Title: A study of the comfort of patients with lower limb injury using the AlterG Antigravity Treadmill©

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Acknowledgement

We would like to thank everyone who helped and supported us during this research project.

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Boutersem, 06/06/2017 N.D.

Hasselt, 06/06/2017 M.L.

Research context

This study is situated in the domain of musculoskeletal rehabilitation. This project is part of the master program and was written to obtain the degree of master in Rehabilitation Sciences and Physiotherapy at the University of Hasselt. Last year a literature search was performed to investigate the currently available techniques to train in altered gravity. Besides, the effects of altered gravity on the internal structures of the knee were investigated. This year a study was conducted to investigate the experience of patients with lower limb pathology using the AlterG Antigravity Treadmill© during their rehabilitation.

Research showed that the AlterG Antigravity Treadmill© is an effective device in the rehabilitation of lower limb injuries such as pelvic stress injuries, lower limb stress fractures, anterior cruciate ligament repair, total knee replacement, achilles tendon repair, etc. [1-5] Lower body positive pressure unweighting can help to decrease pain and swelling in the early stages of recovery. Hip, knee and ankle range of motion can be enhanced by encouraging active range of motion. [6] Although research showed that there is a positive impact of training in altered gravity when recovering from a knee injury, no data are available of the experience of patients with lower limb injury using the AlterG Antigravity Treadmill©. It is very important to reassure that patients experience no discomfort and no pain. Besides, it is important that patients feel safe and stable while using the device in order to create an optimal rehabilitation setting. The data gathered during this study can help physicians that are using the AlterG Antigravity Treadmill© to optimize the use of the device in a rehabilitation program and possible improvements can be highlighted.

This study was set up by two students (Nina Debecker and Mérithe Luyten). The research method and study design were determined by the students and approved by the promotor (Prof. Dr. Johan Bellemans). Recruitment of participants was done in cooperation with the hospital of Sint-Truiden, practice Callewaert-Wemel and practice Peter Laus. Data-acquisition and data processing were done by the students. The academic writing process was executed by the two students.

A study of the comfort of patients with lower limb injury using the AlterG Antigravity Treadmill©

A descriptive survey

Hasselt, 2017

Content

1 Abstract

Background: The AlterG Antigravity Treadmill© is an important tool in the rehabilitation of lower limb injuries but only little is known about the experience of the patients using this device during their rehabilitation. In order to provide the best possible care for the patient it is important to get insight into the experience of a patient training with the AlterG Antigravity Treadmill©.

Objectives: The main purpose of this study was to examine whether patients experience discomfort, pain or other unpleasant sensations while training with the AlterG Antigravity Treadmill©.

Methods and participants: Twenty patients with lower limb injury rehabilitating with the AlterG Antigravity Treadmill© were included. Patients completed three questionnaires after a training on the AlterG Antigravity Treadmill©. Questionnaire 1 was a self-compounded questionnaire, questionnaire 2 measured the localized musculoskeletal discomfort and questionnaire 3 was the BORG-scale.

Results: The overall average score, representing the overall experience of the patient, was calculated by 15 variables of questionnaire 1. The score was 7.79 on a scale of 10. No significant difference was found in pain after training when compared to pain before training. No significant difference was found when comparing knee injuries with ankle injuries, men with women, different age categories and patients with a different duration of rehabilitation. When comparing the mean scores in discomfort of different zones of the body, it was seen that the lower extremities had the highest score followed by the trunk and upper extremities.

Discussion and conclusion: Patients feel safe and comfortable while using the AlterG Antigravity Treadmill©. The patients had an overall positive experience while using the device and the rate of perceived exertion was fairly light. The device was found to be suitable for different age categories, for men and women and for patients with a different rehabilitation duration. The AlterG Antigravity Treadmill© seems to be an appropriate device to use in the rehabilitation of lower limb injury.

Key words: AlterG Antigravity Treadmill©, experience, discomfort, lower limb injury, survey

2 Introduction

The lower extremity, as it is described by the MeSH-term, is the region of the lower limb extending from the gluteal region to the foot, including the buttocks, hip and leg. [7] Injury or surgery of the lower extremity could lead to inflammation, this is a biological response that is often seen. Chronic inflammation and pain can cause stiffness of the joints. This could lead to arthrofibrosis, which limits the range of motion (ROM) and weakens the muscular system. Eventually, this can lead to anomalies in gait and functionality, extending the normal healing time. [6] To prevent a delayed recovery it is important to start the rehabilitation program as soon as possible. By unweighting an individual, pain can be modified and healing tissues are protected. [6]

In 2016 a literature study has been carried out to investigate the effect of reduced impact loading (antigravity training) in the rehabilitation after meniscal or chondral injury at the knee joint. In contrast to this subject little is known about the experience of the patient with a lower limb injury using the AlterG Antigravity Treadmill© (fig. 1).

Figure 1. AlterG Antigravity Treadmill©

One of the aspects that was investigated was the degree of discomfort experienced by the patient while training with the AlterG Antigravity Treadmill©. Comfort is a very complex and difficult term. It seems to compromise thermal and non-thermal factors. Following Slater (1985) and Hatch (1993), comfort expresses a physiological, neurophysiological, psychological and physical equilibrium between the person and its surroundings. Comfort is being pain free and experiencing no discomfort, which is described as a neutral state. On the

other hand discomfort can be seen as tingling, prickling, hot and cold. Important to understand is that comfort is built on a subject's perception that includes visual, thermal and tactile sensations as well as psychological processes, body apparel interaction and effects from the external environment. [8]

In this study the physiological aspect of comfort is topic of interest. The body has to attain a thermal equilibrium at normal body temperature, the normal internal body temperature of humans is 37°C. Within this equilibrium there has to be a minimal amount of bodily regulation. [8]

Following Pontrelli (1977) variables that influence comfort status could be listed and classified into three groups, named Comfort's Gestalt. These three groups include physical variables of the environment and the clothing, psycho-physiological parameters of the wearer and physiological filters of the brain. Important to notice is that this is a subjective perception. [8] There are three aspects of comfort in clothing, namely: thermal comfort, sensorial comfort and body movement comfort. In athletic clothing important characteristics are thermal retention, cooling capacity, sweat absorption, rapid drying and antibacterial properties. [9] These characteristics are also important to investigate in the AlterG Antigravity Treadmill© shorts (fig. 2), because these factors could contribute to discomfort experienced by the patient. Further research has to be carried out to be able to improve the design of these shorts.

