

**The long-term effectiveness of a blended intervention for patients with non-specific low back pain: a six months follow-up pilot study.**

Master thesis

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“ONDERGETEKENDE

Renske van Maris

bevestigt hierbij dat de onderhavige verhandeling mag worden geraadpleegd en vrij mag worden gefotokopieerd. Bij het citeren moet steeds de titel en de auteur van de verhandeling worden vermeld.”

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## Abstract

**Background:** Low back pain (LBP) is a prevalent health care problem. National and international guidelines recommend physiotherapy for patients with LBP which can consist of information, advice and exercises. However, compliance is a challenge in exercise therapy. Blended care, which is an integration of face-to-face care with web-based care, has advantages like the ability to remind patients to exercise and being physically active. The aim of this study was to evaluate the preliminary long-term effectiveness of a blended exercise therapy for patients with LBP. The hypothesis was that blended care is effective in the long term in patients with LBP on pain, disability, physical activity and pain related fear.

**Method:** The current study is a continuation of a pilot study named e-Exercise LBP. This pilot study was focused on the feasibility and preliminary short-term effectiveness (3 months) of a blended intervention. A total of 41 patients between 18 and 65 year with non-specific LBP that participated in the original pilot study, were contacted after 6 months to assess their pain, disability, physical activity and pain related fear for this current study. For measuring these factors a questionnaire was used that contained the Quebec Back Pain Disability Score (QBPDS), Visual Analogue Scale (VAS), Short QUestionnaire to ASsess Health enancing (SQUASH) and Fear Avoidance Beliefs Questionnaire (FABQ). For analyzing the preliminary effectiveness over time (baseline, three months-, and six months follow-up), longitudinal-data analyses were performed by using the non-parametric Friedman test.

**Results:** The Friedman test showed an overall significant difference in decrease of disability and pain over time ( $P = <0.0005$ ,  $P = <0.0005$ ). The post hoc test showed a significant difference in disability and pain between baseline and three months' follow-up ( $P = <0.0005$ ,  $P = <0.0005$ ) and between baseline and six months' follow-up ( $P = 0.010$ ,  $P = 0.001$ ).

**Conclusion:** The blended intervention e-Exercise LBP seems a promising intervention for improving disability and pain in patients with LBP. The accents on technology and personalized care fit well in the current health. However, blended care is new for physiotherapists and needs further development with specific attention for implementation in the future.

**Keywords:** Physical therapists, Low back pain, Exercise, Telemedicine, Blended care.

## Background

Low back pain (LBP) is worldwide one of the most common health problems<sup>1</sup>. LBP is the leading cause of activity limitations and work absence, and causes an enormous economic burden on individuals, communities, industry and governments<sup>1</sup>. In the Netherlands, 27% of the adults suffer from LBP<sup>2</sup>. 90% of all LBP cases is non-specific LBP, which is characterized by the absence of an identifiable cause<sup>3</sup>. Patients mostly experience pain in the lumbosacral region, sometimes associated with radiating pain to the buttock and/ or leg<sup>4</sup>. Activities and participation will gradually increase when there is a normal recovery, but in absence of a normal recovery no or minimal improvement of activities and participation is seen within three weeks<sup>5</sup>. Patients with LBP often experience several episodes of LBP. A quarter of the adults report at least a daylong episode of LBP in the previous three months<sup>6</sup>. This indicates that interventions with a positive long-term effect will be meaningful to these patients.

Physiotherapy is recommended in patients with LBP by national and international guidelines<sup>4,7</sup>. The role of the physiotherapist is to inform, advice and activate the patient, according to the Royal Dutch Society for Physiotherapy (KNGF) guideline LBP<sup>4</sup>. Therapeutic exercises provided by a physiotherapist can consist of mobilising and strength exercises, lumbar stabilization and extensor muscle training of the (lower) back<sup>7,8</sup>. Several studies have shown the efficacy of exercise therapy, in terms of pain relief and functional recovery<sup>9-13</sup>. Mannion (2009) showed that patients adherence is associated with a decrease in pain and disability<sup>14</sup>. However, adherence is a common issue in exercise therapy<sup>14-16</sup>. There are different reasons for lack of adherence which might be due to motivation, the complexity of the movement, time consuming, present knowledge about LBP and the lack of feedback during home exercise<sup>17,18</sup>.

A potential solution to this problem, and an opportunity to improve physiotherapy care, could include a shift from traditional delivery models of care (including face-to-face care) to web-based interventions or a combination of those two, called blended care<sup>19</sup>. Blended care has the ability to remind patients to exercise and be physical active and also gives the patient 24/7 accessibility and support at home<sup>20</sup>. Jansen- Kosterink et al. (2015) assumed that higher use of web-based interventions is related to a higher exercise adherence thus leading to a better outcome regarding to pain and disability on the short and long term<sup>21</sup>.

Previous research in web-based interventions showed small beneficial effects in patients with LBP<sup>22,23</sup>. These web-based interventions are without face-to-face support, which can partially explain these small effects<sup>21</sup>. A review of Dario et al. (2017) suggest that web-based interventions, when used as an adjunct to usual care, appear to optimize the effects of usual care in patients with onset of LBP symptoms<sup>24</sup>. The integration of a web-based intervention with face-to-face contact is recommended in several studies<sup>21,25,26</sup>. Therefore e-Exercise LBP was developed consisted of face-to-face physiotherapy contacts integrated within a 12-weeks physical activity (PA) web-based program. The pilot study e-Exercise (Kloek et al. in progress) showed positive results on the short-term, but results on the long-term are unknown.

