This deliverable consists of two reviews. Part A is a systematic review on published studies and study protocols on the characteristics, components, and effects of digital interventions to support patient self-management of low back pain while Part B maps the current landscape and development of case-based decision support systems that cover the scope of SELFBACK. Together, the two reports form the scientific state of the art and serve the purpose of informing the scientific decisions in the SELFBACK system.
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Preface

This deliverable consists of two reviews undertaken to ensure that all parts of SELFBACK are conducted on top of the available relevant knowledge, which can qualify the SELFBACK program. SELFBACK is a highly multidisciplinary program ranging from the technical development of the software to the clinical testing of the developed product. Therefore, the present deliverable consists of two separate reviews, provided as part A and B with separate authorship and each providing the scientific state of the art within two key topics by content experts.

Part A consists of a systematic review on published studies and study protocols on the characteristics, components, and effects of digital interventions to support patient self-management of low back pain. This part will form essential input for the design of the protocol of the randomised controlled trial conducted in WP 5 and the important features to focus on in WP 2 and 3.

Part B maps the current landscape and development of case-based decision support systems that cover the scope of SELFBACK. It describes the technical features in developing and designing a case based reasoning system and the choice of feature extraction as the source for providing advice about self-management. This part is essential input for the ongoing work in WP 1, WP 2 and WP 3.

Together, the two reports form the scientific state of the art and serve the purpose of informing the scientific decisions in the SELFBACK system.

1 Introduction

Musculoskeletal disorders are one of the major contributors to the global burden of disease, and low back pain (LBP) is the most prevalent musculoskeletal disorder [1]. In the World Health Organization’s Global Burden of Disease study, LBP was ranked as the greatest contributor to disability in 12 of 21 world regions and it was stated that 9.2% of the global population suffer from LBP at any given moment [1]. In Western Europe, the age-adjusted point-prevalence is higher with approximately 15% of the population suffering from LBP at any given time [2]. However, LBP starts early in life and is considered a problem for all age-groups. When disease is measured in terms of years lived with disability, LBP is the health condition that carries the greatest burden worldwide [1]. It is among the most common causes of long-term work absence, and has a major impact on productivity at work [3, 4]. In the UK, annual costs of back pain have been estimated to be approximately £10.7 billion for indirect factors, including workplace productivity costs [5, 6], therefore LBP presents a major burden for health-care systems and society at large [1]. Besides the economic burden and the society cost of LBP, the implications for the individual with LBP are further disability and activity limiting pain affecting everyday management and quality of life [7].

Evidence suggests that chronic LBP is on the rise [8], which calls for effective treatment strategies that are cost-effective, safe and easy to administer. Self-management and physical activity are two such strategies that are consistently recommended in international guidelines on the management of LBP [9-11]. Self-management focuses on the patient’s ability to manage their own condition rather than treatment being based within the healthcare system or centred on a healthcare professional. The aim is to restore autonomy to the patient, and include educational, or learning, components to position the patient at the core of their own management process and to help them acquire and maintain competencies to enable them to efficiently manage their condition [8].

Self-management as a management strategy can be summarised as the individual’s own ability to: (1) lead a healthy lifestyle appropriate for their condition; (2) meet their social, emotional, and psychological needs; (3) care for their long-term condition including coping with disease variation, symptoms and treatments; and (4) prevent further illness or accidents [12-15]. In a systematic review from 2012, Oliviera et al. investigated the effectiveness of self-management for LBP and reported moderate-quality evidence that self-management interventions had small, but clinically relevant, effects on reducing pain and disability when compared to minimal interventions [13]. They found that all the eligible studies included some sort of education or general information as a key component of prevention and treatment of LBP [13]. In addition, the self-management interventions ranged from receiving written information, attending face-to-face educational programs, functional movement training programmes to information from web-sites. Consequently, the mode of delivery for the self-management intervention differed greatly between studies [13].

Digital interventions (i.e. interventions accessed via computer, mobile phone, or other handheld devices, included web-based, desktop computer programmes, or applications (apps)), providing self-management information have been proposed as a promising mode of delivery for self-management interventions. In a Cochrane Review from 2005, the use of Interactive Health Communication Applications was evaluated in
people with chronic disease and found to have a significant positive effect on knowledge, social support and clinical outcomes in conditions such as diabetes and obesity [16]. This finding was supported in a more recent systematic review, which found consistent evidence that online interventions were more efficacious in improving disease specific symptoms for chronic pain, including back pain compared to no treatment, care as usual, placebo or wait list control groups [17]. Consequently, it appears that the effect of self-management interventions may be influenced by the mode of delivery, and that digital interventions hold potential as a platform for health-care. Consequently, it is interesting to look specifically at the benefits, if any, of using a digital platform for providing self-management interventions in LBP.

The review described here was undertaken to describe the characteristics and effects, if any, of digital self-management interventions for LBP. The purpose of our systematic review was to synthesise published evidence concerning the characteristics, components, and effects of digital interventions to support patient self-management of LBP. More specifically, the review aimed to address the following questions:

1. What are the key characteristics and components of digital self-management interventions for LBP, including theoretical underpinnings?
2. What are the key characteristics and components of digital self-management interventions for LBP that appear to be associated with beneficial effects?
3. What outcome measures have been used in randomised trials of digital self-management interventions in LBP and what effects, if any, have been reported?

2 Methodology

2.1 Design

The systematic literature review followed an a-priori defined protocol (PROSPERO CRD42016037954, http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016037954) (Appendix 1) and reporting is consistent with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [18].

2.2 Eligibility criteria

As suggested by the PRISMA statement, the PICO (Population, Intervention, Control, Outcome) approach was used to describe the eligibility criteria of the systematic review [18]. Consequently, the population included adults (18 years or above) with non-specific LBP. The intervention was a digital self-management intervention that included an element of interaction between the patient and digital interface. A digital intervention was defined as any intervention assessed through a computer (work or home), mobile phone, or hand-held device, and included web-based or desktop computer programmes or applications (apps) that provided self-management information or material, which is in keeping with previous reviews in this sphere [19]. The digital intervention had to be “interactive” to be included in the review. For the purpose of this review, interaction was defined as patients entering data into the programme or app, either by entering personal data or making choices that alter the pathways in the programme and produce feedback in response to the patients’ inputted data or choices. Studies that only involved sending information to a remotely located health professional and receiving advice directly from the health professional were excluded from this review. Interventions that included face-to-face contact were only included if this type of interaction was an add-on to an automated, interactive component without direct health professional mediation (e.g.,
users report pain level interactively then receive automated messages advising them to increase/decrease activity levels). The control group was usual care or digital non-interactive or non-digital self-management interventions for LBP. Only published randomised controlled trials (RCT) or protocols for RCTs from peer-reviewed journals were included in this systematic review. Only papers published in English, Danish or Norwegian were included.

