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Chronic low back pain (CLBP) is a common disorder. CLBP is associated with a long burden of disease, a deteriorated quality of life, work absenteeism and high healthcare costs. It is important to manage this economic burden with treatments that decrease or cure CLBP. Podopostural treatment is one of the possible treatment strategies against CLBP.

The aim of this study was to estimate the course of the costs among patients with CLBP who are treated with podopostural soles and to determine which variables are predictors of costs after 18 months of treatment.

This research concerned an observational prospective cohort design. The data for the costs outcomes, healthcare and societal costs, was collected by cost diaries at four time points. Both, the total costs per cost category were calculated and the mean costs per month at each evaluation moment. The data for predictor variables was collected by questionnaires at five time points. Multiple imputations were used for missing data. Univariate linear regression analyses were done to identify possible predictors. Final predictors were selected with multivariate linear regression analyses. Bootstrapping with 5000 replications was performed during the univariate and multivariate analyses to assess statistical uncertainty. A significance level of 0.20 was used for the prediction models.

The main contributor to societal costs (€2370.94) was the costs of lost productivity (€1191.97). Thereafter, the healthcare costs (€1138.64) and the patient costs (€40.34) contributed the least. Pain intensity over the previous week at baseline was a predictor for healthcare costs (B: 45, 80% CI 8; 78). Pain intensity over the previous week at baseline (B: 1466, 80% CI 151; 2917) and general health status at baseline (B: -1873, 80% CI -3905; -371) significantly predicted the societal costs.

Lower costs per month were found at the last evaluation moment compared to the first. A high pain intensity over the previous week at baseline predicted more healthcare and societal costs. A higher general health status predicted lower societal costs. Future research should be conducted on the cost-effectiveness of podopostural treatment in order to compare the treatment with other treatment options.

Low back pain (LBP) is a disorder with a high prevalence.[1] Commonly, LBP is a consequence of disorders in the structures that are located in and around the spine.[1] A wide variety exists in the occurrence of LBP. The pain can be very mild to unbearable. Complaints can be of short duration or be present for a long time and people can be limited in their functioning.[1] The experience and severity of pain differs per person and the pain can radiate to the legs and buttocks.[1] Moreover, LBP can show a strongly varying course, for example a slight pain with occasional worsening.[1] Back complaints are more common among women than men. The number of diagnosed people grows with age.[2] In the Netherlands, approximately 50% to 90% of all adults will experience an episode of LBP in their lifetime. Annually, about 20% of the Dutch population experiences LBP.[1, 3-4]

The effects of LBP are not limited to physical problems. It can lead to work absenteeism, disability, restriction of social activities and a deterioration of quality of life.[5-7] Furthermore, people with LBP have a higher consumption of medication and pay more visits to physiotherapists, physicians, private care and other health services. These consequences result in high healthcare and societal costs.[8]

Every year approximately 6.8% of the Dutch population visits the general practitioner due to LBP and 1.4% is referred to paramedical care, in particular to the physiotherapist.[1] Throughout the years 2008, 2009 and 2010, 15% of the patients of physiotherapists suffered from LBP.[9] Moreover, LBP is an important reason for absenteeism. Approximately 90% of the costs that are associated with LBP are social security payments for disability to work and absenteeism due to sickness.[10] In 2007, the total costs for LBP were estimated at 3.5 billion euros in the Netherlands, the costs for physiotherapy were estimated at 204 million euros and the costs for manual therapy were estimated at 7 million euros.[10] It is important to monitor the development of these costs and to ensure that they remain manageable.

A previous study has looked at work absenteeism and reintegration at work due to LBP. This study showed that 67% of the people that were absent at work, resumed their work within a week. This percentage was 84% after one month and 90% after 2 months.[11] However, those who are still absent at work after 3 months, have a great chance of long-term or permanent disability to work. The change in reintegration at work after 3 months is not a coincidence. People who suffer from LBP for less than 3 months are being labeled as people with acute low back pain and people who suffer from LBP for at least 3 months are being labeled as people with chronic low back pain (CLBP).[5] Studies including only patients with CLBP showed a more stable, but more negative picture for both pain and costs.[12-14] More than half of the patients with CLBP still have complaints after 1 or 2 years.[12-14] It seems that the longer the pain in the back lasts, the worse the prognosis is. This certainly is the case with absenteeism. Most costs come from the people with CLBP, therefore this study will focus on CLBP patients only.[15]

Several treatments are supported by clinical guidelines: mobilization/ manipulation, yoga, acupuncture, massage therapy back school, and multidisciplinary treatment. These treatments are used to cure, decrease or prevent the pain in the back.[5, 16-17] However, adverse effects, complexity and the costs of those treatments are factors that play a role in the growing interest in alternative

treatments.[18] A commonly used alternative treatment is the use of podopostural soles. Some research has already been carried out into the functioning of the podopostural soles.

