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Effectiveness and cost-utility of a multifaceted eHealth strategy to improve back pain beliefs of patients with non-specific low back pain: a cluster randomised trial

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ABSTRACT

Objectives To assess the effectiveness and cost-utility of a multifaceted eHealth strategy compared to usual care in improving patients' back pain beliefs, and in decreasing disability and absenteeism.

Design Stepped-wedge cluster randomised trial with parallel economic evaluation.

Setting Dutch primary healthcare.

Participants Patients diagnosed with non-specific low back pain by their general practitioner or physiotherapist. Patients with serious comorbidities or confirmed pregnancy were excluded. 779 patients were randomised into intervention group (n=331, 59% female; 60.4% completed study) or control group (n=448, 57% female; 77.5% completed study).

Interventions The intervention consisted of a multifaceted eHealth strategy that included a (mobile) website, digital monthly newsletters, and social media platforms. The website provided information about back pain, practical advice (eg, on self-management), working and returning to work with back pain, exercise tips, and short video messages from healthcare providers and patients providing information and tips. The control consisted of a digital patient information letter. Patients and outcome assessors were blinded to group allocation.

Primary and secondary outcome measures The primary outcome was back pain beliefs. Secondary outcome measures were disability and absenteeism, and for the preplanned economic evaluation quality of life and societal costs were measured.

Results There were no between-group differences in back pain beliefs, disability, or absenteeism. Mean intervention costs were €70— and the societal cost difference was €535—in favour of the intervention group, but no significant cost savings were found. The incremental cost-effectiveness ratio indicated that the intervention dominated usual care and the probability of cost-effectiveness was 0.85 on a willingness-to-pay of €10.000/quality adjusted life year (QALY).

Conclusions A multifaceted eHealth strategy was not effective in improving patients' back pain beliefs or in decreasing disability and absenteeism, but showed promising cost-utility results based on QALYs.

Strengths and limitations of this study

► Robust study design: stepped-wedge cluster randomised controlled trial.
► Comprehensive, multifaceted eHealth strategy for low back pain.
► Effectiveness and cost-utility evaluated.
► High rate of loss to follow-up in intervention group (40%) compared with control group (23%).

BACKGROUND

Low back pain (LBP) is a major medical problem throughout the world. The global 1-month point prevalence is estimated to be 23.2%.[1] LBP is the leading cause of musculoskeletal and work disability, and years lived with disability (YLDs) worldwide.[2 3] Recent estimates from the Global Burden of Disease Study indicate that LBP accounts for 57 million YLDs, and that over 250 million people develop LBP annually.[2] The economic burden of LBP is high. Estimates of the annual economic burden of LBP vary from between AU$9.17 billion in Australia, £12.3 billion in the UK, and US$91 billion in the USA.[4–6] In the Netherlands, recent estimates report the costs of LBP to be around €1.3 billion, a quarter of all healthcare costs due to musculoskeletal disorders.[7] However, indirect costs due to absenteeism and to reduced productivity while at work are not included in this estimate. Previous research has shown that indirect costs make up 88% of all societal costs due to LBP.[8] Since LBP leads to a high proportion of work absence, the costs of LBP in the Netherlands are much

higher than suggested.[7] Besides the burden on society, LBP has a high burden on the lives of individuals. Over the past decades, several studies have shown that people with negative back pain beliefs have more pain, disability, negative work-related outcomes (ie, productivity loss and sickness absence), and higher healthcare utilisation.[9–12]

Many guidelines for LBP recommend self-management for patients, which is a reflection of a newly proposed definition of health, that is, 'health as the ability to adapt and self-manage'.[13 14] A systematic review on the effectiveness of education programmes designed to improve self-management suggested that these programmes are effective in improving pain intensity and disability, but did not measure actual self-management.[15]

Underlined by the high economic, societal, and individual burden of LBP, no highly effective treatment for LBP has yet been found. However, eHealth, which is the provision of (personalised) healthcare at a distance (eg, through internet and thus digital), has shown promise with regards to its' effectiveness and cost-effectiveness in improving outcomes such as patient health, patient satisfaction, self-management and healthcare costs in patients with physical diseases.[16 17] Therefore, the current study aimed to assess the effectiveness and cost-utility of a multifaceted eHealth strategy to improve beliefs, knowledge, and self-management of LBP compared with usual care in improving patients' back pain beliefs, and in decreasing their disability and absenteeism.

