



Development and proof of concept of a blended physiotherapeutic intervention for patients with non-specific low back pain

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Abstract

Objective To develop a blended physiotherapeutic intervention for patients with non-specific low back pain (e-Exercise LBP) and evaluate its proof of concept.

Design Focus groups with patients, physiotherapists, and eHealth and LBP experts were conducted to investigate values according to the development of e-Exercise LBP. Proof of concept was evaluated in a multicentre study.

Setting Dutch primary care physiotherapy practices ($n = 21$ therapists).

Participants Adults with non-specific LBP ($n = 41$).

Intervention e-Exercise LBP was developed based on clinical LBP guidelines and the focus groups, using the Center for eHealth Research Roadmap. Face-to-face physiotherapy sessions were integrated with a web application consisting of 12 information lessons, video-supported exercises and a physical activity module with the option to gradually increase individuals' level of physical activity. The intervention could be tailored to patients' risk of persistent disabling LBP, according to the STarT Back Screening Tool.

Main outcome measures Functional disability, pain, physical activity, sedentary behaviour and fear-avoidance beliefs, measured at baseline and 12 weeks.

Results After 12 weeks, improvements were found in functional disability [Quebec Back Pain Disability Scale: mean difference (MD) $-12.2/100$; 95% confidence interval (CI) 8.3 to 16.1], pain (Numeric Pain Rating Scale: MD $-2.8/10$; 95% CI 2.1 to 3.6), subjective physical activity (Short Questionnaire to Assess Health Enhancing Physical Activity: MD 11.5 minutes/day; 95% CI -47.8 to 24.8) and objective sedentary behaviour (ActiGraph: MD -23.0 minutes/day; 95% CI -8.9 to 55.0). Small improvements were found in objective physical activity and fear-avoidance beliefs. The option to gradually increase physical activity was activated for six patients (15%). On average, patients received seven face-to-face sessions alongside the web application.

Conclusions The results of this study provide the first indication of the effectiveness of e-Exercise LBP, particularly for disability and pain among patients with LBP. Future studies will focus on end-user experiences and (cost-) effectiveness.

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Keywords: Low back pain; Physiotherapy; e-Health; Telemedicine

Introduction

In most countries, low back pain (LBP) is the leading cause of disability [1]. LBP contributes to high direct costs within

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health care, as well as high indirect costs in terms of loss of productivity [2]. LBP can be caused by a specific pathology or trauma; however, an underlying disease is absent in 90% of cases [3]. The clinical course of this so-called ‘non-specific LBP’ varies; some people recover within a couple of days or weeks, and other people experience persistent disabling symptoms leading to chronic LBP [4–6]. In the Netherlands, back pain is one of the most common reasons for visiting a physiotherapist [7].

Clinical LBP guidelines recommend that physiotherapists, as well as other caregivers, should identify patients’ risk of persistent disabling symptoms at an early stage and stratify treatment to individual needs [8–11]. An example of an instrument to assess an individual’s risk of chronicity is the STarT Back Screening Tool [10]. Generally, patients at low risk benefit from education and general exercise recommendations. Patients at medium or high risk need a personalised and supervised exercise programme, in combination with cognitive behavioural components if necessary [3,8,12,13]. A crucial pre-condition for the effectiveness of exercise therapy in general is patient compliance with exercise prescriptions [14,15]. Stimulation of exercise compliance is one of the greatest challenges for physiotherapists, as 45%–70% of patients do not (completely) follow their exercise recommendations [16,17].

Online applications, such as websites and apps, provide new solutions to stimulate patients’ ability to manage their condition independently, and increase exercise compliance between face-to-face sessions [18]. The integration of supervised physiotherapy with a web application is called ‘blended physiotherapeutic care’ [19]. However, as this is a new field, blended physiotherapeutic interventions for LBP remain understudied [20]. Recently, the authors’ research group developed and evaluated a blended physiotherapeutic intervention for patients with osteoarthritis of the hip and/or knee (e-Exercise Osteoarthritis) [21,22]. Patients treated with e-Exercise Osteoarthritis experienced improvements in physical functioning, pain, tiredness, quality of life and self-efficacy [23]. Moreover, patients were highly positive and satisfied with the availability of information and assignments regardless of time or place [24]. The treatment of non-specific LBP is similar in nature to osteoarthritis of the hip and/or knee, as core treatment elements include physical activity, exercise and information. As such, it was anticipated that the integration of face-to-face care with online support would also be applicable in patients with non-specific LBP. Therefore, this study aimed to: (1) develop a blended physiotherapeutic intervention that matches the values of end-users; and (2) investigate the proof of concept of e-Exercise in patients with non-specific LBP.

