UNIVERSITY OF BIRMINGHAM

DO MORE

NHS Birmingham Community Healthcare NHS Foundation Trust

Young People aged 16 – 25 Participant Information Sheet

Version 5 (06/10/2021) 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 you 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 family may be able to take part.

Why do you want my family and I to take part?

Young people who use a wheelchair most of the time and are unable to walk, or only walk short distances using 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 and be able to communicate using English language online or in a focus group and have enough 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?

You and/or your family can help with developing the programme by coming to 3 virtual co-design workshops.

If you are participating, you will be asked to complete a consent form online. You will be emailed a copy of your consent form.
You and/or your family will need to agree to accept the ground rules about how people participating should speak to each other in the virtual co-design workshops, to make sure everyone taking part respects each others opinions. After giving your consent to take part, you/your family members 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.

There will be 3 steps you can contribute to that help me to:
1) understand the problem
2) decide how the programme 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. There will be 2 virtual co-design workshops held at each step; one for 12-15 year olds, and a second for all participants over 16. Between 3 and 10 people will be in each workshop. Workshops will last for 45 – 90 minutes.

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

Focus group attenders will receive £10 as a thank you for coming.

Do we have to take part?

No. It is up to you and/or your family members. Your 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 you receive. We will still use any information we have already collected, but it will remain anonymous.

When will it be and how long will it last?

This part of the study (developing the programme) will take place between April 2021 and February 2022.

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 digitally enabled 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 will have helped them 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 in the virtual co-design workshops. The ground rules will help to reduce the risk of this happening.

Families participating need to find time for contributing to the virtual co-design workshops. Workshops may be held in school or working hours.

Will anyone else know we are taking part?

If you take part in a virtual co-design workshop, 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 you, the researchers and the other people at any workshops you attend will know you have participated unless you want to tell them about it.

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 (which means it won't be readable by anyone who shouldn't see it) and/or password protected. 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 it will always be anonymous.

How many others are taking part?

Between 2 and 10 people will be in each virtual co-design workshop. Overall, we expect 30-40 people will take part in the co-design.

Will it affect my normal healthcare?

The study is not related to your routine healthcare. This will not change as a result of your participation.

What happens when the study is finished?

You will be able to keep up with what's happening and find out the results of the study via our website (**do-more.org.uk**). The programme we design 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 young people 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 the research. The young Persons Steering Group and public and patient involvement representatives have lived experience of long-term disability. A lay member sits on the study steering committee.

The public and patient 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 assisted with disseminating the adverts via relevant networks they are members of and in their local communities.

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 obtained from you 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 information, or raise a complaint about how your 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 name, email address, NHS number and your contact details to contact you 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 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 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 and will not be able to find out your name, your NHS number or your contact details. However, the researchers running the workshop will be aware of your 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 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 co-design.

Under the General Data Protection Regulation (GDPR), some of the personal data which will be collected from you 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 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 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 co-design workshops will be typed up by the researchers. They will remove anything that might identify you.
If you would like further information about how your 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 activity 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 virtual co-design workshops. Participants will be signposted to appropriate local support services on the study website and workshops 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.