



Parent / Guardian / Family Member Participant Information Sheet

Version 4 (23/07/2020) IRAS Project ID: 271259

Research Title: **Developing an intervention to reduce sedentary behaviour in non-ambulant young people with long-term disabilities (DoMore).**

Chief Investigator: **Mrs Marilyn Bradbury, HEE/NIHR Clinical Doctoral Research Fellow, Birmingham Community Healthcare NHS Foundation Trust**



I'm Marilyn Bradbury. I would like to invite your family to be involved in my research project. To help you to decide whether to take part, this form explains what you would need to do. Please take time to read the information and contact me if you have any questions. It can be helpful to talk to your friends and family about the research project when you are deciding whether to participate.

What is the study about?

Previous research has shown that young people with disabilities do less physical activity than able-bodied young people. Supporting them to increase their physical activity has, therefore, been identified as a high priority for research.

I want to help young people who use a wheelchair and are unable to walk due to their disability, to spend less time being sedentary. Being sedentary means you're awake, but using very little energy. This includes:

- Time on your phone
- Watching TV
- Playing video games
- Reading

Spending long periods of time being sedentary reduces fitness, and can increase the risk of obesity, heart disease and mental health issues.

Aim of the study

The aim of this study is to develop a programme to encourage young people who are unable to walk due to their disability to be active more regularly through their day. The programme will include an app on a tablet.

Different groups of people will be getting involved with developing the programme. The groups are: young people who are unable to walk as a result of their disability, family members of young people with disabilities, professionals who work with young people with disabilities, experts / academics who are interested in disability, physical activity or using technology in health care and other interested parties. You and your child/family member may be able to take part.



Why do you want my family to take part?

Young people who use a wheelchair most of the time and are unable to walk, or only walk short distances with the help of a body support walker are being invited to take part. They need to be 12 - 25 years old, have a long term disability, live in the UK, be able to communicate using English language online or in a virtual focus group (video conference) and have sufficient understanding to be able to answer the questions asked.

All family members or carers (aged 16 and above) of children and young people who are unable to walk due to a long term disability can also take part.

What will we need to do?

There are two ways you and/or your child/family member can help with developing the programme. You can choose which one works best for you.

You and/or your child/family member can contribute to an anonymous workshop online which you can access at any time, or you can come to a virtual focus group which will be held online at a specific time.

If you are participating, you will be asked to complete a consent form and questionnaire online. If your child is under 16 and would like to take part, please read through the participant information sheet for 12-15 year olds with them. If you have doubts about your child’s understanding of the study or ability to answer the questions, please don’t take any further action. You can still take part as a family member. If you and your child are happy for them to participate, click the link to participate and select “I am a:

- Young person aged 12-15 and I am unable to walk, or I use a walker similar to those pictured below.”

When prompted, enter your contact details and we will arrange a virtual online consent meeting with both of you (using video) to discuss their participation. Following this we will email you a link and password that allows you to provide consent for them to participate online. They will not be able to access the online workshop or virtual focus groups until you have completed a consent form for them. They will also be asked to agree that they want to take part. request If you are participating and think your child / another family member / friend would also like to please encourage them to visit the website with you and read about the study or share this link with them: <https://do-more.org.uk/welcome>. The link can be shared via social media.

You will be emailed a copy of the consent form and your child’s agreement form if they are also taking part.

After consenting to take part, you/your child/family member will be asked to:

- provide some basic information about yourselves, including your diagnosis if you have a disability



- complete a short survey before you contribute to the workshop or focus group (you can't contribute to both).

You and/or your child will need to agree to accept the ground rules about how people participating should speak to each other both in the workshop and the focus groups, to make sure everyone taking part respects each others opinions.

There will be 3 steps you can contribute to that help me to:

- 1) understand the problem
- 2) decide how the app can best support young people to move regularly
- 3) decide how the support should be delivered.

I would like you to participate in all 3 if you can. Each step will happen at different times. The online workshop will open for approximately 2 weeks at each step. There will be several questions you can respond to at each step. You don't have to respond to them all. You can spend as much or a little time as you choose to on the online workshop.

There will be 2 focus groups held at each step; one for 12-15 year olds, and a second for all participants over 16. Focus groups will last for 45 – 90 minutes. Between 3 and 10 people will be in each focus group.

