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FACULTEIT GENEESKUNDE EN LEVENSWETENSCHAPPEN
*master in de revalidatiewetenschappen en de
kinesitherapie*

Masterproef

High-intensity interval training in non-specific chronic low back pain: a clinical pilot trial.

Promotor :
Prof. dr. Frank VANDENABEELE

Copromotor :
Prof. dr. Annick TIMMERMANS

Caroline Vandepoel , Philippe Vandepoel

*Scriptie ingediend tot het behalen van de graad van master in de revalidatiewetenschappen
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Prof. dr. Bert Op 't Eijnde and drs. Charly Keytsman, for investing a great deal of time and effort in testing the participants and for their close involvement in this master's thesis.

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Our parents, for the encouragements and for supporting us through university, and Jeroen Claes, for not letting an acute appendectomy hinder him in proofreading this master thesis.

Background

Non-specific chronic low back pain is a widespread and important socio-economic disorder in adults of the Western world. The prevalence of non-specific chronic low back pain (henceforth referred to as NSCLBP) is estimated up to 23% of the adult population (Airaksinen et al., 2006). This implies it is likely that every physiotherapist will be confronted with NSCLBP in his career.

NSCLBP is the type of chronic low back pain which is not attributable to a known cause or pathology, but a multi-faceted problem that requires a multidisciplinary rehabilitation approach (Airaksinen et al., 2006). In Belgium, patients with NSCLBP can participate in a multidisciplinary rehabilitation program for spinal disorders at the departments of Physical Medicine of numerous hospitals. This rehabilitation program comprises physiotherapy, occupational therapy, psychology and spine ergonomics. Although the interventions in this rehabilitation program are scientifically substantiated, patient satisfaction and motivation are empirically experienced to be rather low. Furthermore, not all patients seem to benefit from this program.

This master's thesis aims to contribute to the physiotherapeutic aspect of the multidisciplinary rehabilitation of NSCLBP. The clinical pilot trial of this master's thesis is part of a more comprehensive clinical pilot trial. The recruitment will continue past the master's thesis until a total of 20 participants is recruited. The results of this pilot will determine the course of a larger randomized clinical trial.

The promotor of this master's thesis is Prof. dr. Frank Vandenabeele and the co-promotor is Prof. dr. Annick Timmermans, both professor in musculoskeletal rehabilitation at the Hasselt University. The subject of this master's thesis was developed by promotor and co-promotor. The interpretation of the subject and the development of a clinical trial was resolved in a multidisciplinary team. This team consisted of Prof. dr. Frank Vandenabeele, Prof. dr. Annick Timmermans, Prof. dr. Bert Op 't Eijnde, dr. Inez Wens, drs. Charly Keytsman, Caroline Vandepoel and Philippe Vandepoel. Furthermore, the team determined that Caroline and Philippe would execute a clinical pilot trial on the subject, in order to study the effects and feasibility of a high-intensity interval training protocol in NSCLBP.

Caroline and Philippe drafted the study protocols based on a rough draft by Prof. dr. Annick Timmermans and subsequently Caroline covered the necessary paperwork for the medical ethical committees of the Hasselt University and the Jessa Hospital. Prof. dr. Frank Vandenabeele presented and defended the study protocols at both committees with the assistance of Philippe at the Jessa Hospital and with Caroline at the Hasselt University.

Prof. dr. Annick Timmermans assured the cooperation of the Jessa Hospital through dr. med. Guido Claes, dr. med. Kristof Kempeneers and Mr. Enzo Oliveiri. Caroline and Philippe arranged the practical organization of the study at the Jessa Hospital with MSc. Stefanie Vanbrabant.

After a first screening of suitable NSCLBP patients by the physiotherapists at the Jessa Hospital, Philippe and Caroline managed the effective recruitment of participants. At some points during the recruitment they also assisted with the first screening. They coordinated the physical measurements of participants with Prof. dr. Op 't Eijnde, drs. Charly Keytsman and Prof. dr. Frank Vandenabeele. Due to their internships they assisted with merely 40% of these measurements. They

collected the questionnaires for their own study and the encompassing clinical pilot trial and coordinated the application of accelerometry for the latter. Philippe effectuated 80% of this work and Caroline 20%, due to the scheduling of the internships.

The participants of the control group followed the rehabilitation program of the department of Physical Medicine and Rehabilitation at the Jessa Hospital under the supervision of the local physiotherapists. The participants of the intervention group also trained at the Jessa Hospital, but under the supervision of Caroline and Philippe. The first two weeks of the study, they supervised the trainings together, twice per week for one hour. Thereafter, Philippe supervised the trainings independently, while Caroline attended an internship abroad. Caroline ensured the continuation of the study after the data collection for the master's thesis through further recruitment and trainings.

Caroline processed the data autonomously after approval of the statistical methods by Prof. dr. Frank Vandenabeele and Prof. dr. Annick Timmermans. Of the actual writing process, Caroline completed 80% and Philippe 20%.

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High-intensity interval training in non-specific chronic low back pain: a clinical pilot trial

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Abstract

Background:

Non-specific chronic low back pain (NSCLBP) inflicts a great socio-economic burden on the Western society. To test whether or not physical reconditioning of NSCLBP patients improves pain and functionality, we conducted a clinical pilot trial to test the effects and feasibility of a high-intensity interval training (HIIT) in NSCLBP.

Methods:

We conducted a clinical pilot trial with 8 NSCLBP participants. The experimental group (n=6) participated in a HIIT program and the control group (n=2) participated in a standard rehabilitation program for spinal disorders.

Two types of outcome measures were collected: measures of physical condition and self-reported measures. The self-reported measures assessed pain, functioning at activity level, motivation and satisfaction.

