APPENDIX D
ETHICAL APPROVALS

Study Title: ***Stress Analysis of Seating Systems for Children with Special Needs***

REC Reference Number: ***10/S1001/41***

NHS R&D offices Reference Number: ***GN10CO288***

Documents:

- Research Protocol
- Information sheet for parent
- Information sheet for child
- Information sheet for school
- Parent consent form
- Child assent form

Research Protocol

Title:

Stress Analysis of Seating Systems for Children with Special Needs

Researcher:

Ms Katika Samaneein

Researcher ethics committee:

West of Scotland Research Ethics Committee

Bioengineering Unit

University of Strathclyde

Research Protocol: Version 1.0-13/May/2010

Study Summary

Title	Stress Analysis of Seating Systems for Children with Special Needs
Methodology	The forces applied to a Mygo seating system will be recorded during normal activities of daily living.
Study Duration	The proposed monitoring time is 2 to 6 hours in total, which would be agreed with the child and parent involved in advance
Study Centre(s)	There is no specified location to do the study. However, the study will be taken in the activities of daily living within the community.
Objectives	To determine the loads imparted to the Mygo seating system during community-based activities of daily living and, in particular, during an extensor spasm.
Participants	Ten children with cerebral palsy will be recruited to participate. They all have been prescribed a Mygo wheelchair by WestMARC
Study Product	The Mygo Seating System, which is a rigid seating system designed for disabled children aged 4-10, will be used in this study.
Duration of administration	• Each participant will spend less than a total of 14 days in this study. • Initial identification of suitable participants, introduction, information sheet, question and answering, 1 hour. • Set up and observation arrangement, 2 hours • Upon agreement with parent and the child involved, monitoring and actual study should last from 2 to 6 hours. • Participants will be given a week to decide whether or not to take part
Confidentiality	Each participant will be registered with a unique reference number without any allusion to personal details.

1. Introduction

A wheelchair is one of the most common devices used to assist users who have limited abilities to walk or move. The wheelchair user population includes children, adults, and elderly persons.

In 1994, Barnaby and team performed a survey by interviewing over 3,000 wheelchair users at the Dundee Limb Fitting Centre in which they described that 50% of total users are 30-60 years old and approximately 10% are children under the age of 20. For children the largest diagnostic categories are multiple sclerosis 26%, spina bifida 10%, rheumatoid arthritis 9% and cerebral palsy 8% (Barnaby, 1994).

Cerebral palsy is a group of central nervous system disorders which affects the body's ability to control movement and posture. The cerebellum plays a major role in regulating muscle tone, the lesions of this can make patients have either high muscle tone, low muscle tone, or a combination of the two (fluctuating tone). Based upon the form of motor impairment, cerebral palsy can be divided into four types: spastic cerebral palsy, choreoathetoid cerebral palsy, hypotonic cerebral palsy and mixture of all.

The most common type is spastic cerebral palsy, which causes children to have stiff and jerky movements. A widely accepted definition of spasticity, which is classically defined by Lance: is “a motor disorder characterised by a velocity-dependent increase in tonic stretch reflexes with exaggerated tendon jerks, resulting from hyper-excitability of the stretch reflex” (Lance, 1980). In the other words, spasticity is a hyperactive muscle fast stretch reflex which is a result of uncoordinated agonist and antagonist muscle activity due to dysfunction of the electrical signal from the motor neuron system.

Special seating designed for children with disabilities considers requirements like, stage of development, disabilities, and other disorders. The mobility and posture problems that disabled people face may be due to muscle weaknesses, muscle imbalances and spasm or poor sensation. First and foremost importance for the disabled is stable sitting, because unstable sitting makes balance difficult to control by the upper body. Ideally the sitting position should balance weight and movement

in all planes (Letts, 1991). Therefore, a special seat base with a back support can be used to assists the positioning for physical therapy.

The problem of the seating for spastic children occurs when muscles stretch producing a strong force between seat back and their bodies. The high forces produced during this extension indicate that the seating structure must be strong and durable. This study considers the biomechanics of seated children with cerebral palsy and the forces imparted by them on their seating system. Biomechanical outcomes will provide a better understanding of a suitable special chair for the participants with cerebral palsy, which in turn, could lead to improvements in custom made wheelchair design. And prescriptions could be designed in a way that promotes the health, well-being, and productivity for disabled people.

2. Objective

This study aims to collect force data on the Mygo seating system (James Leckey Design Ltd, Belfast, U.K.) when used with children with limited mobility who have cerebral palsy in either high muscle tone, low muscle tone, or a combination of the two (fluctuating tone) during activities of daily living.

3. Research Question

What loads are imparted to the Mygo seating system during community-based activities of daily living and, in particular, during an extensor spasm?

4. Methodology

4.1 Participants

Individuals for participation in this study will be recruited from Westmarc who will ensure each participant meets the study criteria. Ideally 10 children with cerebral palsy will participate in the research project, whether they have hypertonia or hypotonia muscle tone. The study will be discussed and explained in detail to children and their parents.

4.1.1 Inclusion criteria

Children between 4 and 10, boy or girl, who have been prescribed a Mygo by Westmarc.

4.1.2 Exclusion criteria

Children who are within 6 months after a surgical procedure, or have a current illness, or are on temporary medication.

4.2 Recruitment procedures

The University researchers will prepare unaddressed envelopes which contain the participant information sheet. These envelopes will be passed to Westmarc who will put on the address of potential participants based on their database. At this point the University team will not know the names and addresses of those invited to participate. Potential volunteers will contact the University research team who can address any questions or concerns of the research. Only when the participants are happy to take part, the researcher will arrange to visit them to obtain informed consent (parent) and assent (child) and to arrange a time and a date for the participation. A specially designed assent form has been created in order for the child to assent to the research. If the agreed time and date includes a visit to a school or other similar premises, then a letter shall be sent to them asking for their permission for this to take place on their premises.

4.3 Duration of study

Participation will involve the child sitting in a Mygo seating system which has been modified in order to collect force data on it throughout a typical morning or afternoon. The data collection unit will be battery operated, contained within the seating system with no exposed or trailing wires. The researcher will discreetly follow and simultaneously log an activity diary in order to associate recorded forces with an activity. It is intended that this project should cause a minimal amount of disruption, because the main aim is to collect data about normal activities. At the end of the agreed time, the child shall be returned to their normal chair and the data will be downloaded and analysed in conjunction with the activity diary. There is no

minimum or maximum specified time that we would expect the child to be in the seat and no specified place to do the trial. Typically, we would expect the monitoring to last 2 to 6 hours in total and would be agreed with the child and parents involved in advance. We would expect this time would include the child being lifted in an out of the seat a number of times and to include travel to and from a school or alike.

4.4 Study Product

The Mygo Seating System, will be used in this study, is an activity chair which has been designed for children with disabilities aged 4-10 for use at home, in the school environment or outside, if used on a mobility base. James Leckey Design Ltd as manufacturer with sole responsibility declares that the Mygo Seating System conforms to the requirements of the 93/42/EEC Guidelines, Medical Device Regulations 2002 and EN12182 Technical aids for disabled persons and test methods.

4.5 Measurement tools

The equipment which will be utilized for the force analysis consists of strain gauges, amplifiers and a data logging ultramobile PC. This equipment will fit within a standard Mygo wheelchair base.

4.6 Potential risks

There are minimal additional risks in taking part over and above the participants' normal daily routine. At the outset, the modified chair may not match the child's own chair identically, which may upset the child. The researcher will, with the parent's help, quickly adjust the chair accordingly. If the child continues to be upset by the chair, then we can abandon participation for that day, and either withdraw completely, or find another day to try again.

There is also a very small risk associated with electrical safety. To minimise this, all the electronics will be housed such that they can't be touched.

4.7 Adverse reactions

Participants will be asked to inform the investigator of all adverse events occurring in the period before each study visit. All serious adverse events (SAEs) should be reported to the sponsor as soon as possible.

5. Confidentiality

Each participant will be registered with a unique reference number without any allusion to personal details. Data collected will be named with the reference number and stored in a password protected Westmarc computer. Access to the data will only be provided to the Chief Investigator and other research staffs. Personal details (name, address, telephone number only) will be kept in paper format along with the relevant trial reference number in a locked filling cabinet in the Bioengineering Unit, University of Strathclyde.

6. Publication Policy

The results of this work will be disseminated through conference presentations and scientific journal publications. Moreover, the researchers will be happy to explain the results of the study to the participants if they so wish.

7. Declaration of interest

This protocol is not associated with any commercial interests and is not in receipt of any government, NHS or commercial research or service delivery funding. Ms Katika Samaneein is undertaking a full time PhD in relation to this trial. Dr Philip Riches is the academic supervisor and Professor Philip Rowe is the second supervisor to the PhD programme.

8. References

Barnaby A. (1994) A survey og maginal wheelchair users. Journal of Rehabilitation Research and Development 31:297-302.

Lance J. (1980) Pathophysiology of spasticity and clinical experience with baclofen. In: Feldman RG, Young RR, Koella WP (eds), Chicago.

Letts R. (1991) General principles of seating Boca Raton : CRC Press.