Figure 2. AlterG Antigravity Treadmill© Shorts

The primary aim of this study was to investigate the experience of the patients with a lower limb injury using the AlterG Antigravity Treadmill© during their rehabilitation program. Several variables such as degree of discomfort, pain, overall experience, stability, safety, hygiene and rate of perceived exertion (BORG-score) were administered in order to get a complete image of the experience of the patient while training with the device. After analyzing the results it can be derived whether the device is useful and practical to use in the rehabilitation of lower limb injuries.

3 Methods

3.1 Participants

3.1.1 Recruitment and patients

Participants were recruited at the department outpatient rehabilitation in the St-Trudo hospital (Sint-Truiden, Belgium). Participants were also recruited in practices Callewaert-Wemel (Waregem, Belgium) and Peter Laus (Halle, Belgium). A total of twenty participants was included (fig. 3). Participants were interviewed in March 2017 and April 2017. Before participating participants read and signed an informed consent. Participation in the study was voluntary.

3.1.2 Inclusion criteria

- Lower limb pathology
- Subjects using the AlterG Antigravity Treadmill© during physical therapy

3.1.3 Exclusion criteria

- Subjects not using the AlterG Antigravity Treadmill© during physical therapy
- Subjects with a neurological condition
- Polytrauma patients

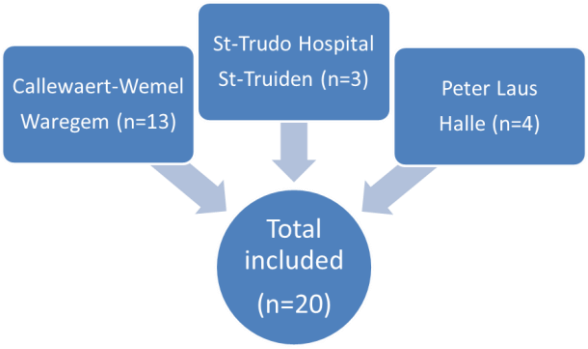

Figure 3. Flow chart

3.2 Procedure

3.2.1 Set-up and approval

In consultation with the promotor it was decided to search for an AlterG Antigravity Treadmill© available for testing. After some research the St-Trudo Hospital was contacted. In October 2016 the first meeting with the physiotherapists of the Department of Orthopedic

Rehabilitation took place. Afterwards, it was decided to test on two additional locations, the practice Callewaert-Wemel in Waregem and the practice of Peter Laus in Halle.

Request for approval of the study was sent to the committee of ethics of the University of Hasselt, Hospital Zuid-Oost-Limburg in Genk and the St-Trudo Hospital in Sint-Truiden. The ethics committees approved the study, number 17/005U, on march 17th 2017.

For the St-Trudo hospital it was decided which patients could participate and when the survey could take place in consultation with the physiotherapists of the Department Orthopedic Rehabilitation. For the independent practices the researchers discussed the study design, the questionnaires and the inclusion criteria with the physiotherapists. The patient recruitment was done by the physiotherapists of the practices.

3.2.2 Intervention

After the patient's oral agreement to participate in the study, the patient completed a treatment under supervision of the physiotherapist of the hospital or the independent practice. During this treatment the researchers did not intervene.

The patients were asked to read and sign an informed consent after the treatment. This paper contained information about the study design, what the patients could expect and what was expected from the patient, as well as the rights and obligations of the patient.

The questionnaires were administered after signing the informed consent. The questionnaires administered in the St-Trudo Hospital were completed in cooperation with the researchers. The researchers were present to prevent misinterpretation of the questions and to provide help when the patients had additional questions. The questionnaires administered in the independent practices were completed in cooperation with one of the physiotherapists.

3.2.3 Outcome measures and questionnaires

The aim of this study was to determine the overall experience of a patient using the AlterG Antigravity Treadmill© in the rehabilitation after lower limb injury. In order to be able to give an answer to this question it was investigated whether a patient with lower limb injury experienced any discomfort, pain or unpleasant sensations while training with the AlterG Antigravity Treadmill©. It was decided to use a self-compounded questionnaire, the BORG-

scale and the questionnaire for measurement of localized musculoskeletal discomfort. The questionnaires were set up in Dutch to increase the understanding of terminology for the patient.

Questionnaire 1 (appendix 1) – Self-compounded questionnaire

The first questionnaire is a self-compounded questionnaire. The questionnaire can be divided into two main parts: general information and the experience of the patient using the AlterG Antigravity Treadmill©.

The first part contains questions concerning general information about the patient. This information is important in order to understand the background of the patient and the injury. This part contains questions about:

- Gender
- Date of birth
- Body weight (kg)
- Body length (m)
- Detailed information considering disease/injury/surgery
- Start of rehabilitation (date)
- Previous experience with the AlterG Antigravity Treadmill©
- Level of physical activity before the injury/disease/surgery

The second part of the questionnaire contains questions concerning the experience of the patient while using the AlterG Antigravity Treadmill©. These questions should provide insight into:

- Pain
- Overall experience while running on the AlterG Antigravity Treadmill©
- Feelings of discomfort
- Feelings of impediment
- Experience regarding hygiene
- Experience regarding safety feeling
- Experience regarding accessibility

While analyzing the data of the self-compounded questionnaire it was noticed that the scoring system differed for several questions. More specifically, in some questions a score of zero represented the best option possible, whereas in other questions a score of zero represented the worst option possible. In order to perform a correct and reliable analysis, the scores were all equalized in a way that zero always meant the worst option possible (pain, discomfort, hindrance, etc.) and ten always meant the best option possible (no pain, no discomfort, no hindrance, etc.).

Questionnaire 2 (appendix 2) - Measurement of localized musculoskeletal discomfort

The second questionnaire, named measurement of localized musculoskeletal discomfort, aims to discover local musculoskeletal discomfort. [10] In this questionnaire discomfort is described as tension, fatigue, soreness, heat, tremor, pressure, feelings of effort etc. The discomfort can be muscular or non-muscular. The discomfort can be experienced for a short period or for a longer period of time. It can decrease, increase or stay the same.

The amount of discomfort is measured using a rating scale. This scale ranges from zero to ten, where a score zero presents no discomfort at all and a score of ten presents the maximal amount of discomfort. A body map, divided into different zones, is used to localize the discomfort.