The desired effect of podopostural treatment is to reduce or cure CLBP by improving the foot position and body posture with thin, activating soles. Small elements of cork within these soles are used to stimulate the foot position and posture muscles. A change in foot position affects the ankles, knees, hips, back and shoulders, eventually resulting in a change of the total body posture. The podopostural soles activate the body to put itself into a new balanced state, causing CLBP to possibly disappear.[19-20]

Little evidence is available on the effectiveness of podopostural soles.[21] No research is conducted on the costs that are generated by patients receiving podopostural treatment. Therefore, this pilot study was performed on the costs among CLBP patients who started the podopostural treatment.
The aim of this study is to estimate the course of the healthcare and societal costs among patients with CLBP who are treated with podopostural soles and to determine which variables are predictors of costs after 18 months of treatment.

Design and procedures

This study concerned an observational prospective cohort design. The research was conducted between May 2014 and March 2018; all participants were followed 18 months over time. A primary care podopostural practice in the Netherlands was participating in the study. All new patients in the practice that were having CLBP, were informed about the study during their first consult. More information was given in written form when patients showed their interest in the study. Approximately two days after receiving the information, patients were expected to make a decision whether or not to participate in the study. After agreeing to participate, the podopostural therapist obtained an informed consent and collected baseline questionnaires. During the first consult, the body posture of the patient was checked. An imbalance in body posture that could be related to the CLBP complaints, was necessary to start with the podopostural soles treatment and to be included in the present study. The patient's general practitioner would be informed by the podopostural therapist. During every following consult, the body posture was checked again. If necessary, the soles would be adjusted so the body posture could improve even more.

Research population

To be eligible, the participants needed to have CLBP with or without radiation to the leg. Furthermore, the participants had to meet the minimum age of 18 years old and needed to accept the consequences of the treatment. Patients were excluded from the study when they had neuropathic pain, presumably a serious disease, a rheumatic disease, severe cardiovascular disorders, central and peripheral neurologic disorders, insulin dependent diabetes or dementia. Treatment for psychiatric disorders, insufficient knowledge of the Dutch language and pregnancy were exclusion criteria as well.

The study primarily started with 54 patients. One participant stopped before the start of the treatment. As a result, the study was performed with 53 participants.

Predictor variables

The data comes from four questionnaires that were administered at baseline. Previous studies have shown that the following variables predict costs for CLBP: gender, age, highest completed education, unemployment, pain intensity over the previous week, general health status and functional status.[2, 22-27] The data for the variables gender, age, education, unemployment and pain intensity over the previous week was obtained from a characteristics questionnaire at baseline. The variable age was dichotomized into the groups age until 54 years old, 19 to 54 years old and age upwards from 55 years old, 55 years and older.[28] The variable highest completed education contained several categories without participants. Therefore, the variable was dichotomized into the categories lower/middle education and higher education. The lower/middle education consisted of elementary education, vocational education and secondary education. The higher education consisted of applied sciences and university.[29] The variable pain intensity over the previous week was dichotomized into the categories low intensity of pain 0 to 5 and high intensity of pain 6 to 10.[30-31] General health status and functional status were measured with the Rand-36 Health survey.[32] This questionnaire is an instrument to measure self-assessed health or health-related quality of life. The questionnaire consists of the following subcategories: physical functioning, social functioning, role limitations due to physical or emotional problems, mental health, energy, pain and general health experience.

Recoding and summation of several questions is needed to obtain a total score between 0 and 100. Functional status consisted of the subcategories physical functioning (Rand-36 Health survey) and social functioning (Rand-36 Health survey). Higher total scores indicate a better health condition.[33] General health status and functional status were dichotomized into the categories lower general health/functional status 0 to 54 and higher general health/functional status 55 to 100, based on the school grading system (insufficient/sufficient) in The Netherlands.[34]

Outcome variables

The first dependent variable, the total healthcare costs, consisted of primary care (general practitioner visits, therapist visits and alternative care), secondary care (specialist visits, hospital research and hospitalization), prescription medication and treatment costs. The second dependent variable was the total societal costs which consisted of patient costs (no prescribed medication, (un)paid help, tools), healthcare costs and lost productivity costs (absenteeism of paid labour and absenteeism of unpaid labour).