METHODS
Study design
This study was part of a cluster-randomised controlled trial with a preplanned parallel economic evaluation, that was registered in 2013 with the Netherlands Trial Register (NTR).[18] The trial lasted from September 2013 to September 2017, with the actual intervention being provided between April 2014 and December 2016. A detailed description of the design of this study has been published elsewhere.[18] This study is reported following the Consort statement (online supplementary file 1) and the Cheers statement (online supplementary file 2).

Participants
Twenty-five general practices, 19 physiotherapy practices and 29 occupational physicians (OPs) in the Amsterdam area participated in this study and recruited patients for this trial. Patients were aged 18–75 years and were diagnosed with non-specific LBP by their general practitioner (GP) or physiotherapist (PT), whom they had visited due to back complaints no longer than 3 months prior to inclusion in the study. Non-specific LBP was defined as LBP with or without motor and/or sensory deficits in one or both legs, including sciatica and radiculopathy, that is not caused by underlying specific pathology (red flags), that is, a tumour, (osteoporotic) vertebral fracture, ankylosing spondylitis and cauda equina syndrome. Exclusion criteria were: serious comorbidities including Alzheimer's
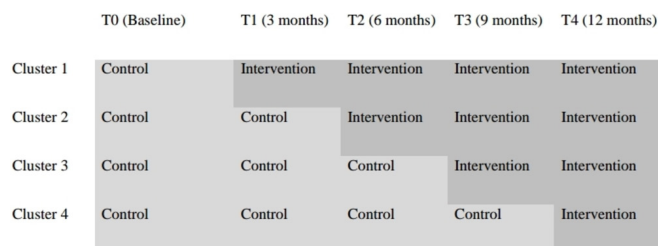

	T0 (Baseline)	T1 (3 months)	T2 (6 months)	T3 (9 months)	T4 (12 months)
Cluster 1	Control	Intervention	Intervention	Intervention	Intervention
Cluster 2	Control	Control	Intervention	Intervention	Intervention
Cluster 3	Control	Control	Control	Intervention	Intervention
Cluster 4	Control	Control	Control	Control	Intervention

Figure 1 Design of the stepped-wedge cluster randomised controlled trial.

disease, multiple sclerosis, Parkinson's disease, amyotrophic lateral sclerosis, cerebrovascular accident in the last year, malignancy in the last 5 years, and severe psychiatric disorders, that is, schizophrenia and bipolar disorder. Patients with confirmed pregnancy in the last year were also excluded. Assessment of exclusion criteria was done electronically using software, as well as manual assessment by the referring GP or PT.

Randomisation
This study was a stepped-wedge cluster randomised controlled trial. The participating general practices, physiotherapy practices, and OPs were assigned to one of four clusters based on their geographic proximity to each other. The clusters sequentially received a multifaceted continuing medical education training (illustrated by figure 1). This clustering allowed for minimisation of contamination between the participants. Patients were allocated according to the group their GP, PT or OP were assigned, that is, patients registered within a practice that was in the control group at time of enrolment were allocated to the control group for patients, thus randomisation and allocation were performed on cluster level. However, patients were blinded and not aware of group allocation, and thus concealment was on individual level. Randomisation was performed by means of computer-generated allocation, using specific software. An independent research assistant performed the concealed allocation, enrolling of participants, and assignment of participants to groups. Outcome assessors were blinded to individual patient allocation.

Intervention and control
The intervention was provided to patients on an individual level. Patients in the cluster whose GP or PT was randomised into the intervention group received access to a multifaceted eHealth strategy that aimed to reduce patients' negative back pain beliefs and improve their knowledge and self-management of LBP. The campaign included an informative website, digital monthly newsletters, and social media platforms. The website provided comprehensive information about LBP, such as practical advice (eg, on self-management), working and returning to work with LBP, exercise tips, and short video messages. In these videos, actors and healthcare professionals shared their experiences with LBP and provided tips on self-management, coping and working with LBP.