PARENTAL/GUARDIAN INFORMATION SHEET

Stress Analysis of Seating Systems for Children with Special

Information Sheet : Version.2-05/08/2010

Dear Parent or Carer

My name is Katika Samaneein and I am a PhD research student working at the Bioengineering Unit at the University of Strathclyde in Glasgow. I am interested in the biomechanics of seated children who have cerebral palsy and the forces imparted by them on their seating system. In gathering this data, we aim to be able to design better seating systems in the future. My research is being conducted in collaboration with Westmarc, the West of Scotland Mobility and Rehabilitation Centre, which provides rehabilitation technology services for the West of Scotland, and is part-funded by James Leckey Design Ltd, the makers of the Mygo seating system. The research has been approved by the West of Scotland Research Ethics Committee.

I would really appreciate it if you and your child would consider volunteering for my research project. We gave Westmarc the envelope containing this information sheet and they put your name and address on it and posted it. At the moment, the University do not have any details about you and your child, and this will remain the case unless you wish to volunteer to take part in my research study. In terms of informed consent, before you and your child decides it is important for you to understand why the research is being done and what it would involve. Please read the following information carefully and discuss it with your child and others as appropriate. I have also written a children's version of the information sheet which may help you in this.

This adult version of the information sheet hopefully provides a clear explanation of the study including the research aims, benefits and risks and also what participation would mean for your child and any implications concerning their involvement. If there is any aspect of the study which is unclear, which you or your child would like further information on, please contact me or my supervisor who will be happy to answer your questions. Our contact details can be found at the end of this information sheet.

Thank you for your time.

1. What is the purpose of this investigation?

The project will collect data on the Mygo seating system so as to know the forces that are imparted on it during activities of daily living.

2. What is the medical device that is being tested?

The "Mygo Seating System" is an activity chair which has been designed for children with disabilities aged 4-10 for use at home, in the school environment or outside, if used on a mobility base. James Leckey Design Ltd as manufacturer with sole responsibility declares that the "Mygo Seating System" conforms to the requirements of the 93/42/EEC Guidelines, Medical Device Regulations 2002 and EN12182 Technical aids for disabled persons and test methods.

3. Why have I been invited to take part?

Your child has been invited to take part in this project because you and your child have been familiarized with the Mygo seating system for a few months. Your child is being invited to participate in this research as one of 10 participants.

4. Do I have to take part?

Participation in this study is entirely voluntary. You are free to consider whether or not to take part. If you and your child decide to participate, you will be asked to sign a form to confirm that the study was clearly explained to you and your child, and that you and your child agree to take part. Your child will also be given a form on which they can express their willingness to take part. You and your child will be free to withdraw at any time, without giving a reason. If you or your child decides not to take part, or withdraws from the research, then this will not affect any relationship you and your child has with the NHS or University.

5. What does taking part involve?

If you contact us, I will arrange to visit you to discuss the project in more detail, to complete the forms if you wish to continue, and to agree a time and date for your participation. Participation will involve your child sitting in a new Mygo seating system. The parents will be required to transfer the child from their own chair into the new

chair which has been modified so that we can collect force data on it throughout a typical morning or afternoon. The data collection unit will be battery operated, contained within the seating system with no exposed or trailing wires. The researcher will discreetly follow and simultaneously log an activity diary in order to associate recorded forces with an activity. At the end of the agreed time, your child shall be returned to their own chair. It is intended that this project should cause a minimal amount of disruption, because the main aim is to collect data about normal activities.

6. What will you do in the project?

You will help me in the research by telling me the most appropriate time for participation according to your weekly timetable. Hopefully the agreed time will be between 2 and 6 hours in length. On the day of the participation, after seating your child in our adapted Mygo and making sure they are happy and that the configuration is identical to your own chair, I hope that you carry on as per your normal day.

7. What are the potential risks to your children of taking part?

I do not think that there are many additional risks in taking part over and above your normal daily routine. At the outset, I may not have adjusted our chair to match your one identically, which may upset your child. I will, with your help, quickly adjust the chair accordingly. If your child continues to be upset by the chair, then we can abandon participation for that day, and either withdraws completely, or we could find another day to try again. There is a very minimal risk associated with electrical safety. To minimise this, all the electronics will be housed such that they can't be touched.

8. What are the possible benefits of taking part?

There will be no immediate benefit of taking part. However, the information collected will result in modifications being made to the Mygo seating system. You may be invited in the future to assess these modifications, which may be of benefit to your child. We will publish data from this study enabling all manufacturers, not just the makers of the Mygo system, to better understand the loads imparted on such

wheelchairs during daily activity, which should result in better designs ultimately benefitting many, many children.

9. Will my taking part in the study be kept confidential?

Your child will be given a unique reference number which will be used to code all the data collected. The piece of paper relating your name and address to the code will be kept in a locked filing cabinet in my supervisors' office at the University of Strathlcyde. All electronic data will therefore be anonymous, but nonetheless will be stored on a password protected University computer. The University of Strathclyde is registered with the Information Commissioner's Office who implements the Data Protection Act 1998. All the information your children give us will be confidential and used for the purposes of this study only. The data will be collected and stored in accordance with the Data Protection Act 1998 and will be disposed of in a secure manner.

10. What will happen to the results of the research study?

The results will be published through peer reviewed scientific journals and conference presentations. Manufacturers will be able to access the results via these publications. If you wish, at the end of the study, we will be very happy to explain the outcome of the research to you.

11. What happens next?

If you and your child are happy to be involved in the study please contact one of us, using the details in the next section, or fill your details in a slip of paper then tear off it and return to Westmarc. After that I will arrange a time to come and visit you to discuss the project further. I will also send you the consent forms so that you can see them in advance of our meeting.

If you, or your child, do not wish to participate, we thank you for your time and attention. You do not have to do anything else. We may send you a reminder letter in a couple of weeks, just in case you want to take part but didn't find the time to let us know.

12. If your children have any further questions?

If you and your children would like more information about the study and wish to speak to one of us please contact either:

Miss Katika Samaneein

Bioengineering Unit

Wolfson Centre

106 Rottenrow

University of Strathlcyde

Glasgow, G4 0NW

07733839343

katika.samaneein@strath.ac.uk

Dr Philip Riches (supervisor)

Bioengineering Unit

Wolfson Centre

106 Rottenrow

University of Strathlcyde

Glasgow, G4 0NW

0141 548 5703

philip.riches@strath.ac.uk

If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Secretary to the University Ethics Committee

Research & Knowledge Exchange Services

University of Strathclyde

Graham Hills Building

50 George Street Glasgow

G1 1QE

Telephone: 0141 548 3707

Email: ethics@strath.ac.uk

This investigation was granted ethical approval by the NHS Greater Glasgow and Clyde.

Thank you for your time and co-operation.

Project: Stress Analysis of Seating Systems for Children with Special Needs

☐ *Interested* ☐ *Not Interested*

Your name:

.....

Your child name:

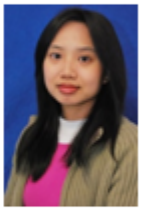
.....

Contact details:

.....

Information Sheet

Information Sheet: Version.1-13/05/2010



Hi. My name is Katika and I am a student at the University of Strathclyde.

I am inviting you to help me with a study that I want to do. I would like to know how hard you push and pull on your chair during a normal day. This information will help make better chairs in the future.

I am inviting you to take part because you already have a Mygo chair. I would like to swap your chair for another Mygo chair for a few hours. My chair has a computer on it which can measure how hard you push and pull on it.

If you want take part, I will come and visit you to work out when and where you want to use it and for how long. Then, on the agreed day, I will deliver my Mygo chair to you and you should spend your day as normal. At the same time, I will write a few notes about what you are doing. When the time is over, you can get back into your own chair.

If you want to stop, you can get your own chair back **at any time**.

If you want to help me, please let your mum, dad or carer know, and they can contact me. Thank you for reading this and I hope to meet you soon.

Katika

Stress Analysis of Seating Systems for Children with Special Needs

INFORMATION SHEET FOR SCHOOLS AND NURSERIES

Information Sheet: Version.1-13/05/2010

My name is Katika Samaneein and I am pursuing a PhD in the Bioengineering Unit at the University of Strathclyde. My research aims to measure the forces imparted on special seating during normal daily activities, in order to design improved seating systems in the future. Mr and Mrs XXXX (name to be inserted) and their child (NAME) have indicated that they would like to take part in this research, and have suggested that a suitable time and date is…… This time and date includes the time when XXXX is with you and therefore we are asking for your permission if this research can proceed on your premises. The following pages detail the project which will help you understand why the research is being done and precisely what it will involve.

Please ask us if there is anything that is not clear or if you would like more information.

1. Who are the researchers?

The Chief Investigator is Katika Samaneein, a PhD student working in the Bioengineering Unit at the University of Strathclyde in Glasgow. The research is being conducted in collaboration with Westmarc, the West of Scotland Wheelchair and Seating Service, which provides rehabilitation technology services for the West of Scotland, and is part-funded by James Leckey Design Ltd, makers of the Mygo seating system. The study has been granted ethical approval by the research ethics committee of the NHS Greater Glasgow and Clyde. The research staff has enhanced Disclosure Scotland to the highest level.