Non parametrical analysis were used for a comparison within the experimental group, all comparisons containing control group data were processed with descriptive statistics.

Results:

In the experimental group, significant changes were found for maximal workload ($p=0.042$), time to fatigue ($p=0.038$) and PASIPD ($p=0.028$). After a correction for an outlier, VO_2max also presented as significantly improved in the experimental group. Remarkable were the graphics for NPRS and MVAS. Where the NPRS changed positively in the experimental group, it deteriorated in the control group. The MVAS only improved a little in the experimental group, but decreased in the control group.

Conclusion:

A HIIT program is feasible in NSCLBP, the intensity is well accepted and did not induce any adverse effects. Improvements of pain and functionality in NSCLBP can be achieved without back exercises.

1. Introduction

Low back pain in the Western world has a lifetime prevalence up to 84% and a one year prevalence up to 65%, 11-12% of the population is estimated to be disabled by it (Airaksinen et al., 2006). Low back pain is defined as “pain and discomfort, localized below the costal margin and above the inferior gluteal folds, with or without referred leg pain” in the “European Guidelines for the management of chronic non-specific low back pain” (Airaksinen et al., 2006). Low back pain can present itself in acute or chronic types. An episode of low back pain is chronic when it persists for at least 12 weeks (Airaksinen et al., 2006).

Chronic low back pain can be divided into subtypes. Non-specific chronic low back pain (NSCLBP), which is chronic low back pain not attributable to a known cause or pathology, has the most important socio-economic effect on society (Airaksinen et al., 2006; Davis et al., 2012; Hong et al., 2013).

The main goal in the management of NSCLBP is to reduce pain and to improve functioning. There is evidence that exercise therapy has positive effects on pain and functionality in patients with NSCLBP (Airaksinen et al., 2006; Hayden et al., 2005). Since exercise therapy entails a certain level of physical activity, it is possible to explain the positive effects of exercise therapy through the health benefits of physical activity (Penedo and Dahn, 2005; Warburton et al., 2006). Furthermore, low levels of physical activity appear to be associated with a poor outcome of the low back pain episode (Holtermann et al., 2014; Pinto et al., 2014; Thomas et al., 1999). These observations might suggest there is a possible subgroup of NSCLBP who would improve solely through physical reconditioning. The latest trend in NSCLBP research is to identify subgroups of NSCLBP and adapt rehabilitation programs to these groups (Airaksinen et al., 2006; Fersum et al., 2010). Evidence already points to the existence of a movement-control subgroup (O’Sullivan, 2005; Fersum et al., 2010), but is not so clear about the existence of a physical deconditioned subgroup.

To test whether or not physical reconditioning of NSCLBP patients improves pain and functionality, and to identify a deconditioned subgroup, a method for physical reconditioning needed to be established. When examining the recommendations for physical activity to promote and maintain health in normal adults, it became clear that a higher intensity of physical activity promotes more health benefits (Haskell et al., 2007). High-intensity interval training (HIIT) has been recently promoted as an effective, low volume and time-efficient training (Burgomaster et al., 2008; Khaled et al., 2013) method for improving fitness and health related parameters (Burgomaster et al., 2008; Bruseghini et al., 2015). It was already used for physical reconditioning and health benefits in other populations: post lung cancer resection (Edvardsen et al., 2015), rheumatic arthritis (Sandstad et al., 2015), cardiovascular diseases (Rognmo et al., 2004; Wisløff et al., 2007), and metabolic syndrome (Tjønnå et al., 2008).

Regarding NSCLBP, there are studies which suggest that rehabilitation programs at a higher intensity give better outcomes (Bendix et al., 2000; Jousset et al., 2004; van Geen et al., 2007; Waterschoot et al., 2014). However, in these studies ‘intensity’ relates to the quantity of therapy per week, or a high therapy volume, and not the workload.

In this clinical pilot trial, the effects and feasibility of a high-intensity interval training (HIIT) program in NSCLBP on pain, activity level, physical condition, motivation and satisfaction are investigated. The purpose of the HIIT program is to recondition NSCLBP patients through high intensive, low volume trainings. Additionally, the HIIT program is compared to a standard spinal rehabilitation program.

What's already known about this topic?

- Low levels of physical activity appear to be associated with a poor outcome of the low back pain episode
- Exercise therapy in general has a positive effect on pain and functionality in NSCLBP
- Research tries to identify NSCLBP subgroups, with a lot of attention to motor control impairments

What does this study add?

- A HIIT program is feasible in NSCLBP, the intensity is well accepted and did not induce any adverse effects
- Improvements of pain and functionality in NSCLBP can be achieved without back exercises

2. Methods

2.1 Participants and study design

Patients were recruited when registering for rehabilitation at the department of Physical Medicine and Rehabilitation at the Jessa Hospital (campus Virga Jesse, Hasselt). The initial intent was to recruit 30 participants between January 2015 and March 2015 and to complete a pilot randomized clinical trial within this master's thesis. However, the enrollment ratio of NSCLBP patients at the Jessa Hospital was lower than expected. By the end of February 2015, only 4 participants were recruited and randomized. Therefore it was decided to prolong the recruitment and readjust the focus of this master's thesis to the effects and feasibility of the experimental HIIT protocol in NSCLBP. The randomization was terminated, and the following 4 participants, recruited between March and May 2015, were then allocated to the experimental group. The recruitment will continue until a total of 20 participants is recruited, in order to allocate 10 participants to each intervention group. The required minimal sample size for pilot trials is reported to be 10 participants per group (Hertzog, 2008).