In the online workshop, you will be able to read other people's responses to the questions, and there is a button to agree or disagree with what they have written. You can write a reply about what they have written too. You will not be able to tell who has written responses. There is a ground rule that asks you not to use your name, or give too many details about yourself that could allow someone to know who you are. If someone writes something that upsets or offends you, or you feel would allow you to know who that person is, you can flag what they have written, and it will be removed either permanently, or until the platform administrators have reviewed what was said and edited it if needed. There will only be young people aged 12-15 contributing to the online platform your child/family member will take part in. Young people aged 16-25 and family members / carers, professionals and experts will each have their own separate platform to write on.

Once you have participated in one step, I will email to invite you to the next step, unless you ask me not to.

If you attend a focus group, you will receive a £10 shopping voucher as a thank you.

Do we have to take part?

No. It is up to you and your child. Your child's healthcare will not change whether you decide to take part or not.

What if we change our minds about taking part?

You can pull out at any stage and it won't change the care your child receives. We will still use any information we have already collected, but this will remain anonymous.



When will it be and how long will it last?

This part of the study (developing the app) will take place in October or November 2020 and last for 6-8 months.

What are the benefits of taking part?

- The programme will be designed using the information everyone who participates has given us. This means its much more likely to work well, and you will have helped us to achieve that.
- You will have contributed to a new digital treatment, that 20 young people with disabilities will use in our small study to test it.
- I hope that lots of young people will use the programme in the future, helping them to live healthy lifestyles and you/your child will have helped with this.

What are the disadvantages of taking part?

There is a small risk of participants becoming upset, distressed or offended by the content of discussions in the online workshop or in the virtual focus groups. The ground rules and ability to flag any content you feel should be removed will help to reduce the risk of this happening.

Families participating need to find time for contributing to the online workshop or attending a virtual focus group. Groups may be held in school or working hours.

Will anyone else know we are taking part?

If you take part in a focus group, confidentiality cannot be assured, because the other participants will know your first name and see you on the video. Participants are asked in the ground rules to avoid making comments that could identify them. No one other than your family, the researchers and the other people at any focus groups you attend will know you have participated unless you want to tell them about it. Everything you say in the online workshop will be anonymous.

When we share the results of the study, we will use some quotes, but it won't say who said them. All electronic information will be encrypted and/or password protected (which means it won't be readable by anyone who shouldn't see it). Any information kept on paper will be transported in the same secure way as health records, and will be kept in a locked filing cabinet that is only accessed by the researchers.

We may publish our data, or use it in other research, but this will be anonymous.

How many others are taking part?

Its hard to know how many people will sign up to the online workshop, we hope lots of people will! Please share this information and the website with any friends or family you think would be interested in participating.

Will it affect my child's normal healthcare?

The study is not related to your child's/family members routine healthcare. This will not change as a result of their participation.



What happens when the study is finished?

You will be able to keep up with what's happening and the results of the study via our website (do-more.org.uk). The programme we designed together will be produced and there will be a small study to see if it can be used in the NHS and what the young people think of it. The results will be used to write presentations and to publish in a medical magazine so we can share what we find out with other families who have children with disabilities and other professionals.

Who is organising and funding the research?

Birmingham Community Healthcare NHS Foundation Trusts are responsible for running the study in accordance with existing research legislation and guidelines. The study is funded by the National Institute for Health Research and Sport Inspired charity.

Who is reviewing the research?

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 a favourable ethical opinion by a research ethics committee. It has also been reviewed by the National Institute for Health Research, the study steering group and an expert fellowship collaborator who holds a highly regarded academic post in childhood disability and has considerable clinical and research experience.

How have patients and the public been involved in this study?

Members of the West Midlands Young Persons Steering Group, public and patient involvement representatives who are non-ambulant young people, parents of young people with disabilities and adults attending a day centre for people with cerebral palsy have been involved in developing this research. The Young Persons Steering Group and patient and public involvement representatives have lived experience of long-term disability. A lay member sits on the study steering committee.

The patient and public involvement representatives have been involved in developing the participant information sheets and adverts for the crowdsourcing platforms, and have contributed to production of the website. They will assist with disseminating the adverts via relevant networks they are members of, opportunities in their local communities and face to face activities where possible.

Will my data be kept confidential?

Birmingham Community Healthcare NHS Foundation Trust is the sponsor for this study based in the United Kingdom. They will be using information about you/your child/family member obtained from you/your family member in order to undertake this study. Birmingham Community Healthcare NHS Foundation Trust will act as the data controller for this study. This means that they are responsible for looking after this information and using it properly. Birmingham Community Healthcare NHS Foundation Trust will keep the identifiable information collected for 5 years after the study has finished.