2. What is the Research Project involve?

The project aims to measure the mechanical forces on the Mygo seating system during activities of daily living in order to better design similar seating systems in the future. The project will involve XXXX (NAME) sitting in a Mygo seating system which has been modified so that we can collect force data on it throughout a typical morning or afternoon session. The data collection unit will be battery operated, contained entirely within the Mygo system with no exposed or trailing wires. I, Katika, will discreetly follow and simultaneously log an activity diary so I can associate the recorded forces with an activity. At the end of the agreed time, XXXX shall be returned to their chair and I will remove the modified chair. It is intended that this project should cause a minimal amount of disruption, because the main aim is to collect data about normal activities. You should not do anything differently than what you would normally do on account of this research project. No photographs, audio or video will be taken on your premises.



3. Who are the participants?

We aim to recruit 10 children with cerebral palsy who have been prescribed a Mygo by Westmarc. One of the children is XXXX, and that is why we are contacting you.

4. What does the school or nursery have to do?

Your school or nursery can help the study by allowing me to visit and perform part of the data collection in your area on the day and time suggested by the parent and child. Apart from that, you do not have to do anything differently as per normal. If the day or time is not suitable for you, but are in general willing to give permission for such a visit, please contact me below, and we can rearrange the time and date accordingly.

5. If you have any further questions?

If you would like more information about the study and wish to speak to the research staff please contact:

6. What do you have to do now?

If you are happy for this research to proceed on your premises, please could you let me or my supervisor know by contacting us; our details are below. If I have not heard from you within a week or so, please forgive me if I try to contact you again.

Miss Katika Samaneein 0773 383 9343
(katika.samaneein@strath.ac.uk)

Dr Philip Riches 0141 548 5703
(philip.riches@strath.ac.uk)

Bioengineering Unit

Wolfson Centre

106 Rottenrow

University of Strathlcyde

Glasgow, G4 0NW

If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Secretary to the University Ethics Committee

Research & Knowledge Exchange Services

University of Strathclyde

Graham Hills Building

50 George Street, Glasgow

G1 1QE

Telephone: 0141 548 3707

Email: ethics@strath.ac.uk

This investigation was granted ethical approval by the NHS Greater Glasgow and Clyde.

Thank you for your time.

NHS
Greater Glasgow and Clyde

University of Strathclyde Glasgow

Subject number:

PARENTAL/GUARDIAN CONSENT FORM

Stress Analysis of Seating Systems for Children with Special Needs

Katika Samaneein

Consent Form: Version.1-13/05/2010

Please initial the BOX

1. I confirm that I have read and understand the information sheet dated for the above study and have had the opportunity to ask questions ☐
2. I understand that my child's participation is voluntary and that I am free to withdraw my child at any time, without giving any reason, without my child medical care or legal rights being affected. ☐
3. I agree to my child taking part in the above study ☐

| --- | --- | --- |
Name of Parent/Guardian	Date	Signature
Name of Researcher	Date	Signature

When completed, you will be given a copy of this from to keep for your record.

Subject number:

ASSENT FORM FOR CHILDREN

Stress Analysis of Seating Systems for Children with Special Needs

Katika Samaneein

Assent Form: Version.1-13/05/2010

Parents or carers, please can you either read this form to your child, or make sure that they have read it and that they understand what it means.

Please think about these sentences:

- I know all about this project.
- Someone has talked to me about this project.
- I understand what this project is about.
- I have asked all the questions I want to ask.
- I have understood the answers to my questions.
- I know I can stop taking part at any time.

If you agree with **all** of these and are you happy to take part, please circle, or make a mark in pen, crayon or paint near the happy face.

If you do not want to take part, please circle, or make a mark in pen, crayon or paint near the unhappy face.

Yes

No

ASSENT FORM FOR CHILDREN

Your parent or carer must write and sign their name here, to confirm that you have given your agreement to take part:

Print name .....

Sign .....

Date .....

The researcher who explained this project to you needs to sign too:

Print name .....

Sign .....

Date .....

Thank you!

Thank you for your help

Study Title: Stress Analysis of a Dynamic Seating System for Children with Special Needs

REC Reference Number: 11/AL/0367

NHS R&D offices Reference Number: GN11CO368

Documents:

- Research Protocol
- Information sheet for parent
- Information sheet for child
- Information sheet for school
- Parent consent form
- Child assent form

Research Protocol

Title:

Stress Analysis of a Dynamic Seating System for Children with Special Needs

Researcher:

Miss Katika Samaneein

Researcher ethics committee:

West of Scotland Research Ethics Committee

Bioengineering Unit

University of Strathclyde

Research Protocol: Version B2_12/08/2011

Study Summary

Title	Stress Analysis of a Dynamic Seating System for Children with Special Needs
Methodology	The forces applied to a Mygo dynamic backrest system will be recorded during normal activities of daily living.
Study Duration	The proposed monitoring time is 2 to 6 hours in total, which would be agreed with the child and parent involved in advance
Study Centre(s)	There is no specified location to do the study. However, the study will be taken in the activities of daily living within the community.
Objectives	To determine the loads imparted to the Mygo dynamic backrest system during community-based activities of daily living and, in particular, during an extensor spasm.
Participants	Ten children with cerebral palsy will be recruited to participate. They all have been prescribed a Mygo wheelchair by Westmarc
Study Product	The Mygo Seating System, which is a dynamic backrest designed for disabled children aged 4-10, will be used in this study.
Duration of administration	• Each participant will spend less than a total of 14 days in this study. • Initial identification of suitable participants, introduction, information sheet, question and answering, 1 hour. • Set up and observation arrangement, 2 hours • Upon agreement with parent and the child involved, monitoring and actual study should last from 2 to 6 hours. • Participants will be given 2 weeks to decide whether or not to take part
Confidentiality	Each participant will be registered with a unique reference number without any allusion to personal details.

1. Introduction

A wheelchair is one of the most common devices used to assist users who have limited abilities to walk or move. The wheelchair user population includes children, adults, and elderly persons.

In 1994, Barnaby and team performed a survey by interviewing over 3,000 wheelchair users at the Dundee Limb Fitting Centre in which they described that 50% of total users are 30-60 years old and approximately 10% are children under the age of 20. For children the largest diagnostic categories are multiple sclerosis 26%, spina bifida 10%, rheumatoid arthritis 9% and cerebral palsy 8% (Barnaby, 1994).

Cerebral palsy is a group of central nervous system disorders which affects the body's ability to control movement and posture. The cerebellum plays a major role in regulating muscle tone, the lesions of this can make patients have either high muscle tone, low muscle tone, or a combination of the two (fluctuating tone). Based upon the form of motor impairment, cerebral palsy can be divided into four types: spastic cerebral palsy, choreoathetoid cerebral palsy, hypotonic cerebral palsy and mixture of all.

The most common type is spastic cerebral palsy, which causes children to have stiff and jerky movements. A widely accepted definition of spasticity, which is classically defined by Lance: is “a motor disorder characterised by a velocity-dependent increase in tonic stretch reflexes with exaggerated tendon jerks, resulting from hyper-excitability of the stretch reflex” (Lance, 1980). In the other words, spasticity is a hyperactive muscle fast stretch reflex which is a result of uncoordinated agonist and antagonist muscle activity due to dysfunction of the electrical signal from the motor neuron system.

Special seating designed for children with disabilities considers requirements like, stage of development, disabilities, and other disorders. The mobility and posture problems that disabled people face may be due to muscle weaknesses, muscle imbalances and spasm or poor sensation. First and foremost importance for the disabled is stable sitting, because unstable sitting makes balance difficult to control by the upper body. Ideally the sitting position should balance weight and movement

in all planes (Letts, 1991). Therefore, a special seat base with a back support can be used to assists the positioning for physical therapy.

The problem of the seating for spastic children occurs when muscles stretch producing a strong force between seat back and their bodies. The high forces produced during this extension lead pain and injury for children and indicate that the seating structure must be strong and durable. Dynamic seating system, the new design of the seating to include mechanisms to better dissipate and control the applied forces, reducing the stress on the child and seat. In the expectation that it will respond appropriately to the users with strong muscle spasm, reduce the pain and reduce pressure from restricted posture. This study considers the biomechanics of seated children with cerebral palsy and the forces imparted by them on their seating system. Biomechanical outcomes will provide a better understanding of a suitable special chair for the participants with cerebral palsy, which in turn, could lead to improvements in custom made wheelchair design. And prescriptions could be designed in a way that promotes the health, well-being, and productivity for disabled people.

2. Objective

This study aims to collect force data on the Mygo seating system (James Leckey Design Ltd, Belfast, U.K.) The Mygo Seating has special designed for children with limited mobility who have cerebral palsy in either high muscle tone, low muscle tone, or a combination of the two (fluctuating tone) during activities of daily living. Dynamic backrest system is the modified design to better dissipate and control the applied forces, an alternative design for user who has a strong extensor body.

3. Research Question

What loads are imparted to the Mygo dynamic backrest seating system during community-based activities of daily living and, in particular, during an extensor spasm?