Criteria for inclusion were: 1) non-specific chronic low back pain ("European Guidelines for the management of chronic non-specific low back pain", Airaksinen et al., 2006), 2) age over 18 years, 3) < 30 Physical Activities Scale for Individuals with Physical Disabilities (PASIPD) score, 4) able to understand Dutch (spoken and written).

Exclusion criteria were: 1) invasive surgery at the lumbar spine in the last 18 months (arthrodesis was excluded, microsurgery was allowed), 2) radiculopathy (uni- or bilateral), 3) comorbidities: paresis and/or sensory disturbances by neurological causes, diabetes mellitus, rheumatoid arthritis, pain > 8/10 on the Numeric Pain Rating Scale (NPRS) in the last 48 hours, pregnancy, 4) ongoing compensation claims and/or (work)disability > 6 months, 5) rehabilitation/exercise therapy program for LBP in the past 6 months. In March 2015, exclusion criterion 5 was removed to promote participant recruitment.

After inclusion, echocardiographic (ECG) data was acquired using a 2.5 MHz probe on a Vivid 7 ultrasound (GE Vingmed), to ensure that there were no contra-indications for the HIIT protocol. If ECG findings were normal according to the 'Seattle criteria' (Drezner et al., 2013), the participants were allocated to the intervention groups. Patients with abnormal ECG findings had to be cleared by a cardiologist before they could participate in the study. The initial randomization procedure was performed by an independent person using nontransparent cards with the names of the intervention groups. After discontinuation of the randomization, participants were allocated directly by one of the researchers.

2.2 Medical ethics

The clinical pilot trial was approved the medical ethical commissions of UHasselt (Comité voor Medische Ethiek UHasselt) and Jessa Hospital (Ethische Toetsingscommissie), and it was registered as protocol 14.87/REVA14.12. The participants signed a patient information and permission form prior

to inclusion. When patients decided to participate in the study, the patient fee for their rehabilitation was discarded.

2.3 Intervention

Participants of both groups followed a six week rehabilitation program with two training sessions per week at the department of Physical Medicine and Rehabilitation at the Jessa Hospital. The control group participated in the standard program of the multidisciplinary rehabilitation program for spinal disorders. The participants in the experimental group followed a HIIT program. Additionally, all participants were encouraged to attend five educational sessions. Two of these educational sessions were physiotherapeutic, two were occupational therapeutic and one was psychological.

If participants were unable to attend a whole week of training because of preplanned trips (business, family holidays) or sickness, their training period was extended in order to give them the opportunity to complete a six week training program.

After finishing the trial's program, all participants could complete their rehabilitation at the department of Physical Medicine and Rehabilitation at the Jessa Hospital.

2.3.1 Standard program

The standard program was composed of general condition training and individual exercise therapy, supervised by the local physiotherapists. One training session lasted 2 hours, but actual training volume was approximately 1.5 hours. The training sessions did not occur at fixed times, but were planned individually.

The condition training consisted of cycling, cross-training and/or walking on a treadmill at an intensity of 60 to 65% of the maximal heart rate. Prior to exercise therapy, patients were screened for program of motor control impairments (Comerford and Mottram, 2012; O'Sullivan, 2005; Sahrman, 2001). Next, an individual exercise therapy program was composed, adjusted to patient specific needs. The exercises comprised learning the neutral position of the lumbar spine, mastering pelvic movements, and addressing the inherent motor control impairment. Progression of the exercise therapy was determined individually.

2.3.2 High-intensity interval training program

The experimental program consisted of HIIT cycling and circuit resistance training, based on a protocol by dr. Inez Wens (unpublished). Figure 1. displays all components of the HIIT program. Training sessions occurred under the supervision of the researchers, every Tuesday and Thursday from 18h00 - 19h00. The training volume was 1 hour. The training sessions were initially planned to occur during the day, but a lot of eligible patients were only available in evening hours.

The training session started with a 5-minute warming up on a leg cycle ergometer. The actual HIIT cycling started at cycling 5 bouts of 1 minute at the workload (Watt) belonging to 100% of the maximal heart rate (HRmax), separated by 1 minute of rest. The duration of the HIIT cycling increased weekly with 10 seconds, until the cycling time in week 6 was 1 minute and 50 seconds.

After 5-minutes of cooling down, the participants performed squatting exercises, to provoke anticipatory postural adjustments (APA's) in order to better maintain stability during resistance training

(Heiss et al. 2001). Additionally, special attention was paid to a good postural control of the lower back during training. Participants were taught to maintain a neutral posture of the lumbar spine during HIIT cycling and circuit resistance training.

The resistance training contained 3 upper body and 3 lower body exercises: arm curl, chest press, vertical traction, leg press, leg extension and leg curl. For resistance training, the participants started at 1x 10 repetitions at an intensity of 10 RM. The training progressed with an increased number of repetitions to 2x 15 repetitions at an intensity of 15 RM.

At the end of each training session, the participants stretched the quadriceps, hamstrings, triceps surae, pectoral muscles, and upper back muscles (30 seconds each).



Figure 1. High-intensity interval training

2.4 Outcome measures

The participant characteristics obtained at baseline were age (years), gender (male/female), time since onset of low back pain (years), medication use (yes/no and amount), time spent sitting at work (hours), time spent standing at work (hours) and time spent moving at work (hours) and the baseline PASIPD score. The latter was to assure that no participants with a great Following data about therapy adherence were collected: number of weeks completed (with at least 1 session per week), number of sessions completed, absence due to low back pain, attendance to the education sessions (number of sessions).