The videos were inspired by the effective Australian mass media campaign 'Back Pain: Don't Take It Lying Down'.[19] Social media platforms included a forum on the website, and a Facebook page where patients could contact researchers, healthcare providers and other patients. All parts of the intervention were also available in a mobile version that was adaptive to any electronic device. Patients were required to use preset usernames and passwords to enter the intervention website. The patient intervention was supported by continuing medical education for GPs, PTs and OPs. More detailed descriptions of the patient and professional based interventions are published elsewhere.[20 21] Patients in the control group received a digital patient information letter and had no access to the intervention website, materials or social media platforms. Results of the professional based intervention have been published elsewhere.[22]

Sample size and outcomes

The primary outcome measure was back pain beliefs, assessed using the Back Beliefs Questionnaire (BBQ). The BBQ is designed to measure beliefs about the inevitable consequences of LBP (eg, there is no real treatment for back trouble, back trouble must be rested). It is a validated questionnaire consisting of 14 items, and rates back pain beliefs on a scale of 9–45, with higher scores indicating more positive (better) back pain beliefs (eg, exercising through LBP is good).[23 24]

The sample size calculation was based on a hypothesised 10% improvement in back pain beliefs as measured by the BBQ, based on an observed mean improvement of 9.6% between three successive surveys in the Australian campaign.[19] An intra-class correlation coefficient (ICC) of 0.05 was applied to adjust for the cluster randomisation design. Assuming a 10% improvement from a mean score of 26.5 (95% CI 26.1 to 26.8, SD 6) on the BBQ, and applying an ICC of 0.05, the necessary sample size was estimated to be 500 patients. This calculation takes into account a dropout-rate of 20%, power (1-beta) of 0.90 and an alpha of 0.05.

The secondary outcomes included disability, measured with the Roland Disability Questionnaire (RDQ-24), which has been shown to be a valid and reliable instrument for patients with LBP.[25] The RDQ-24 consists of 24 items, rating disability on a scale of 0–24, with higher scores indicating more disability. The EQ-5D-3L was used to measure quality of life for the purpose of the economic evaluation.[26] Healthcare use, absenteeism, presenteeism and unpaid productivity losses were measured with the generic Productivity and Disease Questionnaire (PRODISQ) and the Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (TIC-P).[27 28] Resource use data was collected using 3-month recall periods. All outcomes were measured at baseline and after 3, 6 and 12 months follow-up. The study protocol initially included measuring the level of pain using the Pain Coping Inventory questionnaire. However, as this questionnaire proved to put an unreasonable (time) burden on the patients, it was no longer used and measured. Instead, having back pain at baseline was measured and reported.

For the economic evaluation, the scores on the EQ-5D-3L were converted into utility scores using the Dutch tariff.[29] These utility scores range from 0 (death) to 1 (maximum health). Quality adjusted life years (QALYs) were calculated using linear interpolation between measurement points.

Societal costs are the sum of intervention costs, costs for the use of healthcare, and costs for informal care (ie, care provided by family and other volunteers), work absenteeism, presenteeism (ie, reduced productivity at work), and unpaid productivity losses (ie, reduced productivity in unpaid activities, such as volunteer work). The intervention costs comprised all costs related to the development and implementation of the intervention (online supplementary file 3). Intervention costs were microcosted, meaning that detailed data were collected on the number of resources consumed as well as their associated unit prices (online supplementary file 4 shows unit costs). Information on the costs of materials was collected from a detailed overview of project budget expenditures. The time investments of the intervention providers were costed using estimates of their gross hourly salaries. There were no costs for the control group. Healthcare utilisation included primary healthcare (eg, GP, PT), secondary healthcare (eg, diagnostic imaging, medical specialist), alternative healthcare (eg, acupuncture or massage), and medication (both prescribed and over-the-counter medication related to LBP). To value healthcare utilisation, prices from the Dutch Manual for Costing (DMC) were used.[30] Where standard costs were unavailable, prices provided by healthcare professionals' associations were used. Medication use was valued using the prices of the Royal Dutch Society of Pharmacy.[31] Informal care was valued using a recommended Dutch shadow price according to the DMC.[30] Absenteeism was calculated and valued using patient data collected with the PRODISQ and TIC-P. In accordance with the DMC, patients' daily absenteeism cost was calculated by dividing their self-reported gross annual salary by their total number of workable days per year. Using the Friction Cost Approach (friction period 23 weeks), absenteeism costs were estimated by multiplying the total number of sick leave days during follow-up by their associated costs. Presenteeism was calculated using patient data collected with the TIC-P, where patients indicated how many days they went to work while having LBP. To obtain workday equivalents lost to presenteeism, this number of days was multiplied by a self-reported inefficiency score ranging between 0 (could not perform any tasks) and 1 (could perform all tasks as efficient as without LBP). Presenteeism costs were subsequently calculated by multiplying the total number of presenteeism days by their associated costs. All costs were transformed to 2016 Euros. As follow-up was 12 months, discounting was not necessary.