4. Methodology

4.1 Participants

Individuals for participation in this study will be recruited from Westmarc who will ensure each participant meets the study criteria. Ideally 10 children with cerebral palsy will participate in the research project, whether they have hypertonia or hypotonia muscle tone. The study will be discussed and explained in detail to children and their parents.

4.1.1 Inclusion criteria

Children age 4 -10, boy or girl, who have been prescribed a Mygo seating by Westmarc.

4.1.2 Exclusion criteria

Children who are within 6 months after a surgical procedure, or have a current illness, or are on temporary medication.

4.2 Recruitment procedures

The University researchers will prepare unaddressed envelopes which contain the participant information sheet. These envelopes will be passed to Westmarc who will put on the address of potential participants based on their database. At this point the University team will not know the names and addresses of those invited to participate. Potential volunteers will contact Westmarc or the University research team who can address any questions or concerns of the research. Only when the participants are happy to take part, the researcher will arrange to visit them to obtain informed consent (parent) and assent (child) and to arrange a time and a date for the participation. A specially designed assent form has been created in order for the child to assent to the research. If the agreed time and date includes a visit to a school or other similar premises, then a letter shall be sent to them asking for their permission for this to take place on their premises.

4.3 Duration of study

Participation will involve the child sitting in a Mygo seating system which has been modified in order to collect force data on it throughout a typical morning or afternoon. The data collection unit will be battery operated, contained within the seating system with no exposed or trailing wires. The researcher will discreetly follow and simultaneously log an activity diary in order to associate recorded forces with an activity. It is intended that this project should cause a minimal amount of disruption, because the main aim is to collect data about normal activities. At the end of the agreed time, the child shall be returned to their normal chair and the data will be downloaded and analysed in conjunction with the activity diary. There is no minimum or maximum specified time that we would expect the child to be in the seat and no specified place to do the trial. Typically, we would expect the monitoring to last 2 to 6 hours in total and would be agreed with the child and parents involved in advance. We would expect this time would include the child being lifted in an out of the seat a number of times and to include travel to and from a school or alike.

4.4 Study Product

The Mygo Dynamic Seating System which be used in this study is an activity chair which has been designed for children with disabilities aged 4-10 for use at home, in the school environment or outside, if used on a mobility base. James Leckey Design Ltd. as manufacturer with sole responsibility declares that the Mygo Seating System conforms to the requirements of the 93/42/EEC Guidelines, Medical Device Regulations 2002 and EN12182 Technical aids for disabled persons and test methods.

The Dynamic backrest system is the new design by James Leckey Design Ltd. An active gas spring mechanism has been included in the back tube to better dissipate and control the applied forces. As a replacement for the back angle inner extrusion, both end sides of gas spring was fitted in the joints of backrest and seat. The different size of gas springs will be used depends on the load of each user by fully adjustable in a difference of thrust loads: 50, 100 and 150 N.

Figure 0.1 Dynamic backrest: the gas spring
put inside the back tube

The systems permits forward and backward movement as the occupant extends and retracts their body, instead of child maintaining their position during a spasm. In support of the advantages offered by the dynamic mechanism, the new design is supposed to absorb the high contact forces. Therefore reducing the pain experienced by the children during extensor thrust. For people with physical disabilities, especially patients who have strong extensor spasticity, the dynamic design is able to prevent pressure ulcers and injury from impact.

4.5 Measurement tools

The equipment which will be utilized for the force analysis consists of strain gauges, amplifiers and a data logging ultra mobile PC. These equipments will be fitted within a standard Mygo wheelchair base.

4.6 Potential risks

There are minimal additional risks in taking part over and above the participants' normal daily routine. At the outset, the modified chair may not match the child's own chair identically, which may upset the child. The researcher will, with the parent's help, quickly adjust the chair accordingly. If the child continues to be upset by the chair, then we can abandon participation for that day, and either withdraw completely, or find another day to try again. There is also a very small risk associated with electrical safety. To minimise this, all the electronics will be housed such that they can't be touched.

4.7 Adverse reactions

Participants will be asked to inform the investigator of all adverse events occurring in the period before each study visit. All serious adverse events (SAEs) should be reported to the sponsor as soon as possible.

5. Confidentiality

Each participant will be registered with a unique reference number without any allusion to personal details. Data collected will be named with the reference number and stored in a password protected Westmarc computer. Access to the data will only be provided to the Chief Investigator and other research staffs. Personal details (name, address, telephone number only) will be kept in paper format along with the relevant trial reference number in a locked filling cabinet in the Bioengineering Unit, University of Strathclyde.

6. Publication Policy

The results of this work will be disseminated through conference presentations and scientific journal publications. Moreover, the researchers will be happy to explain the results of the study to the participants if they so wish.

7. Declaration of interest

This protocol is not associated with any commercial interests and is not in receipt of any government, NHS or commercial research or service delivery funding. Ms Katika Samaneein is undertaking a full time PhD in relation to this trial. Dr Philip Riches is the academic supervisor and Professor Philip Rowe is the second supervisor to the PhD programme.

8. References

Barnaby A. (1994) A survey og maginal wheelchair users. Journal of Rehabilitation Research and Development 31:297-302.

Lance J. (1980) Pathophysiology of spasticity and clinical experience with baclofen. In: Feldman RG, Young RR, Koella WP (eds), Chicago.

Letts R. (1991) General principles of seating Boca Raton : CRC Press.

PARENTAL/GUARDIAN INFORMATION SHEET

Stress Analysis of a Dynamic Seating System

for Children with Special Needs

Information Sheet: Version B2.1_12/10/2011

Dear Parent or Carer

My name is Katika Samaneein and I am a PhD research student working at the Bioengineering Unit at the University of Strathclyde in Glasgow. I am interested in measuring the forces applied to a wheelchair by its user and in particular a wheelchair user with cerebral palsy. Hopefully this data will result in improved wheelchair design: a wheelchair that works with the user and not against them. My research is being conducted in collaboration with Westmarc, the West of Scotland Mobility and Rehabilitation Centre, which provides rehabilitation technology services for the West of Scotland, and is part-funded by James Leckey Design Ltd, the makers of the Mygo seating system. The research has been approved by the West of Scotland Research Ethics Committee.

I would really appreciate it if you and your child would consider volunteering for my research project and ask that you read through the attached information sheet.

We gave Westmarc the envelope containing this information sheet and they put your name and address on it and posted it. At the moment, the University do not have any details about you and your child, and this will remain the case unless you wish to volunteer to take part in my research study. In terms of informed consent, before you and your child decides it is important for you to understand why the research is being done and what it would involve. Please read the following information carefully and discuss it with your child and others as appropriate. I have also written a children's version of the information sheet which may help you in this.

This adult version of the information sheet hopefully provides a clear explanation of the study including the research aims, benefits and risks and also what participation would mean for your child and any implications concerning their involvement. If there is any aspect of the study which is unclear, which you or your child would like further information on, please contact me or my supervisor who will be happy to answer your questions. Our contact details can be found at the end of this information sheet.

Thank you for your time.

1. What is the purpose of this investigation?

The project will collect force data on the Mygo dynamic seating system so as to know the forces that are applied to it during normal daily activity.

2. What is the medical device that is being tested?

The Mygo Seating is an activity chair which has been designed for children with disabilities aged 4-10 for use at home, in the school environment or outside, if used on a mobility base. James Leckey Design Ltd as manufacturer with sole responsibility declares that the "Mygo Seating System" conforms to the requirements of the 93/42/EEC Guidelines, Medical Device Regulations 2002 and EN12182 Technical aids for disabled persons and test methods. The Mygo Dynamic Seating System is a new design that contains a gas spring mechanism which allows the backrest to recline under load.

3. Why have I been invited to take part?

We are inviting you to take part in this project because you and your child have been familiarized with the Mygo seating system for a few months. Your child is being invited to participate in this research as one of 10 participants.

4. Do I have to take part?

Participation in this study is entirely voluntary. You are free to consider whether or not to take part. If you and your child decide to participate, you will be asked to sign a form to confirm that the study was clearly explained to you and your child, and that you and your child agree to take part. Your child will also be given a form on which they can express their willingness to take part. You and your child will be free to withdraw at any time, without giving a reason. If you or your child decides not to take part, or withdraws from the research, then this will not affect any relationship you and your child has with the NHS or University.

5. What does taking part involve?

If you contact us, I will arrange to visit you to discuss the project in more detail, to complete the forms if you wish to continue, and to agree a time and date for your participation. Participation will involve your child using the new Mygo seating system for a few hours of one day. We will ask you to transfer the child from their own chair into the new chair which has been modified so that we can collect force data on it throughout a typical morning or afternoon. Ideally, we would like you to be present during the whole observation period. However, if you have agreed for the session to take place at school (we will ask their permission on your behalf), we will ask for the trained support workers to transfer the child between seats if the child would like to go back to his own chair during the test.

The data collection unit will be battery operated, contained within the seating system with no exposed or trailing wires. I will discreetly follow and simultaneously log an activity diary in order to associate recorded forces with an activity. At the end of the agreed time, your child shall be returned to their own chair. It is intended that this project should cause a minimal amount of disruption, because the main aim is to collect data about normal activities.