Healthcare utilization and societal costs were measured by means of cost diaries. The cost diaries were returned to the researchers after 2, 5, 9 and 18 months of follow-up.

The course of the costs was split up into 7 categories. The patient costs, the healthcare costs, the primary care, the secondary care, the prescription medication, the lost productivity costs and the societal costs as shown in Table 3.

The treatment costs per patient were measured at the end of the study. Therefore, the treatment costs were only included in the total healthcare and societal costs.

The costs of each cost category were calculated per patient at T1-T4. The costs per patient were divided by the number of months between the evaluation moments, because of the different time ranges between the evaluation moments. In addition, the total costs were calculated for each cost category.

The costs for healthcare utilization were valued using the standard costs of the Dutch guidelines for cost studies of 2016.[38] All prices however, were adjusted to the year 2017 using consumer price indices.[39] Medication prices were estimated using unit prices from the Dutch care institute pharmacy database.[40] The prices for paid help and tools were already filled in by the participants. The prices per cost categories used in the study are shown in Table 1.

Statistical analysis

The statistical analysis of the study was performed with Statistical Package for the Social Sciences (SPSS 23.0).

Predictive Mean Matching multiple imputations of 5 were done to impute missing data in the small dataset. The pooled mean of the 5 imputed datasets was calculated and used as value for each variable in the analysis.

The dependent variables total healthcare costs and total societal costs were checked on normal distribution in SPSS with the histogram. The dependent variables were non-normally distributed. Therefore, bias-correcting bootstrapping of 5000 replications was used to assess statistical uncertainty during the analyses. A linearity check was done for each continuous predictor variable. The variables age, pain intensity over the previous week, general health status and functional status were not linearly distributed with the dependent variables and therefore dichotomized.

All predictor variables were checked univariately on their relation with the dependent variable.

The linear regression analysis with bias-correcting bootstrapping of 5000 replications was done for

the univariate analysis because of the continuous character of the dependent variables. A significance level of 0.20 was used as cut-off for predictors. Thereafter, the variables that significantly predicted the outcome were checked on their correlation with each other by the Pearson test. No correlation of 0.8 or more was found.
Since there were only 53 participants a maximum of 5 predictors was set beforehand to keep the prediction models more reliable. The backward selection procedure was used as the method for the multivariate analyses. Likewise, the linear regression analysis with bias-correcting bootstrapping of 5000 replications was done for the multivariate analyses. The variable with the largest p value and a significance level larger than 0.20 was excluded from the multivariate analyses. This was done until all variables significantly predicted the outcome. The quality of the prediction models was assessed by the R-squares.

Prices used in the economic evaluation

Healthcare costs	
Primary care	
General practitioner, per visit	33.76
Manual therapy, per treatment session	33.76
Mensendieck therapy, per treatment session	39.18
Chiropractic therapy, per treatment session	34.79
Occupational therapy, per treatment session	39.18
Physical therapy, per treatment session	33.76
Sports masseur[a]	33.76
Pelvis physiotherapist[a]	33.76
Movement-cure therapy[a]	33.76
Sports physiotherapist[a]	33.76
Podopostural treatment[a]	33.76
Orthomanual therapy [a]	33.76
Osteopath, per treatment session	39.18
Masseur[b]	39.18
Shiatsu masseur[b]	39.18
Magnetizer[b]	39.18
Haptonoma[b]	39.18
Acupuncture[b]	39.18
Oriental massage[b]	39.18
Secondary care	
X-ray, per image	143.24
Echo, per visit	81.85
MRI scan, per scan	219.97
Blood test, per visit	29.73
Pain clinic, per visit[c]	81.85
Surgeon, per visit	74.69
Neurologist, per visit	101.66
Otorhinolaryngologist, per visit[c]	81.85
Anesthetist, per visit	74.69
Orthopedist, per visit[c]	81.85
Hospitalization, per day	453.25
Non-healthcare costs	
Informal care, per hour	14.32
Absenteeism paid labour, per hour	35.55
Absenteeism unpaid labour, per hour	14.32

[a]Based on the price of the physiotherapist.

[b]Based on the price of the osteopath.

[c]The reference price for an outpatient clinic visit.

The characteristics of the research population and descriptive data per variable are described in Table 2. The total research population consisted of 53 participants. At the start of the study, 13 men and 40 women in the age of 19 to 77 years old were participating. A few noticeable characteristics were observed among the participants. A majority of the participants (62.3%) completed lower/middle education, most participants had a job (73.6%) and 11.3% of the participants received a sickness benefit.