You can find out more about how Birmingham Community Healthcare NHS Foundation Trust will use your/ your family member's information, or raise a complaint about how your/ your family member's personal data has been handled by contacting their Data Protection Officer:

- **Tel:** 0121 466 7033
- **Email:** bchc.dpo@nhs.net
- **Address:** Data Protection Officer, Corporate Affairs, Birmingham Community Healthcare NHS Foundation Trust, 3 Priestley Wharf, Holt St, Birmingham. B7 4BN

If you are not satisfied with their response or believe they are processing personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). Tel: 0303 123 1113, www.ico.org.uk).

We will use your/ your family member's name, email address, NHS number and your/your family member's contact details to contact you/them about the research study, and to oversee the quality of the study. This information will only be used for the DoMore study. It will not be used for any other purpose. Clever Together will have access to all information you enter online via the study website. They have a strict privacy policy for handling this information, that you can access via the study website. Two weeks after the study ends Clever Together will delete all the data they hold relating to this study. Your consent form will be transferred to a representative at Birmingham Community Healthcare NHS Foundation Trust. Your anonymised responses will be retained by the researcher team.

Individuals from Birmingham Community Healthcare NHS Foundation Trust, Clever Together (who are hosting the online workshop) and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in Birmingham Community Healthcare NHS Foundation Trust who will have access to information that identifies you/your family member will be people who need to contact you to audit the data collection process or the research and innovation team who are archiving the study information when the study has finished. The people who analyse the information will not be able to identify you/your family member and will not be able to find out your name, your NHS number or your contact details. However, if you attend a focus group, the researchers running the group will be aware of your/their name and appearance, and may later analyse the data.

Birmingham community Healthcare NHS Foundation Trust Research and Innovation Team will securely store identifiable information about you/your family member from this study for 5 years after the study has finished. Clever Together will only keep the information they have for 14 days after the end of the workshop.

Under the General Data Protection Regulation (GDPR), some of the personal data which will be collected from you/your family member is categorised as "sensitive data" (e.g. your name and contact details). The processing of this data is necessary for scientific research in accordance with safeguards. This means that study has gone through an ethical committee to ensure that the appropriate safeguards are put in place with respect to the use of your/your family member's personal data. Personal data will be processed on the public



task basis. Individuals' rights to erasure and data portability do not apply if you are processing on the basis of public task. However, individuals do have a right to object. If you/your family member withdraw from the study, we will keep the information we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Clever Together will pass data collected during the study to Birmingham Community Healthcare NHS Foundation Trust securely.

We would need to break confidentiality and share identifiable information with external agencies if we think there is a risk of harm to you or others at any point in the study, or disclosures of criminal activity are made. In this case we will follow the Trust's Safeguarding Policies and inform appropriate staff or agencies.

What is said in the recordings of the focus groups will be typed up by the researchers. They will remove anything that might identify you.

If you would like further information about how your/your family member's data is managed in health research, please follow the link below:

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/>

What if there are any problems?

It is very unlikely, but if during the study any concerns about clinical care, criminal activities or safeguarding concerns are highlighted, the researchers have to share this information with the relevant authorities.

Some people may feel anxious about taking part in the online workshops or focus groups. Participants will be signposted to appropriate local support services on the study website and at focus groups if required.

What if I want to complain?

Please speak to the research team initially if you are worried about the study (tel: 07701371838, email: domore.study@nhs.net). If you wish to formally complain, you can contact customer services (formerly the patient advice and liaison service) at Birmingham Community Healthcare NHS Foundation Trust using the details below:

Anne Pemberton (Patient Experience Manager) or Zarina Mansuri (Advise and liaison officer), Birmingham Community Healthcare NHS Trust Customer Services
Moseley Hall Hospital, Alcester Road, Moseley, Birmingham, B13 8JL
Tel: 0800 917 2855 or 0121 466 6502 (Anne), 0121 466 6507 (Zarina)
e-mail: contact.bchc@nhs.net



What if I want to find out more about the study?

If you have questions about any aspect of the study that are not answered by this information sheet, please contact Marilyn Bradbury, HEE/NIHR Clinical Doctoral Research Fellow, Medical Directorate, Research and Innovation, Birmingham Community Healthcare NHS Foundation Trust, Trust Headquarters, 3 Priestley Wharf, 20 Holt Street, Birmingham, B7 4BN. Tel: 07701371838. E-mail: domore.study@nhs.net

Thank you for taking time to read this information.