6. What will you do in the project?

If you agree to join this study, we will agree with you an appropriate time for participation. Hopefully the agreed time will be between 2 and 6 hours in length. On the day of the participation, after seating your child in our adapted Mygo and making sure they are happy and that the configuration is identical to your own chair, I hope that you carry on as per your normal day.

7. What are the potential risks to your children of taking part?

In this investigation, we believe that there are no additional risks in taking part over and above your child's normal daily routine.

Since the child will be given a new chair for the session, he or she might feel not familiar with it. However, the chair is fully adjustable and will be matched to their chair. If your child continues to be discomforted by the chair, we can abandon

participation for that day, and you may either withdraw completely, or we could find another day to try again.

8. What are the possible benefits of taking part?

There will be no immediate benefit of taking part. However, the information collected will result in modifications being made to the Mygo seating system which may be of benefit to future users. We will publish data from this study enabling all manufacturers, not just the makers of the Mygo system, to better understand the loads imparted on such wheelchairs during daily activity, which should result in better designs ultimately benefitting many children.

9. Will my taking part in the study be kept confidential?

Your child will be given a unique reference number which will be used to code all the data collected. The piece of paper relating your name and address to the code will be kept in a locked filing cabinet in my supervisors' office at the University of Strathlcyde. All electronic data will therefore be anonymous, but nonetheless will be stored on a password protected University computer. The University of Strathclyde is registered with the Information Commissioner's Office who implements the Data Protection Act 1998. All the information your children give us will be confidential and used for the purposes of this study only. The data will be collected and stored in accordance with the Data Protection Act 1998 and will be disposed of in a secure manner.

10. What will happen to the results of the research study?

The results will be published through peer reviewed scientific journals and conference presentations. Manufacturers will be able to access the results via these publications. If you wish, at the end of the study, we will be very happy to explain the outcome of the research to you.

11. What happens next?

If you and your child are happy to be involved in the study please contact one of us, using the details in the next section, or fill your details in a slip of paper then tear off it and return to Westmarc or contact the University research team. After that I will arrange a time to come and visit you to discuss the project further. I will also send you the consent forms so that you can see them in advance of our meeting.

If you, or your child, do not wish to participate, we thank you for your time and attention. You do not have to do anything else. We may send you a reminder letter in a couple of weeks, just in case you want to take part but didn't find the time to let us know.

12. If your children have any further questions?

If you and your children would like more information about the study and wish to speak to one of us please contact either:

Miss Katika Samaneein
Bioengineering Unit
Wolfson Centre
106 Rottenrow
University of Strathclyde
Glasgow, G4 0NW
07733839343
katika.samaneein@strath.ac.uk

Dr Philip Riches (supervisor)
Bioengineering Unit
Wolfson Centre
106 Rottenrow
University of Strathclyde
Glasgow, G4 0NW
0141 548 5703
philip.riches@strath.ac.uk

If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Secretary to the University Ethics Committee

Research & Knowledge Exchange Services

University of Strathclyde, Graham Hills Building

50 George Street, Glasgow, G1 1QE

Telephone: 0141 548 3707, Email: ethics@strath.ac.uk

This investigation was granted ethical approval by the NHS Greater Glasgow and Clyde.

Thank you for your time and co-operation.

Project: Stress Analysis of a dynamic Seating System for Children with Special Needs

☐ *Interested* ☐ *Not Interested*

Your name:

.....

Your child name:

.....

Contact details:

.....

Information Sheet

Information Sheet: Version B2_12/08/2011

Hi. My name is Katika and I am a student at the University of Strathclyde.

I am inviting you to help me with a study that I want to do. I would like to know how hard you push and pull on your chair during a normal day. I hope that information will help make better chairs in the future.

I am inviting you to take part because you already have a Mygo chair. I would like to swap your chair for another Mygo chair for a few hours. My chair has a computer on it which can measure how hard you push and pull on it.

If you want take part, I will come and visit you to work out when and where you want to use it and for how long. Then, on the agreed day, I will deliver my Mygo chair to you and you should spend your day as normal. At the same time, I will write a few notes about what you are doing. When the time is over, you can get back into your own chair.

If you want to stop, you can get your own chair back **at any time**.

If you want to help me, please let your mum, dad or carer know, and they can contact me. Thank you for reading this and I hope to meet you soon.

Katika

INFORMATION SHEET FOR SCHOOLS AND NURSERIES

Stress Analysis of a Dynamic Seating System for Children with Special Needs

Information Sheet: Version B2_12/08/2011

My name is Katika Samaneein and I am pursuing a PhD in the Bioengineering Unit at the University of Strathclyde. My research aims to measure the forces imparted on special seating during normal daily activities, in order to design improved seating systems in the future. Mr and Mrs XXXX (name to be inserted) and their child (NAME) have indicated that they would like to take part in this research, and have suggested that a suitable time and date is…… This time and date includes the time when XXXX is with you and therefore we are asking for your permission if this research can proceed on your premises. The following pages detail the project which will help you understand why the research is being done and precisely what it will involve.

Please ask us if there is anything that is not clear or if you would like more information.

1. Who are the researchers?

The Chief Investigator is Katika Samaneein, a PhD student working in the Bioengineering Unit at the University of Strathclyde in Glasgow. The research is being conducted in collaboration with Westmarc, the West of Scotland Wheelchair and Seating Service, which provides rehabilitation technology services for the West of Scotland, and is part-funded by James Leckey Design Ltd, makers of the Mygo seating system. The study has been granted ethical approval by the West of Scotland Research Ethic Committee 5. The research staff has enhanced Disclosure Scotland to the highest level.

2. What is the research project involve?

The project aims to measure the mechanical forces on the Mygo dynamic seating system during activities of daily living in order to better design similar seating systems in the future. The project will involve XXXX (NAME) sitting in a Mygo seating system which has been modified so that we can collect force data on it throughout a typical morning or afternoon session. The data collection unit will be battery operated, contained entirely within the Mygo system with no exposed or trailing wires. I, Katika, will discreetly follow and simultaneously log an activity diary so I can associate the recorded forces with an activity. At the end of the agreed time, XXXX shall be returned to their chair and I will remove the modified chair. It is intended that this project should cause a minimal amount of disruption, because the main aim is to collect data about normal activities. You should not do anything differently than what you would normally do on account of this research project. No photographs, audio or video will be taken on your premises.

3. Who are the participants?

We aim to recruit 5 children with cerebral palsy who have been prescribed a Mygo by Westmarc. One of the children is XXXX, and that is why we are contacting you.

4. What does the school or nursery have to do?

Your school or nursery can help the study by allowing me to visit and perform part of the data collection in your area on the day and time suggested by the parent and child. Apart from that, you do not have to do anything differently as per normal. If the day or time is not suitable for you, but are in general willing to give permission for such a visit, please contact me below, and we can rearrange the time and date accordingly.

The parents will be required to transfer the child from their own chair into the new chair in the beginning of the test. However if the child would like to go back to his own chair during the investigation we would like to ask for a proficient person in your place assist to transfer the child between seats.

5. If you have any further questions?

If you would like more information about the study and wish to speak to the research staff please contact:

6. What do you have to do now?

If you are happy for this research to proceed on your premises, please could you let me or my supervisor know by contacting us; our details are below. If I have not heard from you within a week or so, please forgive me if I try to contact you again.

Katika Samaneein 0773 383 9343
(katika.samaneein@strath.ac.uk)
Dr Philip Riches 0141 548 5703
(philip.riches@strath.ac.uk)
Bioengineering Unit
Wolfson Centre
106 Rottenrow
University of Strathclyde
Glasgow, G4 0NW

If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Secretary to the University Ethics Committee

Research & Knowledge Exchange Services

University of Strathclyde

Graham Hills Building

50 George Street

Glasgow, G1 1QE

Telephone: 0141 548 3707

Email: ethics@strath.ac.uk

This investigation was granted ethical approval by the NHS Greater Glasgow and Clyde.

Thank you for your time.

Participant number:

Parental/Guardian Consent Form

Stress Analysis of a Dynamic Seating System for Children with Special Needs

Katika Samaneein

Consent Form: Version B2_12/08/2011

Please initial the BOX

1. I confirm that I have read and understand the information sheet dated for the above study and have had the opportunity to ask questions ☐
2. I understand that my child's participation is voluntary and that I am free to withdraw my child at any time, without giving any reason, without my child medical care or legal rights being affected. ☐
3. I agree to my child taking part in the above study ☐

----------	----------	----------
Name of Parent/Guardian	Date	Signature
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Name of Researcher	Date	Signature

When completed, you will be given a copy of this from to keep for your record.

Subject number:

PARENTAL/GUARDIAN CONSENT FORM

Stress Analysis of a Dynamic Seating System for Children with Special Needs

Katika Samaneein

Consent Form: Version B2_12/08/2011

Please initial the BOX

1. I confirm that I have read and understand the information sheet dated for the above study and have had the opportunity to ask questions ☐
2. I understand that my child's participation is voluntary and that I am free to withdraw my child at any time, without giving any reason, without my child medical care or legal rights being affected. ☐
3. I agree to my child taking part in the above study ☐

----------	----------	----------
Name of Parent/Guardian	Date	Signature

----------	----------	----------
Name of Researcher	Date	Signature

NHS
Greater Glasgow and Clyde

Subject number:

University of Strathclyde Glasgow

ASSENT FORM FOR CHILDREN

Stress Analysis of a Dynamic Seating System for Children with Special Needs

Katika Samaneein

Assent Form Version B2_12/08/2011

Parents or carers, please can you either read this form to your child, or make sure that they have read it and that they understand what it means.