Two types of outcome measures were collected: measures of physical condition and self-reported measures. The self-reported measures assessed pain, functioning at activity level, motivation and satisfaction. The motivation and satisfaction of participants were important measures for the feasibility of the HIIT protocol. The outcome measures were evaluated upon inclusion in the study (pretreatment) and after completing a six week rehabilitation program (post treatment). The persons

who performed the physical measures were blinded to the adhered intervention, and were not involved in training or data analysis. The self-reported measures were collected by the researchers themselves, and were verified and analyzed by the researcher who was the least involved in the training. Additionally, subjective reports of the patients were collected to ascertain the feasibility of the HIIT program.

2.4.1 Measures of physical condition

Endurance capacity test

Endurance capacity was tested to volitional fatigue on an electronically braked cycle ergometer (eBike Basic, General Electric GmbH, Bitz, Germany). Participants performed a continuous graded exercise test (cycling frequency: 70 rpm) to determine maximal oxygen uptake (VO_{2max} in ml/kg/min), maximal workload (W_{max} in Watt), peak lactate concentration (PLC in mmol/l), and time to fatigue (TTF in minutes). Maximal oxygen uptake was determined through pulmonary gas exchange analysis (Jaeger Oxycon, Erich Jaeger GmbH, Germany). Using a 12-lead ECG device, the maximal heart rate (HR_{max}) was obtained for training purposes. The peak lactate concentration was registered with lactate monitoring.

Dual Energy X-ray Absorptiometry (DEXA)

Lean tissue mass (LTM) of the whole body was obtained by means of a Dual Energy X-ray Absorptiometry (DEXA) scan (Hologic Series).

2.4.2 Self-reported measures

Numeric Pain Rating Scale (NPRS)

The NPRS is a scale on which the participant indicates the amount of pain he feels. It consists of eleven scores (0-10), whereby the left of the scale (score 0) means 'no pain' and the right (score 10) means 'worst pain imaginable'. An improvement of 2 levels or more is accepted as clinically relevant (Childs et al., 2005; Pengel et al., 2004).

Roland Morris Disability Questionnaire (RMDQ)

The RMDQ is a reliable and valid questionnaire (24 items) for evaluating the activity level of the patient with low back pain (Pengel et al., 2004; Roland and Morris, 1983). A change of 5 is the minimal clinically important difference (Maughan and Lewis, 2010).

Physical Activities Scale for Individuals with Physical Disabilities (PASIPD)

The Dutch version of the PASIPD is a 12 item questionnaire which gives information about leisure, household and work related physical activity over the preceding 7 days. The metabolic equivalent (MET) * hours/week can be calculated (van den Berg-Emons et al., 2011; Washburn et al., 2002).

Motivation Visual Analog Scale (MVAS)

The MVAS is a scale on which the participant indicates the amount of motivation he feels. It consists of eleven scores (0-10), whereby the left of the scale (score 0) means 'no motivation' and the right

(score 10) means 'very high motivation'.

Satisfaction Visual Analog Scale (SVAS)

The SVAS is a scale on which the participant indicates the amount of satisfaction he feels. It consists of eleven scores (0-10), whereby the left of the scale (score 0) means 'not satisfied' and the right (score 10) means 'very satisfied'.

2.5 Data analysis

Data analysis was executed in SPSS 22.0 (SPSS Inc., Chicago, ILL). The small sample size determined the selection of statistical methods. For the comparison of pretreatment and post treatment measures within the experimental group, the Wilcoxon signed ranks test was used. The group was too small to apply parametrical analysis. All comparisons containing control group data were processed with descriptive statistics.

