

# BMJ Open Back2Action: effectiveness of physiotherapy blended with eHealth consisting of pain education and behavioural activation versus physiotherapy alone – protocol for a pragmatic randomised clinical trial for people with subacute or persistent spinal pain

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## ABSTRACT

**Introduction** Psychosocial factors predict recovery in patients with spinal pain. Several of these factors are modifiable, such as depression and anxiety. However, primary care physiotherapists who typically manage these patients indicate that they do not feel sufficiently competent and equipped to address these factors optimally. We developed an eHealth intervention with a focus on pain education and behavioural activation to support physiotherapists in managing psychosocial factors in patients with spinal pain. This paper describes the protocol for a pragmatic randomised clinical trial, which evaluates the effectiveness of this eHealth intervention blended with physiotherapy compared with physiotherapy alone.

**Methods and analysis** Participants with non-specific low back pain and/or neck pain for at least 6 weeks who also have psychosocial risk factors associated with the development or maintenance of persistent pain will be recruited in a pragmatic multicentre cluster randomised clinical trial. The experimental intervention consists of physiotherapy blended with six online modules of pain education and behavioural activation. The control intervention consists of usual care physiotherapy. The primary outcomes are disability (Oswestry Disability Index for low back pain and Neck Disability Index for neck pain) and perceived effect (Global Perceived Effect). Outcomes will be assessed at baseline and at 2, 6 and 12 months after baseline. The results will be analysed using linear mixed models.

**Ethics and dissemination** The study is approved by the Medical Ethical Committee of VU Medical Center Amsterdam, The Netherlands (2017.286). Results will be reported in peer-reviewed journals, at national and international conferences, and in diverse media to share the findings with patients, clinicians and the public.

## Strengths and Limitations of this study

- This study assesses a blended intervention that aims to optimise treatment for patients with subacute or persistent non-specific spinal pain by increasing patients' understanding of pain and provide them with tools to re-engage in value-based activities.
- The experimental intervention will provide tools to complement the skillset of physiotherapists to help manage psychosocial factors in patients with non-specific spinal pain in primary care.
- Although the experimental intervention is intended to be biopsychological in nature, there might be a discrepancy between the eHealth and physiotherapy component, if the physiotherapist reverts to a more biomedical approach.
- Because psychologically informed interventions are typically not anticipated by patients when consulting a physiotherapist, acceptance of the intervention and recruitment may be affected.
- Cluster randomisation may lead to postrandomisation selection bias.

**Trial registration number** NL 5941; The Netherlands Trial Register.

## INTRODUCTION

Low back pain and neck pain are two conditions in the top 10 leading causes of disability worldwide for adults, as are depression and anxiety.<sup>1</sup> Moreover, spinal pain and psychosocial conditions, such as depression and anxiety, often coexist: 15%–45% of patients with spinal pain also experience depression

and/or anxiety.<sup>2-4</sup> Various psychosocial factors, such as depression, anxiety, and also fear-avoidance, catastrophising, low self-efficacy and passive coping strategies, are associated with poor recovery in patients with low back pain and neck pain.<sup>5-8</sup> Influencing these psychosocial factors is considered important for favourable outcomes in patients with spinal pain.<sup>9</sup>

Previous research showed that appropriate management of psychosocial factors improved outcomes and reduced pain-related disability in patients with low back pain.<sup>10-13</sup> Various interventions, such as cognitive behavioural therapy (CBT),<sup>14 15</sup> are effective to improve disability and psychological factors in patients with subacute and persistent low back pain. These interventions show comparable effect sizes for pain and depression<sup>16 17</sup> and are typically provided by a psychologist or specialised physiotherapist in rehabilitation centres. Up til now, evidence-based interventions targeting psychosocial factors are not readily accessible in routine primary care physiotherapy practices yet.<sup>18</sup>

Patients in primary care who seek treatment for spinal pain often only consult their physiotherapist, even when they experience comorbid mental health symptoms. Recent studies reveal that physiotherapists do not feel sufficiently competent or equipped to treat psychosocial factors adequately.<sup>12 19</sup> Many physiotherapists favour incorporating psychological interventions but there are significant barriers.<sup>19</sup> The most frequently cited barrier is a lack of knowledge. Physiotherapists stated that neither their initial training nor currently available professional courses instilled them with the requisite skills and confidence to successfully address the multidimensional pain presentations of these patients. Another consistent and highly relevant barrier for implementation of a psychological intervention is time constraints.<sup>18 19</sup>