Methods

The Center for eHealth Research (CeHRes) Roadmap – a five-step development, evaluation and implementation

approach – was used for development of e-Exercise LBP (Appendix A, see online supplementary material) [25]. The model is based on the principles of participatory design, which means that e-Exercise LBP was developed collaboratively with physiotherapists, patients, developers, a commercial eHealth entrepreneur and researchers [26]. The first three steps of the CeHRes Roadmap were followed in the development of e-Exercise LBP: contextual inquiry, value specification and design. Proof of concept of the e-Exercise LBP prototype was tested in a feasibility study. The results of this study and the experiences of end-users will be used to improve and further evaluate e-Exercise LBP in a future phase.

Steps 1 and 2. Contextual inquiry and value specification

The aim of the contextual inquiry was to identify the health problem. First, national and international clinical LBP guidelines were studied. Second, the results and experiences from the previous study on e-Exercise Osteoarthritis were used [21–23].

Next, three focus groups were conducted: one with patients with LBP (recruited in a physiotherapeutic training group at a primary care physiotherapy practice), one with physiotherapists and one with experts in the field of eHealth (i.e. physiotherapists with experience in blended therapy, researchers and eHealth entrepreneurs). The primary aim of the focus groups was to identify the values and requirements of end-users in consideration with e-Exercise LBP. All focus groups lasted for 60 minutes. A topic guide (Appendix B, see online supplementary material) was used to discuss the following subjects: the content of usual physiotherapy for patients with non-specific LBP, problems in current physiotherapy for LBP, intervention requirements of stakeholders and end-users, and integration of online care within physiotherapeutic care. All focus groups were audio-recorded and transcribed. Two authors (CK and MvT) independently identified themes, coded them into meaningful sections, and categorised them into general themes. Codes and themes were discussed between CK and MvT until consensus was reached.

Step 3. Design

During the design phase, the researchers cooperated with HCHHealth, a commercial eHealth entrepreneur, which supplied an online physiotherapy platform to offer video-supported exercises and information to patients. The aim of this collaboration was to facilitate a lasting implementation of e-Exercise in physiotherapeutic care. The research team provided input for the content of the web application, and HCHHealth integrated this content into their platform. Content of the web application was based on Steps 1 and 2 as described above and a Dutch self-help book for patients with back pain [27].

Feasibility study

Proof of concept of the prototype was tested in a multi-centre feasibility study.

Procedure and participants

Fifty physiotherapists working in primary care were invited to participate in the study. Most of them had participated in the previous e-Exercise Osteoarthritis study [22], and others were recruited from the authors' professional network. Physiotherapists were eligible if they treated at least 10 patients with non-specific LBP per year. In total, 21 physiotherapists participated. All physiotherapists attended a half-day face-to-face group training session about the study procedures and the e-Exercise LBP intervention, and were provided free access to the online part of the intervention. As the aim of this study was to include at least 40 patients, physiotherapists were asked to recruit at least two patients with LBP. All patients received the intervention. The inclusion criteria for patients were: (1) age 18–65 years and (2) non-specific LBP according to the physiotherapists. Exclusion criteria were: (1) contraindications for physical activity without supervision according to the Physical Activity Readiness Questionnaire [28]; (2) received physiotherapy for LBP in the last 6 months; (3) no access to the internet; or (4) no mastery of the Dutch language. Physiotherapists informed eligible patients about the study, and provided interested patients with an information letter. All patients were asked to sign an informed consent form. Patients' contact information was stored separately from the research outcomes.

Outcome measures

Functional disability was assessed using the Quebec Back Pain Disability Scale (QBPDS), which consists of 20 items about the difficulty of performing daily activities. The total score ranges from 0 to 100 (0 = no problems in daily activities; 100 = maximally disabled in daily activities) [29].

Pain was assessed using the Numeric Pain Rating Scale (NPRS) (0 = no pain; 10 = worst possible pain) [30].

Global effect was assessed using a five-point Likert scale about the degree of change in LBP symptoms since baseline measurements (1 = much worse; 5 = much better).

Physical activity was measured objectively with the Acti-Graph GR3X tri-axial accelerometer [31]. Patients were asked to wear the monitor for five unspecified consecutive days, and to complete a short activity diary about the times when the accelerometer was taken on and off and reasons for doing so. The accelerometers and diaries were returned by post. Freedson's thresholds were used for data analysis [32]: 0–99 counts per minute for sedentary activities, 100–1951 counts per minute for light physical activity, 1952–5724 counts per minute for moderate physical activity, 5725–9498 counts per minute for vigorous physical activity, and ≥ 9499 counts per minute for very vigorous physical activity. Data were recorded at 1-minute intervals. The average number of minutes of moderate and vigorous activity per

day was used for analysis. Next, physical activity was measured subjectively with the Short Questionnaire to Assess Health Enhancing Physical Activity [33]. This questionnaire measures light, moderate and vigorous physical activity over a normal week. For analysis, the average number of minutes of moderate and vigorous activity per day was used.