2.3 Primary outcomes

The primary outcomes for the systematic review include:

a) Details of outcome measures used to determine the effects of interventions for self-management of LBP
b) Effects on pain-related disability

2.4 Secondary outcomes

As one of the aims of this review was to investigate which outcomes are used in RCTs, we were interested in the range of secondary outcomes reported in digital self-management interventions for LBP. The following domains of outcomes were a-priori defined as potential secondary outcomes:

a) Effects on:
   a. Pain intensity
   b. Quality of life
   c. Depression
   d. Fear avoidance
   e. Pain catastrophizing
   f. Physical activity
   g. Medication use
   h. Health care utilisation (e.g., primary and secondary care visits, emergency department visits)
   i. Health care costs
   j. Knowledge of LBP
   k. Markers of self-care
   l. Self-efficacy
b) A summary of the key characteristics and components reported as being present in the interventions including theoretical underpinnings.

2.5 Search strategies

The searches were performed by an experienced Librarian at the Norwegian University of Science and Technology. The strategies were informed by the intervention search terms used by team members involved in two previous reviews of digital self-management interventions of hypertension and asthma [19, 20]. The search strategy combined three concepts: 1) back pain, 2) digital interventions, and 3) self-management. The full version of the search terms used, including specifications on use of title, keywords or abstract screening, is documented in Appendix 2.

2.6 Information sources

A systematic search of the following databases was undertaken: CINAHL, CDSR, CENTRAL, Cochrane Library (including DARE and HTA databases), DoPHER, Embase, MEDLINE, PsycINFO, TROPHI and Web of Science (Social Science Citation and Science
Citation Index). All databases were searched from 2000 until March of 2016. Reference and citation searching were also undertaken.

2.7 Study selection (screening, eligibility, included)
All identified citations from the searched databases were uploaded to Distiller software (Evidence Partners, Ottawa, Canada). An integrated duplication detection tool was used to identify duplicates. All suggested duplicate pairs were screened for correctness by one reviewer. Title and abstract screening was performed by two independent reviewers. Disagreement between the two reviewers resulted in inclusion of the citation to full text screening. Full-text screening was similarly performed by two independent reviewers assessing eligibility of the citation, any disagreement was resolved through discussion mediated by a third reviewer.

2.8 Data extraction
Online data collection forms were a-priori set up in the Distiller software. Similar to the study selection process, data extraction was performed by two reviewers independently and conflicts resolved by one reviewer revisiting the original paper to adjudicate on inclusion. Data was extracted regarding: study settings (country, inclusion and exclusion criteria, recruitment and participation numbers); study population (baseline characteristics such as age, gender, ethnicity, duration of symptoms, comorbidities); description of the intervention (details on the key components, characteristics and underlying theoretical concepts); and outcome measures (time-points for outcome assessment, choice of primary outcomes, included secondary outcomes and effects, if any, noted as well as attrition rates, where available).

2.9 Risk of bias assessment
The methodological quality of all included studies was assessed using the Cochrane Collaboration’s tool for assessing risk of bias in randomised trials [21]. Two reviewers independently assessed selection bias (allocation concealment and randomisation procedure), blinding of participants, personnel and outcomes assessors, completeness of data, selective outcome reporting and other potential biases [21]; any disagreements were resolved through discussion by the two independent reviewers.

2.10 Data analysis
The study population, interventions and outcomes used in the included studies were narratively described. Due to the heterogeneity of identified studies, meta-analysis was not possible. Quantitative results from the individual studies were described as either favouring the intervention group, no difference between groups or favouring the control group.

3 Results

3.1 Study selection
Our searches identified a total of 7014 citations, of which 8 citations were identified from searching reference lists of included studies. From these, 2316 were excluded as duplicates. In total, 4698 references were screened based on their title. Of these, 729 references were screened at abstract level, and 89 references were screened in full-text.
After full-text screening, eleven references met the inclusion criteria [22-32]. The eleven references concerned nine separate studies, describing five RCT study protocols and six RCT reports. The PRISMA flow chart demonstrating the screening process of papers in the systematic review is illustrated in Figure 1.


3.2 Description of included studies

Of the nine separate studies, four studies were undertaken in the United States; two in Germany; one in the United Kingdom, one in Australia, and one in Spain. The studies were published during 2010 to 2016. The six completed RCT reports included a total of 2706 participants, with a range of 114-1343 participants per study (Table 1).