An eHealth psychologically informed intervention addresses some of these barriers by providing an informed and structured programme that is suited for physiotherapists and patients to use in addition to face-to-face treatments. eHealth interventions based on CBT are effective in treating mild-to-moderate depressive and anxiety symptoms, with effect sizes comparable to face-to-face psychotherapy.<sup>16</sup> For patients with chronic pain, CBT applied as a guided eHealth intervention, has also been found to be effective in reducing disability, catastrophising and pain intensity.<sup>20</sup> However, the cognitive component of CBT in particular requires specific training and expertise, which most physiotherapists do not feel they possess. Behavioural activation does not need extensive psychological expertise, has proven to be effective and is easy to use for both patient and practitioner.<sup>21 22</sup>

An important consideration in treating psychosocial factors in routine primary care physiotherapy practices is patient acceptability. A psychological intervention is typically not anticipated by patients when consulting a physiotherapist and, therefore, patients might be hesitant to participate.<sup>23</sup> Negative treatment expectations and acceptability are associated with poor recovery.<sup>23 24</sup> Acceptability

of psychological interventions can be improved by explaining how pain may be influenced by psychosocial factors. Systematic reviews show that pain education added to physiotherapy is an effective treatment in patients with musculoskeletal pain in reducing pain disability and pain catastrophising.<sup>25-27</sup>

The combination of pain education and behavioural activation in an eHealth intervention may optimise self-management by providing patients' education about pain and reassurance to increase activities and practical tools for how to become more active themselves. By adding the eHealth intervention to physiotherapy management, our hypothesis is that this blended treatment will benefit patients with at least 6 weeks of spinal pain more than physiotherapy alone. The aim of this paper is to describe the design of the study and the content of the interventions.

## METHODS AND ANALYSIS

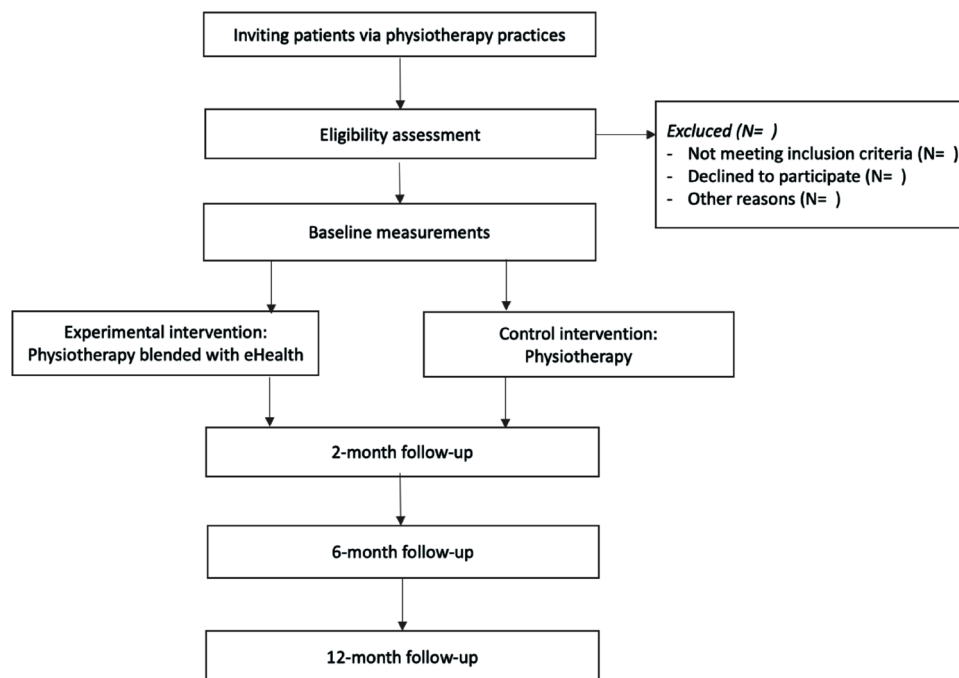
### Design

The study is a pragmatic cluster randomised controlled trial (RCT). Physiotherapy blended with an eHealth intervention will be compared with physiotherapy alone. This protocol paper is reported according to the Standard Protocol Items: Recommendations for Interventional Trial statement.<sup>28</sup> The TIDier checklist<sup>29</sup> is used to describe the intervention. The trial was registered at The Netherlands Trial Register prior to the start of inclusion at 15 September 2016.