Statistical analyses

Analyses were performed according to the intention-to-treat principle. Descriptive statistics were used to compare baseline characteristics between intervention and control group participants as well as between participants with complete and incomplete data. Missing values for costs and effects were imputed using Multiple Imputation by Chained Equations, and imputations were performed separately for the intervention and control group.[32 33] Variables associated with the 'missingness' of data, outcomes and potential confounders were included in the imputation model. Cost and effect measure values were imputed per time point, costs were imputed at the cost category level and effects were imputed at the outcome level. Using predictive mean matching, a total of 10 complete data sets were generated in order for the loss of efficiency to be below 5% and pooled estimated were calculated according to Rubin's rules.[32–35] Effectiveness analyses were performed using maximum likelihood estimation longitudinal mixed-effects models with multilevel structure to account for clustering effects, and 'missing at random' assumptions.[36] Analyses of effect and cost data were performed in Stata V.14, and the statistical significance level was set at $p < 0.05$. Regression coefficients or ORs were calculated with 95% CIs.

A cost-utility analysis (CUA) was performed from a societal perspective. Imputation models included intervention costs, age, gender, educational level, nationality, being employed, performing physically demanding work, physical activity (minutes per week), and available cost and effect measure values. Cost and effect difference estimates between intervention and control group were analysed using seemingly unrelated regression, while simultaneously adjusting for the possible correlation between costs and effects.[37] Incremental cost-effectiveness ratios (ICERs) were calculated by dividing the adjusted mean cost differences by those in effects. Uncertainty surrounding the cost differences and ICERs was estimated using Bias Corrected and Accelerated bootstrapping with 5000 replications, and presented by 95% CIs and plotted on cost-effectiveness planes.[38] Cost-effectiveness acceptability curves presented the probability of the intervention being cost-effectiveness at different values of willingness-to-pay.[39] A sensitivity analysis was performed, in which only patients with complete data on all measurement points were included.

Patient involvement

The Dutch patient association for spinal disorders ('NVV De Wervelkolom') was involved in the design of this study and provided advice about the content of the intervention.

RESULTS
Participants

In total, 5181 eligible patients were invited to participate in this study. Of these patients, 779 (response rate of 15%)
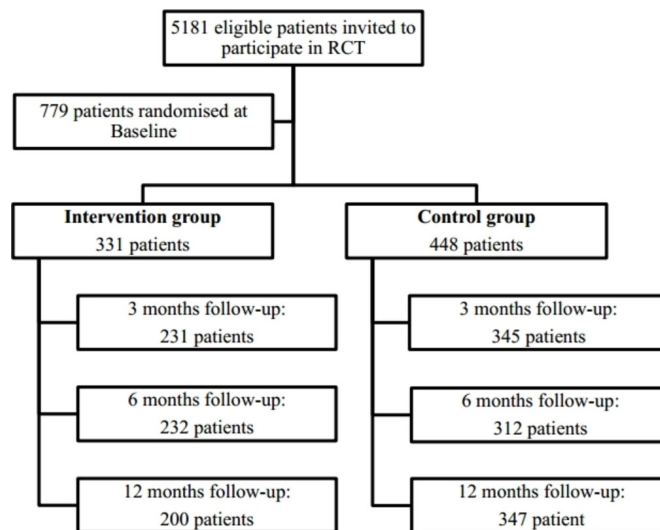

Figure 2 Flow-chart of patient inclusion.

agreed to participate and were randomised to the intervention (n=331) and control (n=448) groups (figure 2). Follow-up responses in the intervention group were 69.8% at 3 months follow-up, 70.1% at 6 months follow-up, and 60.4% at 12 months follow-up. The follow-up responses in the control group were higher than in the intervention group at 3 months follow-up (77%) and 12 months follow-up (77.5%). At 6 months follow-up the responses in the control group were similar to those in the intervention group (69.6%).