3.3 Study population

Characteristics of the study population in each of the studies are described in Table 1. The studies varied in duration of LBP symptoms, content and delivery of the interventions, and the outcomes measured. LBP was defined by participant self-report in six studies [22-24, 27, 30, 32] and in three studies by general practitioner evaluations [26, 31] or diagnosis codes from medical records [29]. Seven studies included participants with pain for more
than 3 months [22-24, 27, 29, 31, 32]. One study included participants with current LBP [26], while Simon et al. [30] used acute LBP participants, defined as participants who had experienced pain for less than 3 months. The included populations had a mean age ranging from 42.5 to 52.7 years, and one study did not report age of the population [27]. While two studies had an upper age limit of 65 years [27, 31] all remaining seven studies did not report any upper limit in their inclusion criteria. In five [23, 24, 27, 30, 32] of six RCT reports, the majority of the participants was female, with the proportion ranging from 58% to 83%. The sixth study, which was conducted within the American Department of Veterans Affairs, included only 11% females in the intervention group and 14% in the control group [29]. Included participants were generally Caucasian (74% to 87%) and the majority (42% to 75%) reported educational levels as years of college or more.
<table>
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<tr>
<th>Study</th>
<th>Definition of LBP</th>
<th>Duration of LBP</th>
<th>Eligibility</th>
<th>N (attrition rate)</th>
<th>Age (mean (SD))</th>
<th>Sex (%)</th>
<th>Ethnicity (%)</th>
<th>Comorbid (%)</th>
<th>SES (%)</th>
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<tr>
<td>Chiaruzzi et al, 2010</td>
<td>Presence of LBP for at least 10 days each month for at least 3 consecutive months</td>
<td>&gt; 3 months</td>
<td>1. LBP at least 10 days each month for at least 3 consecutive months; Spinal origin of pain; Sufficient English skills 2. Access computer and e-mail 3. Ineligibility: Medical conditions causing pain, cervical pain without LBP, psychiatric hospitalizations past year</td>
<td>N = 209</td>
<td>I = 47.3 (12.2)</td>
<td>White F = 67%</td>
<td>White I = 85%</td>
<td>White C = 87%</td>
<td>N/R</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>(6 months I = 67/104 C = 88/105)</td>
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<tr>
<td>Simon et al, 2012</td>
<td>Self-report of acute LBP, defined as pain less than 3 months.</td>
<td>&lt; 3 months</td>
<td>1. Insured at specific insurance company 2. Acute LBP or depression by self-assessment 3. Ineligible if both conditions present at recruitment</td>
<td>N = 1343</td>
<td>I = 45.8 (12.7)*</td>
<td>F (82%)*</td>
<td>N/R</td>
<td>N/R</td>
<td>Education, 60% high education level*</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>(Post-use I = 147/691 C = 195/652)</td>
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<td></td>
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<td></td>
<td>(3 months I = 40/691 C = 25/652)</td>
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<tr>
<td>Carpenter et al, 2012</td>
<td>Self-report of non-specific LBP within the past 6 months.</td>
<td>&gt; 6 months</td>
<td>1. Self-reported LBP &lt; 6 months 2. Pain intensity ≥4 out of 10 3. Access to internet and e-mail 4. Sufficient English skills 5. No participation in cognitive behavioural therapy for past 3 years</td>
<td>N = 141</td>
<td>42.5 (10.3)</td>
<td>F (83%)</td>
<td>White (77%)</td>
<td>N/R</td>
<td>Education, 54% &lt; 2 years college</td>
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<td></td>
<td>(3 weeks I = 63/70 C = 68/71)</td>
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<tr>
<td>Krein et al, 2013,</td>
<td>Patients with two or more outpatient encounters within past 12 months with a diagnosis of back pain with no neurologic findings (ICD9CM codes)</td>
<td>&gt; 3 months</td>
<td>1. &gt;18 years or older 2. In VA electronic medical record system. 3. Persistent LBP &gt;3 months, 4. Self-reported sedentary lifestyle (&lt;150 minutes of PA/week)</td>
<td>N = 229</td>
<td>I = 51.2 (12.5)</td>
<td>F (11%)</td>
<td>White I = 74%</td>
<td>N/R</td>
<td>Education, 72%</td>
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<td>Krein et al, 2010</td>
<td></td>
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<td>(12 months I = 102/111)</td>
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<td></td>
<td></td>
<td>College or higher</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>Income, 82%</td>
</tr>
<tr>
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<td>Country</td>
<td>Study Design</td>
<td>Eligibility Criteria</td>
<td>N</td>
<td>I</td>
<td>C</td>
<td>Notes</td>
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<td>Irvine et al, 2015 USA</td>
<td>USA</td>
<td>Temporary nonspecific LBP with no medical signs of a serious underlying condition (e.g., cancer, infection, fracture, spinal stenosis).</td>
<td>&gt; 3 months</td>
<td>Recruited through insurance companies 1. Age 18 - 65 years in USA 2. At least half time employment, retired, or family member of an employee at recruiting company 3. LBP within past 3 months 4. Not experiencing back pain interfering with everyday life 5. No history of medical care or prescription for back pain 6. No participation in a monitored exercise program for back pain 7. Working email address, and able to play video 8. No medical risks</td>
<td>N = 398</td>
<td>I = 199</td>
<td>C = 199</td>
<td>White, I = 76%, C = 82%</td>
<td>Education, I = 58%, C = 55% Report college degree or more Income, I = 89%, C = 94% ≥$20,000 annually</td>
</tr>
<tr>
<td>Weymann et al, 2015 Germany</td>
<td>Germany</td>
<td>Chronic LBP defined as pain almost every day for more than 12 weeks, self-reported</td>
<td>&gt; 12 weeks</td>
<td>1. Age &gt; 18 years 2. Access to the Internet 3. Sufficient computer or internet literacy 4. Self-reported diagnosis of type 2 diabetes or chronic LBP</td>
<td>N = 368</td>
<td>I = 190</td>
<td>C = 188</td>
<td>I = 52.2% (13.1)<em>, C = 52.7% (13.0)</em></td>
<td>N/R</td>
</tr>
<tr>
<td>Geraghty et al†, 2015 UK</td>
<td>UK</td>
<td>LBP in the past 3 months diagnosed in consultation with general practitioner</td>
<td>&lt; 2 weeks</td>
<td>1. Age &gt; 18 years 2. Current LBP (experienced pain within past 2 weeks) 3. Access to the internet and email 4. Prior LBP consultation within 20-30 pr. group</td>
<td>20-30 pr. group</td>
<td>-</td>
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<tr>
<td>Study</td>
<td>Design/Inclusion Criteria</td>
<td>Dissemination Level</td>
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</table>
| Valenzuela-Pascual et al, 2015 Spain | Chronic LBP diagnosis by the participant’s family physician  
1. LBP longer than 6 months  
2. Age 18-65  
3. Spanish and Catalan language skills  
4. Access to the Internet, computer/laptop and email address  
5. Ineligibility: any red flags conditions | PU                  | 29 pr. group | -                 |
| Amorim et al, 2016 Australia | Chronic LBP persisting > 12 weeks but without radicular symptoms, self-reported  
1. 18 years of age with chronic LBP persisting > 12 weeks but without radicular symptoms;  
2. Discharged from a hospital-based, LBP physiotherapy program with consistent pain of at least 3 on NRS  
3. Access to internet-connected device  
4. Fluency in English  
5. Ineligibility: red flags, co-morbidities restricting physical activity, ongoing litigation, pregnancy | PU                  | 34 pr. group | -                 |

SD: Standard Deviation, SES: Socioeconomic Status, F: female, N/R: data not reported, NRS: Numerical Rating Scale, LBP: low back pain, VA: Veteran Affairs, I: intervention group, C: control group, attrition rates reported as number of completed cases in relation to total number of participants randomised to the group, *population comprised of more conditions than LBP, numbers refer to the general population and were not available for LBP group only, †protocol paper, no data available unless reported alongside the RCT results paper.
3.4 Description of the interventions

Key components of the digital interventions are summarised in Table 2.

3.4.1 Aim of interventions

Eight of the nine studies aimed to investigate the effectiveness of the digital intervention to improve clinical outcomes such as pain intensity, attitudes towards pain, pain-related disability by comparison to a control group either given usual care, or a non-digital intervention (Table 3). One study explored the feasibility of the digital intervention as the main objective [26].

3.4.2 Characteristics

3.4.2.1 Format and delivery

Seven of nine studies assessed digital interventions, which were accessed over the internet and by use of a computer, and two studies assessed digital intervention, which were app-based, but accessible from both computer and handheld devices (tablets or smartphones) [22, 27].

3.4.2.2 Frequency, duration of use and intervention duration

Large variation was seen in the reported frequency and duration of use of the digital interventions. Six studies reported unlimited access to the programmes with no report of recommendations given regarding frequency of use [22, 27, 29-32]. Geraghty et al. [26] recommended a frequency of one session per week, Chiauzzi et al. [24] and Carpenter et al. [23] reported usage twice per week. In three studies weekly reminders to visit the website or app were sent to participants in the intervention groups [23, 27, 29]. Although all studies reported frequency of use, only two of the nine studies reported duration of use per visit with a range of 20 min per session to 1-1.5 h per session [23, 24]. Several studies reported that they registered user data, such as log-in frequency, use of pathways in the programme, duration of use, and content used. However, none of the identified studies reported these data. Similarly, the interventions varied greatly in the duration, with three RCTs reporting shorter durations ranging between 2-4 weeks [23, 24, 31], one study reported eight weeks [27], three RCTs reported three months [26, 30, 32], one study reported six months [22] and the longest duration was reported to be 12 months [29].