### Study population

Patients older than 18 years presenting to physiotherapy care with at least 6 weeks of non-specific low back pain and/or neck pain with comorbid psychosocial factors are eligible for inclusion.<sup>30 31</sup> Psychosocial factors are screened online using the Patient Health Questionnaire (PHQ-9) for depressive symptoms, the Generalised Anxiety Disorder Scale (GAD-7) for anxiety and a screening item of the Tampa Scale of Kinesophobia (TSK-Item 10) for kinesophobia. Patients are eligible to participate if they experience symptoms in two of the following three domains: (1) experience mild to moderately severe depressive symptoms (PHQ-9  $\geq 5$  and  $\leq 19$ ), (2) anxiety symptoms (GAD-7  $\geq 5$  and  $\leq 14$ ) or (3) fear of movement (TSK-Item 10 positive). Furthermore, patients must be proficient in Dutch, have access to a computer with internet access and provide written informed consent.

Potential participants are excluded if they have specific spinal pathology (eg, lumbar or cervical radiculopathy, tumour, fracture), systemic diseases (eg, rheumatoid arthritis or diabetes), if they received treatment by a mental health professional (including pharmacological treatment for psychological disorders) or a physiotherapist less than 2 months prior to volunteering for the study or if they experience severe depression (PHQ-9  $\geq 20$  points) or severe anxiety (GAD-7  $\geq 15$  points). Patients who start up new treatment or medication for their pain or psychological symptoms during the intervention



**Figure 1** Flowchart of the study.

period are excluded from the trial. Health care use during follow-up will be monitored.

### Procedure

Primary care physiotherapy practices are eligible to participate if their physiotherapists regularly treat patients with spinal pain (minimum of 20% of the patient population). Practices are recruited through advertisements and newsletters posted on relevant professional platforms (MSG Science Network and the Low Back Pain network of primary care physiotherapy practices) and social media platforms, such as LinkedIn.

Participants are recruited by physiotherapists in primary care. Participants who are eligible and provide informed consent will undergo baseline measurements (see figure 1). Patients are allocated to the experimental group (physiotherapy +eHealth) or control group (physiotherapy alone). The aim is to deliver the intervention over 6 weeks, with a maximum treatment duration of 8 weeks. Follow-up outcome measures will be assessed online at 2, 6 and 12 months after baseline. Patients receive a maximum of two e-mail reminders and one telephone call in order to promote participant retention.

### Control intervention

Physiotherapy treatment is provided according to the Dutch Clinical Practice Guidelines for low back pain<sup>30</sup> and neck pain,<sup>31</sup> developed by the Royal Dutch Society for Physiotherapy (in Dutch: Koninklijk Nederlands Genootschap voor Fysiotherapie: KNGF). These recommendations are comparable to international guidelines.<sup>32</sup> Guidelines for low back pain advise therapists to use supervised exercise and elements from CBT for patients at risk of developing persistent low back pain.<sup>32</sup> In the control group, patients receive 6–9 physiotherapy

sessions, as recommended in the guidelines. Depending on patient-specific characteristics and the physiotherapist's clinical judgement, the content and number of the physiotherapy sessions per patient can vary but can not exceed 8 weeks. Number of sessions and type of interventions will be recorded.

### Experimental intervention

Patients in the experimental group receive a blended intervention combining eHealth modules guided by their treating physiotherapist alongside face-to-face physiotherapy.

### The eHealth intervention

The eHealth intervention is developed by experts from the field of musculoskeletal health and mental health. The first step in developing the intervention consisted of reviewing the scientific literature and existing eHealth interventions as well as consulting patients, experts, educators and specialised practitioners. The main conclusions were that the intervention had to include an education component to explain the impact of psychosocial factors on pain and focus on reactivation. The intervention had to be suitable to be guided by non-psychologists and accessible for patients. Following the development of an initial draft, the eHealth intervention was pilot tested by patients, therapists and scientific experts (N=15) for intelligibility and usefulness for the patient. This led to minor revisions in writing style, typographical errors and rewriting of one patient example to include a patient type who persists through pain.

The eHealth intervention incorporates pain education and behavioural activation. Pain education addresses patients' fear and avoidance patterns and provides reassurance. It does so by providing insights that pain works

as a protective mechanism, is dependent on context and can be overprotective.<sup>33</sup> Patients learn that it is safe to move and are encouraged to gradually increase their value-based activities.<sup>25 26</sup> While pain education provides an important reason *why* an active lifestyle is important, behavioural activation provides people with tools *how* to achieve this themselves through activity scheduling.<sup>21</sup> Behavioural activation is effective in treating depression and anxiety through eHealth<sup>21</sup> although it is not yet investigated in patients with persistent spinal pain.