Questionnaire 3 (appendix 3) – BORG-scale

The third questionnaire, named the BORG RPE-scale (Ratings of Perceived Exertion), is a subjective scale to measure the amount of load the patient experiences. This scale measures the degree of effort, load and fatigue using a scale from six to twenty. The highest possible score (twenty) means maximum perceived exertion and the lowest score (six) means very light perceived exertion. Except from a series of numbers, the scale consists of a short description accompanying the odd numbers. De description is short and concise. This way the objective score can be matched with a subjective perception of the amount of load.

3.3 Data-analysis

Data were analyzed using Microsoft Office Excel 2007 (Excel) and IBM SPSS Statistics 22 (SPSS).

3.3.1 Group characteristics

Mean values and confidence intervals were calculated by SPSS.

3.3.2 Normality and homoscedasticity

The Shapiro-Wilk test was carried out to examine normality. This test was chosen above the Kolmogorov-Smirnov because the sample contained less than fifty subjects. [11] The Levene's test was carried out to examine homoscedasticity. Both assumptions, normality and homoscedasticity, need to be met in order to carry out reliable parametric testing. As the obtained data did not show normality or homoscedasticity, non-parametric testing was carried out. When data are measured on a nominal or ordinal scale non-parametric testing is often chosen for statistical analysis. Non-parametric testing can provide an objective mechanism to support statistical hypotheses in case of using these levels of variables. [12]

3.3.3 Grouping of the variables

To make the statistical analysis easier it was decided to divide following variables into groups: age, body mass index (BMI) and duration of rehabilitation.

3.3.4 Correlation analysis

The dataset included many different variables making the statistical analysis difficult. A correlation analysis was carried out to see if there was any correlation between the variables. Two tests to perform this correlation analysis are the Pearson's Product-Moment Correlation Coefficient or the Spearman's Rank-Order Correlation Coefficient. The Pearson's Correlation is developed to test continuous data and the data have to be normally distributed. The Spearman's Correlation is the non-parametric analogue and can be used in ordinal data that are not normally distributed. [13, 14] Because the data in this research were not normally distributed the Spearman's test was carried out. To assess whether a correlation is high or low, the intervals presented in table 1 were used. [13] When a high or very high positive correlation was found one variable of the two variables is omitted. It can be assumed that these two variables act the same so there is no need to do statistical analysis on the second variable.

Table 1. Interpreting the size of the Correlation Coefficient	
Size of the correlation	**Interpretation**
0.90 to 1.00 (-0.90 to -1.00)	Very high positive (negative) correlation
0.70 to 0.90 (-0.70 to -0.90)	High positive (negative) correlation
0.50 to 0.70 (-0.50 to -0.70)	Moderate positive (negative) correlation
0.30 to 0.50 (-0.30 to -0.50)	Low positive (negative) correlation
0.0 to 0.30 (0.00 to -0.30)	Negligible correlation

3.3.5 Statistical analysis

To assess patient's overall experience fifteen variables of questionnaire one were investigated. Means were calculated through SPSS.

Four different tests were used for statistical testing of the expected differences. An overview of the tests that were used can be found in table 2. A p-value less than 0.05 was used as a cut-off value. The paired sample t-test was used to test for a difference in score in one subject, so that subjects are compared only with themselves. [15] Before performing a paired sample t-test normal distribution of the residuals has to be fulfilled. The Mann-Whitney U test is a non-parametric test for two independent samples. When performing this test the groups do not need to have the same sample sizes. [16] When more than two groups were compared the Kruskall-Wallis test was used. This is a non parametric test that can be used for ordinal data. [17] Spearman's Rank-Order Correlation Coefficient was used to investigate if there was a correlation between two variables. [14] To investigate which region of the body experienced the most discomfort mean values per region were calculated through Excel.

Table 2. Statistical analysis			
Hypothesis question	**Variables**	**Test**	**Upper limit of p-value**
Is $pain_{before}$ the training higher than $pain_{after}$the training?	$Pain_{before}$ the training $Pain_{after}$ the training	Paired sample t-test	$p<0.05$
Is discomfort of patients with knee pathology higher than discomfort of patients with ankle pathology?	Discomfort knee pathology Discomfort ankle pathology	Mann-Whitney U test	$p<0.05$
Is there a difference in score for hygiene between men and women?	Hygiene men Hygiene women	Mann-Whitney U test	$p<0.05$
Is there a difference in score for discomfort between men and women?	Discomfort men Discomfort women	Mann-Whitney U test	$p<0.05$

Is there a difference in score for $pain_{after}$ the training between men and woman?	$Pain_{after}$ the training men $Pain_{after}$ the training women	Mann-Whitney U test	p<0.05
Is there a difference in the score for hygiene between different age groups?	Age groups Hygiene	Kruskall-Wallis test	p<0.05
Is there a difference in the score for discomfort between different age groups?	Age groups Discomfort	Kruskall-Wallis test	p<0.05
Is there a difference in score for $pain_{after}$ the training in different age groups?	Age groups $Pain_{after}$ the training	Kruskall-Wallis test	p<0.05
Is there a difference in the score for rate of perceived exertion between different age groups?	Age groups Rate of perceived exertion (BORG-score)	Kruskall-Wallis test	p<0.05
Is there a difference in the score for discomfort between different groups with a different rehabilitation duration?	Rehabilitation duration groups Discomfort	Kruskall-Wallis test	p<0.05
Is there a difference in the score for $pain_{after}$ the training between different groups with a different rehabilitation duration?	Rehabilitation duration groups $Pain_{after}$ the training	Kruskall-Wallis test	p<0.05
Is perceived exertion correlated with BMI?	Rate of perceived exertion BMI	Spearman's rank-order correlation coefficient	p<0.05*
* Correlation Coefficient >0.70 was considered as a good correlation between to variables.			

4 Results

4.1 Group characteristics

The group characteristics of the subjects participating in the study are presented in table 3.