This study aims to assess the preliminary long-term effectiveness of the blended intervention e-Exercise LBP on disability, pain, PA and pain related fear. The secondary aim is to determine the level of knowledge about LBP and to assess the use of the web-based part of the intervention, after completing the intervention.

## **Methods and settings**

### **Study design**

The pilot study e-Exercise LBP was a multicenter uncontrolled intervention study which consisted of a baseline and three months follow-up. This current study is a continuation of the pilot study e-Exercise LBP and focusses on the preliminary long-term (six months) effectiveness on disabilities, pain, physical activity and pain related fear. The CONSORT-EHEALTH checklist (beta – V.1.5)<sup>27</sup> was used to report this study.

### **Participants**

#### ***Physical therapists***

A total of 30 (general and specialized) physiotherapists practicing in primary care (e.g. Noord Holland, Utrecht and Gelderland) were invited by e-mail to participate in the pilot study. Contact details from participating physiotherapists were obtained from a previous study (e-Exercise osteoarthritis<sup>20</sup>) and from the work field of the researchers. A total of 22 physiotherapists were willing to participate, signed the clinical agreement trial and followed a half-day instruction course about study procedure and the intervention e-Exercise LBP.

#### ***Patients***

All physiotherapists were asked to recruit at least two patients with non-specific LBP within five months. Eligibility criteria of patients participating in the study concerned: age between 18- 65 year, non-specific LBP, access to the internet, master the Dutch language in both written and spoken and have had no physical treatment for LBP in the six months before study participation. Exclusion criteria were patients with lumbosacral radicular syndrome or back pain due to a potentially serious underlying specific disease. In total 46 eligible patients were recruited for the pilot study and 41 signed the informed consent (23 women and 18 men).

#### ***Study procedure***

In March 2016 the included physiotherapists had a half-day instruction course about the examination procedure (e.g. timeframe of the pilot study, inclusion and exclusion criteria, measurements) and the web-based part of e-Exercise LBP (content and operation). There was a timeframe of five months for the inclusion of patients. Physiotherapists informed eligible patients about the study and screened them on the in- and exclusion criteria. At the first face-to-face contact an advice about the number of face-to-face treatments was given based on the results of the start back screening tool (SBST). The SBST is a prognostic questionnaire that helps clinicians identify modifiable risk factors for back pain disability<sup>28</sup>. The resulting

score stratifies patients into low, medium or high risk categories. Furthermore, patients' were instructed to perform the first module of the web-based program. Each included patient started with the e-Exercise intervention after the first face-to-face contact. The first patient started the intervention in May 2016, the last patient started November 2016.

To inform the patients about the purpose of this six months follow-up study, an informed consent and informative letter were sent by mail. A week after the information letter a questionnaire was sent by mail to all participants. If there was no response to the questionnaire within a week, a reminder was sent. If there was no response on the reminder, the participant was called by the researcher, when patients' phone number was available. To encourage more people to complete the questionnaire a gift card of €25 was raffled among the participants.

## **Interventions**

### ***e-Exercise***

The intervention e-Exercise LBP is based on the KNGF guideline LBP and e-Exercise osteoarthritis and is an integration of face-to-face contacts with a physiotherapist and a 12-weeks (each week a module) PA web-based program.

### ***Face-to-face contact***

During the first face-to-face contact (week 1) physiotherapists provided information about LBP and selected together with the patients a central activity (e.g. walking, swimming, cycling). The SBST was used to determine the number of face-to-face contacts. The advice from the protocol was four, 12 or 20 face-to-face contacts corresponding with the score of low, medium or high on the SBST. This was just an advice from which therapists may depart. The physiotherapist selected and instructed four strength and stability exercises. Patients were instructed to perform the first module of the web-based part of the intervention. In this module, the patient was asked to perform a baseline test for their central activity (once a day, three times in the first week) to determine their physical load ability. The second assignment was the performance of the strength and stability exercises.

During the second face-to-face contact (week 2) the result of the 3-day baseline test for the central activity was discussed and personal short and long-term goals were formulated. When the level of the central activity needed to improve on baseline, the physiotherapists switched on the graded activity module. In this module, assignments of PA gradually increased until the patients' individual short-term goal was reached. The strength and stability exercises were trained again and patients were instructed to perform four online modules for the next four weeks.

During face-to-face session patients progress and exercises were discussed. In addition, physiotherapists received an online report that was automatically sent. This report contained a summary of website visits and patients experience with the strength and stability exercises. Physiotherapists were recommended to treat patients according to the e-Exercise LBP

protocol. But, with respect to their clinical competences, physiotherapists were free to deviate from the protocol.

### **Web-based intervention**

The web-based part of e-Exercise LBP is based on the web-based part of e-Exercise osteoarthritis<sup>20</sup>. The web-based part consists of three topics: 1. Graded activity module: the duration of patients' chosen PA will gradually be increased until the persons' short-term goal was reached. 2. Exercise module: contained exercises on strength and stability, each week there were two different exercises in the schedule by which the number of repeats gradually increased. 3. Information module: information about LBP, PA, pain-management, weight management, motivation, medication and social influences on pain. Every week a new online schedule was compiled. When the new schedule was available, participants received an email.

### **Health care measures**

*Limitations in activities* were measured by the Quebec Back Pain Disability Score (QBPDS)<sup>29</sup> and measured the extent to which people with LBP experience difficulty performing everyday activities. The QBPDS consists of 20 items regarding daily activities. Each item consists of a six point Likert scale ("not difficult at all" = 0 to "unable to do" = 5). Patients were asked to answer the QBPDS about the difficulty they are experiencing to perform the activities on the current day ("today")<sup>30</sup>. The total score on the QBPDS is the sum of all items with a maximum of 100 (maximal disabled). The minimal important change (MIC) is 20 points in total<sup>31</sup>.