The eHealth intervention consists of six modules that each focus on a different theme: (1) 'understanding pain', (2) 'feeling safe', (3) 'feeling balanced', (4) 'your story', (5) 'feeling motivated' and (6) 'future goals' (see [table 1](#)). Patients are encouraged to finish one module per week. They may request online feedback through the platform from their treating physiotherapist, or items can be further discussed during the face-to-face physiotherapy sessions.

Patients access the eHealth intervention on an interactive online platform (MindDistrict; Amsterdam; The Netherlands; [www.minddistrict.com](http://www.minddistrict.com)). Access and data are protected by username and password (see 'Data monitoring and management'). Notifications when a module is available or completed, or when feedback is requested or sent, are generated automatically through the hosting platform. Patients and physiotherapists receive these notifications via e-mail.

### Training for the physiotherapist

All physiotherapists randomised to the experimental intervention receive a 3-hour training session. Diverse topics are covered during the training, such as study details, how to navigate the online platform themselves, how to explain the platform to their patients and how to influence psychosocial factors using the eHealth modules. When they include their first patient, they receive guidance (~one hour) with the process, and later in the trial when needed. Throughout the trial, a psychologist is available for consultation either online or via phone for the physiotherapist on request.

### Outcome measures

Patients complete online surveys (Qualtrics, Amsterdam, The Netherlands; [www.qualtrics.com](http://www.qualtrics.com)) to collect data. [Table 2](#) provides an overview of the questionnaires and timing. Follow-up measurements are planned at 2-month follow-up (short-term effects), and at 6 and 12-month follow-up (long-term effects) ([figure 1](#)). The baseline measurements take 30–45 min to complete, the 2 and 12-month follow-ups take approximately 30 min, and the 6-month follow-up takes approximately 10 min.

### Primary outcomes

#### Disability

Disability is measured with the Oswestry Disability Index (ODI)<sup>34</sup> for patients with low back pain and with the Neck Disability Index (NDI)<sup>35</sup> for patients with neck pain. Both

measures consist of 10 items, scored on a 6-point Likert Scale with scores ranging from 0 to 50. These questionnaires assess patient's self-reported pain intensity and limitations in daily activities and is a recommended core outcome.<sup>36</sup> Both outcome measures are frequently used, reliable and internally consistent.<sup>37</sup> A clinically important change is defined as a minimum change score of 10 points for the ODI<sup>38</sup> and 10.5 points for the NDI.<sup>39</sup>

### Perceived effect

Perceived effect is measured with Global Perceived Effect (GPE) scale, a measure of the patient's perceived recovery compared with baseline.<sup>40 41</sup> This questionnaire comprises one item scored with a 7-point Likert scale (labels: worse than ever, a lot worse, a bit worse, the same, slightly improved, much improved, completely recovered). Recovery is defined when the patients' score in the two highest categories.<sup>38</sup> This is a reliable measure with a test–retest correlation ranging from 0.89 to 0.98<sup>38</sup>.

### Secondary outcomes

Secondary outcome measures are pain intensity measured with a Numerical Pain Rating Scale,<sup>42 43</sup> depressive symptoms measured with the PHQ-9,<sup>44 45</sup> anxiety symptoms measured with the GAD-7,<sup>46 47</sup> kinesiophobia measured with the Tampa scale for Kinesiophobia,<sup>47 48</sup> pain catastrophising measured with the Pain Catastrophising Scale,<sup>49 50</sup> self-efficacy measured with the Pearlin Mastery Scale<sup>51 52</sup> and quality of life measured by the Short Form (SF)-12.<sup>53</sup> The effect of the intervention on knowledge of pain is measured with the Neurophysiology of Pain Questionnaire.<sup>54</sup>

### Additional variables

Additional variables include patients' healthcare use, work-related health and costs (Trimbos/iMTA questionnaire for Costs Associated with Psychiatric Illness)<sup>55</sup> and the therapeutic alliance (Working Alliance Inventory- Short Form).<sup>56</sup> Physiotherapists will complete a questionnaire post-treatment regarding the patient's physiotherapy treatment; number and duration of physiotherapy sessions and types of interventions provided. They will also complete the Pain Attitudes and Beliefs Scale that is used to assess the strength of biomedical and biopsychosocial treatment orientations of healthcare practitioners towards low back pain.<sup>57</sup>

Data is extracted from the online platform to determine treatment adherence of the eHealth intervention, including number of modules completed, and number of online contacts with the physiotherapist.