3.4.2.3 Interactive elements

The interactive elements reported in the studies included: 1) keeping a log or journal of use of the intervention [24, 27]; 2) simulated dialogue between the user and the system, where the user’s answer(s) were used to create individualised information [23, 30, 32]; 3) small exercises, such as quizzes, drag and drop questions [23]; 4) patient’s report of outcome data and receiving feedback in the form of revised goals, i.e., goals for steps per day based on pedometer data [22, 29]; or graphs illustrating changes in pain intensity [22, 27]; 5) targeted messages with information and motivational feedback from the system [22, 26, 27, 29]; and 6) online discussion forums with peers and health-care professionals [29].

3.4.2.4 Tailoring

Seven of nine studies reported that the content of the digital intervention was tailored to the individual participant. Three studies reported using either participants’ characteristics or data entry of key information, e.g., pain intensity or pedometer data as tailoring variables. While Krein et al. [28, 29] used gender as a tailoring variable, and Chiauzzi et al.
[24] used participant responses and characteristics (not further specified). Irvine et al. [27] used job-type assessed by questionnaires and Geraghty et al. [26] used pain intensity and pain obstruction as tailoring variables. Two studies reported a systematic theoretical underpinning for the tailoring: Simon et al. [30] used the Ottawa Decision Support framework and Weymann et al. [32, 33] reported the Avoidance Endurance Model and Health-Literacy as tailoring frameworks. Valenzuela-Pascual et al. [31] reported tailoring of the digital intervention, but did not explain the basis for this. Carpenter et al. [23] and Amorim et al. [22] did not have a tailored content to their digital self-management intervention.
<table>
<thead>
<tr>
<th>Study</th>
<th>Characteristics</th>
<th>Components</th>
<th>Theoretical underpinning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chiauzzi et al, 2010</td>
<td>Website: 2 times weekly, for 4 weeks, hereafter unlimited</td>
<td>Interactive element: Complete log of activities and content viewed during sessions.</td>
<td>Yes: System matched patient characteristics to educational content, articles and interactive tools.</td>
</tr>
<tr>
<td></td>
<td>Frequency: 2 times weekly for each session</td>
<td>Tailoring: Yes</td>
<td>Intervention duration: 4 week intervention period, access for 6 months</td>
</tr>
<tr>
<td></td>
<td>Duration of visit: &lt; 20 min for each session</td>
<td>Components: Educational material</td>
<td>Content: Content not more specifically described</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wellness activities: Enhance good sleep, nutrition, stress management, exercise practices.</td>
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</tr>
<tr>
<td>Simon et al, 2012</td>
<td>Website: Unlimited access but no required frequency</td>
<td>Interactive element: Simulated dialogue between user and system. Text or graphics varied based on needs of users and their responses.</td>
<td>Yes: Ottawa Decision Support Framework Tailoring based on four or more tailoring concepts.</td>
</tr>
<tr>
<td></td>
<td>Frequency: Unlimited access but no required frequency</td>
<td>Tailoring: Yes</td>
<td>Intervention duration: 1 time use required, access for 3 months</td>
</tr>
<tr>
<td></td>
<td>Duration of visit: N/A</td>
<td>Components: Condition specific information</td>
<td>Content: Epidemiology, aetiology, diagnostics, treatment options</td>
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<tr>
<td>Carpenter et al, 2012</td>
<td>Website: Text and graphic suppl. by audio narration</td>
<td>Interactive element: Reflective exercises choose individual answer to statement, Interactive exercises drag and drop, fill in the blank, skill practice.</td>
<td>No:</td>
</tr>
<tr>
<td></td>
<td>Frequency: 2 times weekly, email reminders</td>
<td>Tailoring: No</td>
<td>Intervention duration: 3 weeks intervention period</td>
</tr>
<tr>
<td></td>
<td>Duration of visit: 1.5 hour/ log-in</td>
<td>Components: Educational chapters</td>
<td>Educational chapters: Introduction, all about pain, Thoughts and Pain, Stress and Relaxation, Getting Active, Relaxation and Meditation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Didactic material and interactive exercises</td>
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<td></td>
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<td></td>
<td>Patient stories</td>
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<td></td>
<td></td>
<td></td>
<td>Guided relaxation and meditation exercises</td>
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<tr>
<td>Study</td>
<td>Platform</td>
<td>Access Level</td>
<td>Communication Features</td>
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<tr>
<td>------------------------------</td>
<td>--------------------------------------------------------------------------</td>
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<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>Krein et al, 2013</td>
<td>Website</td>
<td>Unlimited</td>
<td>Pedometer data, used to create weekly PA goals and track</td>
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<tr>
<td></td>
<td></td>
<td>N/A</td>
<td>progress</td>
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<td></td>
<td></td>
<td></td>
<td>Targeted messages</td>
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<td></td>
<td></td>
<td></td>
<td>Discussion on online forum with peers and health-personnel</td>
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<tr>
<td>Irvine et al, 2015</td>
<td>Web-app, accessible from internet and mobile</td>
<td>Unlimited</td>
<td>Pain and PA self-monitoring tool</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N/A</td>
<td>Journal keeping function</td>
</tr>
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<td></td>
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<td></td>
<td>7 and 30 day graphs of pain</td>
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<td></td>
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<tr>
<td>Weymann et al, 2015</td>
<td>Website</td>
<td>Unlimited</td>
<td>Simulated dialogue between user and system. User-control</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N/A</td>
<td>to navigate site by reply to at least three options</td>
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<tr>
<td></td>
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<td>after each text passage.</td>
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</tbody>
</table>

*Social Cognitive Theory*
<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th>Frequency</th>
<th>PA/NA</th>
<th>User select PA, system generates activity-goals. Goals are revisited weekly. User may navigate the content as they find best.</th>
<th>Intervention Period</th>
<th>Educational Information</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geraghty et al., 2015</td>
<td>Web-site</td>
<td>1 session per week</td>
<td>N/A</td>
<td>Yes Extend of pain obstructing daily activities produce feedback</td>
<td>3 months intervention period</td>
<td>Educational information</td>
<td>Goal review Feedback on goal achievement and functional level, Sessions: sleep, pain relief, flare-up, work, mood daily living. Supporting advice Managing pain Modelling expectation through patient stories Reinforcing positive behaviour through automated feedback Simple instructions on back exercises/behaviour</td>
</tr>
<tr>
<td>Valenzuela-Pascual et al.,</td>
<td>Web-site</td>
<td>Unlimited access</td>
<td>N/A</td>
<td>Yes (content not yet developed)</td>
<td>2 weeks intervention period</td>
<td>Content not yet developed, but will be based on qualitative study including interview with patients.</td>
<td>Pain neurophysiology as educational intervention</td>
</tr>
<tr>
<td>Amorim et al., 2016</td>
<td>App – accessed via computer or smartphone</td>
<td>Unlimited access, no recommendations on frequency or duration</td>
<td>N/A</td>
<td>No</td>
<td>6 months intervention period</td>
<td>Educational material ‘Make your move – Sit less, be active for life!’ Information on how to increase PA and decrease sedentary behaviour Health-Coaching by health-care professional. FitBit activity monitor/feedback device</td>
<td>None reported</td>
</tr>
</tbody>
</table>