*Pain* was measured by the Visual Analogue Scale (VAS). The VAS is an a-specific measuring scale which consists of eleven numbers (0 = no pain to 10 = the worst pain). The MIC is one and a half point on the VAS scale<sup>31</sup>. When the baseline measurement is taken into account a 30% improvement is considered a useful threshold for identifying clinically meaningful improvement<sup>31</sup>.

For subjectively measuring *physical activity*, the Short QUestionnaire to ASsess Health enhancing PA (SQUASH) was used. The SQUASH questionnaire is based on the Dutch Standard of Health Activity (DSHA) and developed for monitoring physical activities<sup>32</sup>. The SQUASH consists of 11 items combined to one score. The SQUASH measures the frequency, duration and intensity of four different physical activities: to and from work/school, at work/school, household and in leisure time. A higher score responds to more time spend on physical activities. The SQUASH is a reliable and valid questionnaire.<sup>33</sup>

The Fear Avoidance Beliefs Questionnaire (FABQ) assess *fear avoidance* beliefs in patients with back pain. The questionnaire consists of 16 items with a maximum score of 96 with two subcategories; PA with a maximum score of 30 and work with a maximum score of 66. The answers are rated on a 7-point Likert scale. The higher the scores the more pain (limitations) is experienced.



### ***Knowledge measures***

For the secondary study aim data was gathered about the knowledge of the participants about LBP and their use of the web-based part after completing the intervention. Questions about the use of e-Exercise after completing the intervention and 15 good or wrong statements, based on the information given during the e-Exercise intervention, were added to the questionnaire. Each correct answer on the statements was one point, with a maximum score of 15.

### **Ethical and Legal considerations**

The participants received information by mail about the study, and subsequently gave consent to participate before the start of the questionnaire. The Medical Ethical Committee of the Utrecht University Medical Centre declared that this research project did not fall under the Dutch Medical Research Involving Human Subjects Act (WMO).

### **Statistical analysis**

For the statistical analysis, the Statistical Package for the Social Science (SPSS 22, Chicago, IL) was used. By using descriptive statistics demographic and clinical characteristics at baseline (T0), three months (T1) and six months (T2) were presented as mean and standard deviation (SD) or percentage, as appropriate. When applicable, a two-tailed p-value of <0.05 was considered statistically significant within all the statistics tests. Data was checked on outliers by using descriptive statistics and a scatterplot.

To compare the means of the measurements, repeated measurements analyse of variance (RM ANOVA) was used initially to determine the difference over time. Since the assumptions of normal distribution and sphericity were not met, the non-parametric related-samples Friedman's two-way analysis of variance by ranks was used as alternative. When results on the Friedman test were significant a post hoc test using the Wilcoxon signed-rank test was used. For the post hoc test a Bonferroni correction was applied, resulted in a significance level set at  $0.05/3 = P 0.017$ .

### ***Missing values***

Baseline characteristics from T2 between the response and the non-response group were performed to investigate selective attrition. Among participants with missing values (T0, T1 and T2), values were checked with the little's missing completely at random (MCAR) test in SPSS and characteristic of the participants were compared between T0, T1 and T2. If the missing values were completely at random the multiple imputation method was used to estimate missing values.

### **Results**

Forty-one individuals with LBP participated in the study at baseline, of whom 18 males and 23 females with a mean age of 44 year and standard deviation (SD) of 10.4. There was a drop-out of 23 participants leaving a sample of 18 participants at the six months follow-up. A

flow diagram of participants is documented at figure 1. No differences in characteristics has been found between the respondents and drop-outs after inclusion. 50% of the participants had complaints for one year or on each time point. A total of 89% had a middle or high educational level. Table 1 presents descriptive data on demographic and other relevant characteristics.

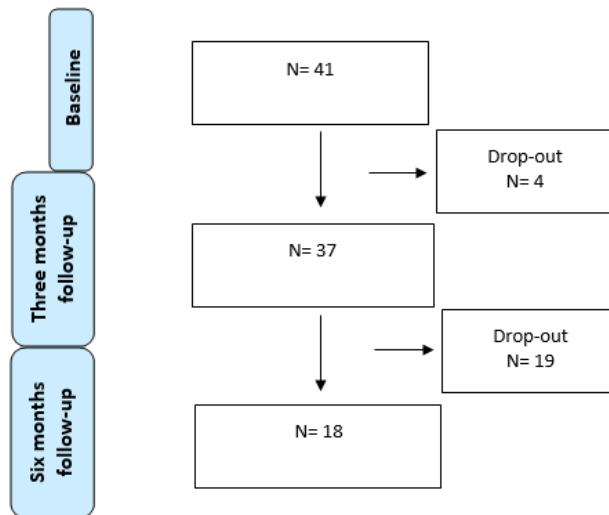


Figure 1 Flow-chart of participants

Table 1 Characteristics

	T0 N= 41	T1 N=37	T2 N=18
<b>Age</b> M ± SD	44.3 ± 10.4	44.7 ± 10.7	44.8 ± 12.2
<b>Gender</b>			
Male N (%)	18 (43.9)	17 (45.9)	6 (33.3)
Female N (%)	23 (56.1)	20 (54.1)	12 (66.7)
<b>BMI</b> M ± SD	25.9 ± 4.7	26.3 ± 4.8	25 ± 4.3
<b>Duration of complaints</b>			
0-6 weeks N (%)	5 (12.2)	4 (10.8)	3 (16.7)
6-12 weeks N (%)	6 (14.6)	5 (13.5)	4 (22.2)
12 weeks- 12 months N (%)	9 (22)	8 (21.6)	2 (11.1)
>1 year N (%)	21 (51.2)	20 (54.1)	9 (50)
<b>Education level</b>			
Low N (%)	4 (9.8)	4 (10.8)	0 (0)
Middle N (%)	17 (41.5)	14 (37.8)	4 (22.2)
High N (%)	20 (48.8)	19 (51.4)	14 (77.8)
<b>Comorbidities</b>			
Non N (%)	18 (43.9)	16 (43.2)	9 (50)
One N (%)	15 (36.6)	14 (37.8)	5 (27.8)
>1 N (%)	8 (19.5)	7 (18.9)	4 (22.2)