At baseline, characteristics of patients in the intervention group were similar to those in the control group. Table 1 shows that a high percentage of participants were female, 60% (intervention group) and 57% (control group) had a high educational level, and over half of the participants were employed. They performed about 3 hours of physical activity per week. Table 1 also shows the baseline scores on the BBQ, RDQ-24, and absenteeism for both groups. At baseline, there was a lower absenteeism rate in the intervention group compared with the control group.

Intention-to-treat effectiveness analysis

Table 2 shows the mean scores on the BBQ, RDQ-24, absenteeism and quality of life of the intervention group compared with the control group. Table 3 shows the results of the intention-to-treat analysis. There were no significant differences in back pain beliefs, disability and absenteeism between groups at any time point. The interaction term with gender was significant for disability, showing that the effect for males was larger than that for females.

Cost-utility analysis

Intervention costs per patient were €70. Direct costs for primary care and medication were lower in the intervention than in the control group, while direct costs for secondary and alternative care were higher in the intervention than in the control group. Indirect costs due to

Table 1 Baseline characteristics of patients

	Intervention (n=331)	Control (n=448)
Mean age (SD)	55.7 (13.9) (n=320)	56.6 (14.6) (n=439)
Female gender (%)	188 (59) (n=320)	252 (57) (n=439)
Back pain at baseline (%)	201 (63) (n=320)	275 (63) (n=439)
Nationality (%)	(n=320)	(n=439)
Dutch	298 (93)	409 (93)
Western countries immigrant	16 (5)	23 (5)
Non-western countries immigrant	6 (2)	7 (2)
Educational level (%)	(n=320)	(n=439)
None (never attended school):	9 (3)	12 (3)
Lower (primary school)	25 (8)	42 (10)
Vocational (college)	92 (29)	134 (30)
Higher (university and university of applied sciences)	194 (60)	251 (57)
Mean activity minutes/week (SD)	161 (109) (n=196)	166 (104) (n=254)
Employed (paid work) (%)	183 (57) (n=320)	232 (53) (n=439)
Physically demanding work (%)	88 (28) (n=320)	121 (28) (n=439)
Mean back pain beliefs score (SD) (*measured by BBQ, range 9–45; higher score means more positive back pain beliefs*)	24.7 (6.0) (n=295)	24.8 (6.2) (n=394)
Mean disability score (SD) (*measured by RDQ-24, range 0–24; higher score means more disability*)	5.1 (4.7) (n=317)	5.9 (5.3) (n=434)
Mean absenteeism days (SD) (*self-reported number of days over past 3 months*)	2.2 (7.0) (n=187)	4.0 (13.2) (n=246)
Mean quality of life score (SD) (*utility score measured by EuroQoL EQ-5D; range 0–1; higher score means better quality of life*)	0.79 (0.22) (n=331)	0.75 (0.25) (n=448)

BBQ, Back Beliefs Questionnaire; RDQ, Roland Disability Questionnaire.

absenteeism, presenteeism and unpaid productivity loss were lower in the intervention than in the control group. The crude total cost differences were not significant (table 4).

During the 12-month follow-up, intervention and control group participants gained 0.881 (SEM=0.008) and 0.837 (SEM=0.008) QALYs, respectively. There was a statistically significant difference in QALYs (adjusted for age, gender, educational level, nationality, employment, and physically demanding work, and baseline utility value) over the 12-month follow-up period between the control and intervention group (adjusted effect difference 0.03; 95% CI 0.001 to 0.042). The intervention did not yield significant cost savings (adjusted for age, gender, educational level, nationality, employment and physically demanding work cost difference €−748 per patient; 95% CI €−2341 to 878). The ICER for QALYs indicated that the intervention dominated usual care. The majority (79%) of incremental cost-effectiveness pairs was located in the southeast quadrant of the cost-effectiveness plane (figure 3), indicating that the intervention was on average more effective and less costly. Figure 4 shows that the intervention has a probability of 0.85 of being cost-effective on a willingness-to-pay of €10.000 per QALY gained,

increasing to a probability of 1.00 on a willingness-to-pay of €80.000 per QALY gained. Results of the sensitivity analysis differed extensively from those of the main analysis (adjusted cost difference €1780 per patient; 95% CI €−1298 to 6945; adjusted effect difference −0.002; 95% CI −0.079 to 0.075), suggesting that the 'missingness' of data is likely related to various observed factors.