Table 3. Group characteristics				
Variable	**Mean**	**Confidence Interval**	**Minimum**	**Maximum**
Gender (females, %)	8 (40%)	/	/	/
Age (yr)	33.1	[24.8-41.4]	16	74
BMI (kg/m²)	24.85	[22.78-26.91]	19	33
Duration of the rehabilitation (months)	11.5	[3.0-20.0]	2	73

4.2 Grouping of the variables

Age

Age was divided into four groups as seen in table 4. [18]

Table 4. Age groups	
	Age
Group 0	15 – 24 years
Group 1	25 – 44 years
Group 2	45 – 64 years
Group 3	≥65 years

BMI

BMI was divided into three groups following guidelines of the World Health Organization. Normally the classification of BMI exists of six groups, but none of the participants had a BMI lower than 18.5 or higher than 34.9 so these groups were not described. The BMI groups are presented in table 5.

Table 5. BMI groups	
	BMI
Group 0	18.5 – 24.9 (normal)
Group 1	25 – 29.9 (pre-obese)
Group 2	30 – 34.9 (obese class 1)

Duration of rehabilitation

Duration of rehabilitation was divided into five groups as seen in table 6.

Table 6. Duration rehabilitation groups	
	Duration rehabilitation
Group 0	0 – 3 months
Group 1	4 – 6 months
Group 2	7 – 9 months
Group 3	10 – 12 months
Group 4	>12 months

4.3 Correlation analysis

Since the large number of variables a correlation analysis using the Spearman's rank-order correlation coefficient was performed. After this correlation analysis a reduction in variables was done. For large sample sizes the reduction can be done by performing a principal component analysis (PCA). Since the minimal sample size to perform a reliable PCA is fifty subjects, and this study only includes twenty subjects, a PCA cannot be done. [19]

The other method to reduce the number of variables is to look at the correlation between two or more variables. When the variables have a very high or high correlation, one of the variables can be chosen for further statistical analysis. Because of the correlation between the two variables, results of the further statistical analysis can be applied to both variables. Correlations found using Spearman's Rank-order Correlation Coefficient are presented in table 7.

Table 7. Correlations between variables		
Correlation	**Variables**	**Correlation coefficient**
Very high positive correlation	$Pain_{during}$ the training $Pain_{after}$ the training	0.93*
Very high positive correlation	Itchy shorts Itchy trunk	0.94*
High positive correlation	Comfort of the shorts Material of the shorts	0.80*
High positive correlation	Tightness of the trunk Tightness of the lower body	0.78*
High positive correlation	Normal muscle tone LB Normal muscle tone UB	0.75*
High positive correlation	Irritation of the skin Itchy shorts	0.77*
High positive correlation	Irritation of the skin Itchy trunk	0.83*

High positive correlation	Pleasant experience Worth repeating	0.75*
High positive correlation	Normal walking pattern Safety	0.75*
High positive correlation	Pleasant experience Normal muscle tone LB	0.71*
High positive correlation	Pleasant experience Normal muscle tone UB	0.79*
High positive correlation	Pleasant experience Tightness trunk	0.71*
High positive correlation	Pleasant experience Tightness LB	0.75*
High positive correlation	Pleasant experience Light feeling during walking	0.72*
High positive correlation	Normal muscle tone LB Tightness UB	0.80*
High positive correlation	Normal muscle tone LB Light feeling during walking	0.79*
High positive correlation	Normal muscle tone UB Light feeling during walking	0.73 *
High positive correlation	Normal walking pattern Itch at shorts	0.70*
High positive correlation	Normal movement UB Tightness trunk	0.70*
*p-value <0.01		
LB=lower body, UB=upper body, BMI=body mass index		

After the correlation analysis it was decided to leave following variables out for further statistical analysis: material of the shorts, normal muscle tone of the upper body, normal muscle tone of the lower body, itchy trunk, worth repeating, tightness of the trunk, heavy feeling during walking and irritation of the skin.

4.4 Statistical analysis

4.4.1 Questionnaires

The variables used in the statistical analysis are presented in table 8.

Table 8. Questionnaires	
Variable	**Question**
Overall experience	This is an average score of 15 variables that were questioned in questionnaire 1 (see appendix 1)*. This gives a general view of the experience of the patient using the AlterG Antigravity Treadmill©. Scores range from 0 to 10**.
BORG-score	Indicate how heavy the physical effort was during the training. The score ranges from 6 (very very light perceived exertion) to 20 (maximum perceived exertion).

Lokalized musculoskeletal discomfort	On the figure below you see a body that is divided in different areas. Please give a score from 0 to 10 to describe the amount of discomfort you experienced, per area, during the training with the AlterG Antigravity Treadmill©. A score of 0 means no discomfort at all, a score of 10 means extreme discomfort.
* Variables used for calculation of overall experience are: pain after training, stability, comfort of the pants, warm or cold feeling, normal walking pattern, pleasant experience, exhausting, itch at shorts, tightness upper body, tightness lower body, discomfort, impediment, hygiene, safety, accessibility.	
** For statistical analysis the scores on these questions are equalized with the other questions, as explained in the methods (procedure).	

4.4.2 Patient experience

Overall experience

The mean value of the overall score, including 15 variables of questionnaire 1 (see appendix 1), was 7.79 on a 10-point scale. Results are presented in table 9.

BORG-score

Results are presented in table 9.

Table 9. Patient experience

Variable	Mean	Confidence Interval	Minimum	Maximum
Pain before training	7.65 (*)	[6.81-8.49]	3	10
Pain after training	7.58 (*)	[6.53-8.62]	4	10
Stability	7.89 (*)	[6.96-8.83]	3	10
Comfort of the shorts	6.68 (*)	[5.64-7.73]	2	10
Warm or cold feeling	7.11 (*)	[5.77-8.44]	0	10
Normal walking pattern	6.95 (*)	[5.76-8.13]	1	10
Pleasant experience	7.84 (*)	[6.68-9.00]	0	10
Exhausting	5.26 (*)	[3.88-6.64]	0	10
Itchy shorts	8.47 (*)	[7.23-9.72]	0	10
Tightness upper body	8.47 (*)	[7.34-9.60]	2	10
Tightness lower body	8.58 (*)	[7.35-9.81]	0	10
Discomfort	8.05 (*)	[6.74-9.36]	3	10
Impedement	9.63 (*)	[9.17-10.09]	6	10
Hygiene	6.63 (*)	[5.52-7.75]	2	10
Safety	9.16 (*)	[8.72-9.59]	7	10
Accessibility	8.53 (*)	[7.98-9.07]	6	10
BORG-score	10.60 (**)	[9.47-11.73]	7	16
(*) On a 10-point scale				
(**) On a scale ranging from 6 to 20				

Lokalized musculoskeletal discomfort

When comparing the mean scores of different zones of the body map, it was seen that lower extremities received the highest scores, with a mean value of 2/10. This is followed by the trunk, with a mean value of 1/10. Whereas upper body/neck/upper extremities received a mean value of 0/10.