Pain-related fear was assessed using the Fear-Avoidance Beliefs Questionnaire, which consists of items related to physical activity (range 0–24) and work (range 0–42). A higher score indicates greater fear and avoidance beliefs about how physical activity and work negatively affect LBP [34].

Other outcome measures

Physiotherapists were asked to complete a registration form for each patient about the subgroup of LBP (i.e. low, medium or high risk for persistent disabling symptoms as assessed using the STarT Back Screening Tool), the number of face-to-face sessions, and the interventions used in the physiotherapy sessions.

Online adherence (i.e. number of log-ins and number of activated graded activity modules) was assessed based on objective web-usage data provided by HCHealth.

Patient characteristics (i.e. age, sex, height, weight, educational level and comorbidities) were assessed as part of the baseline questionnaire.

Analysis

Descriptive statistics were used to describe the general characteristics of the study population, patients' website usage, global effect, physiotherapists' recruitment rates, and the content and number of physiotherapy sessions. As the study had no control group and was not powered sufficiently to test for significance, descriptive statistics were used to describe proof of concept in terms of mean values and mean differences (MD) for disability, pain, physical activity and pain-related fear. Mean values and MD between baseline and follow-up were provided for complete cases. Results were described for the entire group and for each risk group as determined with the STarT Back Screening Tool. All analyses were performed using SPSS Version 24 (IBM Corp., Armonk, NY, USA).

Results

Steps 1 and 2. Contextual inquiry and value specification

Values and requirements that emerged from the focus groups with patients, physiotherapists and experts are provided in Table 1. Patients in the focus group indicated that physical activity and exercises were an important part of the treatment of LBP. One patient stated: 'Walking is the best medication for my back pain'. Furthermore, patients expected that a platform with video-supported exercise recommenda-

Table 1

Results of focus groups with patients, physiotherapists and experts to determine values and requirements of e-Exercise LBP.

Theme	Patients (n = 4) Average age: 53 years Male/female: 2/2	Physiotherapists (n = 5) Average age: 39 years Male/female: 2/3	Experts (n = 4) Average age: 40 years Male/female: 4/0
Physical activity	Physical activity promotion should be an important part of the treatment of LBP	Graded activity is not applicable for every patient with LBP. Graded activity principles should be an optional module	Physical activity promotion should be an important part of the treatment of LBP. Graded activity principles should be an optional module
Strength and stability exercises	Video-supported exercise recommendations are supposed to support exercise compliance	The specific type of exercises depends on the individual patient. A pre-selection of exercises per treatment objective (e.g. mobilisation, stabilisation) would save time	Exercises are important. Evidence about more or less effective exercises is absent. Ideally, the physiotherapist selects specific exercises per patient
Information modules	There is a need for trustworthy information	All information themes are relevant for all risk groups of patients. Ideally, the physiotherapists select which information modules are presented at which time	Physical activity should be the cornerstone of all information modules. Videos with patient experiences should also be included
Stratification of care	Not applicable	Recommendation for STaRT Back Screening tool	Recommendation for STaRT Back Screening tool
Stratification of blended care	Not applicable	An extra tool for stratification of blended care takes too much time	An extra tool for stratification of blended care takes too much time

LBP, low back pain.

tions would support them to accomplish exercises at home, as they often forgot how to execute specific exercises, as well as the number of repetitions. Overall, patients had a positive attitude towards blended care. Physiotherapists suggested the integration of a graded activity module, similar to e-Exercise Osteoarthritis, but only as an optional function. A graded activity module can be used to gradually increase physical activity, in accordance with the principles of graded activity. As one physiotherapist explained: ‘graded activity is indicated only in a minority of LBP patients, namely those who avoid physical activity due to LBP’. Physiotherapists and experts had no preferences for specific strength, mobility or stability exercises. According to limited available time, a pre-selected set of exercises that could be tailored to individual needs would be preferable. Physiotherapists and experts recommended that the same information content should be available to all three subgroups of patients with LBP. As one expert illustrated: ‘A single event of LBP is a risk factor for recurrence of LBP. All patients need to know which factors are related to LBP in order to prevent recurrence’.

Step 3. Design

The e-Exercise LBP intervention is an integration of face-to-face physiotherapy sessions with a web application. Fig. 1 provides an overview of the intervention.