N/Y: no/yes. N/A: data not available, PA, Physical activity, †protocol paper, no data available, *indicates information given in the protocol, not stated in the RCT report.
3.5 Components

3.5.1 Content
The extent of descriptions of the intervention content varied across studies, but the level of detail provided was generally sparse. The content of the digital interventions can be grouped into the following categories. 1) Educational material: all studies report educational material as part of the intervention, which included categories such as information on pain origin, mechanisms and relief, epidemiology of LBP, psychological aspects (e.g., role of depression and mood), diagnostics and treatment-options, such as cognitive or behavioural strategies. 2) Wellness activities: Chiauzzi et al. [24] and Carpenter et al. [23] reported information concerning wellness, such as meditation, relaxation and sleep advice. 3) Exercise advice and goals: five studies [22, 24, 26, 27, 29] described exercise advice, such as recommendations and goal-setting as part of the intervention. Krein et al [29] and Irvine et al. [27] included short videos of exercises. 4) E-community: Krein et al [29] reported a discussion forum with peers and health-professionals from their study in addition to the educational material. 5) Narratives: Carpenter et al. [23] included patient stories as part of the content. 6) Advice: two studies reported standardized advice for pain management [26] and physical activity [22].

3.5.2 Theoretical underpinnings
All studies, except Simon et al. [30], reported some information concerning the theoretical underpinnings of the content. The level of information provided concerning the theoretical underpinning varied, as some studies merely stated the theory used whereas other studies more carefully elaborated on the theoretical underpinning and its application in the intervention. The following theories were mentioned: Cognitive Behaviour Theory [23, 24]; Collaborative Decision Making [24]; Social Cognitive Theory [27, 29]; Theory of Planned Behaviour [27]; and Acceptance and Commitment Therapy [23]. Although, not specific theories, the following approaches were mentioned as underpinning or rationales for the intervention: Mindfulness [23]; Person Based Approach [26] and Self-management principles (not specified further) [24]; and tools such as Goal Setting [29] and information on pain and pain aetiology [27, 31] were also reported as underpinning the interventions. Finally, two studies also reported that the advice given to participants was based on treatment guidelines, either evidence-based or recommendation from Governmental Institutes [22, 32].

3.6 Outcomes and effect

3.6.1 Choice of primary outcomes
A wide range of outcomes were included in the RCTs (Table 3), with a total of 16 different outcomes being reported as a primary outcome measure. The number of primary outcomes per study ranged from one to four across studies. The primary outcome measures covered the domains of pain-related disability, pain intensity and attitude, depression, physical activity knowledge of LBP, markers of self-care and transitional scales, i.e. participant’s assessment of change over time. Of the six completed trials, four studies [27, 29, 30, 32], did not find a statistically significant effect on the primary outcome measures in favour of the intervention group; one study by Carpenter et al. [23] reported an effect in favour of the intervention compared to the control group on their primary outcome Survey of Pain Attitudes (SOPA); while Chiauzzi et al [24] reported a favourable effect in the intervention arm but only in one of four primary outcomes that they measured (the Participants’ Global Improvement of Change).
3.6.2 Pain-related disability

For this review pain-related disability was of special interest, as it measures a construct of the physical functioning domain, which has been recommended as a core domain in LBP research by several authors and guidelines [34-36]. Consequently, this domain was a priori defined as a primary outcome of interest for this review. Four of the included six RCT reports and three of three RCT protocols included a measure of pain-related disability (Appendix 3). Pain-related disability was used as the primary outcome in four of the nine studies. The Roland-Morris Disability Questionnaire (RMDQ) was used in five of the nine studies. Carpenter et al. [23] reported a significant difference in favour of the intervention group in RMDQ after three weeks of online intervention compared to a waiting list control group. Krein et al. [29] similarly used the RMDQ, but observed reduced disability in chronic LBP with a 12-months pedometer-based internet-supported intervention of the same magnitude as the control group. The three protocols for RCT trials [22, 26, 31] all expected to use RMDQ as measure of pain-related disability. The Oswestry Disability Index (ODI) was stated as the primary outcome measure in two of the six RCT reports. Chiauzzi et al. [24], did not find a difference in ODI score between the intervention and control group after four weeks of access to a pain information website compared to static participant information. Irvine et al. [27] did not report the trial results of ODI even though it was stated as a primary outcome in the trial registration at www.clinicaltrials.gov. None of the three protocols planned to use ODI.

3.7 Secondary outcomes

Similar to choice of primary outcome, there were a large variety of secondary outcome measures described (Table 3). An overview of all outcome measures included in the review is provided in Appendix 3. The outcome measures covered the following domains: pain-related disability; pain; health-related disability; depression/mood; fear of movement; pain catastrophizing; physical activity; knowledge of LBP, markers of self-care and a range of other outcomes not held within the a-priori defined domains. For the RCT reports only one outcome (i.e. the Fear-Avoidance Belief Questionnaire [FABQ]) was reported in more than two studies, nine outcomes were reported in two studies and 28 outcomes were reported in just one study. For the three protocols of future RCTs, a more consistent choice of outcomes was seen, as two outcomes, RMDQ and pain intensity, were planned to be measured in all three RCT protocols and three outcomes, the Tampa Scale of Kinesiophobia (TSK), Pain Catastrophizing Scale (PCS) and the International Physical Activity Questionnaire (IPAQ), were planned in two of the three RCT protocols. Consequently, the outcomes most frequently identified from the nine included studies were: RMDQ (five of nine studies), pain intensity (five of nine studies), FABQ (four of nine studies), and PCS (four of nine studies).

In the following section, we provide an overview of the reported treatment effects reported in the six RCT reports. This information is also graphically displayed in Appendix 3, along with an overview of outcomes planned for the three protocols for future RCTs.

3.7.1 Pain intensity

Pain intensity measured with either an 11-point Numerical Rating Scale (NRS) or a 100 mm Visual Analogue Scale (VAS) was reported in three of six RCT reports [23, 27, 29]. Only Irvine et al. [27] reported an effect in favour of the intervention group on pain intensity, however, this was reported as a composite pain measure combining pain intensity, duration and frequency. Carpenter et al. [23] and Krein et al. [29] did not observe any between-group differences.
3.7.2 Quality of life
Health-related quality of life was reported in two studies, but with two different outcome measures. Irvine et al. [27] used the Darmouth Primary Care Cooperative Information Project (CO-OP) and Krein et al. [29] the Short-Form 12-Item questionnaire (SF-12). Only, Irvine et al. [27] reported an effect in favour of the digital intervention, however again using a composite outcome measuring functionality, well-being and quality of life.

3.7.3 Depression
Depression was reported in three of the six RCTs. Chiauzzi et al. [24] did not report any difference between the digital self-management intervention and control group as measured with the Depression and Anxiety Stress Scale (DASS). Carpenter et al. [23] reported a treatment effect in favour of the digital intervention as measured with the Negative Mood Regulation Scale. Krein et al. planned in their protocol paper [28] to assess depression using the Centre for Epidemiologic Studies Depression Scale, however no data was provided in report of their RCT [29].