M= mean, SD= standard deviation N= number of participants

### Missing data

At T1 there was 10% of missing data, at T2 this was 56%. Reasons for non-response are unknown. Missing data were completely at random with a *P* value of 0.881 on the little MCAR test and imputed ten times with the multiple imputation method considering the range of each questionnaire. Multiple imputation is performed with a maximum case draw of 50 and a maximum parameter draw of 5.

### Repeated measures

The results shows an overall statistically significant improvement for disability (QBPDs) and pain (VAS) over time. Table 2 shows the mean, median and SD of disability, pain, PA pain related fear and an overview of the repeated measurement.

The combination of Chi- Square statistics for multiple imputed data is calculated using the program R statistics version x64 3.4.0.<sup>34</sup>

Table 2 Results of the measurements on each timepoint and repeated measurements.

	Time	Mean	Median	SD	Friedman test		
					F	Mean rank	P
Disability	T0	34.1	31	16.1	13.34	2.65	<0.0005*
	T1	21.8	19	17.6		1.46	
	T2	24.3	23.6	10.2		1.90	
Pain	T0	6.2	7	1.8	18.015	2.80	<0.0005*
	T1	3.3	2.5	2.4		1.78	
	T2	2.5	2.4	1.5		1.43	
Fear avoidance-total	T0	30.1	26	14.8	0.697	2.11	0.499
	T1	29.1	26.6	16.3		1.87	
	T2	28.9	28.3	12.2		2.02	
Fear avoidance-PA	T0	14.1	14	5.3	0.289	2.08	0.749
	T1	13.1	12.2	5.5		1.93	
	T2	14.2	14.4	3.9		1.99	
Fear avoidance-work	T0	16.7	15	14.5	0.195	2.01	0.823
	T1	16	15	15.2		1.88	
	T2	14.8	14	10.9		2.11	
Physical activity	T0	124.4	94.3	99.2	0.891	1.81	0.414
	T1	137.9	102.9	134.3		2.01	
	T2	151.5	147.9	71.4		2.18	

Results of the Friedman test are pooled results of 10 imputed data sets.

SD=standard deviation

\*overall statistically significant improvement over time.

### Post Hoc test

Results on the Wilcoxon signed-rank test shows a statistically significant decrease in disability and pain between T0-T1 and between T0-T2. No statistically significant difference is found between T1 and T2 in both, disability and pain. Table 3 gives an overview of the results on the Post Hoc test. Figure 2 shows the mean values of each measurement on each time point.

Table 3 Differences between two measurement points

	<b>Z</b>	<b>P</b>
<i>Disability</i>		
T0- T1	-4.596	<0.0005*
T1- T2	-1.717	0.086
T0- T2	-2.587	0.010*
<i>Pain</i>		
T0- T1	-4.722	<0.0005*
T1- T2	-2.019	0.043
T0- T2	-3.421	0.001*

Wilcoxon Rank test on the original data with Bonferroni correction  $p=0.017$ .

\*statistically significant improvement

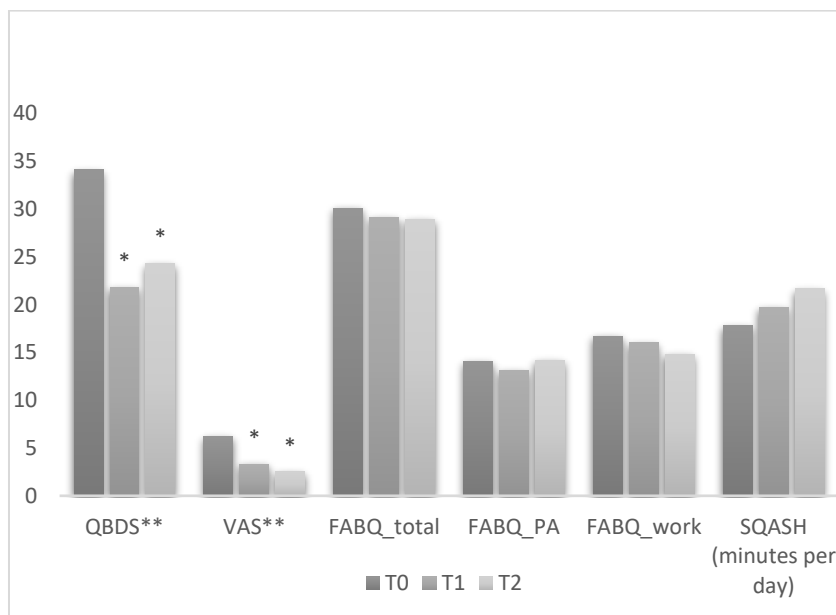


Figure 2 Mean scores on T0, T1 and T2

\* statistically significant improvement compared to T0

\*\* statistically significant improvement over time

### **Use of the web-based part after completing the intervention**

The questionnaire used for the secondary aim was answered by 16 participants. These were 11 females and five male (appendix 1). After following the e-Exercise intervention 56% of the participants were free of LBP but, 81% experienced a new episode of LBP after completing the intervention. Although, 50% remained active and 63% often performed muscle strength and/or mobilizing exercises learned from the e-Exercise intervention. The physiotherapist advised 63% of the participants to keep using the online program. After completing the intervention, 38% logged in on the web based part due to complaints with the purpose of reading the description of the exercises again.