e-Exercise LBP protocol

During the first face-to-face session, the physiotherapist identified each patient’s risk (i.e. low, medium or high) for persistent disabling symptoms using the STaRT Back Screening Tool [11]. Based on patients’ physical capacity and risk profile, physiotherapists had the ability to tailor e-Exercise LBP to meet their specific needs [10]. As recommended by

the experts, patients at low risk for persistent disabling symptoms had four face-to-face physiotherapy sessions, patients at medium risk had 12 sessions and patients at high risk had 20 sessions. However, according to the physiotherapists’ clinical knowledge, physiotherapists were free to deviate from this protocol. The application consisted of three modules. The first module consisted of 12 weekly lessons (text and video) about the aetiology of LBP, physical activity, patient experiences, pain management and psychosocial factors related to LBP. The second module consisted of video-instructed exercises. Physiotherapists could choose the pre-selected exercises or create an individualised exercise programme. The third module consisted of physical activity recommendations. Based on a 3-day baseline test within this module, the physiotherapists could calculate the patients’ current level of physical activity. If patients were insufficiently physically active, the physiotherapist could activate the graded activity functionality and set a goal to reach within 12 weeks. This graded activity functionality with tailored feedback has been studied previously in two osteoarthritis studies [23,35]. Patients received weekly reminders to visit the web application. The online modules lasted for 12 weeks. Physiotherapists could watch patients’ usage of the web application, monitor evaluated assignments, select other types of exercises, and communicate with patients using a messenger service. A print screen of the online e-Exercise LBP application is given in Appendix C (see online supplementary material).

Feasibility study

Participants

In total, 46 eligible patients were recruited between May and October 2016. Of these patients, 41 signed informed con-

e-Exercise Low Back Pain



Face-to-face physiotherapy



Stratification

Physiotherapists use the STarT Back Screening Tool to assess patients' risk on chronicity and stratify care accordingly.



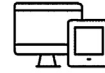
Sessions

Physiotherapists treat their patients in accordance with clinical guidelines. Recommended number of sessions is: 4 for patients with low risk, 12 for patients with medium risk and 20 for patients with high risk on chronicity.



Integration

Physiotherapists can select exercises based on patients individual needs. They can also monitor patients' progress and adherence to the web-application. There is also a communication chat-function. Reminder e-mails to the patient were automatically sent.



Online web-application



Information

Text- and video supported information modules about the etiology of low back pain, pain education, risk factors for chronicity, pain medication, goal setting, physical activity and long-term behavior change. Frequency: 1 per week.



Exercises

Video supported strength-, mobility- and relaxation exercises. Pre-selection made by the developers. Frequency: 3 times/week 2 exercises. Selection, frequency and iterations could be tailored to patients' individual needs by the physiotherapist.



Physical activity

After a 3-day baseline measurement for a self-chosen central activity like walking or cycling, the physiotherapist and patient decided whether exercise assignments should gradually increase or not. Frequency: 3 times per week. Automated tailored feedback was provided based on individual evaluation.

Fig. 1. Overview of the blended intervention e-Exercise LBP.

sent forms and completed the baseline questionnaire. After 12 weeks, 37 patients (90%) completed the follow-up questionnaire. No differences in baseline characteristics were found between responders and non-responders. Accelerometer data were available from 30 patients (73%) at baseline, from 22 patients (54%) at follow-up, and from 20 patients at both baseline and follow-up (45%). Fig. 2 provides an overview of the study process. Patient demographics at baseline are presented in Table 2.

Physiotherapy and online adherence

Overall, the average number of face-to-face sessions was 6.8 [standard deviation (SD) 4.0]. Face-to-face sessions most frequently consisted of providing information, exercises and active/passive mobilisation. The average total number of log-ins was 28 (SD 27) over 12 weeks. Six patients (15%) received the graded activity module; most of them were classified as

low risk. Table 3 provides an overview of the number and content of the face-to-face sessions. The number of face-to-face sessions differed between risk groups [low risk: 5.7 (SD 2.9); medium risk: 6.5 (SD 4.9); high risk: 9.6 (SD 3.2)], but the content of these sessions and website usage were comparable (Table 3).

Proof of concept

Levels of functional disability, physical activity, fear avoidance, pain at baseline and at 12-week follow-up, and global effect are presented in Table 4. An improvement was found in functional disability [MD −12.2/100; 95% confidence interval (CI) 8.3 to 16.1], pain (MD −2.8/10; 95% CI 2.1 to 3.6), subjective physical activity (MD 11.5 minute/day; 95% CI −47.8 to 24.8), objective physical activity (3.1 minute/day; 95% CI −8.8 to 2.7), objective sedentary behaviour (MD −23.0 min/day; 95% CI −8.9 to