Please think about these sentences:

- I know all about this project.
- Someone has talked to me about this project.
- I understand what this project is about.
- I have asked all the questions I want to ask.
- I have understood the answers to my questions.
- I know I can stop taking part at any time.

If you agree with **all** of these and are you happy to take part, please circle, or make a mark in pen, crayon or paint near the happy face.

If you do not want to take part, please circle, or make a mark in pen, crayon or paint near the unhappy face.

Yes

No

Participant number:

ASSENT FORM FOR CHILDREN

Your parent or carer must write and sign their name here, to confirm that you have given your agreement to take part:

Print name .....

Sign .....

Date .....

The researcher who explained this project to you needs to sign too:

Print name .....

Sign .....

Date .....

Thank you!

Thank you for your help

Study Title: ***Effect of a dynamic backrest seating system on a child with CP***

UEC Reference Number: ***UEC1012/48***

Documents:

- Research Protocol
- Information sheet for parent
- Parent consent form
- Parent assessment of new backrest
- Information sheet for physiotherapist
- Physiotherapist consent form
- Alignment assessment

Research Protocol

Title:

Effects of dynamic backrest seating system on a child with CP

Researcher:

Katika Samaneein

Bioengineering Unit

University of Strathclyde

Research Protocol: Version C1_19 Mar 2012

Study Summary

Title	**Effects of dynamic backrest seating system on a child with CP**
Methodology	The functional movement of participant will be measured routinely in quantity and quality then will be analysed to show the improvement after the dynamic backrest system is used for 6 months.
Study Duration	6 months.
Study Centre(s)	Biomechanics laboratory, Bioengineering Unit University of Strathclyde, Glasgow.
Objectives	To evaluate the long term effects and clinical benefits of using the dynamic backrest system.
Participants	1-3 children with cerebral palsy who use a Mygo seating system and your child has previously participated our previous research.
Study Product	The Mygo Seating which has been placed a dynamic backrest system.
Duration of investigation	• The potential participants will be recruited by sending an invitation, they will be given 2 weeks to decide whether or not to take part • If you contact us, the more project detail will be discussed agree the measurement and agree a time and date for the participation • An initial assessment for the baseline data, 1 hour • After using the dynamic seating system for a month, the participant will spend around 1 hour for the monthly follow up assessment
Confidentiality	The participant will be registered with a unique reference number without any allusion to personal details.

1. Introduction

Spasticity commonly occurs in people who have cerebral palsy (Krägeloh-Mann & Cans, 2009; Shevell, et al., 2003), it is a group of central nervous system disorders which affects the body's ability to control movement and posture (O'Shea, 2008; Salihu, 2008). A widely accepted definition of spasticity, which is classically defined by Lance: is “a motor disorder characterised by a velocity-dependent increase in tonic stretch reflexes with exaggerated tendon jerks, resulting from hyper-excitability of the stretch reflex” (Lance, 1980). In the other words, spasticity is a hyperactive muscle fast stretch reflex which is a result of uncoordinated agonist and antagonist muscle activity due to dysfunction of the electrical signal from the motor neuron system.

Problems with spasticity are issues that influence postural sitting, when muscles stretch or experience an extensor spasm; it produces a strong force between backrest and user. A force against the backrest leads to unconditional posture and physical discomfort. The high impact forces suddenly produced and result in high contact forces leading pain and injury for them (Hermes, 2006) and affect the development of spinal curves in children (Onushko, Hyngstrom, & Schmit, 2010; Paleg, 2011). In addition, the high forces produced during the extension indicate that the seating material must be strong, durable and fatigue resistant.

The new dynamic seating system includes mechanisms to better dissipate and control the applied forces, reducing the stress on the child and seat. The systems permits forward and backward movement as the occupant as they extend and retract their body, instead of the child’s position being fixed during a spasm. In support of the advantages offered by the dynamic mechanism, the new design is supposed to absorb the high contact forces, reduce the pain experienced by the children during extensor thrust. In the expectation that it will respond appropriately to the children with strong muscle spasm, reduce the pain and reduce pressure from restricted posture, but still provide support. Furthermore the backrest provides physical benefits or improves the functional performance during activities of children who have cerebral palsy. However, the effects of the dynamic backrest system use in children with cerebral palsy remain unclear; evidence is required to show clinical

benefits of the dynamic backrest system. Children who lack of postural control need the support devices from the special seating to seat them in a symmetric position with the pelvis placed to maximise trunk and head stability. Although increasing of the range of motion on pelvis and lower spine of the dynamic backrest system may lead to asymmetrical posture and lack of the right pelvic support (D. Hobson & Crane, 2001).

2. Objective

The objective of this study is to understand the interaction of the Mygo seating system with its user during daily living activities, to investigate the effect of a dynamic backrest on motor function and quality of movement over a long period of time.

This study is the last phase of study series on special seating systems for use by children with special needs. The objective is to understand the interaction of the Mygo seating system with its user during daily living activities, to investigate the result on motor function, quality of movements and everyday activities for a long term period of at least six months. Assessment of seating forces imparted through daily activity by children with special needs by using the rigid backrest system (work package A) and the dynamic backrest system (work package B) was explicitly investigated. For this study (work package C) is a long term field trial, appropriate assessments both quantitative and qualitative methods will be use to evaluate the long term effects of using of the dynamic backrest system.

3. Research Questions

What is the long-term benefit of using a dynamic backrest seating system? Can such seating system help to decrease the spasm incident or improve any performance of functional movement during activities of daily living for children with cerebral palsy?

4. Methodology

4.1 Participants

Ideally 3 children will be participated in this study. The inclusion criteria were children with spastic cerebral palsy, ranging in age from 4-10 years, experienced in extensor spasm and has been use a Mygo seating system and has previously participated our previous research. Exclude children who are within 6 months after a surgical procedure, or have a current illness, or are on temporary medication.

4.2 Recruitment procedure

The potential participants will be recruited by sending an invitation. Only when the participants are happy to take part, the researcher will arrange a time and a date for the initial assessment.

4.3 Study Product

Participants will use their own Mygo wheelchair during investigation period. We will change only one component of their Mygo seating, it is a simple assembly and not permanent changed on the chair. An active gas spring mechanism will be included in the back tube of your child's Mygo seating intended to better dissipate and control the applied forces. The systems permits forward and backward movement as the child moves instead of maintaining the child in the rigid position.

The Mygo Dynamic Seating System is an activity chair which has been designed for children with disabilities aged 4-10 for use at home, in the school environment or outside, if used on a mobility base. James Leckey Design Ltd. as manufacturer with sole responsibility declares that the Mygo Seating System conforms to the requirements of the 93/42/EEC Guidelines, Medical Device Regulations 2002 and EN12182 Technical aids for disabled persons and test methods.

Figure0.2: Dynamic backrest: the gas spring put inside the back tube

The dynamic backrest is an option for the Mygo Seating System for children with extensor patterns. An active gas spring mechanism has been included in the back tube to better dissipate and control the applied forces. As a replacement for the back angle inner extrusion, both end sides of gas spring was fitted in the joints of backrest and seat. The different size of gas springs will be used depends on the load of each user by fully adjustable in a difference of thrust loads available in 50N, 100N and 150N. The systems permits forward and backward movement as the occupant extends and retracts their body, instead of child maintaining their position during a spasm. In support of the advantages offered by the dynamic mechanism, the new design is supposed to absorb the high contact forces. This intended to reduce the pain experienced by the children during extensor thrust and to improve tone when using in long term.

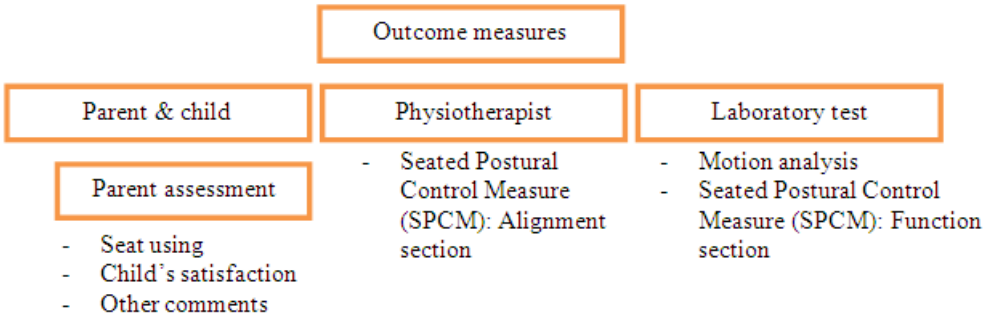
4.4 Duration of study

Volunteers will be given a Mygo seating with dynamic backrest system for a six month period.