### Randomisation and blinding

Physiotherapy practices are randomly allocated to deliver the experimental intervention (physiotherapy +eHealth) or the control intervention (physiotherapy) on a 1:1 ratio using a computer-generated cluster randomisation scheme by an independent researcher not involved in the study. A cluster randomisation at the level of physiotherapy practice is conducted, as we assume that the

**Table 1** Overview of the eHealth intervention

Target concept	Content, delivery mode and resources	Evaluation
<b>Theme week 1: understanding pain</b>		
<ul style="list-style-type: none"> <li>▶ Pain is normal, personal and always real.</li> <li>▶ Danger sensors, rather than pain sensors.</li> <li>▶ We have our own drug cabinet in the brain.</li> <li>▶ Value-based activities help decrease pain and improve mood.</li> <li>▶ Learning about pain can help the individual and society.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Introduction to the online course and to the two model patients who are followed throughout the course.</li> <li>▶ Stating intentions and goals for the treatment.</li> <li>▶ Education about pain as a protective mechanism (72).</li> <li>▶ Exploring the relationship between pain, mood and neurotransmitters.(Open the Drug Cabinet in your Brain; EP Supercharged).</li> <li>▶ Tasks to identify personal values and corresponding value-based activities.</li> <li>▶ Introduction to scoring pain and mood daily via an app embedded in the online course.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Appropriate and realistic goal setting.</li> <li>▶ Identification and planning of value-based activities.</li> <li>▶ Correct answers to two true/false statements.</li> </ul>
<b>Theme week 2: feeling safe</b>		
<ul style="list-style-type: none"> <li>▶ Pain and tissue damage often do not relate.</li> <li>▶ Pain may depend on the balance of perceived danger and safety.</li> <li>▶ We are bioplastic.</li> <li>▶ Pain relies on context.</li> <li>▶ Time-contingent exercises, rather than mood or pain-contingent.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Education about the balance between perceived safety and unsafety in relation to pain using the metaphor of 'pain works as a fire alarm'.</li> <li>▶ Tissue damage (identifiable on imaging) and pain experience rarely correlate (Video†).</li> <li>▶ The ability of training your brain to dampen danger signals.</li> <li>▶ Tasks to identify what makes you feel safe and plan to change what makes you feel unsafe (EP Supercharged).</li> <li>▶ Introduction to activity scheduling by planning value-based activities that make you feel safe.</li> <li>▶ Reflecting on first week of activities.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Identifying 'Danger in Me' (DIMS) to 'Safety in Me' (SIMS) and introducing change where needed and possible.</li> <li>▶ Correctly answering four true/false statements.</li> <li>▶ Explaining to others how pain works.</li> <li>▶ Identifying a connection between pain, mood and activities using the app embedded in the online course.</li> </ul>
<b>Theme week 3: feeling balanced</b>		
<ul style="list-style-type: none"> <li>▶ Active treatment strategies promote recovery.</li> <li>▶ Passive coping strategies are maladaptive in the long term.</li> <li>▶ Healthy behaviour needs small, achievable goals.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Recognising stress and anxiety signals (physical, mental and behavioural signals).</li> <li>▶ Association between pain and energy.</li> <li>▶ Information and tasks to reduce burden and increase mental and physical strength through lifestyle changes (including physical exercise, diet and sleep hygiene).</li> <li>▶ Physical activity with pain is essential (Video*).</li> <li>▶ Evaluation of planned activities past week and the correlation with experienced pain and mood.</li> <li>▶ Activity scheduling emphasis on value-based activities in keeping with a healthy lifestyle.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Recognising personal stress signals (including pain).</li> <li>▶ Formulation of healthy goals and activities.</li> <li>▶ Correctly answering four true/false statements.</li> <li>▶ Identifying a connection between pain, mood and activities using the app embedded in the online course.</li> </ul>
<b>Theme week 4: your story</b>		
<ul style="list-style-type: none"> <li>▶ Pain is normal, personal and always real (reinforced).</li> <li>▶ Learning about pain can help the individual and society (reinforced).</li> <li>▶ Pain relies on context (reinforced).</li> <li>▶ Physical and mental peace help you cope with pain.</li> </ul>	<ul style="list-style-type: none"> <li>▶ The importance about reflecting on your pain and the meaning and place it has in your life by taking a step back (video *).</li> <li>▶ Tasks to recognise eliciting- and maintaining factors in (the onset of) pain.</li> <li>▶ Explanation about the association between pain and our modern lifestyle(video *)</li> <li>▶ Introduction to relaxation exercises(Audio-file progressive relaxation and muscle relaxation†)</li> <li>▶ Education about rumination and catastrophising in pain(video †)</li> <li>▶ Tasks on how to control rumination and reflecting on priorities and current activities (distinction between important and urgent).</li> <li>▶ Evaluation of planned activities past week and the correlation with experienced pain and mood.</li> <li>▶ Tasks to identify helpful solutions before- and throughout the course.</li> <li>▶ Activity scheduling with emphasis on taking a step back to slow down life.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Connecting life circumstances to the onset and maintenance of pain in order to formulate lessons learnt.</li> <li>▶ Formulating and reviewing priorities</li> <li>▶ Formulating helpful solutions that have worked in the past and in this course.</li> <li>▶ Identifying a connection between pain, mood and activities using the app embedded in the online course.</li> </ul>
<b>Theme week 5: feeling motivated</b>		