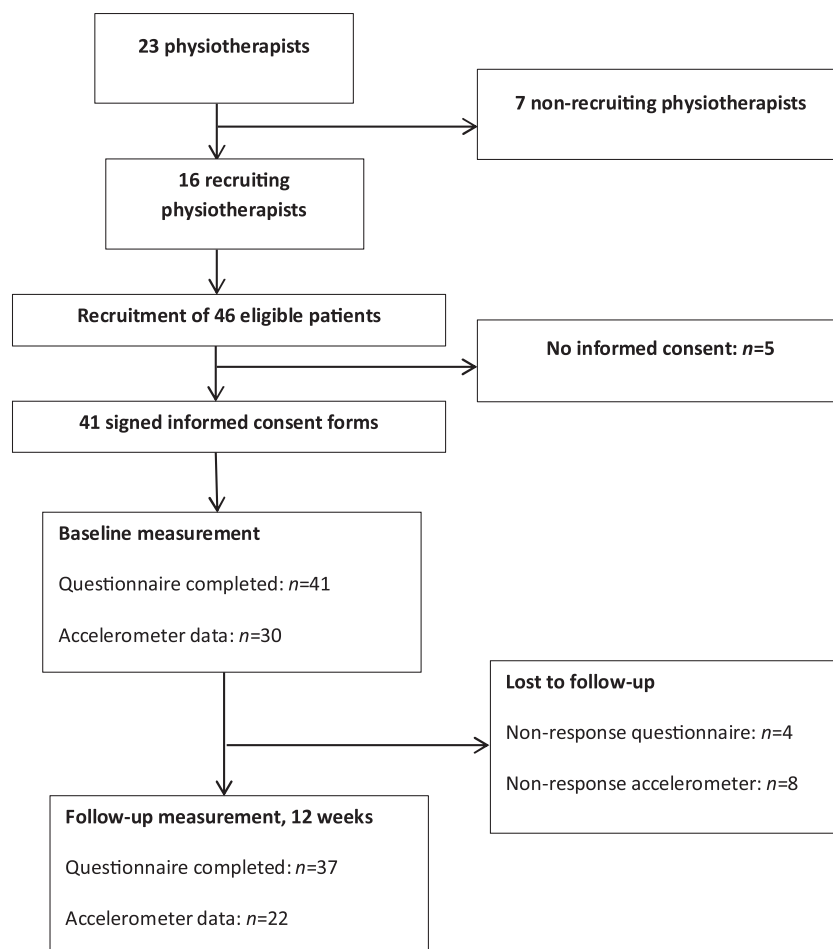


Fig. 2. Flowchart.

Table 2

Patient demographics, entire group and subgroups.

	Total group	Low risk	Medium risk	High risk
Number of respondents	<i>n</i> = 41	<i>n</i> = 18	<i>n</i> = 15	<i>n</i> = 8
Gender, <i>n</i> (%)				
Male	18 (44)	10 (56)	7 (47)	1 (13)
Female	23 (56)	8 (44)	8 (53)	7 (88)
Age in years, mean (SD)	44.3 (10.4)	44.9 (10.5)	42.0 (12.0)	47.5 (5.8)
BMI, mean (SD)	25.9 (4.7)	25.7 (3.8)	27.0 (6.4)	24.4 (2.8)
Education level, <i>n</i> (%)				
Low	4 (10)	1 (6)	1 (7)	2 (25)
Middle	17 (42)	9 (50)	5 (33)	3 (38)
High	20 (49)	8 (44)	9 (60)	3 (38)
Disease duration, <i>n</i> (%)				
0 to 6 weeks	5 (12)	2 (11)	2 (13)	1 (13)
6 to 12 weeks	6 (15)	3 (17)	2 (13)	1 (13)
12 weeks to 12 months	9 (22)	4 (22)	4 (27)	1 (13)
>12 months	21 (51)	9 (50)	7 (47)	5 (63)
Comorbidities, <i>n</i> (%)				
None	18 (44)	8 (44)	7 (47)	3 (38)
1	15 (37)	7 (39)	6 (40)	2 (25)
>1	8 (20)	3 (17)	2 (13)	3 (38)

BMI, body mass index (kg/m²); SD, standard deviation.

Table 3

Description of face-to-face sessions and usage of the web application.

	Overall (<i>n</i> = 41)	Low risk (<i>n</i> = 18)	Medium risk (<i>n</i> = 15)	High risk (<i>n</i> = 8)
Number of face-to-face sessions, mean (SD)	6.8 (4.0)	5.7 (2.9)	6.5 (4.9)	9.6 (3.2)
Most frequent content of face-to-face sessions, <i>n</i> (%)	Information: 97% Exercises: 75% Mobilisation: 75%	Information: 94% Exercises: 63% Mobilisation: 69%	Information: 100% Exercises: 85% Mobilisation: 70%	Information: 100% Exercises: 86% Mobilisation: 86%
Total number of log-ins, mean (SD)	28 (27)	26 (25)	27 (28)	37 (32)
Number of weeks with ≥ 1 log-in, mean (SD)	7.3 (4)	7.4 (4)	7.0 (4)	7.5 (4)
Number of patients with GA module, <i>n</i> (%)	6 (15)	4 (22)	1 (7)	1 (13)

SD, standard deviation; GA, graded activity.

Table 4

Proof of concept of e-Exercise LBP (baseline, 12 weeks and mean difference).