4.4.3 Expected differences

Results of statistical analysis are presented in table 10 and 11. Statistical tests that were used for this statistical analysis are described in table 2. No significant difference was found between $pain_{before}$ training and $pain_{after}$ training (p=0.69). No significant difference was found for discomfort when comparing knee pathology to ankle pathology (p=0.16). Furthermore no significant difference was found between men and women for the following variables: hygiene (p=0.37), discomfort (p=0.62) and $pain_{after}$ training (p=0.37). Also between different age categories no significant difference was found for the following variables: hygiene (p=0.82), discomfort (p=0.30), $pain_{after}$ training (p=0.42) and rate of perceived exertion (BORG-score) (p=0.59). No significant difference was found between groups with a different duration of rehabilitation for the following variables: discomfort (p=0.35) and $pain_{after}$ training (p=0.86). The correlation between BMI and BORG-score was not significant (p=0.53).

Table 10. p-values part 1

	Between men and women	Between different age-groups	Between different rehabilitation-duration
Hygiene	0.37*	0.82	/
Discomfort	0.62*	0.30	0.35
$Pain_{after}$ training	0.37*	0.42	0.86
BORG-score	/	0.59	/
* two-tailed			

Table 11. p-values part 2

Variables	p-value
Pain before training – pain after training	0.69*
Knee pathology – ankle pathology	0.16*
Correlation BMI – BORG-score	0.53
* two-tailed	

5 Discussion

5.1 Observations

Three different questionnaires were used to measure the experience of patients using the AlterG Antigravity Treadmill© in the rehabilitation after lower limb injury and to get insight in the discomfort experienced by the patient.

These questionnaires contained a lot of different questions, which resulted in a lot of different variables, so it was decided to perform a correlation analysis using the Spearman's Rank-order Correlation Coefficient. Using the results of the correlation analysis, it was evaluated which variables should be used to perform the statistical analysis of the hypothesis research questions.

The mean value of the overall score, including fifteen variables of questionnaire one, was 7.79 on a 10-point scale. This indicates that patients have an overall positive experience while training with the AlterG Antigravity Treadmill©. This is also demonstrated by the fact that every patient would recommend the device to other patients and that every patient thinks the device is practical to use, as seen in the results of questionnaire one.

However, there were two variables with a slightly lower average score. These variables are both linked with the AlterG Antigravity Treadmill© shorts, namely comfort of the shorts and hygiene. All the remarks made considering hygiene and comfort were about the shorts. The most common remarks were that the shorts sometimes smelled sweaty and took up a lot of sweat during training. The shorts were also described as moistly, tight and warm. Another disadvantage reported was the fact that the shorts are often used by more than one patient per day. It needs to be noticed that this recurring complaint is dependent of the facility where the questionnaires were administered. In one independent practice, where the patient always received freshly washed shorts, it was seen that none of the patients had remarks about the hygiene.

The mean value of the variable 'exhausting', measured with question four in questionnaire one, showed an average level of exhaustion with a score of 5.26 on a scale of ten. This was mainly in line with the average score found for the BORG-score, with a score of 10.6 on a scale from six untill twenty. This score is described as 'fairly light'. It can be suggested that

the patients participating in this study experienced a training with the AlterG Antigravity Treadmill© as light to moderate intense.

The questionnaire for measurement of localized musculoskeletal discomfort was used to measure discomfort in different areas of the body. It was seen that the lower limbs received the highest score for discomfort. This is probably associated with the fact that all the patients suffered from lower limb injury. Several patients indicated that they scored higher for these zones because of their injury and not necessarily because of discomfort caused by the device. The upper body and upper extremities received the second highest scores. This can be declared by the fact that several patients used their arms to take some extra support while running, causing muscle tension. The neck and trunk received the lowest score, with a mean score of zero on a scale of ten, indicating no discomfort at all.

The numeric rating scale was used for measuring pain. The patient was asked to score the pain on a scale from zero to ten, wherein zero represented no pain at all and ten represented the worst pain possible. [20] This is a validated and reliable measuring instrument for measuring pain. [21] Results showed that there is no significant difference in $pain_{before}$ and $pain_{after}$ the training.

The BORG-score was used to determine the rate of perceived exertion, this is a validated and standardized measuring instrument for measuring fatigue. [22] No significant correlation was found between BMI and BORG-score. This could indicate that patients with a higher BMI do not necessarily score higher on perceived effort. This is important for rehabilitation purposes because it could mean that the AlterG Antigravity Treadmill© is suited for patients with normal weight as well as for pre-obese and obese patients.

It might be possible that the device is equally suitable for knee pathology and ankle pathology, since no significant difference was found in scores for the questions considering discomfort. Future investigation needs to be done to compare the comfort of using the AlterG Antigravity Treadmill© for other types of pathology.

The suitability of the AlterG Antigravity Treadmill© for men and women was compared. No significant difference was found for the variables hygiene, discomfort and $pain_{after}$ training. It

was decided to test these three parameters because it was thought that these could be different between men and women.

The device was used for every age category. No significant difference was found for the variables hygiene, discomfort and $pain_{after}$ training between different age groups. Also for the BORG-score no significant difference between different age categories was found.

No significant difference was found for the variables discomfort and $pain_{after}$ training in groups with a different rehabilitation duration. It was expected that there would be less discomfort and less $pain_{after}$ training for patients with a longer rehabilitation duration. It was seen that the scores for $pain_{after}$ training and discomfort for the different groups were similar, so it can be suggested that the device can also be used in the beginning of the rehabilitation.

This was the first study that investigated the experience of patients training on the AlterG Antigravity Treadmill© . Therefore the results of this study cannot be compared to any other research.

5.2 Strengths and limitations

This study has some limitations that need to be discussed. First of all, when questionnaires were completed in the independent practices ´Callewaert-Wemel' and 'Peter Laus' the researchers were not present. The questionnaires were conducted by the therapists treating the patient. This could mean that certain questions were misinterpreted. Besides, it was noticed that in some questionnaires in the independent practices a few questions remained unanswered. This in comparison to questionnaires that were conducted by the researchers where all the questions were answered.