DISCUSSION

This study evaluated the effectiveness and cost-utility of a multifaceted eHealth strategy compared with usual care in improving patients' back pain beliefs, and in decreasing their disability and absenteeism. The study results show that the campaign was not effective on these outcomes. The probability of cost-effectiveness was high: 0.85 per QALY gained at a willingness-to-pay threshold of €10.000, and increased to a maximum probability of 1 per QALY gained at a willingness-to-pay threshold of €80.000.

A possible explanation for the lack of effectiveness might be that in this study, almost 40% of participants did not have back pain anymore at the start of the actual intervention (ie, baseline moment). Patients who had visited

Table 2 Mean scores (SD) on BBQ, RDQ-24, EQ-5D and absenteeism

	Mean (SD) back pain beliefs (measured by BBQ, range 9–45; higher score means more positive back pain beliefs)		
	3 months follow-up	6 months follow-up	12 months follow-up
Intervention group	24.4 (5.8)	24.0 (5.9)	24.1 (5.8)
Control group	24.9 (6.2)	24.6 (6.0)	24.1 (6.3)
	Mean (SD) disability (measured by RDQ-24, range 0–24; higher score means more disability)		
	3 months follow-up	6 months follow-up	12 months follow-up
Intervention group	4.4 (4.7)	3.9 (4.3)	3.9 (4.3)
Control group	5.2 (5.1)	4.8 (4.8)	4.5 (4.7)
	Mean (SD) absenteeism (self-reported number of days over past 3 months)		
	3 months follow-up	6 months follow-up	12 months follow-up
Intervention group	1.2 (6.5)	0.9 (4.8)	0.7 (2.7)
Control group	2.6 (9.8)	0.7 (4.1)	0.7 (4.4)
	Mean (SD) quality of life (utility score measured by EQ-5D; range 0–1; higher score means better quality of life)		
	3 months follow-up	6 months follow-up	12 months follow-up
Intervention group	0.857 (0.209)	0.904 (0.163)	0.914 (0.152)
Control group	0.824 (0.236)	0.857 (0.214)	0.866 (0.191)

BBQ, Back Beliefs Questionnaire; RDQ, Roland Disability Questionnaire.

their GP or PT no longer than 3 months prior to recruitment could participate in this study. As a consequence, some patients may have agreed to participate while they had already recovered from their LBP at the start of the intervention. With the recruitment protocol used it was not possible to select only the chronic LBP cases. Therefore, the intervention may no longer have been necessary for the participants that did not have LBP at the start of the intervention, and for them effectiveness was not to be expected. The back pain beliefs of the study population were quite low at baseline compared with those of the Australian mass media campaign by which the current

study was inspired.[40] Mean BBQ scores in the Australian study were 26.5 at the start of the campaign and increased significantly to 29.7, while in the current study the BBQ scores were 24.7 and 24.8 in the intervention and control groups, respectively. This indicates that there was room

Table 3 Adjusted effects of the intervention based on intention-to-treat analyses

Outcome	Difference between intervention and control	95% CI
Back pain beliefs*	−0.13	−0.90 to 0.65
Disability		
Male	−1.13	0.93 to 1.37
Female	−0.79	0.68 to 0.93
Absenteeism†‡	−0.94	0.69 to 1.29

*Adjusted for educational level, physical activity, having back pain at baseline, being employed, comorbidity.
†Adjusted for age, physical activity, having back pain at baseline.
‡Only for participants who were employed at baseline (intervention group n=183; control group n=232).