	Descriptive statistics		
Outcome measure	Baseline, <i>n</i> = 41, mean (SD)	12 weeks, mean (SD)	Mean difference (95% CI)
Functional disability (0 to 100), <i>n</i> = 37	33.4 (15.7)	21.2 (17.2)	−12.2 (8.3 to 16.1)
VAS – pain (0 to 10), <i>n</i> = 37	6.1 (1.9)	3.3 (2.4)	−2.8 (2.1 to 3.6)
Physical activity, subjective (minutes/day), <i>n</i> = 37	125.2 (93.5)	136.6 (132.5)	11.5 (−47.8 to 24.8)
Physical activity, objective, moderate and vigorous (minutes/day), <i>n</i> = 20	30.7 (21.0)	33.8 (17.9)	3.1 (−8.8 to 2.7)
Sedentary behaviour (minutes/day), <i>n</i> = 20	490.7 (78.0)	467.8 (62.9)	−23.0 (−8.9 to 55.0)
Fear-avoidance, activity (0 to 30), <i>n</i> = 33	14.5 (5.3)	13.0 (6.1)	−1.5 (−1.2 to 4.2)
Fear-avoidance, work (0 to 66), <i>n</i> = 33	16.1 (14.5)	16.0 (16.9)	−0.1 (−3.1 to 3.2)
Global effect (1 to 5), <i>n</i> = 36		3.7 (1.0)	

VAS, visual analogue scale; CI, confidence interval; SD, standard deviation.

55.0), fear avoidance activity subscale (MD −1.5; 95% CI −1.2 to 4.2) and fear avoidance work subscale (MD −0.1; 95% CI −3.1 to 3.2). Due to practical reasons, not all participants wore an accelerometer (*n* = 20). The average level of global effect was 3.7 (SD 1.0) on a five-point scale. Differences per subgroup were somewhat comparable to the entire group (data not shown).

Discussion

This study described the participatory development of a blended physiotherapeutic intervention for patients with non-specific LBP (e-Exercise LBP). Face-to-face physiotherapy sessions were integrated with a web application which consisted of 12 weekly information, exercise and physical activity modules. The STarT Back Screening Tool was used to stratify the offline and online part of e-Exercise LBP to patients' individual needs [11]. Proof of concept of e-Exercise LBP was evaluated in a feasibility study which suggested that e-Exercise LBP is effective, especially for disability (QBDS: MD −12.2/100; 95% CI 8.3 to 16.1) and pain (NPRS: MD −2.8/10; 95% CI 2.1 to 3.6).

The CeHRes Roadmap provided guidance during the development of e-Exercise LBP. This approach is not technology driven, but takes the complexity of health care into account [25]. The aim was to develop an intervention that meets the values of patients, physiotherapists and experts. Patients' recommendations for the design of the intervention were less concrete than physiotherapists' and experts'

recommendations. This may have been due to the difficulty of providing feedback at a very early stage in development, when there is only an unfamiliar non-material concept. In future development studies, it is recommended that patients should receive drafts or previews of the intervention in order to make it more concrete, and to make it easier for them to provide feedback about the design.

The improvements seen in disability and pain can be considered as clinically meaningful as both outcomes decreased by >30% [30]. A Cochrane review on the effectiveness of exercise therapy compared with no treatment described a substantially smaller pain reduction of 0.59 points/100 in acute LBP, −1.89 points/100 in subacute LBP and −10.2 points/100 in chronic LBP [36]. In the current study, the sample sizes were too small to perform inferential statistics as well as subgroup analyses. The average number of face-to-face sessions in e-Exercise LBP was slightly lower than the general average number of treatment sessions for patients with back pain in The Netherlands (7 vs 9) [37]. Therefore, the results of this study tentatively indicate that e-Exercise LBP may lead to a reduction in physiotherapeutic costs. The effectiveness of e-Exercise LBP should be further investigated in a randomized controlled trial. A reduction in physiotherapeutic costs was also seen in the comparison of e-Exercise and usual physiotherapy in patients with hip and knee osteoarthritis, where the number of face-to-face sessions could be reduced from 12 to five [38].

Stratifying blended care to patients at low, medium or high risk of persistent LBP appeared to be challenging. Physiotherapists and experts recommended integration of the STarT

Back Screening Tool in combination with recommendations for the average number of treatment sessions per risk group. Within the current study, patients in the low-risk group visited the physiotherapists more often than the e-Exercise LBP protocol recommended, whereas the medium- and high-risk groups received fewer sessions than the protocol recommended. These findings are in line with a recent investigation of stratified LBP care in the Netherlands, which indicated that low-risk patients were generally over-treated and high-risk patients were generally under-treated compared with recommendations in clinical guidelines [39]. Stratifying the online part of e-Exercise LBP was possible by applying the graded activity functionality. Clinical guidelines specifically recommended this behavioural approach in patients at high risk for persistent LBP [8,9]. Remarkably, this functionality was only applied in one of the eight patients at high risk. A forthcoming mixed-methods study will provide more insight into patients' and physiotherapists' experiences with the stratification of e-Exercise LBP, as well as how this stratification can be improved.