Characteristics and descriptive data of the research population

	N = 53; (%)*
Men	13 (24.5)
Age upwards from 55 years old	19 (35.8)
Previous episodes of low back pain	30 (56.6)
Higher completed education	20 (37.7)
Employed	39 (73.6)
Received sickness benefit	6 (11.3)
High pain intensity over the previous week	31 (58.5)
Rand-36[a]	
Higher general health status	22 (41.5)
Higher functional status	33 (62.3)

*All values are pooled means of the five imputed datasets

[a]Rand-36 Health survey

Table 3 shows the total costs of CLBP generated by patients over 18 months of podopostural treatment and the costs at each evaluation moment during the study, starting from the cost diary at T1. The cost categories with the highest burden per month were the costs of lost productivity at T0-T1 and T1-T2 and the healthcare costs at T2-T3 and T3-T4. The prescription medication was the category that contained the least costs per month at all evaluation moments. Table 3 shows an increase in several cost categories at T1-T2 and T2-T3 compared to the previous evaluation moment. The costs per month at T3-T4 were lower than the costs per month at T0-T1 in all costs categories. The total societal costs per patient over an 18 month period were €2370.94 and €1138.64 for total healthcare costs. The total costs of lost productivity (€1191.97) were the main contributor to the societal costs with 50.3%. Thereafter, the healthcare costs with 48.0% and patient costs contributed the least with 1.7%.

The course of the costs per month and the total costs.

Patient costs	€ 1.38	€3.04	€5.22	€0.30	€40.34
Healthcare costs[a]	€85.53	€54.19	€38.57	€17.96	€1138.64
Primary care	€67.11	€27.68	€25.36	€15.04	€434.55
Secondary care	€17.79	€20.01	€12.38	€2.65	€180.06
Prescription medication	€0.64	€0.05	€0.06	€0.01	€2.26
Costs of lost productivity	€184.98	€205.65	€7.04	€1.66	€1191.97
Societal costs[b]	€272.13	€273.95	€45.99	€19.95	€2370.94
Podopostural treatment	-	-	-	-	€521.76

*All values in this category are pooled means of the five imputed datasets

[a]Healthcare costs are the sum of the primary healthcare costs, secondary healthcare costs, prescription medication and podopostural treatment costs

[b]Societal costs are the sum of the patient costs, healthcare costs and costs of lost productivity

The possible predictor variables were checked univariately and multivariately on their relation with the total healthcare costs as shown in Table 4. Solely, a high pain intensity over the previous week was a predictor for healthcare costs. The multivariate model indicated that patients with a high intensity of low back pain over the previous week at baseline would make €38 more healthcare costs than patients with a low intensity of low back pain over the previous week at baseline.
An R-square of 0.020 was found for the prediction model with healthcare costs. The pain intensity over the previous week explained 2.0% of the variance within the healthcare costs.

Univariate and multivariate analysis with the total healthcare costs

Men	-143	
	(-377; 90)	
Age upwards from 55 years old	-63	
	(-295; 174)	
Higher completed education	-90	
	(-335; 153)	
Employed	-295	
	(-712; 97)	
High pain intensity over the previous week	45	45
	(8; 78)	(8; 78)
Higher general health status	-116	
	(-348; 114)	
Higher functional status	106	
	(-107; 304)	

*All values in this category are pooled means of the five imputed datasets

Likewise, all possible predictor variables were checked univariately and multivariately on their relation with the total societal costs as shown in Table 5. The variables gender, pain intensity over the previous week and general health status predicted societal costs in the univariate analysis. The highest correlation between those variables was 0.702 for gender and general health status.
The final prediction model for societal costs consisted of a high pain intensity over the previous week at baseline (B: 1466, 80% CI 151; 2917) and a higher general health status at baseline (B: -1873, 80% CI -3905; -371).
An of 0.064 was found for the prediction model with societal costs. Pain intensity over the previous week and general health status explained 6.4% of the variance within the societal costs.

Univariate and multivariate analysis with the total societal costs

Men	-1194	
	(-2430; -226)	
Age upwards from 55 years old	-987	
	(-2416; 115)	
Higher completed education	845	
	(-696; 2545)	
Employed	717	
	(-128; 1612)	
High pain intensity over the previous week	1010	1466
	(16; 2064)	(151; 2917)
Higher general health status	-1516	-1873
	(-3103; -325)	(-3905; -371)
Higher functional status	-1634	
	(-3961; 92)	

*All values in this category are pooled means of the five imputed datasets

The aim of this study was to estimate the course of the costs among patients with CLBP who are treated with podopostural soles and to determine which variables are predictors of costs after 18 months of treatment.