Continued



Table 1 Continued

Target concept	Content, delivery mode and resources	Evaluation
<ul style="list-style-type: none"> <li>▶ Passive coping strategies are maladaptive in the long term (reinforced).</li> <li>▶ Active treatment strategies promote recovery (reinforced).</li> <li>▶ Healthy behaviour needs small, achievable goals (reinforced).</li> <li>▶ Pain and tissue damage often do not relate (reinforced).</li> </ul>	<ul style="list-style-type: none"> <li>▶ Education about avoidance when experiencing depression and/or anxiety and pain.</li> <li>▶ Information about flare-ups and managing these emphasising that your pain can be overprotective (Twin Peaks model; EP Supercharged)</li> <li>▶ Tasks to re-engage in daily life to get out of a downward spiral of avoidance by committing to tackle a small challenge.</li> <li>▶ Evaluation of planned activities past week and the correlation with experienced pain and mood.</li> <li>▶ Reflecting on the most helpful solutions in the past weeks and incorporate them once again;</li> <li>▶ Activity scheduling emphasis on tackling a small challenge</li> </ul>	<ul style="list-style-type: none"> <li>▶ Providing appropriate advice to an imaginary patient with similar symptoms who is avoiding activities in daily life.</li> <li>▶ Identifying downward spirals that connect mood and pain with circumstances</li> <li>▶ Identifying a connection between pain, mood and activities using the app embedded in the online course.</li> </ul>
<b>Theme week 6: future goals</b>		
<ul style="list-style-type: none"> <li>▶ The road to recovery will have its ups and downs.</li> <li>▶ I can influence my pain by influencing my activities.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Reflecting on the small challenges identified and planned in the previous week.</li> <li>▶ Evaluation of planned activities past week and the correlation with experienced pain and mood.</li> <li>▶ Education that the road to recovery is not a steady climb but a rocky road (video †).</li> <li>▶ Tasks to identify and formulate knowledge, skills and insights gained during the course.</li> <li>▶ Tasks to recognise and prevent symptoms in the future.</li> <li>▶ Formulating a 'personal health plan' for the future to continue growing and recovering by using the skills and knowledge acquired throughout the course.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Identifying a connection between pain, mood and activities using the app embedded in the online course.</li> <li>▶ Reflecting over the past weeks and formulation of a realistic and attainable personal health plan</li> </ul>
<p>*Video Brainman translated and adapted with permission [Available from: <a href="https://www.youtube.com/watch?v=5KrUL8tOaQs">https://www.youtube.com/watch?v=5KrUL8tOaQs</a>]</p> <p>†Own production</p>		

training prior to the study for physiotherapists in the experimental intervention and the eHealth application may influence their 'care-as-usual'. Concealed allocation is performed by an independent researcher who provides the result of the randomisation using opaque, sealed envelopes. Due to the nature of the eHealth intervention and design of the study, blinding of the physiotherapists and participants is not possible. The researchers conducting the data analyses are blinded for group allocation.

### Sample size

Results from a previous RCT including patients comparable to our RCT revealed a medium effect size of 0.46 for an eHealth intervention on disability (Cohen's *d*).<sup>58</sup> Furthermore, a meta-analysis for psychological interventions for patients with low back pain revealed effect sizes for disability ranging between 0.36 and 0.53.<sup>13</sup> Based on 80% power, an alpha of 0.05 and three follow-up measurements, the sample size calculation indicated that 151 participants are required for individual randomisation. Since we randomise at practice level, the sample size has to be increased with a factor called 'the design effect'.<sup>59</sup> We anticipate that 25 physiotherapy practices will participate and that the average cluster size will be  $(151/25)=6$  patients per cluster. Because the intervention is aimed at behavioural change at the patient level and we do not

expect much variation between patients, we estimate a relatively small intraclass correlation coefficient (ICC) of 0.04.<sup>60</sup> The sample size is, therefore, multiplied with  $(1 + (\sim n - 1) \times ICC) = 1.2$ , where  $\sim n$  is the average cluster size.<sup>59</sup> The adjusted sample size is, therefore,  $N=182$ . Allowing up to 10% dropout, the required total sample size is  $N=202$ .