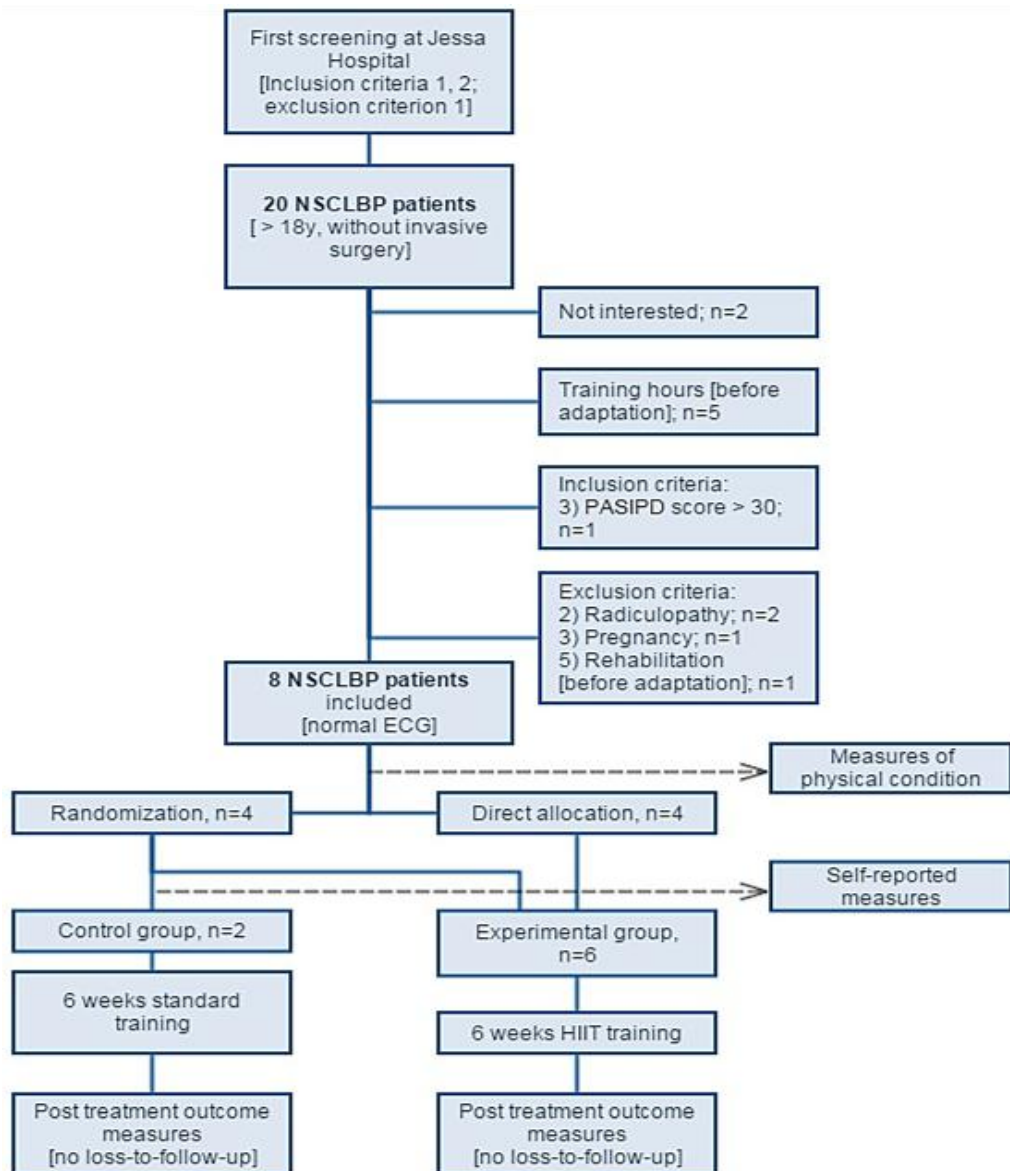


Figure 2. Flow-chart

3. Results

3.1 Patient characteristics

A total of 8 participants was recruited, 2 in the control group and 6 in the experimental group. Figure 2. shows the flow chart of the clinical pilot trial. At recruitment, 1 participant presented with an abnormal ECG, but participation was approved by a cardiologist.

Characteristics of the participants in both groups are presented in Table 1. Differences in baseline characteristics between the two groups are more likely than unlikely given the small sample sizes of the groups. Therapy adherence was in the experimental group somewhat lower than in the control group, but therapy sessions in the experimental group were not flexible to the participants availability. Furthermore, the department Physical Medicine and Rehabilitation closes on holidays, so 3 participants missed a training session involuntarily. None of the control group patients was absent from a training session due to back pain, but 1 of the participants had to take a break of 2 weeks in the program due to knee problems. In the experimental group, 1 patient was 1 time absent due to low back pain, which had started in the weekend (and not after a training session).

Table 1. Participant characteristics

	Control	HIIT
Baseline		
Number (F/M)	2 (2/0)	6 (2/4)
Age (y) ^A	52.0 ± 5.7	39.7 ± 14.3
Weight (kg) ^A	74.0 ± 8.5	78.8 ± 8.1
Time since onset (y) ^A	6.5 ± 4.9	4.1 ± 6.8
Medication use: Yes/No	1/1	2/4
Amount medication ^A	1.5 ± 2.1	1.0 ± 1.5
Working: Yes/No	2/0	3/3
Sitting at work (h) ^A	12.5 ± 17.7	28.8 ± 10.8
Standing at work (h) ^A	/	8.3 ± 14.4
Moving at work (h) ^A	10 ± /	5.3 ± 8.38
PASIPD ^A	16.96 ± 3.76	9.21 ± 5.22
Therapy adherence		
Weeks completed (/6) ^A	6 ± /	6 ± /
Sessions (/12) ^A	12 ± /	10.8 ± 1.5
Absence due to LBP	0	1
Education (/5) ^A	1.5 ± 2.1	1.0 ± 2.0

^A Mean ± SD

3.2 Outcome measures

The change of median from pretreatment to post treatment values are presented as graphics in Figure 3 (measures of physical condition) and Figure 4 (self-reported measures) for both groups. Substantial values for the experimental group are summarized in Table 3.

3.2.1 Measures of physical condition

The maximal oxygen uptake (VO₂max) showed a clear progression in the control group, but not in the experimental group. With change of medians from 33.05 to 32.80, no significant difference (p=0.173) was demonstrated in the latter. These VO₂max results are likely affected by the deterioration of 1 participant. Seven of the 8 participants improved their VO₂max, including both control group participants. One of the participants of the experimental group, the one with the abnormal pretreatment ECG displayed a lower VO₂max after 6 weeks of HIIT. After the post treatment endurance test, the participant reported a shortness of breath. He claimed this was a consequence of warmer weather. An analysis of the VO₂max without this participant gave a change of medians [IQR] from 29.00 [18.65 ; 37.45] to 29.80 [20.60 ; 40.50], which was significant (p= 0.043). One of the participants of the control group displayed an unusual progression of VO₂max (45%), which distorted the results.

The maximal workload (Wmax), peak lactate concentration (PLC) and time to fatigue (TTF) changed in both groups. The changes of Wmax and TTF presented themselves as slightly steeper slopes in the experimental group. With a change of medians from 210.0 to 232.5 Watt and from 13.0 to 14.5 minutes, the changes of Wmax ($p=0.042$) and TTF ($p=0.038$) are statistically significant in the experimental group. The participants were able to cycle longer before volitional fatigue and cycled at higher workloads. The lean body mass (LBM) and bodyweight did not change in either group.

3.2.2 Self-reported measures

The change in median scores on the RMDQ, the SVAS and the PASIPD differed little between both groups. Where the SVAS score remained constant in the control group, it improved slightly in the experimental group. The change of medians from 7.5 to 8.0 in the latter was insignificant ($p=0.336$), but the results were influenced by the decrease in satisfaction of just 1 participant. The participant subjectively reported discontent since he was not completely painless after the 6 week program.