3.7.4 Fear avoidance
Three studies reported fear of movement with the FABQ. Carpenter et al. [23] reported an effect in favour of the digital intervention group, whereas Krein et al. [29] did not report any group difference. Chiauzzi et al. [24] reported data for this outcome, though did not investigate any difference between the intervention and control groups in their report of the RCT. One study by Irvine et al. [27] used the TSK as a measure of fear avoidance, here no between-group difference was reported.

3.7.5 Pain Catastrophizing
The PCS questionnaire was the consistent choice for assessment of pain catastrophizing in two RCT reports. Carpenter et al. [23] found an effect in favour of the digital intervention as compared to the waiting list control, while Chiauzzi et al. [24] did not report any results for this outcome measure.

3.7.6 Physical activity
Physical activity was assessed with pedometer as an objective and self-reported measure. However, only one of the six RCT reports, by Krein et al. [29], described measuring physical activity. The study assessed physical activity by a functional performance test, the 6-min walking test, a self-reported questionnaire, the Short-Form 36-Item function scale, and by the number of daily steps objectively measured with a pedometer. No differences were found on any of the physical activity measures between the intervention and control group.

3.7.7 Medication use
No studies reported medication use.

3.7.8 Health care utilisation
No studies reported details of health care utilisation (e.g., primary and secondary care visits, emergency department visits).

3.7.9 Health care costs
No studies reported on health-care costs or cost effectiveness.

3.7.10 Knowledge of LBP
Three of the RCT reports used participant’s knowledge of LBP as an outcome measure. Simon et al. [30] and Weymann et al. [32] used the same self-developed questionnaire, neither study found a difference between the digital intervention and control group.
Irvine et al. [27] assessed knowledge using a self-developed questionnaire. Irvine reported an effect in favour of the intervention group, however as a composite score of three different outcomes (self-efficacy, behaviour intentions and knowledge).

### 3.7.11 Markers of self-care
In total, 14 different outcomes were identified as markers of self-care. Overall, five of the 14 outcomes showed an effect in favour of the digital invention when compared to a control group. Ten of the 14 outcomes were reported in only three of six RCT reports. Of these, the study by Simon et al. [30] and Weymann [32] originate from the same research group, and consequently there is considerable overlap between the intervention described and outcomes assessed in both trials. Both studies included LBP participants but their populations were recruited specifically for each separate study. Irvine et al. [27] reported an effect on three outcomes of self-care in favour of the digital mobile application FitBack, when compared to the control group.

### 3.7.12 Self-efficacy
Four different measures of self-efficacy were reported in four RCT reports. The Self-Efficacy for Exercise Scale (SEES) was used by Carpenter et al. [23], who found an effect on self-efficacy in favour of the digital intervention group as compared to the waiting list control. Irvine et al. used a self-developed self-efficacy scale in a composite outcome score, and reported a difference in favour of the digital intervention, however again reported in the composite score. Chiauzzi et al. [24] used the Pain Self-Efficacy Questionnaire (PSEQ) and Krein et al. [29] used the Exercise Regular Scale (ERS), neither study reported any between group differences.

### 3.7.13 Other outcomes
Ten outcomes could not be classified within the a-priori defined outcome domains. These ten included work-related outcomes, such as the Stanford Presenteeism Scale (SPS), time off work and the Work Limitations Questionnaire (WLQ), and procedural and implementation outcomes which included issues such as feasibility, treatment adherence, as well as credibility and expectations of the intervention. Four outcomes were additionally placed in an ‘other’ category: The Chronic Pain Coping Inventory (CPCI); Participants Global Impression of Change (PGIC); StartBack Screen Tool and the Problematic experience of Therapy Scale. For these other outcomes, Irvine et al. [27] reported a between group difference favouring the digital intervention for the SPS and WLC in a composite score and Chiauzzi et al. [24] reported between group difference favouring the digital intervention for the CPCI and PGIC outcomes.
### Table 3: Study aim, available outcomes and main results

<table>
<thead>
<tr>
<th>Study</th>
<th>Aim</th>
<th>Primary Analysis</th>
<th>Secondary outcomes</th>
<th>Main result</th>
<th>Control condition</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Outcomes</td>
<td>Measurement Times</td>
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<tr>
<td></td>
<td></td>
<td>Brief Pain Inventory (BPI)</td>
<td>Baseline Post-intervention (4 weeks) 3 months 6 months</td>
<td>Pain catastrophizing (PCS)  Fear avoidance belief questionnaire (FABQ)</td>
<td>Educational material “A back pain guide” from the National Institute of Neurological Disorders and Stroke.</td>
</tr>
<tr>
<td>Chiauzzi et al, 2010</td>
<td>To determine whether an interactive self-management website for people with chronic LBP would significantly improve emotional management, coping, self-efficacy to manage pain, pain levels and physical functioning compared with standard text-based materials</td>
<td>Oswestry disability Questionnaire (ODQ)</td>
<td></td>
<td></td>
<td>Control group did not receive reminder emails</td>
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<tr>
<td></td>
<td></td>
<td>Depression/Axiety and Stress scale (DASS)</td>
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<td>Global rating of improvement (PGIC)</td>
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<tr>
<td></td>
<td></td>
<td><em>Brief Pain Inventory (BPI)</em> <em>Oswestry disability Questionnaire (ODQ)</em> <em>Depression/Axiety and Stress scale (DASS)</em> <em>Global rating of improvement (PGIC)</em></td>
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<td>Bottom line</td>
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<td></td>
<td></td>
<td>Decisional Conflict Scale (DCS)</td>
<td>Baseline Post intervention 3 months</td>
<td>Preparation for decision making scale  Preference for participation, knowledge  Doctor facilitation  Information exchange  Decision regret  Treatment adherence</td>
<td>Intervention was effective in the short term in the people who used it.</td>
</tr>
<tr>
<td>Simon et al, 2012</td>
<td>To investigate whether insures with either depression or LBP experienced more favourable decision-related outcomes after using a web-based tailored decision aid than after using non-tailored, static patient information.</td>
<td><em>Decisional Conflict Scale (DCS)</em> <em>Preparation for decision making scale</em> <em>Preference for participation, knowledge</em> <em>Doctor facilitation</em> <em>Information exchange</em> <em>Decision regret</em> <em>Treatment adherence</em></td>
<td></td>
<td></td>
<td>Same information as intervention, website, but no tailoring to the individual user</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The Survey of Pain Attitudes (SOPA)</td>
<td>Baseline, 3 weeks 6 weeks</td>
<td><em>The Fear Avoidance Belief Questionnaire (FABQ)</em> <em>The Negative Mood Regulation Scale</em> <em>The Pain Catastrophizing Scale (PCS)</em> <em>The Roland-Morris Disability Questionnaire (RMDQ)</em> <em>A Pain Self-Efficacy Scale</em></td>
<td></td>
</tr>
<tr>
<td>Carpenter et al, 2012</td>
<td>To report on the efficacy of a pilot version of an online CBT intervention for individuals suffering from chronic LBP.</td>
<td><em>The Fear Avoidance Belief Questionnaire (FABQ)</em> <em>The Negative Mood Regulation Scale</em> <em>The Pain Catastrophizing Scale (PCS)</em> <em>The Roland-Morris Disability Questionnaire (RMDQ)</em> <em>A Pain Self-Efficacy Scale</em></td>
<td></td>
<td>Difference in favour of the intervention group on all subscales in the SOPA questionnaire with medical cure as the only exception.</td>
<td>Wait list, received no care for 3 weeks, then access to website.</td>
</tr>
<tr>
<td>Krein et al, 2013</td>
<td>To investigate whether a pedometer-based, internet-mediated intervention would reduce pain-related disability and functional interference among patients with chronic LBP at 6 months and 12 month.</td>
<td>Roland-Morris Disability Questionnaire (RMDQ) Short-Form-36 function scale</td>
<td>Baseline 6 months 12 months</td>
<td>Pain intensity (NRS, 11 point) Walking (steps pr. day) Fear Avoidance Belief Questionnaire (FABQ) physical activity subscale Self-efficacy (Exercise Regularly Scale) 6-min walking test* Centre for Epidemiologic Studies Depression Scale (CES-D 100)*</td>
<td>No between-group difference reported as any time-points Reduction in pain-related disability among patients with chronic back pain, although the benefits did not persist for the entire 12 month study period.</td>
</tr>
<tr>
<td>Irvine et al, 2015</td>
<td>To test FitBack in a randomized design with a population of adults at increased risk for chronic LBP due to a recent episode of NLBP.</td>
<td>No primary outcome stated Oswestry Disability Questionnaire stated as primary outcome in registration at <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a></td>
<td>Baseline 8 weeks 16 weeks</td>
<td>Pain: (y/n), level, frequency, intensity and duration Multidimensional pain inventory interference scale (MPI) Dartmouth CO-OP Prevention-helping behaviours (self-developed) Work limitations questionnaire (WLQ) Stanford Presenteeism Scale Patient Activation Measures (PAM) Knowledge (self-developed) Behavioural intentions (self-developed) Self-efficacy (self-developed) Survey of Pain attitudes</td>
<td>No data available for primary outcome analysis.</td>
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<tr>
<td>Study</td>
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</tbody>
</table>
| **Weymann et al, 2015**  
**Dirmaier et al**, 2013 |
| Investigate effectiveness of a web-based, tailored, fully automated intervention for patients with type 2 diabetes or chronic LBP against a standard website with identical content without tailoring. |
| Knowledge (post-intervention)  
Patient empowerment assessed by Health Education Impact Questionnaire (heiQ) (3 months) |
| Baseline Post-intervention 3 months |
| Decisional Conflict Scale (DCS)  
Preparation for Decision Making Scale (PDMS) |
| The tailored intervention failed to have effects in the total study population and on more distal outcomes. |
| Same website material as intervention but not tailored, not presented in a dialogue format. and no guidance through the content |