Table 4 Crude costs per cost category in euros (€)

| Cost category	Mean costs (SEM) in €		Cost difference (95% CI) in €
	Intervention	Control	
Direct costs			
Primary care	340 (26)	405 (26)	−65 (−134 to −2)
Secondary care	478 (228)	229 (42)	249 (58 to 515)
Alternative care	742 (218)	322 (55)	421 (182 to 722)
Medication	29 (7)	44 (9)	−15 (−45 to −0.70)
Intervention	70	0	70 (N/A)
Indirect costs			
Absenteeism	1034 (242)	1547 (235)	−513 (−941 to −77)
Presenteeism	5735 (681)	6342 (537)	−607 (−2076 to −831)
Unpaid productivity	4000 (887)	5047 (616)	−1047 (−1954 to −203)
Total societal costs	8444 (820)	8979 (619)	−535 (−2230 to 1172)
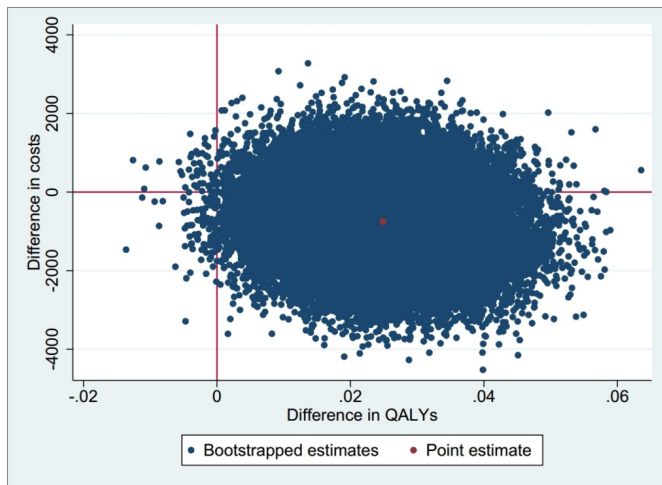
Figure 3 Cost-effectiveness plane for QALYs. QALY, quality adjusted life year.

for improvement in back pain beliefs in the current study.[40] Another study that assessed factors that were associated with beliefs and attitudes of elderly (mean age 69) also found low LBP beliefs scores (mean 23.7).[41] In the current study disability scores measured with the RDQ-24 showed low levels of disability, and absenteeism rates were also low. Quality of life scores were relatively high and similar between groups with no further improvement over time. It is arguable that the participating patients were in good health states from the start and gaining much improvement on these functional outcomes was not realistic. Process evaluations among participating patients and professionals alongside the present study showed that compliance with the intervention was very low.[20 21] Most patients did not comply to the full eHealth intervention: 31% of the participants had not used the campaign materials at all, and 42.9% had only used it once, and professionals almost never discussed the intervention with their patients. Probably most participants did not need the intervention to improve their functional ability, but improvement in back pain beliefs could have
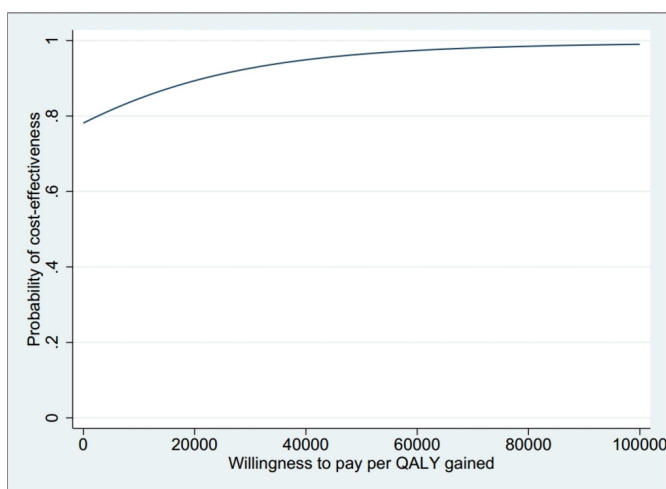

Figure 4 Cost-effectiveness acceptability curve for QALYs. QALY, quality adjusted life year.

been possible had the compliance rates in this study been higher.[20 21]

Self-management is recommended for the management of LBP, and healthcare professionals are advised to provide advice and information, tailored to needs and capabilities, to help patients self-manage their LBP.[42] One possible way to help patients self-manage their LBP is through an eHealth strategy, but evidence regarding the most effective content and mode of delivery for self-management options is lacking.[43] eHealth is easy to deliver, safe, and usually inexpensive (eg, in the current study, the intervention costs were less than €70 per patient). A recent systematic review on digital support intervention for LBP could not find significant beneficial effects of digital self-management interventions.[44] However, most of the participants in the included studies were Caucasian, highly educated, middle-aged females, meaning that the findings of the current study are comparable to similar studies. The results of the current study are in line with other studies that have attempted to improve patient outcomes and costs in LBP by using multifaceted strategies. A systematic review of the effectiveness of multifaceted strategies for guideline implementation in LBP and neck pain did not find that multifaceted strategies changed patient outcomes or costs of care.[45] However, the majority of the studies included in the review did not provide insight into the implementation process, raising the question whether the lack of effectiveness is caused by the failure of the theory (multifaceted strategy) or by failure of the implementation process, making it difficult to compare the current study to others. It is important to evaluate the implementation processes in order to truly understand the effectiveness of multifaceted strategies.

