improve the pain experience of children with cancer pain and their parents or carers for the home setting in the United Kingdom.

**Who will conduct the study?**

I am Betul BAY, a PhD student at the University of Birmingham. I will be conducting the study at the University of Birmingham. I have four academic supervisors who support me and ensure good conduct of the study.  Our contact details are at the end of this information sheet.

**Why have I and/or my child been chosen?**

We are asking you and/or your child to take part in this study because your child is aged between 8-16 years old and may have experienced cancer pain. Other children who have had cancer pain and their parents will also be invited to participate in this study.

**What will I and/or my child be asked to do if I and/or my child took part?**

If you agree to take part, Betul will explain to you what will happen and answer any questions which you and/or your child may have about the study. If you and your child are happy to take part, then you will both be asked to sign a form which is called consent/assent form. These forms include information to confirm you and your child understand what the study involves and agreed to take part.

This study has 3 phases. We would like you and your child to take part in all three. However, you can decide to take part in any of them or all of them.

* Art and talk sessions with children and young people
* Interviews with carers
* Focus group discussions with carers and children and young people

**What is expected from my child?**

We will ask your child to create a piece of art that shows their experience of cancer-related pain. An information sheet about this has been sent to you by email and is available on our study website [include website link].

Once the artwork has been created, we would like you to send an image or video of this to us using email or WeTransfer. Instructions on how to do this are provided in the art and talk guidance we have sent you. Then we will ask you and your child to attend a focus group along with a small number of other parents, carers and children, to talk about the artwork and how it represents their experience of pain.

**What happens in the focus group?**

About five or six children and their parents or carers will be asked to attend an online focus group. I will introduce you to each other and ask each of the children in turn to talk about their artwork, and about how it represents their experience of pain. I will encourage the children to talk to each other about their experiences, and to show each other their art if they wish. As a parent or carer you are there to support your child but not to contribute to the conversation. If you feel it necessary to leave the group, you and your child can do so at any time without needing to explain. If you leave the group during the session, we will contact you by email or text (depending on your contact preferences) to check that you are okay, and to ask if you wish to join a later group.

**Tell me about the interview**

We will arrange an on-line meeting with you on your own lasting about an hour.  The interview will help us to collect information about your experience of your child’s pain at home.

**What will happen to our personal information?**

To do this research project, we will need to collect the following personal information/data about you and your child:

• Contact details (name, contact number or email address)

• Interview and focus group data

• Artwork

We are collecting and storing this personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect your personal information. The legal basis upon which we are using your personal information is “public interest task” and “for research purposes” if sensitive information is collected. For more information about the way we process your personal information and comply with data protection law please see our “The University of Birmingham Data Protection Policy” at https://www.birmingham.ac.uk/documents/university/legal/university-of-birmingham-data-protection-policy.pdf .

The University of Birmingham, as Data Controller for this project, takes responsibility for the protection of the personal information that this study is collecting about you. To comply with the legal obligations to protect your personal data the University has safeguards in place such as policies and procedures. All researchers are appropriately trained, and your data will be looked after in the following way:

Consent/assent forms: Your consent form and your child’s assent form will be paper based and will be stored in a locked filing cabinet at the University of Birmingham for 5 years by the researchers. This is in accordance with the University of Birmingham policy on storage of personal data.

Contact data: Your contact details will be held on a password protected database on University of Birmingham secure servers. This information will only be kept for as long as necessary to share the results of the study with you, and then it will be securely destroyed. If you do not wish for us to contact you about the results, we will remove your contact details from the database.

Artworks: The original artwork that your child creates will stay with you. The images will be used to support the analysis of interviews and focus groups. They may also be published in my doctoral thesis, peer-reviewed journal articles, and in conference papers. We will remove any identifying information from images prior to sharing them outside of the research team.

Interview: Your and you child’s interviews, which will be recorded on an audio-recording device, will be transferred to a computer at the University of Birmingham on the day of the interview and then deleted from the device. Betul Bay will then type up the interview and then delete the audio-recording from the University secure servers once this is completed. The typed-up interview will be retained for 5 years at the University of Birmingham by the researchers.

List of codes: Your/your child’s name will be anonymised by using codes. The list of codes (include your/your child’s name) will be held securely (separate to other research data) by the researcher in a password encrypted file on a secure server (University of OneDrive) and access is restricted to the researcher and supervisors. This file will be retained for 5 years at the University of Birmingham by the researchers.

Only the research team (mentioned previous section) will have access to this information, and all personal identifiable information, that is data which could identify you or your child, will be anonymized as soon as practical.

What are our rights regarding our personal information?

You have several rights under data protection law regarding their personal information. For example, you can request a copy of the information we hold about them, including audio recordings. This is known as a Subject Access Request. If you would like to know more about your different rights, please consult our “The University of Birmingham Data Protection Policy” at https://www.birmingham.ac.uk/documents/university/legal/university-of-birmingham-data-protection-policy.pdf.

If you wish to contact us about your data protection rights, please email dataprotection@contacts.bham.ac.uk or write to Nicola Cárdenas Blanco, Director of Legal Services, The University of Birmingham Edgbaston Birmingham B15 2TT. They are based at the University of Birmingham, and we will guide you through the process of exercising your rights. You also have a right to complain to the “Information Commissioner’s Office”, Tel 0303 123 1113.