First of all, the results of the course and the distribution of the costs compared to previous studies. The course of the costs per month showed that several cost categories increased in costs at T1-T2 or T2-T3 compared to the previous evaluation moment. This might be due to the muscle pain that is associated with the podopostural soles in the first months of treatment.[43] Nevertheless, the course of the costs per month showed a downward trend in all cost categories at T3-T4 compared to T0-T1. The main contributor to societal costs was the costs of lost productivity. Thereafter the healthcare costs and the patient costs contributed the least. This distribution and the amount of it were in accordance with previous studies, except for the amount of healthcare costs.[1, 8, 10, 15] The higher contribution percentage in the present study must be partly due to the inclusion of the treatment costs. Moreover, the present study focused on CLBP instead of LBP in the previous study.[10] CLBP is associated with higher healthcare costs.[15]

Secondly, the results of the prediction models for healthcare and societal costs compared to previous studies. The multivariate analysis showed that a high pain intensity over the previous week at baseline would lead to higher healthcare costs. This finding is in line with a previous study that looked at the predictors of LBP.[23] The prediction can be explained by the fact that patients often initiate primary-care visits, if symptoms limit the ability to perform important daily tasks.[23]

The variables pain intensity over the previous week and general health status were predictors for societal costs. The prediction model indicated that a high pain intensity over the previous week at baseline would lead to higher societal costs than a low pain intensity over the previous week at baseline. A previous study showed that a high pain intensity significantly increased the likelihood of sick leave, which is part of the costs of lost productivity.[44] Together with the explanation for the higher healthcare costs this might be the reason for higher societal costs.[23, 44] The category a higher general health status at baseline made less societal costs compared to the category a lower general health status at baseline. This result could be explained by the fact that general health status can interact with the physical load and with the satisfaction that is derived from work. Patients with a lower general health status are less likely to resume heavy and unsatisfactory work.[45] Work absenteeism causes high societal costs.[10]

The present study contained several limitations and strengths. The power of the analysis was not high due to the small dataset. However, a pilot study was necessary to gain insight into the costs of CLBP together with podopostural treatment. Furthermore, the variables age, pain intensity over the previous week, general health status and functional status were dichotomized because of non-linearity. As a result of dichotomization, relevant information about the variable gets lost. On the other hand, the cut-off for all dichotomized variables was based on literature and beta coefficients are easier to interpret. Some of the costs for therapist visits, alternative care and specialist visits were unknown. Therefore, their costs were based on the price of the physiotherapist, osteopath and the reference price for an outpatient clinic visit. Another limitation was that some patients did not fill in the total amount of medication. The estimated amount was used for the calculation of the costs. Finally, in previous studies more predictors were found for healthcare and societal costs associated with CLBP: gender, age, education, unemployment and functional status.[2, 22-27] Most of those

variables did not significantly predict healthcare or societal costs in the present study. This difference could have been caused by the treatment, since this study examined on the costs among CLBP patients that are treated with podopostural soles. Another explanation for this dissimilarity may be the specific research population that came from one podopostural practice in The Netherlands.
In addition to the above, it is important to note several strengths of the study. The data of the present study was obtained from validated questionnaires. Furthermore, the participants were followed 18 months over time. This period covers the time the body needs to put itself into a new balanced state.[19, 43] Finally, the study did not only focus on healthcare costs but also on societal costs. The societal perspective makes it possible to disaggregate the data, to translate the economic evaluation to another context and to do the analysis from a different perspective.

Conclusion

Total societal costs over 18 months in patients initiating treatment with podopostural soles were high, with lost productivity being the largest contributor. The positive trend in the course of the costs per month showed a decrease at the end of the study (T3-T4) compared to the start of the study (T0-T1) in all cost categories. Furthermore, a high pain intensity over the previous week was a predictor for more healthcare and societal costs. A higher general health status predicted lower societal costs. The course of the costs per month gives rise to conduct future research on the cost-effectiveness of podopostural treatment in order to compare the treatment with other treatment options. In addition, it might be interesting to conduct more research into the predictors associated with costs of CLBP and podopostural treatment in another part of the country and with a large research population to see if the predictors are comparable.

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