### **Knowledge about LBP**

The last part of the questionnaire consisted of statements. Results of the statements shows a lowest score of 11 points and highest score of 15 point with a mean of 12.3. The lowest score was on statement 2; "Imaging material, such as x-ray gives a lot of information about the cause of my back pain" and is wrongly answered by 50% of the participants. Table 4 gives an overview of the statements and scores.

*Table 4 Patients' knowledge about LBP after completing the intervention*

	<b>N= 16</b>	<b>%</b>
1. Changing my mind and behaviour can affect my backpain	15	93.8
2. Imaging material, such as X-ray gives a lot of information about the cause of my backpain.	8	50
3. Body muscles, but also the muscles in the legs around the pelvis can affect low back pain	15	93.8
4. By performing exercises, the muscular load ability can be improved	16	100
5. One purpose of the exercises is to increase the load ability of your back	14	93.75
6. Pain is in relation to your behaviour, certain thoughts and certain feelings	14	87.5
7. If I experience backpain, the best I can do is to lie down in bed or on the couch with a hot jar	15	93.8
8. Painkillers reduce the pain and help to restore my back	10	62.5
9. In low back pain, paracetamol is preferred to other analgesics such as diclofenac	13	81.25
10. Stress can cause you to suffer from low back pain	15	93.8
11. Stress is always harmful	9	56.25
12. Irrational thoughts (thoughts that do not match the facts) do not affect the recovery of low back pain	14	87.5
13. When dealing with low back pain, "weather becomes active" is central	12	75
14. By moving the inserts of the intervertebral discs are fed. Moving is therefore very important for the repair of the vertebral discs	13	81.25
15. If your back pain is over, it is no longer necessary (like your central activity) to keep moving regularly	15	93.8

Number and percentage of participant who answered the statement correctly

### **Discussion**

The main purpose of this study was to examine the preliminary long- term effectiveness of a blended intervention for patients with non-specific LBP, in which face-to-face physiotherapy sessions were integrated with an online application. This study was embedded in a development and feasibility study of e-Exercise LBP. Results show an overall statistically significant improvement in pain and disability over time. For both outcomes, improvements were statistically significant between baseline and three months follow-up and between

baseline and six months follow-up. The effectiveness of e-Exercise LBP on reducing the level of pain was not only statistically significant, but also clinically relevant. Ostelo et al. (2008)<sup>31</sup> described a MIC of 1.5 points and 30% improvement versus baseline for a clinically meaningful improvement on the VAS. The results show a decrease of 3.7 points which is a 60% improvement versus baseline. There was no statistically significant difference in PA and pain related fear over time.

These results are not unusual in the literature about internet-based interventions. Previous research on the effectiveness of internet-based interventions in patients with LBP showed mixed results. For example Chiauzzi et al. (2010) compared a web-based intervention with text-based material. No statistically significant effects were found in self-reported pain and PA over time<sup>35</sup>. In contrast, Buhrman et al. (2004) used an internet-based intervention with telephone support and showed positive effects in reduction of pain<sup>22</sup>. A explanation for these positive results may be the integration of human support with a web-based intervention which has been recommended by different researchers previously<sup>21,25,26</sup>. This recommendation corresponds to the intervention used in this study.

Despite the statistically significant results between T0 and T2, there was an increase of disability and PA related fear between T1 and T2, implying that the effectiveness decreases over time. Despite the fact that many participants were positive about the intervention, 81% of the patients experienced a new episode of LBP between the three and six months follow-up. This is not an unknown pattern in patients with LBP and may be due to the fact that patients stopped doing their exercises. Namely, it appeared that a majority of the patients did not use the web-based part between three and six months follow-up although, they still had access to the web-based part including their exercises. The return of complains can be prevented by keep logging in on the web-based part. Thus, an important role of the physiotherapist is to motivate the patient to continue the use of the web-based part with the aim that patients continue to perform the exercises and stay physically active. More attention is recommended for continuous use of the program after completing the intervention. Attention for the coaching role of the physiotherapist during the instruction-course is also recommended.

The results did not show any statistically significant difference on the outcomes of PA, which was not expected since one module of e-Exercise focused specifically on gradually increasing the level of PA. This is in agreement with the results in the study of Chiauzzi et al. (2010)<sup>35</sup> and may have several reasons. The scores of fear related to PA were already low at baseline and the mean scores on the SQUASH indicated that participants almost met the DSHA standard at baseline. This could indicate that a large group of LBP patients were sufficiently physical active. Therefore, the graded activity module in the pilot study e-Exercise was not widely applied. Several studies showed a growing consensus that (exercise) therapy should be tailored to the patients specific needs<sup>36,37</sup>. Despite PA did not show any statistically significant difference results seem to show an improvement of PA over time. More power could provide better insight in these results. Besides, the use of objective data would be more

reliable than questionnaires. Moreover, these results imply that a graded activity module in the program, available as an option, is useful.