Scores in the RMDQ and the PASIPD improved in both groups, implying a better functionality on activity level. The improvement in the experimental group is slightly higher. The change of medians from 8.5 to 5.0 on the RMDQ was both statistically and clinically insignificant ($p=0.276$). However, the PASIPD score increased significantly ($p=0.028$) with change of medians from 6.96 to 15.45.

Clear differences between groups can be observed in pain (NPRS) and motivation (MVAS) scores. Where the median NPRS score decreased in the experimental group, it increased in the control group. This increase is due to a severe aggravation of the pain of 1 control group participant. Though the median NPRS score improved in the experimental group from 6.5 to 3.0, which is a clinically important difference, the change was not statistically significant ($p=0.072$). Two of the 6 experimental group participants did not improve individually, but subjectively reported large fluctuations in pain.

The MVAS score slightly increased for the experimental group and decreased for the control group. The control group participants reported subjectively that the standard training was strenuous for their back and that the progression of therapy was arduous. In the experimental group a change of medians from 9.5 to 10.0 was observed, which is statistically insignificant ($p=0.083$). However, the participants reported that being able to perform such a intensive training was a great experience, which kept them motivated.

Table 3. Outcome measures in the experimental group

	Pretreatment		Posttreatment		Wilcoxon signed ranks test	
	Median	IQR	Median	IQR	Z	P-value
VO₂max	33.05	20.28 ; 37.80	32.80	21.55 ; 39.60	- 1.363	0.173
Wmax	210.0	112.5 ; 262.5	232.5	125.0 ; 266.3	- 2.032	0.042 ^A
PLC	12.00	7.30 ; 13.00	10.70	9.88 ; 12.38	- 0.314	0.753
TTF	13.0	10.25 ; 16.50	14.5	11.50 ; 16.75	- 2.070	0.038 ^A
Weight	80.00	69.75 ; 86.38	80.50	69.10 ; 88.00	- 0.954	0.340
LTM	52174.80	43883.73 ; 60734.50	52849.65	43915.53 ; 61541.93	- 0.734	0.463
RMDQ	8.5	3.8 ; 11.3	5.0	1.8 ; 11.0	- 1.089	0.276
NPRS	6.5	4.8 ; 7.3	3.0	2.8 ; 7.3	- 1.802	0.072
MVAS	9.5	7.8 ; 10.0	10.0	8.8 ; 10.0	- 1.732	0.083
SVAS	7.5	5.5 ; 8.0	8.0	6.3 ; 9.00	- 0.962	0.336
PASIPD	6.96	5.43 ; 13.75	15.45	8.18 ; 20.14	- 2.201	0.028*

IQR = Interquartile Range, ^A Significance...