Secondly, an important fact that needs to be discussed is the recall bias. Possibly the participants could not completely or accurately answer the questions about the past.

Another weakness in this study can be the fact that a self-compounded questionnaire was used. This questionnaire has not been validated nor tested for reliability yet.

With only twenty patients participating in the study, the sample size of this study is too small. This means that interpretation of the results needs to be done with caution. The sample size should be larger to be able to make profound conclusions.

Besides, it is important to notice that there was a difference in patient population between the independent practices and the hospital. In the hospital the patients mainly walked on the AlterG Antigravity Treadmill© whereas in the private practices the patients more often ran. This could possibly have had an influence on answers because when patients ran at a higher speed it could be possible that the patients produced more sweat and experienced more external forces. Although it is difficult to make a profound conclusion considering this aspect because only three out of twenty patients were rehabilitating in the hospital. Besides, the treadmill speed and percentage of body weight support used during the training session is not known, making it difficult to compare. Knowledge of treadmill speed and percentage of body weight is important because these parameters could have influenced the answers.

Because discomfort is a subjective feeling it is difficult to measure a certain amount of comfort or discomfort. The researchers set up some criteria for measuring this variable themselves but also used validated and reliable scales such as the measurement of localized musculoskeletal discomfort and the BORG-scale. Still the results need to be interpreted with care because of the subjectivity in the scores. Another weakness accompanying the fact that comfort is a subjective feeling, is the fact that the researchers used self-determined cut-off values for evaluation of the average scores. It was decided that a score above seven on a scale of ten indicated a good score.

In questionnaire one the scoring system was different for several questions. As mentioned above in the method section, a score of zero indicated the best option possible in some questions and the worst option possible in other questions. This was possibly confusing for the patient. In the statistical analysis this difference was solved by equalizing the questions and scores. Although it would have been better to use the same scoring system for each question.

Regarding these limitations it is important to know that the results of this study should be interpreted with caution.

A strength of this study is that the self-compounded questionnaire offered a lot of information because a lot of different variables were used. It is also important to notice that for some questions all the patients answered similar or in the same direction. This indicates that, despite the small sample size, some questions could be applied to a bigger population

of patients training with the AlterG Antigravity Treadmill©. Another strength of the study is the fact that the patients were able to give extra remarks and that open questions provided some extra and useful information.

5.3 Recommendations

The difference in use of the AlterG Antigravity Treadmill© in hospitals compared to private practices should be investigated. This allows us to determine whether private practices or hospitals could have more benefit using the device.

It was noticed that hygiene and comfort of the AlterG Antigravity Treadmill© shorts could be a problem for some patients. Remarks were made considering the hygiene (sweaty, moistly, warm) of the shorts because these were used by different patients a day. A possible solution could be that each patient training with the AlterG Antigravity Treadmill© has its own shorts during the time of their rehabilitation. The patient could pay a warranty as long as they use the AlterG Antigravity Treadmill© during their rehabilitation. Afterwards the shorts can be returned and the warranty is given back to the patient. This way the problem of moderate hygiene can be solved. On the other hand the AlterG Antigravity Treadmill© shorts have a cost price of 85-95 dollars/short making this a very big investment for a smaller practice.

There is a need for guidelines regarding the time the patient should train with the AlterG Antigravity Treadmill© and how often the device should be used. Some guidelines for the use of the device in different pathologies can be found on the website of AlterG (www.alterg.com), but there is a lack of strong evidence regarding these guidelines. Therefore an independent research needs to be set up to be able to provide qualitative and scientific correct guidelines for the usage of the device.

6 Conclusion

Little was known about the comfort, pain and perceived exertion while training with the AlterG Antigravity Treadmill©. This preliminary study was set up to give insight in the experience of the patients, the degree of discomfort, the rate of perceived exertion, etc. This study demonstrated that patients feel safe and comfortable while using the AlterG Antigravity Treadmill©. The patients had an overall positive experience while using the device and the rate of perceived exertion was fairly light. The device was found to be suitable for different age categories, for men and women and for patients with a different rehabilitation duration. It can be suggested that the AlterG Antigravity Treadmill© is an appropriate device to use in the rehabilitation of lower limb injury. Although, more research is necessary to make profound conclusions.

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8 Appendix

Appendix 1 – Self-compounded Questionnaire

Questionnaire participant

GENERAL INFORMATION

Gender: M/F
Date of birth:
Body weight:
Body length:
Disease/injury:
Date of the injury (if applicable):
Date of the surgery (if applicable):
Start of rehabilitation on (date):

Do you use the AlterG Antigravity Treadmill© during the rehabilitation process?
How many times a week do you visit the physiotherapist?
How many times a week do you use the AlterG Antigravity Treadmill©?
What is the average time you spent on the AlterG Antigravity Treadmill© during your rehabilitation?

Would you describe yourself as physically active before the disease/injury? Yes/No
If so, how many hours a day do you usually move?

EXPERIENCE WITH THE ALTERG ANTIGRAVITY TREADMILL©

1. How would you describe the physical therapy you're currently getting?

2. Did you hear of the AlterG Antigravity Treadmill© before you started physical therapy with the device? Yes/No

3. Rate your pain on a scale from 0 to 10, wherein 0 represents no pain at all and 10 represents the worst pain ever experienced .

   Before the training:
   0 1 2 3 4 5 6 7 8 9 10

   During the training
   0 1 2 3 4 5 6 7 8 9 10

After the training:

0 1 2 3 4 5 6 7 8 9 10

4. What is your overall experience while running in the AlterG Antigravity Treadmill©? Indicate a score that matches the most with your experience for the following terms.