The secondary aim was to determine the level of knowledge about LBP after completing the intervention. Results on the statements showed that the majority of patients had sufficient knowledge about the etiology of LBP, pain behavior and factors related to LBP. This implies that the participants had sufficient health insight and knowledge about LBP. Unfortunately, we did not test the knowledge at baseline and therefore we can not conclude whether e-Exercise leads to an improvement in this knowledge.

The present study has some weaknesses. This study was embedded in a feasibility trial and had therefore a small sample size. The drop-out at T2 was high and the reasons for drop-out are unknown. This can influence the results but, is considered unlikely since no differences were found in characteristics between the drop-out and respondents. Therefore, multiple imputation was used for completing the data set. Multiple imputation have negligible bias and is more efficient and provides more power than complete-case analysis<sup>38</sup>. Therefore, the results are considered to be a reliable representation of the population. Second, this study was a follow-up of the pilot study e-Exercise LBP. Since the aim of the pilot study was to determine the feasibility of blended care no control group was used. Results of the pilot study showed that the usability is well appreciated by physiotherapists and patients (Kloek et al. in progress) and despite the small sample size of this study, there seems to be a beneficial effect, in both, short- and in long-term. So, further research is recommended with a large sample, a control group, booster mails for the follow-up measurements, baseline measurement of the knowledge and minimal one year follow-up, which would provide more insight in the long-term intervention effects in patients with non-specific LBP. For improvement of the program it is recommended to stimulate the use of the web-based part after completing the intervention and to add or modify the web-based part to trigger patients to log in after completing the intervention. Because blended care is fairly new a good implementation is important taking into account the needs of the physiotherapist and patient.

In conclusion, e-Exercise is an innovation in care with the blended delivery and fits well in the current care by using technology. E-Exercise LBP is a promising intervention in patients with non-specific LBP. This study showed beneficial results on pain and disability over time. However, everyone has to get used to this innovation in care, both, physiotherapists and patients. Blended care is still in the early stages. Improving the intervention is therefore recommended with attention for use of the web-based part after completing the intervention, the coaching role of the physiotherapist, care process and in the future a good implementation. Results of this study can be used to further improve e-Exercise LBP, and to assess (cost-)effectiveness of the adapted version compared to usual physiotherapy in a randomized controlled trial with 24-month follow-up.

## References

1. Hoy D, Brooks P, Blyth F, Buchbinder R. The Epidemiology of low back pain. *Best Pract Res Clin Rheumatol*. 2010;24(6):769-781. doi:10.1016/j.berh.2010.10.002.
2. Dekker-van Weering MGH, Vollenbroek-Hutten MMR, Hermens HJ. A pilot study - the potential value of an activity-based feedback system for treatment of individuals with chronic lower back pain. *Disabil Rehabil*. 2015;37(24):2250-2256. doi:10.3109/09638288.2015.1019009.
3. Hoy D, Bain C, Williams G, et al. A systematic review of the global prevalence of low back pain. *Arthritis Rheum*. 2012;64(6):2028-2037. doi:10.1002/art.34347.
4. Staal J, Hendriks E, Heijmans M, et al. KNGF richtlijn lage rugpijn. <https://www.fysionet-evidencebased.nl/index.php/richtlijnen/richtlijnen/lage-rugpijn-2013/praktijkrichtlijn>. Published 2013.
5. Macedo LG, Maher CG, Latimer J, McAuley JH. Motor control exercise for persistent, nonspecific low back pain: a systematic review. *Phys Ther*. 2009;89(1):9-25. doi:10.2522/ptj.20080103.
6. Palacín-Marín F, Esteban-Moreno B, Olea N, Herrera-Viedma E, Arroyo-Morales M. Agreement between telerehabilitation and face-to-face clinical outcome assessments for low back pain in primary care. *Spine (Phila Pa 1976)*. 2013;38(11):947-952. doi:10.1097/BRS.0b013e318281a36c.
7. Low back pain and sciatica in over 16s: assessment and management | Guidance and guidelines | NICE. <https://www.nice.org.uk/guidance/ng59/chapter/recommendations>. Accessed December 16, 2016.
8. Kline JB, Krauss JR, Maher SF, Qu X. Core Strength Training Using a Combination of Home Exercises and a Dynamic Sling System for the Management of Low Back Pain in Pre-professional Ballet Dancers: A Case Series. *J Danc Med Sci*. 2013;17(1):24-33. doi:10.12678/1089-313X.17.1.24.



9. Kääpä EH, Frantsi K, Sarna S, Malmivaara A. Multidisciplinary group rehabilitation versus individual physiotherapy for chronic nonspecific low back pain: a randomized trial. *Spine (Phila Pa 1976)*. 2006;31(4):371-376. doi:10.1097/01.brs.0000200104.90759.8c.
10. Liddle SD, Baxter GD, Gracey JH. Exercise and chronic low back pain: what works? *Pain*. 2004;107(1):176-190. doi:10.1016/j.pain.2003.10.017.
11. Rainville J, Hartigan C, Martinez E, Limke J, Jouve C, Finno M. Exercise as a treatment for chronic low back pain. *Spine J*. 2004;4(1):106-115. doi:10.1016/S1529-9430(03)00174-8.
12. Staal JB, Rainville J, Fritz J, van Mechelen W, Pransky G. Physical Exercise Interventions to Improve Disability and Return to Work in Low Back Pain: Current Insights and Opportunities for Improvement. *J Occup Rehabil*. 2005;15(4):491-505. doi:10.1007/s10926-005-8030-3.
13. van der Velde G, Mierau D. The effect of exercise on percentile rank aerobic capacity, pain, and self-rated disability in patients with chronic low-back pain: A retrospective chart review. *Arch Phys Med Rehabil*. 2000;81(11):1457-1463. doi:10.1053/apmr.2000.9629.
14. Mannion AF, Helbling D, Pulkovski N, Sprott H. Spinal segmental stabilisation exercises for chronic low back pain: programme adherence and its influence on clinical outcome. *Eur Spine J*. 2009;18(12):1881-1891. doi:10.1007/s00586-009-1093-7.
15. Henchoz Y, Kai-Lik So A. Exercise and nonspecific low back pain: A literature review. *Jt Bone Spine*. 2008;75(5):533-539. doi:10.1016/j.jbspin.2008.03.003.
16. Nava-Bringas TI, Roeniger-Desatnik A, Arellano-Hernández A, Cruz-Medina E. [Adherence to a stability exercise program in patients with chronic low back pain]. *Cir Cir*. 2016;84(5):384-391. doi:10.1016/j.circir.2015.10.014.
17. Escolar-Reina P, Medina-Mirapeix F, Gascón-Cánovas JJ, et al. How do care-provider and home exercise program characteristics affect patient adherence in chronic neck and back pain: a