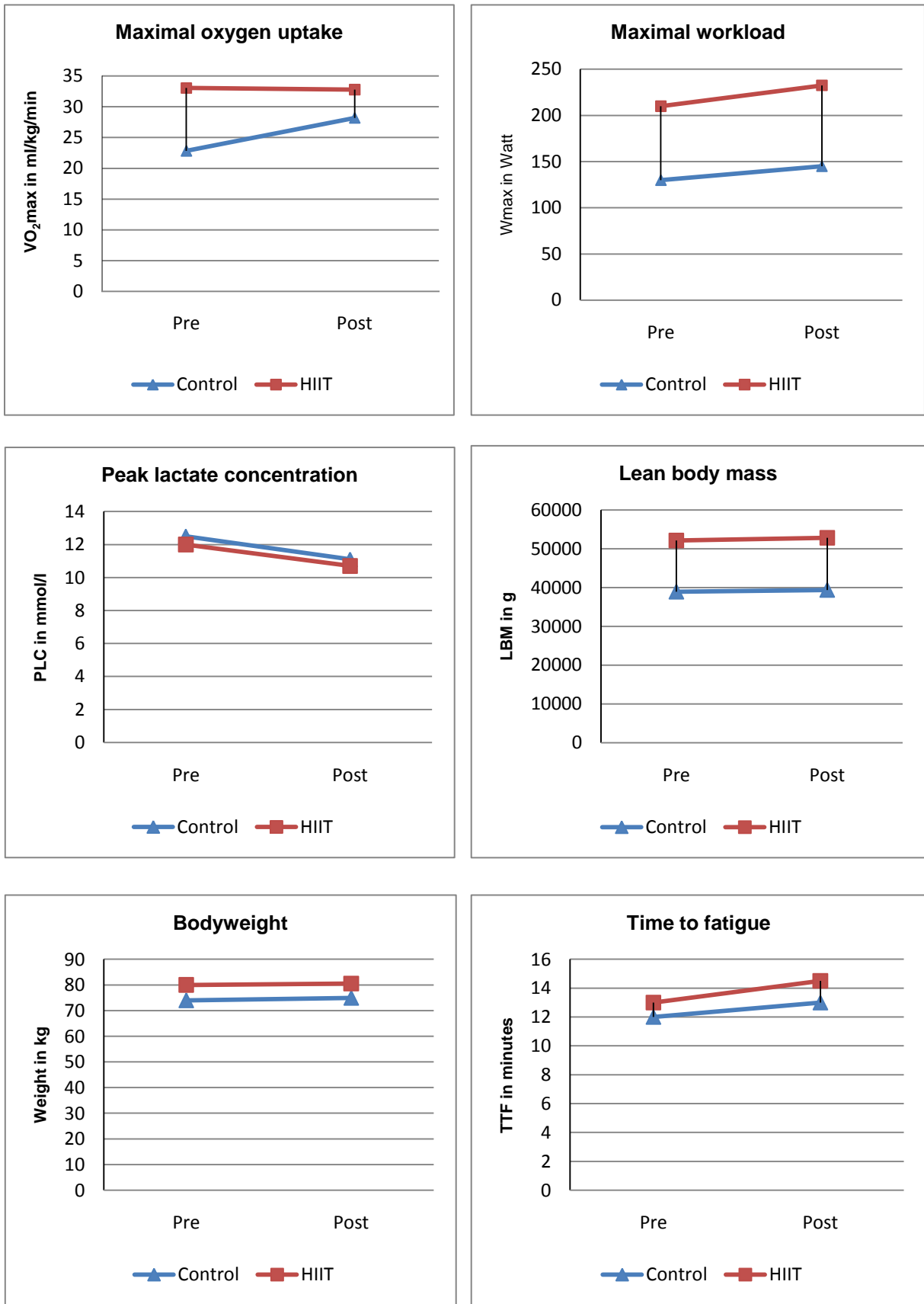


Figure 3. Change of medians in measures of physical condition

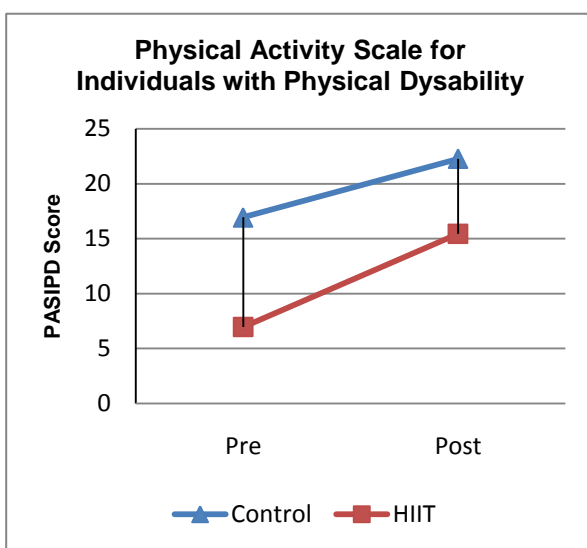
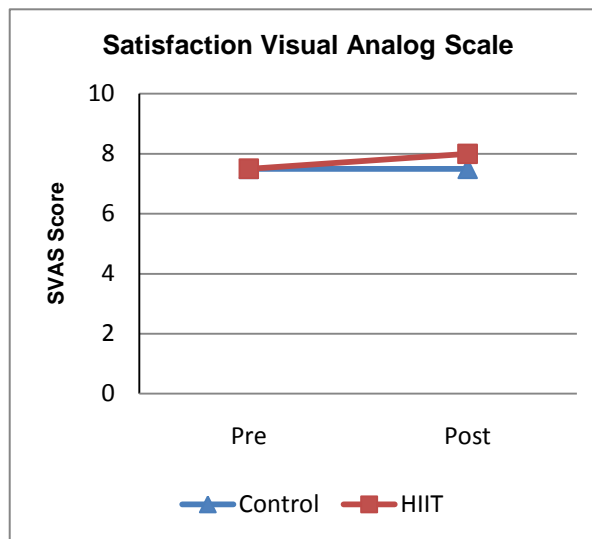
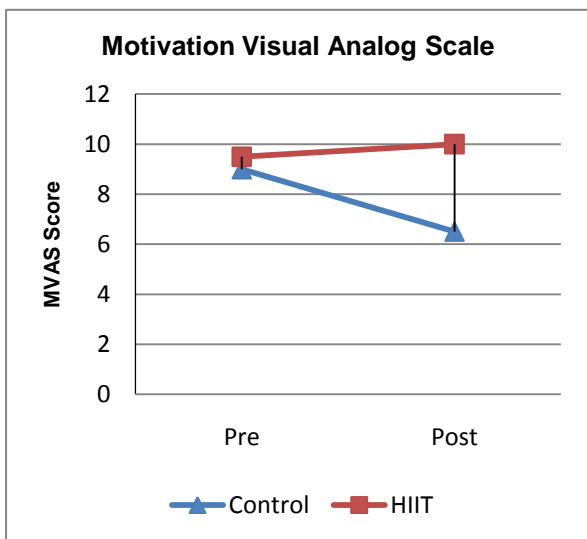
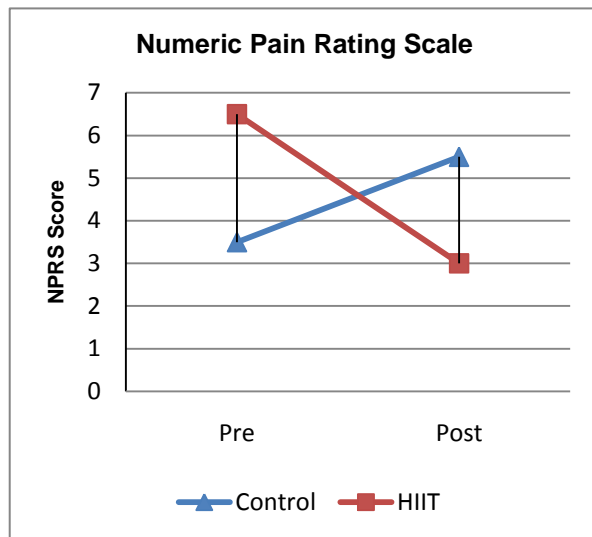
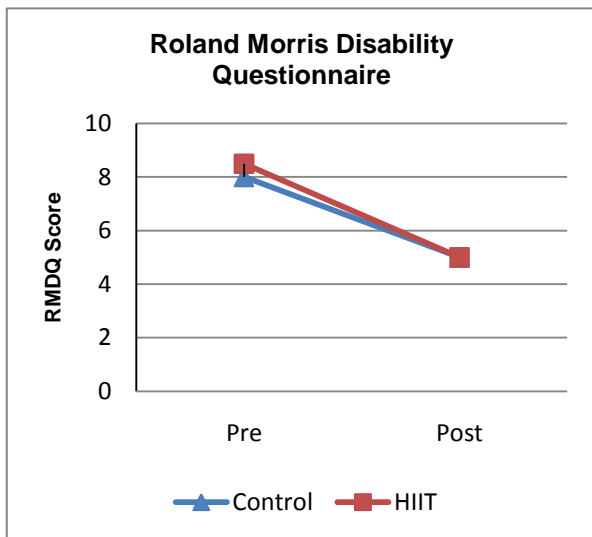