Limitations and recommendations

As this study was primarily focused on the development of e-Exercise LBP and its potential, a control group was not incorporated. Therefore, cause and effect cannot be claimed and it is uncertain whether the improvements in health-related outcomes were due to natural recovery or the effectiveness of e-Exercise LBP. Moreover, the study sample was small and long-term follow-up measurements were not included. Another limitation of this study was the absence of an outcome measurement related to exercise compliance, although it is hypothesised that blended care can stimulate an active role of the patient within the daily situation. The inclusion of measurements for exercise adherence, self-management skills or coping style is recommended for future studies. Furthermore, a future large-scale randomized controlled trial is needed to study the (cost-) effectiveness of e-Exercise LBP compared with usual physiotherapy.

Overall, e-Exercise LBP demonstrated initial indications for effectiveness in reducing disability and pain. The next step will be the investigation of end-user experiences with this prototype. These experiences will be used to further adapt the intervention to the needs of patients and physiotherapists. Hereafter, a randomized controlled trial on the (cost-) effectiveness of e-Exercise LBP compared with usual physiotherapy will be conducted (Steps 4 and 5 of the CeHRes Roadmap).

Ethical approval: The medical Ethical Committee of the Utrecht University Medical Centre declared that the e-Exercise LBP project is not covered by the Dutch Medical Research Involving Human Subject Act (WMO; number 16-231).

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Conflict of interest: None declared.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.physio.2018.12.006>.

References

- [1] GBD 2015 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet* 2016;388:1545–602.
- [2] Vos T, Flaxman AD, Naghavi M, Lozano R, Michaud C, Ezzati M, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 2012;380:2163–96.
- [3] Koes BW, van Tulder MW, Thomas S. Diagnosis and treatment of low back pain. *BMJ* 2006;332:1430–4.
- [4] Chou R, Shekelle P. Will this patient develop persistent disabling low back pain? *JAMA* 2010;303:1295–302.
- [5] Hayden JA, Chou R, Hogg-Johnson S, Bombardier C. Systematic reviews of low back pain prognosis had variable methods and results: guidance for future prognosis reviews. *J Clin Epidemiol* 2009;62:781–96e1.
- [6] Hayden JA, Dunn KM, van der Windt DA, Shaw WS. What is the prognosis of back pain? *Best Pract Res Clin Rheumatol* 2010;24:167–79.
- [7] LLJ. BDK. Zorg door de fysiotherapeut – top-10 gezondheidsproblemen (DCSPH). Uit: NIVEL Zorgregistraties eerste lijn; 2017. Available at: www.nivel.nl/node/4677. [Accessed 17 January 2017].
- [8] Wong JJ, Cote P, Sutton DA, Randhawa K, Yu H, Varatharajan S, et al. Clinical practice guidelines for the noninvasive management of low back pain: a systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMA) Collaboration. *Eur J Pain* 2017;21:201–16.
- [9] Koes BW, van Tulder M, Lin CW, Macedo LG, McAuley J, Maher C. An updated overview of clinical guidelines for the management of non-specific low back pain in primary care. *Eur Spine J* 2010;19:2075–94.
- [10] Foster NE, Mullis R, Hill JC, Lewis M, Whitehurst DG, Doyle C, et al. Effect of stratified care for low back pain in family practice (IMPACT back): a prospective population-based sequential comparison. *Ann Fam Med* 2014;12:102–11.
- [11] Hill JC, Whitehurst DG, Lewis M, Bryan S, Dunn KM, Foster NE, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. *Lancet* 2011;378:1560–71.
- [12] Staal JB, Hendriks EJM, Heijmans M. KNGF-richtlijn Lage rugpijn. [Dutch physiotherapeutic clinical guideline for low back pain].
- [13] Hayden JA, van Tulder MW, Tomlinson G. Systematic review: strategies for using exercise therapy to improve outcomes in chronic low back pain. *Ann Intern Med* 2005;142:776–85.
- [14] van Gool CH, Penninx BW, Kempen GI, Rejeski WJ, Miller GD, van Eijk JT, et al. Effects of exercise adherence on physical function among overweight older adults with knee osteoarthritis. *Arthritis Rheum* 2005;53:24–32.
- [15] 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;18:1881–91.