- qualitative study. *BMC Health Serv Res.* 2010;10(1):60. doi:10.1186/1472-6963-10-60.
18. Hügli AS, Ernst MJ, Kool J, et al. Adherence to home exercises in non-specific low back pain. A randomised controlled pilot trial. *J Bodyw Mov Ther.* 2015;19(1):177-185. doi:10.1016/j.jbmt.2014.11.017.
  19. Kelders SM, Kok RN, Ossebaard HC, Van Gemert-Pijnen JEW. Persuasive system design does matter: a systematic review of adherence to web-based interventions. *J Med Internet Res.* 2012;14(6):e152. doi:10.2196/jmir.2104.
  20. Kloek CJ, Bossen D, Veenhof C, van Dongen JM, Dekker J, de Bakker DH. Effectiveness and cost-effectiveness of a blended exercise intervention for patients with hip and/or knee osteoarthritis: study protocol of a randomized controlled trial. *BMC Musculoskelet Disord.* 2014;15(1):269. doi:10.1186/1471-2474-15-269.
  21. Jansen-Kosterink S, in 't Veld RH, Hermens H, Vollenbroek-Hutten M. A Telemedicine Service as Partial Replacement of Face-to-Face Physical Rehabilitation: The Relevance of Use. *Telemed e-Health.* 2015;21(10):808-813. doi:10.1089/tmj.2014.0173.
  22. Buhrman M, Fältenhag S, Ström L, Andersson G. Controlled trial of Internet-based treatment with telephone support for chronic back pain. *Pain.* 2004;111(3):368-377. doi:10.1016/j.pain.2004.07.021.
  23. Schulz PJ, Rubinell S, Hartung U. An internet-based approach to enhance self-management of chronic low back pain in the Italian-speaking population of Switzerland: Results from a pilot study. *Int J Public Health.* 2007;52(5):286-294. doi:10.1007/s00038-007-5127-9.
  24. Dario AB, Moreti Cabral A, Almeida L, et al. Effectiveness of telehealth-based interventions in the management of non-specific low back pain: a systematic review with meta-analysis. *Spine J.* 2017. doi:10.1016/j.spinee.2017.04.008.

25. Vandelanotte C, Spathonis KM, Eakin EG, Owen N. Website-Delivered Physical Activity Interventions: A Review of the Literature. *Am J Prev Med*. 2007;33(1):54-64. doi:10.1016/j.amepre.2007.02.041.
26. Brouwer W, Kroeze W, Crutzen R, et al. Which intervention characteristics are related to more exposure to internet-delivered healthy lifestyle promotion interventions? A systematic review. *J Med Internet Res*. 2011;13(1):e2. doi:10.2196/jmir.1639.
27. CONSORT-EHEALTH checklist. <http://www.jmir.org/ojs/public/journals/1/CONSORT-EHEALTH-v1-5.pdf>. Accessed February 20, 2017.
28. Keele University. The Keele STarT Back Screening Tool. <https://www.keele.ac.uk/sbst/startbacktool/>. Accessed November 11, 2016.
29. Kopec JA, Esdaile JM, Abrahamowicz M, et al. The Quebec Back Pain Disability Scale. Measurement properties. *Spine (Phila Pa 1976)*. 1995;20(3):341-352. <http://www.ncbi.nlm.nih.gov/pubmed/7732471>. Accessed December 16, 2016.
30. Smeets R, Köke A, Lin C-W, Ferreira M, Demoulin C. Measures of function in low back pain/disorders: Low Back Pain Rating Scale (LBPRS), Oswestry Disability Index (ODI), Progressive Isoinertial Lifting Evaluation (PILE), Quebec Back Pain Disability Scale (QBPDS), and Roland-Morris Disability Questionnaire. *Arthritis Care Res (Hoboken)*. 2011;63(S11):S158-S173. doi:10.1002/acr.20542.
31. Ostelo RWJG, Deyo RA, Stratford P, et al. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. *Spine (Phila Pa 1976)*. 2008;33(1):90-94. doi:10.1097/BRS.0b013e31815e3a10.
32. Terwee CB, Bouwmeester W, Van Elsland SL, De Vet HCW, Dekker J. Instruments to assess physical activity in patients with osteoarthritis of the hip or knee: a systematic review of measurement properties. *Osteoarthr Cartil*. 2011;19:620-633. doi:10.1016/j.joca.2011.01.002.