4.5 Measurement tools

The parent and child will be invited to an initial assessment at the Bioengineering Unit, we will fit the dynamic backrest system and request monthly follow up

assessment over 6 months. Since every participant is different, the researcher, with child's parent(s), will design appropriate measurements to evaluate the long term effects of using the backrest. The follow up assessments will be tested for significant improvement in functional movement, muscle spasticity and tone, and independent functionality. Each session should take no longer than1 hour. We will also provide parent with a short questionnaire, which should also be completed monthly. The SPCM, the assessment of children's sitting abilities and in prescribing adaptive seating systems (Roxborough, Fife, Story, & Armstrong, 1994), will be completed by the child's physiotherapist at school once a month.



4.6 Potential risks

In the tests that you will be undertaking there are no additional risks that one experiences during daily life such as garb the objects, play the toys. The follow up assessment will be done every month in a six month period, if participant shows tiredness during assessment they will be allowed to rest as long as they wish before restarting the measurement. If fatigue prevents the completion of the session then the participant will be offered a repeat visit.

4.7 Adverse reactions

Participants will be asked to inform the investigator of all adverse events occurring in the period before each study visit. All serious adverse events (SAEs) should be reported to the sponsor as soon as possible.

5. Confidentiality

Each participant will be registered with a unique reference number without any allusion to personal details. Data collected will be named with the reference number and stored in a password protected computer. Access to the data will only be provided to the Chief Investigator and other research staffs. Personal details (name, address, telephone number only) will be kept in paper format along with the relevant trial reference number in a locked filling cabinet in the Bioengineering Unit, University of Strathclyde.

6. Publication Policy

The results of this work will be disseminated through conference presentations and scientific journal publications. Moreover, the researchers will be happy to explain the results of the study to the participants if they so wish.

7. Declaration of interest

This protocol is not associated with any commercial interests and is not in receipt of any government, NHS or commercial research or service delivery funding. Ms Katika Samaneein is undertaking a full time PhD in relation to this trial. Dr Philip Riches is the academic supervisor and Professor Philip Rowe is the second supervisor to the PhD programme.

Parent/Guardian Information Sheet

Name of department: Bioengineering

Title of the study: Effect of a dynamic backrest seating system on a child with CP

Dear Parent or Carer

You are being asked to participate in a study that is being conducted by the University of Strathclyde and is part-funded by James Leckey Design Ltd, the makers of the Mygo seating system. The research has been approved by the University of Strathclyde Ethics Committee.

The objective of this study is to understand the interaction of the Mygo seating system with a child during daily living activities by focusing on the effect of a dynamic backrest on the functional and quality of movement over a long period of time.

You and your child have already been participants in the initial part of this study. I would really appreciate it if you and your child would consider volunteering for this research project again. Before you and your child decide it is important for you to understand why the research is being done and what it would involve. Please read the following information carefully and discuss it with your child and others as appropriate.

The following information sheet hopefully provides a clear explanation of the study including the research aims, benefits and risks and also what participation would mean for you and your child. If there is any aspect of the study which is unclear, which you or your child would like further information on, please contact me or my supervisor who will be happy to answer your questions. My contact details can be found below and my supervisor's details at the end of the information sheet.

Thank you for your time.

Katika
Bioengineering Unit
106 Rottenrow, Wolfson Centre
University of Strathclyde
Glasgow, G4 0NW
07733839343
katika.samaneein@strath.ac.uk

1. What is the purpose of this investigation?

The objective of this study is to understand the interaction of the Mygo seating system with its user during daily living activities, to investigate, over a 6 month period, the effect of a dynamic backrest on your child's muscle tone and movement. Since every child is different, the researcher, with your help, will design an appropriate measurement to evaluate the long term effects of using of the dynamic backrest system.

2. What is the device that is being tested?

We will change only one component of the Mygo. An active gas spring mechanism will be included in the back tube of your child's Mygo seating intended to better dissipate and control the applied forces. The systems permits forward and backward movement as the child moves instead of maintaining the child in the rigid position. This dynamic component will replace the rigid manual backrest adjustment tube.

3. Why have you been invited to take part?

Your child has been invited to take part in this project because your child uses a Mygo seating system and has participated in our previous research. Please do not volunteer if your child has undergone surgery in the last 6 months, or has surgery planned in the next 6 months.

4. Do you have to take part?

Participation in this study is entirely voluntary. You are free to decide whether or not to take part. If you and your child decide to participate, you will be asked to sign a form to confirm that the study was clearly explained to you and your child, and that you and your child agree to take part. You and your child will be free to withdraw at any time, without giving a reason and we will revert your wheelchair to its original configuration. If you and/or your child decide not to take part, or

withdraws from the research, then this will not affect any relationship you and your child has with the University, wheelchair company or NHS.

5. What does taking part involve?

If you are interested and agree to take part in this study, please check in the interested box and/or sign the consent form then return to us by the enclosed stamped return envelope.

If you are interested to take part but you need more details, please check in the interested box and give your contact detail in the tear off form at the end of this document then post to us by the enclosed stamped return envelope. We will contact you to discuss the research further.

If you are not interested to take part in this study, please check in the not interested box in the tear off form at the end of this document then post to us by the enclosed stamped return envelope. Or, alternatively, do nothing and we will not contact you again with regards to this research.

If we receive the consent form, you will be contacted shortly by phone to discuss the project in more detail, to ask you for your child's physiotherapists contact details, and to identify the types of task that will be employed in the laboratory for the child. For example, together we might decide that stability during eating may be an appropriate measure and so the timing of the assessment may be chosen with this in mind. Playing with their favourite toy may be another task.

On the first laboratory day, we will fit the dynamic backrest system to your chair and we would like you to keep it on the chair for 6 months. We will also identify the dates for monthly follow- up assessments. Each assessment session should take no longer than1 hour.

Around the same time as the first laboratory day, we will ask your child's physiotherapist at school to complete an assessment of his/her sitting ability.

6. What will you do in the project?

On the day of the assessment, you and your child will be asked to attend the Bioengineering Unit University of Strathclyde, Glasgow at a specific time of day. (For all journeys to the laboratory, reimbursement of travel expenses will be provided).

During motion analysis sessions, we will attach 4 small light-weight reflective markers on your child's wrists, head and chair backrest using non allergenic double sided tape. This is so the motion capture system (VICON) can track the position of the markers. This is not a video recording system and only the markers are "seen" by the system. Therefore you or your child cannot be identified from the motion capture data. Your child will be asked to play with the toys or do certain daily tasks, such as eating. We will observe the movement using a motion analysis system. You will also be asked to complete 1 page evaluation form to document their experience using the dynamic seating system. The whole data collection will take around 1 hour.

One of your roles is to ensure the happiness of your child in the laboratory. If you feel that they are anxious or distressed and that you wish to stop, for whatever reason, please let me know and we'll stop immediately.

7. What are the potential risks to your children of taking part?

In the tests that the child will be undertaking there are no additional risks to taking part in the study compared to normal everyday activity. If your child is upset by the testing, then we can abandon participation for that day, and either withdraw completely, or postpone the activity day.

In addition, at any time in the 6 months, you can request us to reinstate the rigid backrest, and we will do so at the earliest opportunity.

8. What are the possible benefits of taking part?

There may be no immediate benefit of taking part. The new backrest is intended to improve tone. However, the information collected may result in modifications

being made to the Mygo seating system which may be of benefit to your child and other children in the future. We will publish data from this study enabling all manufacturers, not just the makers of the Mygo system, to better understand the loads imparted on such wheelchairs during daily activity, which should result in better designs ultimately benefitting many children.

9. Will my taking part in the study be kept confidential?

Your child will be given a unique reference number which will be used to code all the data collected. The piece of paper relating your name and address to the code will be kept in a locked filing cabinet in my supervisors' office at the University of Strathclyde. All electronic data will therefore be fully anonymous. The University of Strathclyde is registered with the Information Commissioner's Office who implements the Data Protection Act 1998. The data will be collected and stored in accordance with the Data Protection Act 1998.

The anonymous data will be shared with the funders of this work, James Leckey Design Ltd, and with Westmarc, the West of Scotland Mobility and Rehabilitation Centre. Should you wish, and with your approval, a summary of the results will be shared with your child's physiotherapist.

10. What will happen to the results of the research study?

Summaries of anonymous data and result will be used to improve the design of the Mygo seating system. And the results will be published through peer reviewed scientific journals and conference presentations for academic purposes. If you wish, at the end of the study, we will be very happy to explain the outcome of the research to you.

11. What happens next?

If you and your child are happy to be involved in the study please contact one of us, using the details in the next section. After that I will phone you to discuss the project further.

If you, or your child, do not wish to participate, we thank you for your time and attention. You do not have to do anything else. We may send you a reminder letter in a couple of weeks, just in case you want to take part but didn't find the time to let us know.