### Statistical analyses

Analyses are performed according to the intention-to-treat principle. Linear mixed model is a suitable method for the analysis of a longitudinal relationship between continuous variables that are not independent and is also suitable to handle missing data when baseline data are complete.<sup>61</sup> In case of incomplete baseline data with missings (completely) at random, multiple imputation will be used. Appropriate confounders (eg, psychosocial factors and baseline scores) are included in the analysis. Statistical significance is set at  $p < 0.05$ . We will express the difference between groups in effect size calculating Cohen's *d*. The number-needed-to-treat index will also be calculated based on the primary outcome of perceived recovery (GPE). We will perform a sensitivity analysis in which we include only patients who completed the intervention fully or partially.

**Table 2** Overview of the measurements and timing of measurements.

Domain	Questionnaire	Base line	2 months	6 months	12 months
Demographic characteristics	Purpose built	✓	–	–	–
Disability in people with low back pain	ODI	✓	✓	✓	✓
Disability in people with neck pain	NDI	✓	✓	✓	✓
Perceived recovery	GPE	–	✓	✓	✓
Pain intensity	NPRS	✓	✓	✓	✓
Depressive symptoms	PHQ-9	✓	✓	–	✓
Anxiety symptoms	GAD-7	✓	✓	–	✓
Fear of movement	TSK	✓	✓	–	✓
Self-efficacy	Pearlin	✓	✓	–	✓
Pain catastrophising	PCL	✓	✓	–	✓
Neurophysiology of pain knowledge	NPQ	✓	✓	–	✓
Quality of life	SF-12	✓	✓	–	✓
Therapeutic alliance	WAI-SF	–	✓	–	–
Healthcare utilisation	Tic-P	✓	✓	–	✓

GAD-7, Generalised Anxiety Disorder scale 7-item version; GPE, Global Perceived Effect; NDI, Neck Disability Index; NPQ, Neurophysiology of Pain Questionnaire; NPRS, Numerical Pain Rating Scale; ODI, Oswestry Disability Index; PCL, pain catastrophizing list; Pearlin, Pearlin Mastery Scale; PHQ-9, Patient Health Questionnaire 9-item version; SF-12, Short Form 12-item version; Tic-P, Trimbos/iMTA questionnaire for Costs Associated with Psychiatric Illness; TSK, Tampa Scale of Kinesophobia; WAI-SF, Working Alliance Inventory-Short Form.

All secondary outcomes will also be analysed using linear mixed models. All additional parameters will be analysed descriptively. No interim analyses will be performed.

### Data monitoring, integrity and management

The study is monitored by senior researchers in the team (GS-P, MWC, LdW). Patients provide information digitally and data are exported directly to spreadsheets using the programme Statistical Package for the Social Sciences (SPSS, V.27). The log files of the eHealth intervention and the data of participants are both stored on secure online platforms. The key connecting participant names with participant ID codes and logins to access to the online platform is kept in a secure location in the coordinating researcher's office during the research period until after the final publication. After that, the key and the data will be coded by a participant ID code, which cannot be traced back to the individual participants after termination of the study and will be stored in the principal investigator's office for a period of 15 years in accordance with the General Data Protection Regulation (Uitvoering-swet Algemene Verordening Gegevensbescherming, The Netherlands).

### Risks and adverse events

There are no known risks to use an eHealth intervention focusing on pain education and behavioural activation. A meta-analysis on potential deterioration of symptoms of depression during similar interventions showed that participants had a significantly lower risk of deterioration compared with control groups.<sup>62</sup> Some participants may

experience non-serious adverse events, such as a mild or moderate and temporary increase in symptoms that do not require additional care. This is explained in the intervention group and physiotherapists are trained to handle this. These minor adverse events are monitored and discussed with the study coordinator. Serious adverse events (such as symptoms requiring referral to healthcare practitioners) are referred immediately to the principal investigator. Appropriate measures will be taken, which may include referral to a general practitioner, psychologist or psychiatrist.

### Ethics and dissemination

The study is conducted according to the principles of the Declaration of Helsinki (2013) and in accordance with the Medical Research Involving Human Subjects Act (Wet Medisch Wetenschappelijk Onderzoek voor Mensen). Results of this study will be published in national and international peer-reviewed journals. Data will be made available on request.