33. Wendel-Vos GCW, Schuit AJ, Saris WHM, Kromhout D. Reproducibility and relative validity of the short questionnaire to assess health-enhancing physical activity. *J Clin Epidemiol*. 2003;56(12):1163-1169. doi:10.1016/S0895-4356(03)00220-8.
34. R Core team. R: The R Project for Statistical Computing. doi:ISBN 3-900051-07-0.
35. Chiauuzzi E, Pujol LA, Wood M, et al. PainACTION-Back Pain: A self-management website for people with chronic back pain. *Pain Med*. 2010;11(7):1044-1058. doi:10.1111/j.1526-4637.2010.00879.x.
36. Dankaerts W, O'Sullivan PB, Straker LM, Burnett AF, Skouen JS. The inter-examiner reliability of a classification method for non-specific chronic low back pain patients with motor control impairment. *Man Ther*. 2006;11(1):28-39. doi:10.1016/j.math.2005.02.001.
37. Fersum K V, Dankaerts W, O'Sullivan PB, et al. Integration of subclassification strategies in randomised controlled clinical trials evaluating manual therapy treatment and exercise therapy for non-specific chronic low back pain: a systematic review. *Br J Sports Med*. 2010;44(14):1054-1062. doi:10.1136/bjism.2009.063289.
38. White IR, Carlin JB. Bias and efficiency of multiple imputation compared with complete-case analysis for missing covariate values. *Stat Med*. 2010;29(28):2920-2931. doi:10.1002/sim.3944.

## Appendix 1

<b>Questionnaire</b>	
1. Did you suffer from low back pain after completing the e-Exercise intervention?	<ul style="list-style-type: none"> <li>a. Yes</li> <li>b. no</li> </ul>
1b. How can you describe the course of the low back pain?	<ul style="list-style-type: none"> <li>a. The low back pain was/ is continuously present (every day)</li> <li>b. The low back pain was sometimes totally gone, but has also come back one or more times. Number of times the back pain was present:</li> </ul>
2. Are there any learning points from the e-Exercise intervention that you apply to your daily life?	<ul style="list-style-type: none"> <li>a. No, I do not have enough physical activity and do not do any exercises</li> <li>b. Yes, I make sure that, despite any back pain, I stay physically active through activities like walking, cycling or swimming</li> <li>c. Yes, I still do muscle enhancing or releasing exercises of the e-Exercise program</li> <li>d. Other:</li> </ul>
3. Have you been advised to continue using the online program after discontinuing physical therapy treatments?	<ul style="list-style-type: none"> <li>a. Yes</li> <li>b. No</li> </ul>
4. Have you logged in to the site after completing the e-Exercise program?	<ul style="list-style-type: none"> <li>a. Yes, because of low back pain</li> <li>b. Yes, but I had no low back pain problems</li> <li>c. No</li> </ul>
4b. What was the reason for your visit to the website?	<ul style="list-style-type: none"> <li>a. Reading back and viewing information</li> <li>b. Reading back and watching exercises</li> <li>c. Other:</li> </ul>

## Samenvatting

**Achtergrond:** Lage rugpijn is een veel voorkomende klacht. Nationale en internationale richtlijnen raden fysiotherapie aan bij patiënten met lage rugpijn wat bestaat uit infomeren, adviseren en activeren (oefeningen). Maar, therapietrouw blijft een terugkerend probleem bij oefentherapie. Blended care, wat bestaat uit een integratie van face-to-face behandelingen met een web-applicatie heeft verschillende voordelen zoals de mogelijkheid patiënten te kunnen herinneren aan oefeningen en fysiek activiteit. Het doel van deze studie was het onderzoeken van het voorlopige lange termijn effect van blended care oefentherapie bij patiënten met lage rugklachten. De hypothese was dat blended care effectief is op de lange termijn bij pijn, beperkingen, fysieke activiteiten en pijn gerelateerde angst.

**Methode:** Dit onderzoek is een vervolg op de pilot studie e-Exercise lage rugklachten. Deze pilot was gericht op het onderzoeken van de bruikbaarheid en effectiviteit op korte termijn (3 maanden) van e-Exercise lage rugklachten. Totaal 41 patiënten tussen de 18 en 65 jaar met specifieke lage rugklachten die deelnamen aan de pilot studie, zijn na zes maanden benaderd voor het beoordelen van hun pijn, beperkingen, fysieke activiteiten en pijn gerelateerde angst. Voor het meten van deze factoren is gebruik gemaakt van een vragenlijst welke bestond uit de Quebec Back Pain Disability Score (QBPD), Visual Analogue Scale (VAS), Short QUestionnaire to ASsess Health enancing (SQUASH) and Fear Avoidance Beliefs Questionnaire (FABQ). Longitudinale data-analyse is gebruikt voor het analyseren van het voorlopige lange-term effect middels de niet-parametrisch Friedman test.

**Resultaten:** The Friedman test liet een statistisch significante verschil over tijd zien in vermindering van beperkingen en pijn ( $P = <0.0005$ ,  $P = <0.0005$ ). De post hoc test liet bij beperkingen en pijn een statistisch significant verschil zien tussen baseline en drie maanden follow-up ( $P = <0.0005$ ,  $P = <0.0005$ ) en tussen baseline en zes maanden follow-up ( $P = 0.010$ ,  $P = 0.001$ ).

**Conclusie:** De blended interventie e-Exercise lijkt een veel belovende interventie voor het verminderen van beperkingen en pijn bij patiënten met lage rugklachten. Het gebruik van technologie past goed in de huidige zorg. Maar, blended care is nieuw voor fysiotherapeuten en heeft nog verdere ontwikkelingen nodig met aandacht voor een goede implementatie in de toekomst.

**Kern woorden:** Fysiotherapie, lage rug pijn, oefeningen, telemedicine en blended care.