0 1 2 3 4 5 6 7 8 9 10

Instability — Stability

0 1 2 3 4 5 6 7 8 9 10

Uncomfortable shorts — Comfortable shorts

0 1 2 3 4 5 6 7 8 9 10

Unpleasant material shorts — Pleasant material shorts

0 1 2 3 4 5 6 7 8 9 10

Cold feeling — Warm feeling

0 1 2 3 4 5 6 7 8 9 10

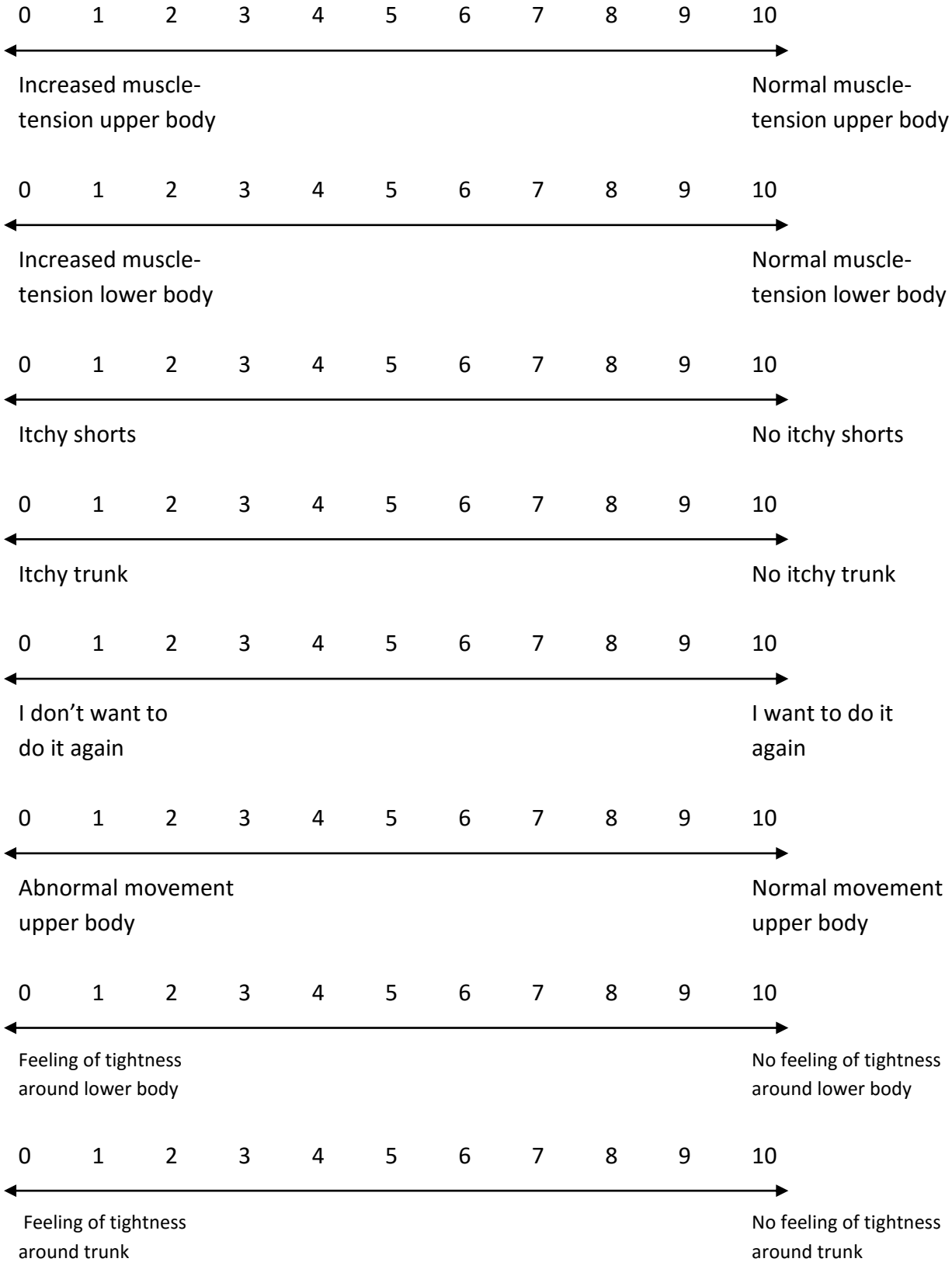
Abnormal walking pattern — Normal walking pattern