<table>
<thead>
<tr>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Geraghty et al, 2015</strong></td>
</tr>
<tr>
<td>To explore the feasibility of providing an internet intervention for patients with LBP in primary care, with and without physiotherapist telephone support (in addition to usual care), compared with usual care alone.</td>
</tr>
</tbody>
</table>
| Feasibility outcomes  
Number need to screen  
Recruitment rates  
Login- and usage information |
| Baseline 3 months |
| Pain: days, duration, intensity  
Roland-Morris Disability Questionnaire.  
Risk of persistent disability (StartBack Screen Tool)  
Tampa Kinesiophobia Scale  
Pain Catastrophizing Scale  
Physical activity (IPAQ).  
Enablement coping (PEI).  
Euro-QoL EQ-5D.  
LBP-related health care use  
Time off work  
Credibility and Expectancy Questionnaire (CEQ)  
Self-Efficacy for Exercise Scale (SESE)  
Reasons for non-adherence (PETS)  
Treatment adherence |
| Usual care from their general practitioner.  
This may consist of education and self-management advice, including advice to stay active. |

<table>
<thead>
<tr>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Valenzuela-Pascual et al, 2015</strong></td>
</tr>
<tr>
<td>To evaluate the effect of a biopsychosocial web-based, educational intervention for chronic</td>
</tr>
<tr>
<td>Pain intensity, 100 mm VAS scale</td>
</tr>
<tr>
<td>Baseline 2 weeks</td>
</tr>
</tbody>
</table>
| Fear Avoidance Belief Questionnaire (FABQ)  
Tampa Kinesiophobia Scale (TSK) |
| Control group is given no intervention, but asked to return to |
| Amorim et al’, 2016 | To investigate the effect of a patient-centred physical activity intervention supported by health coaching and mHealth technology in people with chronic LBP. | Care-seeking associated with LBP | Pain levels (NRS) Roland-Morris Disability Questionnaire (RMDQ) Baseline weekly during intervention 6 months 12 months | Pain Catastrophizing Scale (PCS) Roland-Morris Disability Questionnaire (RMDQ) Health Survey SF:36 QoL | - | Educational material same as intervention ‘Make your move – Sit less, be active for life!’ and advice to work towards increasing physical activity levels and achieving long-term goals. |

LBP: Low back pain, n: number of included patients, I: Intervention group, C: Control group, QoL: Quality of Life, †protocol paper, no data available, *indicates difference between the protocol paper and RCT report.
3.8 Risk of bias/quality assessment

Quality assessment was undertaken using the Cochrane risk of bias assessment tool. As it can only be applied to judge the quality of completed studies, quality appraisal was undertaken of the six completed RCT reports only (Table 4) [21]. Overall, the risk of bias of the included studies was low. One study had one or more items with unclear risk of bias and four studies had one item with high risk of bias. The risk of bias from inadequate randomisation was reported to be low in five of six studies and unclear in one study. Allocation concealment was rated low for three studies [29, 30, 32] and unclear for the remaining three studies. Blinding of the participants was unclear for four of six studies [23, 24, 27, 30], whereas assessor blinding was assessed as low risk of bias in all studies. Only one study was assessed to have a high risk of incomplete data [30] because the attrition rate was extremely high, whereas several studies were assessed to have unclear risk or low risk of bias for selective outcome reporting. One of the studies rated high risk of bias for selective outcome reporting had no published protocol and reported the outcome with highest effect size as primary [23], whereas the other did not report on the primary outcome stated in the published protocol [27]. One study was assessed to have high risk of bias for other biases due to differences in educational level between the groups [32], while three studies had unclear risk [23, 24, 27] and two studies had low risk [29, 30].