Another interesting thing to note is the fact that the costs for secondary care and alternative care are higher in the intervention group than in the control group. This is in contrast with a very similar recent implementation study for the management of LBP. In that study, patients in the intervention group had higher LBP-related costs for primary care, but lower LBP-related costs for secondary care.[46] Other studies within and outside the field of LBP however have shown similar results to the current study, where patients and participants in intervention groups show higher total medical care costs due to secondary care and/or alternative care.[47–51] The literature does not provide explanations for this fact. One explanation could lie, again, in the low compliance rate of patients in this study.[20] On the other hand, the use of alternative care could be seen as self-management, because patients decide what they want, when they want it, and how much they are willing to pay for it. It could very well be that patients try self-management through alternative care for a while, and then get referred to secondary care when and because self-management (through alternative care) did not work for them. It would be interesting to explore the reasons for the higher costs for secondary care further.

While the strategy evaluated in this study did not yield effective results, it might still be worthwhile considering the

possibilities of eHealth interventions from the perspective of outcomes that were not measured in this study but might have improved, for example, actual self-management. A systematic review of randomised controlled trials that have assessed self-management education programmes for osteoarthritis found a mismatch between the aims of such programmes (education and advice about how to self-manage their condition despite their pain and fears) and how the success of the programmes were assessed.[52] Many studies have measured health-related outcomes such as pain and function but have not specifically determined whether the programmes have improved participants' ability to self-manage. Outcomes such as knowledge about the condition and self-management skills may give more insight into the value of self-management education programmes and should be considered essential to measure in future studies evaluating these types of programmes.[52] Looking at the cost savings on absenteeism, presenteeism and unpaid productivity losses in the intervention group compared with the control group, future studies could also benefit from evaluating the effects and cost-effectiveness of eHealth strategies from employer's perspective.

Study limitations

The findings of this study must be interpreted with caution. In this study, the loss-to-follow-up rate was higher for the intervention group (40%) compared with the control group (23%). A possible explanation could be that the strategy provided too much information and participants were contacted too often, making them less willing to comply with completion of the questionnaires over time. A comparison between patients that completed the study and patients that were lost to follow-up showed that, in both the intervention and the control group, patients that completed the study were more likely to have a high educational background. Additionally, in the intervention group, patients that completed the study were more likely to not be employed (ie, involved in paid work) than patients that were lost to follow-up. The high percentage of loss to follow-up may have resulted in a loss of power and in attrition bias. Additionally, it underlines the need to take educational backgrounds and daily activities of participants into account in designing studies and interventions. Furthermore, the majority of participants did not need or use the intervention, and had minimal disability and impaired quality of life at baseline impacting on our ability to test the value of our intervention. Unfortunately, the eHealth strategy is no longer accessible, which makes repeating of this study difficult. As the strategy was financed through the funding for the trial, no financial resources were available to keep the eHealth strategy functioning after the trial ended and funding stopped. Materials and screenshots are still available for future use. Lastly, as for the lack of significant cost differences in light of the CUA, it is known that cost data are highly skewed and therefore require large sample sizes to detect statistically significant differences.[53] In this

study, the sample size calculation was based on back pain beliefs, which may have underpowered it to detect significant cost differences.

Conclusion

Based on this study, a multifaceted eHealth strategy for patients who had presented to primary care (ie, general practice and physiotherapy) with LBP was not effective in improving back pain beliefs, disability, or absenteeism. However, the CUA based on QALYs showed promising results. The multifaceted eHealth strategy should be studied in a different population, that is, a more mixed group of participants in terms of background (eg, education, nationality), and participants with LBP and poorer health states at start of the intervention.

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