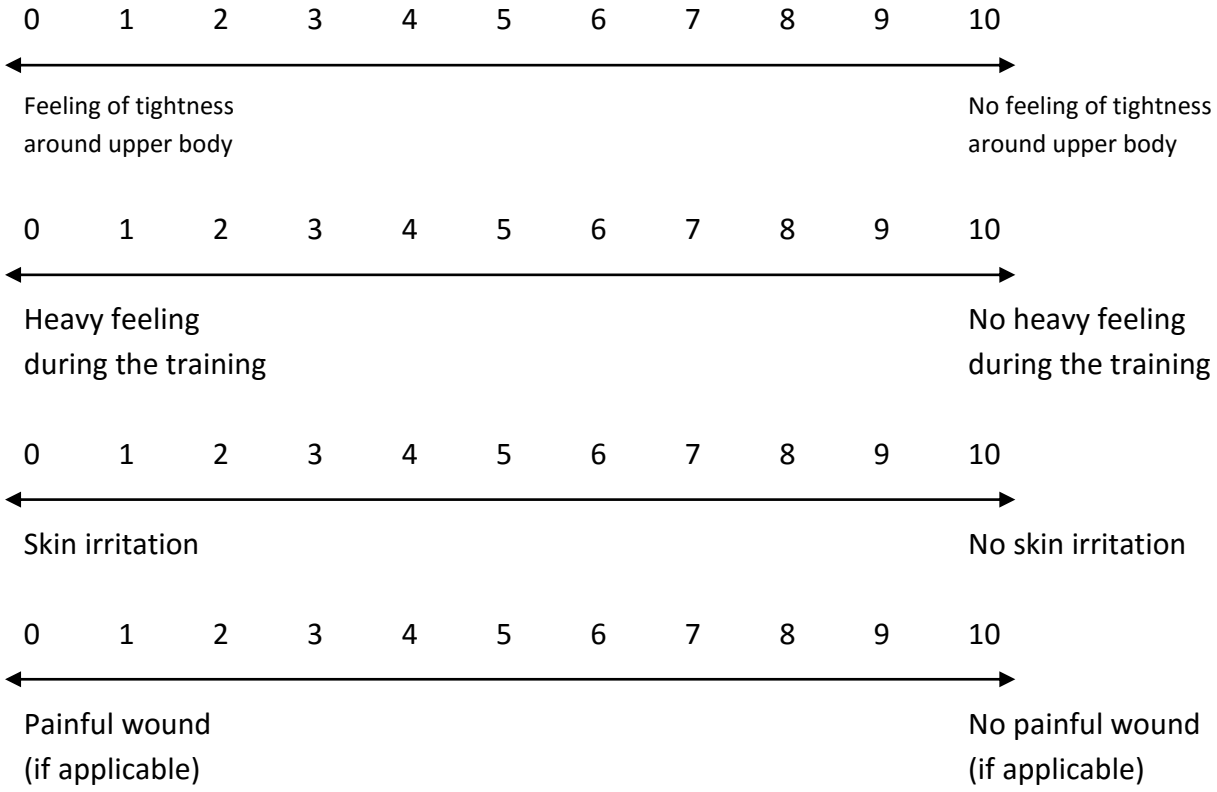
0 1 2 3 4 5 6 7 8 9 10

Unpleasant experience — Pleasant experience

0 1 2 3 4 5 6 7 8 9 10

Not exhausting — Exhausting


0 1 2 3 4 5 6 7 8 9 10
Increased muscle-tension upper body
Normal muscle-tension upper body
0 1 2 3 4 5 6 7 8 9 10
Increased muscle-tension lower body
Normal muscle-tension lower body
0 1 2 3 4 5 6 7 8 9 10
Itchy shorts
No itchy shorts
0 1 2 3 4 5 6 7 8 9 10
Itchy trunk
No itchy trunk
0 1 2 3 4 5 6 7 8 9 10
I don't want to do it again
I want to do it again
0 1 2 3 4 5 6 7 8 9 10
Abnormal movement upper body
Normal movement upper body
0 1 2 3 4 5 6 7 8 9 10
Feeling of tightness around lower body
No feeling of tightness around lower body
0 1 2 3 4 5 6 7 8 9 10
Feeling of tightness around trunk
No feeling of tightness around trunk



5. Did you experience any discomfort during the training? Yes/No

   If so, when and where did you experience the discomfort?

   Rate your discomfort on a scale of 0 to 10, wherein 0 represents no discomfort at all and 10 represents serious discomfort.

   0 1 2 3 4 5 6 7 8 9 10

6. Did you experience walking in the AlterG Antigravity Treadmill© as easier when compared to walking outside the AlterG Antigravity Treadmill©? Yes/No

7. Did you have the feeling of being impeded while training with the AlterG Antigravity Treadmill©? Yes/No

   If so, can you describe what gave you the feeling of being impeded?

   Rate on a scale from 0 to 10 how severe the impediment is, wherein 0 represents no impediment at all and 10 represents serious impediment.

   0 1 2 3 4 5 6 7 8 9 10

8. What is your experience regarding hygiene using the AlterG Antigravity Treadmill©?

   Rate on a scale from 0 to 10 how good/bad you think the hygiene is, wherein 0 represents a very bad hygiene and 10 represents a very good hygiene.

   0 1 2 3 4 5 6 7 8 9 10

9. Did you feel safe during the training? Yes/No

   Rate on a scale from 0 to 10 how safe you felt during the training, wherein 0 represents very unsafe and 10 represent very safe. (An unsafe feeling is the feeling that you might fall)

   0 1 2 3 4 5 6 7 8 9 10

10. Did you experience a difference between the different percentages of body weight support? Yes/No

    If so, was there a percent of body weight support which felt uncomfortable?

11. Is the device easy to use, is it accessible? Yes/No

    Rate on a scale from 0 to 10 how accessible the device is for you, wherein 0 represents not accessible/easy to use, and 10 represents very accessible/easy to use.

    0 1 2 3 4 5 6 7 8 9 10

12. Would you recommend the AlterG Antigravity Treadmill© to other patients? Yes/No

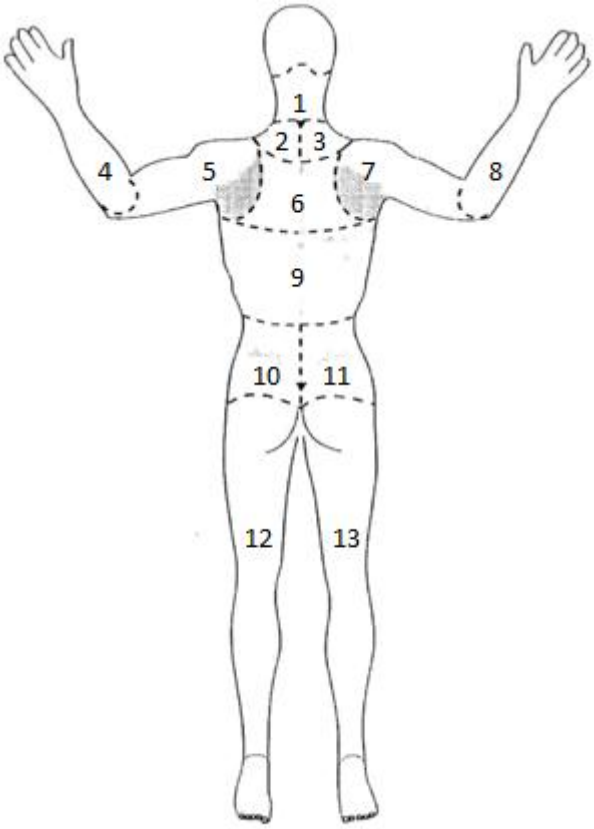
    If no, why wouldn't you recommend the AlterG Antigravity Treadmill© to other patients?

Appendix 2 – Localized musculoskeletal discomfort

Questionnaire 2: measurement of localized musculoskeletal discomfort

Questionnaire participant

On the figure below you see a body that is divided in different areas. Please give a score from 0 to 10 to describe the amount of discomfort you experienced, per area, during the training with the AlterG Antigravity Treadmill©.



10 = extreme discomfort (maximum)
9 = extreme discomfort (almost maximum)
8 = very high discomfort
7 = very high discomfort
6 = high discomfort
5 = high discomfort
4 = somewhat high discomfort
3 = moderate discomfort
2 = little discomfort
1 = very little discomfort
0 = no discomfort at all

Guideline score

Area	Score
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	

Appendix 3 – BORG-scale

Name: Date of birth: Date:

BORG RPE-scale

Load	BORG-SCORE	
	6	
Very very light	7	
	8	
Very light	9	
	10	
Fairly light	11	
	12	
Fairly heavy	13	
	14	
Heavy	15	
	16	
Very heavy	17	
	18	
Very very heavy	19	
Maximum	20	

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Richting: **master in de revalidatiewetenschappen en de kinesitherapie-revalidatiewetenschappen en kinesitherapie bij musculoskeletale aandoeningen**
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