The study has been approved by the Medical Ethical Committee (MEC) of the VU Medical Center Amsterdam, The Netherlands (2017.286) and is registered at the Netherlands Trial Register. Protocol amendments will be submitted for approval to the MEC of the VU Medical Center in the case of important protocol modifications.

### Patient and public involvement statement

In order to ensure the eHealth intervention would be feasible and user friendly, patients and physiotherapists were involved in the development of the eHealth

intervention. They provided valuable information both in the initial selection of appropriate methods incorporated in the eHealth intervention as well as in pilot testing the eHealth intervention.

Patients participating in the trial receive a short-group summary of the study results. For physiotherapists, presentations and symposia will be held to disseminate the results of the study as well as the implications for current physiotherapy practice. Patients and practitioners will be consulted in the implementation of the treatment, if the intervention proves successful.

## DISCUSSION

This study will assess the effectiveness of physiotherapy blended with an eHealth intervention compared with physiotherapy alone in patients with spinal pain for a minimum of 6 weeks on disability and perceived recovery. The eHealth intervention targets those psychosocial factors (depression, anxiety, fear of movement and pain catastrophising) that are associated with poor recovery in patients with spinal pain.<sup>5–8</sup> It does so by increasing an understanding of pain, stimulating value-based activities and self-management. The eHealth component aims to assist physiotherapists in reassuring and activating their patients during and after treatment.<sup>63–65</sup>

A recent Lancet series on the treatment of low back pain confirmed that it is imperative that the treatment of subacute or persistent pain in primary care focuses more on self-management and activation, including education.<sup>66</sup> This eHealth intervention incorporates two treatment methods from different disciplines (physiotherapy and mental healthcare) that both focus on patient activation under a biopsychosocial paradigm, as advised in international guidelines.<sup>32</sup> The first method is derived from pain education,<sup>33</sup> which aims to change pain beliefs and provide an important reason why an active lifestyle is important. The second method is behavioural activation,<sup>67</sup> which provides self-management strategies to achieve and maintain an active lifestyle. These methods are complementary to each other and may be more effective combined than either treatment alone.

The use of an eHealth psychologically informed intervention to supplement face-to-face physiotherapy takes the barriers in addressing psychosocial factors in primary physiotherapy care into account by providing structure and quality information<sup>12</sup> and providing a truly biopsychosocial treatment. Psychological eHealth interventions are effective in reducing disability and psychological symptoms in patients with persistent pain.<sup>12, 20</sup> They also have the potential to be more cost-effective than face-to-face treatments alone as less therapist time is needed,<sup>68</sup> thus reducing the barrier of time constraints.

When designing this study, several limitations have been identified. Providing a true biopsychosocial treatment is not possible if physiotherapists (un)consciously work within a biomedical approach in the face-to-face physiotherapy component of the experimental intervention.<sup>18</sup>

This might undermine the treatment paradigm in the eHealth intervention. The training and guidance of the therapists are used to minimise this pitfall.

Second, cluster randomisation is performed to decrease contamination between the experimental and control interventions. However, this might lead to postrandomisation selection bias, where baseline differences on a patient level can be observed between different physiotherapy practices.<sup>59</sup>

Third, this study does not interfere with usual physiotherapy care in the control intervention, whereas the eHealth intervention may influence the usual care physiotherapy face-to-face component in the experimental intervention. Therefore, treatment data regarding usual care and therapists' attitude will be gathered and analysed for both groups. It should be noted, however, that usual physiotherapy care for persistent low back pain may vary considerably<sup>69</sup> while still in line with the stipulated clinical guidelines.<sup>32</sup>

Another limitation is that eHealth interventions for depressed patients typically have higher drop-out rates compared with trials with other patient groups, and particularly in men, older adults and people with a low education level.<sup>70</sup> Unfortunately, higher age and low education level are also observed in populations that experience persistent pain.<sup>9</sup> By providing this intervention in a blended format and incorporating patients in the design of the intervention, we aim to reduce the number of drop outs.<sup>70</sup>

Finally, only patients who find a psychological intervention acceptable will consent to participate. Furthermore, the prerequisite of having access to a computer and internet may influence recruitment of people with a lower socioeconomic status and education level. This might hinder patient recruitment and may make the results less generalisable.

For future improvement of the intervention and subsequent studies, we would suggest incorporating Ecological Momentary Assessment data in the form of accelerometers.<sup>71</sup> The use of objective measures of physical functioning (ie, accelerometers) might be helpful for physiotherapists and patients to assist in goal setting and outcome measurement for future studies.

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