Figure 4. Change of medians in self-reported measures

4. Discussion

The aim of this clinical pilot trial was to determine the effects and feasibility of a HIIT program in NSCLBP on pain, functionality on activity level, physical condition, motivation and satisfaction. Secondly, we were interested if there would be different effects in the control group and the experimental group. In the experimental group, significant changes were found for maximal workload ($p=0.042$), time to fatigue ($p=0.038$) and PASIPD ($p=0.028$). After a correction for an outlier, $VO_2\max$ also presented as significantly improved in the experimental group. Remarkable were the graphics for NPRS and MVAS. Where the NPRS changed positively in the experimental group, it deteriorated in the control group. The MVAS only improved a little in the experimental group, but decreased in the control group.

The design of this trial had some major limitations, which affected the interpretation of the results. First of all, the sample size was small and most data were processed with descriptive statistics, which does not provide scientific evidence. Until the results of the statistical analysis within the experimental group can be compared objectively with a control group, they have a low impact. Additionally, the use of small groups means that if the scores of 1 participant were abnormal, they distorted the median result.

Then there was the discontinuation of the randomization procedure, whereby all new patients had to participate in the HIIT program. We ran the risk to attract participants based on motivation, since a chance at standard training no longer existed until the experimental group contained 10 participants. In reality, most patients were eager to participate in the trial on account of the chance to participate in the HIIT program, and they were willing to put up with the risk to be assigned to the control group.

The outcomes of $VO_2\max$ were unexpected. We anticipated a greater effect of the HIIT program, based on results in literature (Edvardsen et al., 2015; Khaled et al., 2013; Rognmo et al. 2004; Sandstad et al., 2015; Wisløff et al., 2007). We expect there are 3 possible explanations for the discrepancy between our expectations and the actual results. Firstly, 6 weeks was a short period of time, especially when compared to similar studies in literature. Secondly, the $VO_2\max$ of one of the participants inexplicably deteriorated. This was probably a result of the participant being cardio-respiratory strained. Additionally, the $VO_2\max$ improvement of 45% in 1 of the control group participants is remarkable. This kind of improvement occurs in merely 1% of the population, and even then it occurs only after a longer and more intensive program (Skinner et al., 2000).

The simultaneous improvement of maximal workload and time to fatigue was less surprising, since the workload of a standardized graded endurance test increases with set time intervals. The maximal workload is an important measure because the rationale for the HIIT program is reconditioning at the highest possible workload. It is debatable if reporting the time to fatigue is an asset to the results of the trial.

According to most literature, in the first 4 to 6 weeks of resistance training, there is only an increase strength through neuromuscular adaptations (Aagaard et al., 2002), and not through an increase in muscle mass. Therefore, it is logical no changes in bodyweight or lean body mass were

observed. However, recent literature indicates lean body mass might increase from the start of the training (Lamont et al., 2011).

Gradually it became clear that the duration of the training program constitutes an important constraint on the ability to measure real changes. Perhaps a 12 week program would be more suitable for future research. -

Motivation and satisfaction of the participants, represented by the MVAS and the SVAS scores, were important for therapy adherence. The MVAS score provided some interesting scores. The motivation did not progress spectacular in the experimental group, but baseline motivation was already good and more importantly, motivation did not decrease as in the control group. In the participant's subjective reports, both programs are addressed as strenuous, but in different ways. The participants of the control group report a severe straining of the back, where the participants of the HIIT group report a general exertion. It is unclear what makes the standard rehabilitation so strenuous for the back. The participants reported a low tolerance for the cross-trainer, but it seems unlikely this is the only cause. The hypothetical deconditioning of NSCLBP patients might include deconditioning of the stabilizing muscles of the back. There is evidence indicating disuse atrophy in the m. erector spinae (Mannion, 1999; Mannion et al., 2000) and the m. multifidi (Mazis et al., 2009). Since both muscles fulfill a stabilizing function, whether global or local, they normally consist predominantly of slow glycolytic type I fibers. Histological research shows a change of constitution with less type I fibers, or more of the type II fibers, which is linked to disuse. (Mannion, 1999; Mannion et al., 2000; Mazis et al., 2009). Consequently it is possible these muscles aren't able to fulfill their stabilizing function for the entire duration of the standard rehabilitation program. Although these changes can be reversed through exercise therapy, the process is slow and the changes are small (Storheim et al., 2003).

The researchers also made some subjective reports. The participants of the experimental group did present with motor control impairments and/or stability problems. And without specific exercises targeting these problems, they did improve on pain and functionality. They did have to maintain neutral position during the exercises and they had to stabilize their lower backs, but integrated in other exercises.

For further research we propose a randomized controlled trial with a larger sample size, preferably multi-centered for easier recruitment, with a 12 week program.

5. Conclusion

A HIIT program is feasible in NSCLBP, the intensity is well accepted and did not induce any adverse effects. Improvements of pain and functionality in NSCLBP can be achieved without back exercises.

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