- [16] Sluijs EM, Kok GJ, van der Zee J. Correlates of exercise compliance in physical therapy. *Phys Ther* 1993;73:771–82, discussion 83–6.
- [17] Friedrich M, Gittler G, Halberstadt Y, Cermak T, Heiller I. Combined exercise and motivation program: effect on the compliance and level of disability of patients with chronic low back pain: a randomized controlled trial. *Arch Phys Med Rehabil* 1998;79:475–87.
- [18] Nicholl BI, Sandal LF, Stochkendahl MJ, McCallum M, Suresh N, Vasseljen O, *et al.* Digital support interventions for the self-management of low back pain: a systematic review. *J Med Internet Res* 2017;19: e179.
- [19] Wentzel J, van der Vaart R, Bohlmeijer ET, van Gemert-Pijnen JE. Mixing online and face-to-face therapy: how to benefit from blended care in mental health care. *JMIR Ment Health* 2016;3:e9.
- [20] Dario AB, Moreti Cabral A, Almeida L, Ferreira ML, Refshauge K, Simic M, Pappas E, Ferreira PH. Effectiveness of telehealth-based interventions in the management of non-specific low back pain: a systematic review with meta-analysis. *Spine J* 2017.
- [21] Bossen D, Klok C, Snippe HW, Dekker J, de Bakker D, Veenhof C. A blended intervention for patients with knee and hip osteoarthritis in the physical therapy practice: development and a pilot study. *JMIR Res Protoc* 2016;5:e32.
- [22] Klok 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;15:269.
- [23] Klok CJ, Bossen D, Spreeuwenberg PM, Dekker J, de Bakker DH, Veenhof C. Effectiveness of a blended physical therapist intervention in people with hip osteoarthritis, knee osteoarthritis, or both: a cluster-randomized controlled trial. *Phys Ther* 2018;98:560–70, <http://dx.doi.org/10.1093/ptj/pzy045>.
- [24] de Vries HJ, Klok CJ, de Bakker DH, Dekker J, Bossen D, Veenhof C. Determinants of adherence to the online component of a blended intervention for patients with hip and/or knee osteoarthritis: a mixed methods study embedded in the e-Exercise trial. *Telemed J E Health* 2017.
- [25] van Gemert-Pijnen JE, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, *et al.* A holistic framework to improve the uptake and impact of eHealth technologies. *J Med Internet Res* 2011;13:e111.
- [26] Kensing FBJ. Participatory design: issues and concerns. *Comput Support Coop Work* 1998;7:167–85.
- [27] Coene EK, Erlandsson S. *Zorgboek Rugpijn*. Stichting September; 2011.
- [28] Thomas S, Reading J, Shephard RJ. Revision of the Physical Activity Readiness Questionnaire (PAR-Q). *Can J Sport Sci* 1992;17:338–45.
- [29] Kopec JA, Esdaile JM, Abrahamowicz M, Abenhaim L, Wood-Dauphinee S, Lamping DL, *et al.* The quebec back pain disability scale. Measurement properties. *Spine (Phila Pa 1976)* 1995;20:341–52.
- [30] Ostelo RW, Deyo RA, Stratford P, Waddell G, Croft P, Von Korf M, *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;33:90–4.
- [31] Kelly LA, McMillan DG, Anderson A, Fippinger M, Fillerup G, Rider J. Validity of actigraphs uniaxial and triaxial accelerometers for assessment of physical activity in adults in laboratory conditions. *BMC Med Phys* 2013;13:5.
- [32] Freedson PS, Melanson E, Sirard J. Calibration of the Computer Science and Applications, Inc accelerometer. *Med Sci Sports Exerc* 1998;30:777–81.
- [33] Wendel-Vos GC, Schuit AJ, Saris WH, Kromhout D. Reproducibility and relative validity of the short questionnaire to assess health-enhancing physical activity. *J Clin Epidemiol* 2003;56:1163–9.
- [34] Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain* 1993;52:157–68.
- [35] Bossen D, Veenhof C, Van Beek KE, Spreeuwenberg PM, Dekker J, De Bakker DH. Effectiveness of a web-based physical activity intervention in patients with knee and/or hip osteoarthritis: randomized controlled trial. *J Med Internet Res* 2013;15:e257.
- [36] Hayden JA, van Tulder MW, Malmivaara A, Koes BW. Exercise therapy for treatment of non-specific low back pain. *Cochrane Database Syst Rev* 2005;3:CD000335.
- [37] Leemrijse CJ BJ, Koopman MK, Verberne LDM, Veenhof C, Swinkels ICS. Omvang en kenmerken fysiotherapeutische zorg bij patiënten met rugpijn. Uit: NIVEL Zorgregistraties eerste lijn; 2017. Available at: www.nivel.nl/node/4394. [Accessed 10 July 2017].
- [38] Klok CJ, van Dongen JM, de Bakker DH, Bossen D, Dekker J, Veenhof C. Cost-effectiveness of a blended physiotherapy intervention compared to usual physiotherapy in patients with hip and/or knee osteoarthritis: a cluster randomized controlled trial. *BMC Public Health* 2018;18:1082, <http://dx.doi.org/10.1186/s12889-018-5975-7>.
- [39] Bier JD, Sandee-Geurts JJW, Ostelo R, Koes BW, Verhagen AP. Can primary care for back and/or neck pain in the Netherlands benefit from stratification for risk groups according to the STarT Back Tool-classification? *Arch Phys Med Rehabil* 2017.

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