ISRCTN12389808 https://doi.org/10.1186/ISRCTN12389808

Effects of different dynamic sitting strategies in wheelchair seating

Submission date
12/11/2016

Recruitment status
No longer recruiting

Registration date
18/11/2016

Overall study status
Completed

Last Edited
20/10/2017

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
For people who are wheelchair bound, lower back pain and pressure ulcers (wounds caused when area of skin is placed under pressure) are a big concern. The way a person sits in the wheelchair, including the position of the buttocks and weight put on the spine has an important role in the development of these problems. The aim of this study is to investigate the effects of different sitting positions on back angles and skin pressure in order to see if there is a way to reduce the risk of lower back pain and pressure ulcers in wheelchair-bound people.

Who can participate?
Healthy adult male or female volunteers aged between 20 and 65 years.

What does the study involve?
The participants perform of the seven different sitting positions in random order by drawing lots. Each test lasts for 20 minutes, with periodic changes at 5-minute intervals. The participants are asked to stand up and move around for 5 minutes between each test. Over each 20 minute test, participants have the angle of their spine and pressure on their skin measured.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
Applied Biomechanics Laboratory, National University of Tainan (Taiwan)

When is the study starting and how long is it expected to run for?
March 2015 to November 2015

Who is funding the study?
Ministry of Science and Technology (Taiwan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
A-ER-103-375

Study information

Scientific Title
Biomechanical effects of different dynamic sitting strategies in wheelchair seating

Study objectives
Lumbar-pelvic angle and interface pressure are influenced by different dynamic sitting strategies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of National Cheng Kung University Hospital, 13/03/2015, ref: A-ER-103-375

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Lower back pain and pressure ulcers

Interventions
The initial settings for the experimental wheelchair forms a 100° angle between the backrest and seat cushion, and a 120° angle between the seat cushion and footrest. The seat cushion is adjusted to allow a gap between the cushion and popliteal fossa. When the participants are seated in the experimental wheelchair, they are asked to rest their upper body against the backrest, relax their arms and place them at their sides, try to keep their thighs parallel to the ground, place their feet firmly on top of the footrest at shoulder width, and look directly ahead. Next, they perform each of the 7 DSSs in random order by drawing lots:

1. Lumbar prominent dynamic sitting (LPDS): The lumbar adjustment module is positioned at L3 of participant, and the air bag provides dynamic adjustment by deflating to 0 cm and inflating to 4 cm at periodic intervals.
2. Back reclined dynamic sitting (BRDS): Upper body contact is maintained with the backrest in the experimental wheelchair, and the backrest tilt mechanism provides dynamic adjustment by tilting backward and forward between 100° and 150° at periodic intervals.
3. Femur upward dynamic sitting (FUDS): The femur adjustment module is positioned at the midpoint of the participant's femur, and the air bag provides dynamic adjustment by deflating to 0 cm and inflating to 4 cm at periodic intervals.
4. Lumbar prominent with back reclined dynamic sitting (LBDS): This combines the LPDS and BRDS settings.
5. Lumbar prominent with femur upward dynamic sitting (LFDS): This combines the LPDS and FUDS settings.
6. Back reclined with femur upward dynamic sitting (BFDS): This combines the BRDS and FUDS settings.
7. Lumbar prominent with back reclined with femur upward dynamic sitting (LBFDS): This combines the LPDS, BRDS, and FUDS settings.

Each DSS test lasts for 20 minutes, with periodic changes at 5-minute intervals. The participants are asked to stand up and move around for 5 minutes between each DSS test. Data on lumbar-pelvic angle were collected by the ultrasound-based motion analysis system (CMS20S Measuring

System; zebris Medical GmbH, Isny im Allgäu, Germany), and the data on interface pressure were collected by the pressure-mapping mats (Body Pressure Measurement System; Tekscan Inc, South Boston, Massachusetts, USA).

Intervention Type
Device

Primary outcome measure
Lumbar-pelvic angle is measured using the ultrasound-based motion analysis system over the 20 minutes of each DDS

Secondary outcome measures
Interface pressure is measured using the pressure-mapping mats over the 20 minutes of each DDS

Overall study start date
13/03/2015

Completion date
30/11/2015

Eligibility

Key inclusion criteria
1. Age 20-65 years
2. Able-bodied

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Spinal pathology
2. Musculoskeletal disorder
3. Those who have sought medical treatment for lumbar pain within the previous 6 months

Date of first enrolment
11/05/2015

Date of final enrolment
15/07/2015

Locations

Countries of recruitment
Taiwan

Study participating centre
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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Ministry of Science and Technology, Taiwan

Alternative Name(s)
Ministry of Science and Technology, R.O.C. (Taiwan), Ministry of Science and Technology of Taiwan, MOST

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Taiwan

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/11/2017

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/12/2016		Yes	No