12. If your children have any further questions?

If you and your children would like more information about the study and wish to speak to one of us please contact either:

Miss Katika Samaneein
Bioengineering Unit
106 Rottenrow, Wolfson Centre
University of Strathclyde
Glasgow, G4 0NW
07733839343
katika.samaneein@strath.ac.uk

Dr Philip Riches (supervisor)
Bioengineering Unit
106 Rottenrow, Wolfson Centre
University of Strathclyde
Glasgow, G4 0NW
0141 548 5703
philip.riches@strath.ac.uk

If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Secretary to the University Ethics Committee

Research & Knowledge Exchange Services

University of Strathclyde

Graham Hills Building

50 George Street, Glasgow G1 1QE

Telephone: 0141 548 3707

Email: ethics@strath.ac.uk

Thank you for your time and co-operation, please fill the tear off form in next page and reply to us…

Effects of dynamic backrest seating system on a child with CP

☐ *Interested* ☐ *Not Interested*

Your name:

.....

Your child name:

.....

Contact details:

.....

.....

Parent/Guardian Consent Form

Name of department: Bioengineering Unit

Title of the study: Effect of a dynamic backrest seating system on a child with CP

- I confirm that I have read and understood the information sheet for the above project and the researcher has answered any queries to my satisfaction.
- I understand that our participation is voluntary and that we are free to withdraw from the project at any time, without having to give a reason and without any consequences.
- I understand that I can withdraw our data from the study at any time.
- I understand that any information recorded in the investigation will remain confidential and no information that identifies us will be made publicly available.
- I consent to my child being a participant in the project
- I consent to us being audio and video recorded as part of the project Yes/ No

(PRINT NAME)	Hereby agree to take part in the above project
Signature of Participant:	Date

Parent assessment of the new backrest

Subject number _____

Please evaluate the modified chair, dynamic backrest system, by checking the appropriate boxes.

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
With the chair, it is easy to					
Get my child into/out of the chair	☐	☐	☐	☐	☐
Feed	☐	☐	☐	☐	☐
Change	☐	☐	☐	☐	☐
Get on/off transportation	☐	☐	☐	☐	☐
Adjust the seat	☐	☐	☐	☐	☐
Maintain the seat	☐	☐	☐	☐	☐
Manage in general	☐	☐	☐	☐	☐
The chair helps my child to					
Maintain attention	☐	☐	☐	☐	☐
Communicate	☐	☐	☐	☐	☐
Feel secure	☐	☐	☐	☐	☐
Look stable on the chair	☐	☐	☐	☐	☐
Maintain skin condition	☐	☐	☐	☐	☐
My child likes the chair	☐	☐	☐	☐	☐

Any other comments:

Thank you for taking the time to complete this evaluation form.

Physiotherapist information sheet

Name of department: Bioengineering
Title of the study: Effect of a dynamic backrest seating system on a child with CP

You are being asked to take part in a study because Mr and Mrs *XXXX* (name to be inserted) and their child *(NAME)* have indicated that they would like to take part in this research. The participation is to complete the monthly assessment of children's sitting abilities over 6 months. The following pages detail the project which will help you understand why the research is being done and precisely what it will involve.

Who are the researchers?

The Chief Investigator is Katika Samaneein, a PhD student working in the Bioengineering Unit at the University of Strathclyde in Glasgow. The research is part-funded by James Leckey Design Ltd, makers of the Mygo seating system. The study has been granted ethical approval by the University Research Ethics Committee.

What is the Research Project involve?
The objective of this study is to understand the interaction of the Mygo seating system with its user during daily living activities, to investigate the effect of a dynamic backrest on motor function and quality of movement over a long period of time. The child's wheelchair will be fitted with a new dynamic backrest system and we request monthly follow up assessments over a 6 month period.

We need your help in assessing (NAME)'s posture. If you agree to be part of this research, we will ask you to complete a short questionnaire monthly about *(NAME)*'s alignment on the seat. The form (Seated Posture Control Measure scoring form) will be posted to you with a return addressed stamped envelope.

What do you have to do now?

If you agree to participate in this study, please could you sign the consent form in the next section and return to the University research team.

If you have any further questions?

If you would like more information about the study and wish to speak to the research staff please contact:

Miss Katika Samaneein 0773 383 9343 (katika.samaneein@strath.ac.uk)
Dr Philip Riches 0141 548 5703 (philip.riches@strath.ac.uk)

Bioengineering Unit
106 Rottenrow
University of Strathclyde
Glasgow, G4 0NW

If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Secretary to the University Ethics Committee
Research & Knowledge Exchange Services
University of Strathclyde
Graham Hills Building
50 George Street
Glasgow
G1 1QE
Telephone: 0141 548 3707
Email: ethics@strath.ac.uk

Thank you for your time.

Physiotherapist Consent Form

Name of department: **Bioengineering Unit**
Title of the study: **Effect of a dynamic backrest seating system on a child with CP**

- I confirm that I have read and understood the information sheet for the above project and the researcher has answered any queries to my satisfaction.
- I understand that my participation is voluntary and that I am free to withdraw from the project at any time, without having to give a reason and without any consequences.
- I understand that I can withdraw my data from the study at any time.
- I understand that any information recorded in the investigation will remain confidential and no information that identifies me will be made publicly available.
- I consent to being a participant in the project

(PRINT NAME) Hereby agree to take part in the above project

Signature of Participant: Date

SEATED POSTURAL CONTROL MEASURE: ALIGNMENT SECTION JANUARY, 1994

Sunny Hill Health Centre for Children Vancouver, B.C.

Please circle selections NB: Circle twice to score limb items.

Score: Descriptive / Numeric	Severe 1	Moderate 2	Mild 3	Normal 4	Mild 3	Moderate 2	Severe 1	Score
ANTERIOR VIEW								
1. PELVIC OBLIQUITY Line joining ASIS's **relative to horizontal**	≥25°	15-24	5-14	0±4	5-14	15-24	≥25	
	Right Side High				Left Side High			
2. TRUNK LATERAL SHIFT Line joining sternal notch to midpoint between ASIS's **relative to vertical**	≥25	15-24	5-14	0±4	5-14	15-24	≥25	
	Shift to Right				Shift to Left			
3. SHOULDER HEIGHT Line joining shoulders **relative to horizontal**	≥35	20-34	5-19	0±4	5-19	20-34	≥35	
	Right Side High				Left Side High			
4. HEAD LATERAL TILT Line joining outside corner of eyes **relative to horizontal**	≥35	20-34	5-19	0±4	5-19	20-34	≥35	
	Right Lateral Tilt				Left Lateral Tilt			
5. R, 6. L HIP ROTATION Angle of tibia relative to line joining ASIS's	≥35 R L	20-34 R L	5-19 R L	0±4 R L	5-19 R L	20-34 R L	≥35 R L	
	Rotated to Right				Rotated to Left			
RIGHT LATERAL VIEW								
7. PELVIC TILT Line from PSIS along posterior pelvis to seat surface **relative to vertical**	≥25°	15-24	5-14	0±4	5-14	15-24	≥25	
	Posterior Tilt				Anterior Tilt			
8. LUMBAR CURVE L1 - L5								
	Flexed				Extended			
9. THORACIC CURVE T1 - T12								
	Flexed				Extended			
10. TRUNK INCLINATION Line joining posterior surface T1 and median of line joining PSIS's **relative to vertical**	≥35	20-34	5-19	0±4	5-19	20-34	≥ 35	
	Anterior Inclination				Posterior Inclination			
11. HEAD ANT/POST TILT Line joining corner of eye to tragus **relative to horizontal**	≥16°°	1-15°°	14-0°°	15-24	25-39	40-54	≥ 55	
	Anterior Tilt				Posterior Tilt			

SEATED POSTURAL CONTROL MEASURE: ALIGNMENT SECTION JANUARY, 1994

Sunny Hill Health Centre for Children Vancouver, B.C.

Please circle selections NB: Circle twice to score limb items.

Score: Descriptive / Numeric	Severe 1	Moderate 2	Mild 3	Normal 4	Mild 3	Moderate 2	Severe 1	Score
RIGHT & LEFT LATERAL VIEWS								
12. R, 13. L HIP FLEX/EXT Angle relative to 90° flexion			>15° R L	0 ± 15 R L	>15 R L			
			Hip Flexion		Hip Extension			
14. R, 15. L KNEE FLEX/EXT Angle relative to 90° flexion			>45 R L	0 ± 45 R L	>45 R L			
			Knee Flexion		Knee Extension			
16. R, 17. L ANKLE DORSI/PL FLEXION Angle relative to 0 degrees			>30 R L	0 ± 30 R L	>30 R L			
			Ankle Dorsiflexion		Ankle Plantarflexion			
SUPERIOR VIEW								
18. PELVIC ROTATION Line joining ASIS's **relative to plane of the seat back**	≥25	15-24	5-14	0±4	5-14	15-24	≥25	
			Right Side Forward		Left Side Forward			
19. UPPER TRUNK ROTATION Line joining shoulders **relative to frontal plane** of pelvis	≥35	20-34	5-19	0±4	5-19	20-34	≥35	
			Right Side Forward		Left Side Forward			
20. HEAD ROTATION Line joining ears **relative to frontal plane** of upper trunk	≥35	20-34	5-19	0±4	5-19	20-34	≥35	
			Rotation to Right		Rotation to Left			
21. R, 22. L HIP ADD/ABDUCTION Angle of femur in relation to line joining ASIS's	≥35 R L	20-34 R L	5-19 R L	0±4 R L	5-19 R L	20-34 R L	≥35 R L	
			Hip Adduction		Hip Abduction			