**How is confidentiality maintained?**

Your and your child’s participation in the study will be kept confidential. The information you both provide in the study will be confidential to the study researchers. All personal information from the interview will be removed and your and your child’s name will be replaced with a code. Quotes from interviews and focus groups may be used in written reports or conferences, but no names or identifiable information will be included.

If there are concerns about your and/or your child’s safety or the safety of others, the researcher has a legal duty to break confidentiality.

**Do we have to take part?**

No. Participation is voluntary.  If you decide to take part, you are free to withdraw at any point and you do not need to give a reason. Participation will not affect the care your child receives.

**What happens if we do not want to take part or if we change our minds?**

Taking part is entirely voluntary. Your decision will not affect your rights or the care your child receives whilst in hospital.

If you or your child decide to take part, you are free to withdraw at any time without giving a reason. However, it will not be possible to remove your data from the project once it has been typed up and anonymised as we will not be able to identify your specific data. You will have two weeks from the date of the focus group or interview to ask for your data to be withdrawn from the study. This does not affect your and/or your child’s data protection rights.

Please also note that it is essential to your joint participation in the study that interviews are audio-recorded. Therefore, you and your child must be comfortable with the recording process at all times. However, you or your child are still free to stop recording at any time and your child’s data will be removed, if you wish.

**What are the possible disadvantages and risks of taking part?**

Some people might find it distressing to reflecting on the questions in relation to their child’s experiences of pain and cancer. If you get upset, you can take a break or decide not to continue with the interview or discussion. At the start of the interview and focus groups, we will check with you what support you have available.  If you do not have any support available, we can work with you to identify a person or organisation who can be there for you if you would like.

**What are the possible benefits of taking part?**

Some people find it helpful to describe their experiences aloud.  It can also feel good that your experiences will help to build something helpful for other people who are going through the same thing.

At the conclusion of the project, we will send you a newsletter describing the major findings and telling you about any research publications we have generated from the project.

We are unable to offer any payment for your participation.

**Will the outcomes of the research be published?**

Yes. A report of the research will be written in a PhD thesis that will be available at the University of Birmingham’s library. The results will also be reported in professional publications and conferences. You and your child will remain anonymous and no identifying details will be included in the published articles.

 **Open Access Data Repository**

We want to inform you that the de-identified data collected as part of this research study may be made accessible in an open access data repository. Open access data repositories provide a platform for researchers and the public to access and utilize research data for future studies and collaborations. This approach promotes transparency, scientific advancement, and broader contributions to the field.

If the data from this study is intended for inclusion in an open access data repository, all personal and identifying information will be removed to ensure your privacy and confidentiality. Your data will be presented in a way that preserves your anonymity.

Opt-Out Option: If you have concerns about your data being included in an open access data repository, please notify us during the consent process. You will have the opportunity to discuss any questions or concerns you may have before providing your consent.

**Who is organizing and funding the research?**

The study is funded by The Ministry of National Education of the Republic of Turkey. It is being organized and conducted by researchers from School of Nursing and Midwifery, College of Medical and Dental Sciences, University of Birmingham.

**Disclosure and Barring Service (DBS) Check**

Betul Bay, who will be conducting the interviews, has undergone a satisfactory DBS check.

**Who has reviewed the study?**

The study will be reviewed by University of Birmingham Ethics Committee (REC), the PGR lead and internal assessor in the School of Nursing and Midwifery as part of the Annual Performance Review process and by the research development team and patient and public involvement members at the UK the NIHR Clinical Research Network: West Midlands – Young Person's Steering Group (YPSG).

**What if I want to make a complaint?**

If you or your child are not happy with the study and want to make a complaint, please contact Betul Bay (lead researcher) or one of my supervisory team the first instance. Details can be found on the next page.

You may contact Professor Cara Bailey, Postgraduate Research Lead, for further information about your rights or any concerns about this study.

Post :Institute of Clinical Sciences, University of Birmingham, Edgbaston, Birmingham
B15 2TT UK

Email: c.bailey.2@bham.ac.uk

Tel : +44 (0)121 414 3657

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance, please contact the Research Governance and Integrity Team:

Email: b.whitman@bham.ac.uk

Telephone: 07814 650 003

You may also contact Patient Advice and Liaison Service who will help you deal with any issues you may have about the care provided. You can [find your nearest PALS office](https://www.nhs.uk/service-search/other-health-services/patient-advice-and-liaison-services-pals) on the NHS website at <https://www.nhs.uk/service-search/other-health-services/patient-advice-and-liaison-services-pals>.

**Further information and contact details**

If you would like to discuss your potential involvement in this research, further please contact:

Name: Betul Bay

Job title: Doctoral Student

Email address: bxb179@student.bham.ac.uk

Address: School of Nursing and Midwifery, College of Medical and Dental Sciences, University of Birmingham, Edgbaston, Birmingham B15 2TT

Tel: 74 705 87 311

**Supervisory team:**

Lead supervisor: Dr Amelia Swift, a.swift@bham.ac.uk, 07826 553 669

Co-supervisor: Dr Lucy Kelsall-Knight, l.m.kelsall-knight@bham.ac.uk

Co-supervisor: Dr Sue Neilson, s.j.neilson@bham.ac.uk

Co-supervisor: Dr Alison Twycross, a.m.twycross@bham.ac.uk