Table 4: Risk of Bias assessment

<table>
<thead>
<tr>
<th>Study</th>
<th>Random sequence generation</th>
<th>Allocation concealment</th>
<th>Blinding Patients/personnel</th>
<th>Blinding Assessor</th>
<th>Incomplete data</th>
<th>Selective reporting</th>
<th>Other biases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chiauzzi et al, 2010</td>
<td>Low</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
</tr>
<tr>
<td>Simon et al, 2012</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
<td>Low</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Carpenter et al, 2012</td>
<td>Low</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>Unclear</td>
</tr>
<tr>
<td>Krein et al, 2013</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Irvine et al, 2015</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>Unclear</td>
</tr>
<tr>
<td>Weymann et al, 2015</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
</tr>
</tbody>
</table>

Risk of bias assessment with Cochrane Risk of Bias Tool. Low: indicates low risk of bias, Unclear: indicates unclear risk of bias, High: indicates high risk of bias.

4 Discussion

We have systematically searched and reviewed the literature pertaining to interactive, digital interventions for self-management of LBP. We identified six completed RCTs of moderate methodological quality and RCT protocols for three ongoing studies. The completed trials were conducted in either the United States or Germany. Further, participants were predominantly female, Caucasian, younger and well educated, which renders the external validity of studies low.

Overall, the interventions predominantly consisted of internet-based interventions for computer or handheld devices compared to either usual care or non-digital intervention. The results of this systematic review demonstrates a large degree of heterogeneity regarding the description of the intervention content and delivery, theoretical underpinnings and outcomes reported making comparison between interventions difficult. Although it has been shown that a comprehensive description of
intervention development and use of theory increases effectiveness of interventions [37], these descriptions were either brief or not discussed at all in the included studies. For example, physical activity was identified as a key component in only one study [29], however five studies described information or advice on physical activity as a component of the intervention. Similarly, large variation was seen in the duration of interventions, which ranged from 2 weeks to a 12 months’ period.

Despite international recommendation for reporting core outcome domains (physical functioning, pain intensity and health-related quality of life) in LBP studies [36], we found little consistency in terms of outcome measures chosen. We identified 16 different primary outcome measures covering the domains of pain intensity, attitudes towards pain, pain-related disability, depression, physical activity, knowledge of LBP, markers of self-care and transition scales, and a total of 52 outcome measures were reported. Generally, the included studies were not able to demonstrate significant beneficial effects on either the primary or secondary outcomes. However, interestingly better consistency in choice of outcome measures was seen in the three RCT protocols identified. We expect that these trials will provide more useful information and data for future meta-analyses.

4.1 Strengths and Limitations

Our review has a number of strengths and limitations. The search was undertaken by a team with extensive experience in conducting systematic reviews. We used multiple databases, and a thorough search strategy that was designed iteratively by the research team and an information specialist to account for the three different dimensions of the search (back pain, digital interventions, and self-management). The methodological assessment tool used in our systematic review has been specifically developed to assess the risk of bias in randomised controlled trials [21], and its construct is in line with the recommendations of the PRISMA Statement [18]. All aspects of data extraction, quality appraisal and data analysis were carried out independently by two researchers, with a third party available for adjudication in case of disagreements.

The primary limitation of this systematic review is the sparse literature related to our objectives. Due to the sparsity and heterogeneity of the data, a formal meta-analysis was not possible. Additionally, our search was limited to studies published in English, Danish or Norwegian, which could be construed as a limitation, although there is increasing evidence that this is not a particular problem [38]. Finally, to limit the number of potential references, grey literature was not included.

4.2 Comparison with previous literature

To the best of our knowledge this is the first systematic review of RCTs of digital interventions for self-management of LBP. However, systematic reviews of non-digital self-management for LBP [13] and chronic musculoskeletal pain [39] have been published. These reviews have suggested that there is only moderate-quality evidence that self-management has small effects on pain and disability in people with LBP. These reviews have not dismissed self-management as a treatment option for LBP, but rather suggested that further research is needed to understand the limitations of self-management and whether or how effectiveness can be increased. In addition, these reviews have suggested that future studies should extend the outcomes of interest to include aspects of self-efficacy, and also consider the impact of the duration of the intervention [13, 39]. Like the current review these studies have suggested that self-management is safe but heterogeneity in the published literature has made evaluation difficult. Similar conclusions have been made in systematic reviews of digital self-
management interventions in conditions like asthma [20] hypertension [19] and problematic cannabis use [40].

4.3 Future directions of reporting eHealth interventions

The use of the internet as a platform for delivering health-related interventions has increased within the last decade, as computer and handheld devices, such as tablets and smartphones, are becoming more prevalent especially in the developed and developing countries [41]. A favourable feature of internet-mediated and mobile interventions is that the web-based delivery of the intervention makes it relatively easy to enrol, track and follow-up a large number of patients in both observational and intervention studies, such as RCTs [42, 43]. A drawback is the limited control on the actual compliance of the patients, for example, those interventions focusing on physical activity may find quantification of physical activity challenging.

Alongside the growing use of internet-mediated interventions, guidelines for standardised reporting of such interventions have developed. In 2011, an extension to the Consolidated Standards of Reporting Trials (CONSORT) statement was developed for reporting web-based and mobile health interventions, the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and online TeleHealth) [43], an update of the guideline was published in 2013 and is currently being tested [37]. Additionally, in 2016 Agarwal et al. [41] published a guideline for reporting health interventions using mobile phones, including an evidence reporting and assessment checklist (mERA). In common, across these guidelines is an increasing focus on reporting the technical aspects of the digital intervention as well as reporting the content of the intervention and its theoretical underpinnings [41, 43].

This review could have applied the CONSORT-EHEALTH extension as an appraisal tool for the included studies, though given its recent publication this was not done. In relation to the six RCT reports identified in the present systematic review, it is important to recognize that one study [24] was published before either of these guidelines were developed. The remaining five RCT reports and three RCT protocols all came after the CONSORT-EHEALTH extension. However, none of these studies adhere nor refer to the extension of the guideline. The CONSORT-EHEALTH extension adds sub-items to item 5: intervention, of the existing CONSORT checklist [44]. Four sub-items are labelled ‘essential’ for the reporting, these include: 1) describing access to the intervention; 2) describing mode of delivery, features/functionality/components and comparator, and the theoretical framework; 3) reporting any prompts or reminders used; and 4) describing any co-intervention including training or support [43]. While the RCT reports identified in the present systematic review describe these four sub-items to a varying degree, more information is needed in relation to the sub-items rated ‘highly recommended’ in the CONSORT-EHEALTH extension that concern the technical reproducibility of the internet-mediated interventions. For example, while two RCT reports [27, 32] and two RCT protocols [28, 33] included screen-shots from the intervention websites, only one study provided an URL to the intervention website, and in this instance the page could not be found [33]. In general, the reporting level concerning the technical specifications (i.e., source codes or flowcharts of algorithms used), as well as the digital preservation of the interventions was inadequate across all identified studies. For future RCTs on digital health interventions, such as the selfBACK trial, a more consistent adherence to these reporting guidelines will provide a greater level of detail in reporting the intervention and consequently increase the standardisation and reproducibility of the trial.
In summary, this systematic review provides the following key-messages for the SELFBACK trial

- Up until know the evidence for digital self-management interventions for LBP has been reported on a selected population.
- The choice of primary outcome varies greatly in the studies identified in the systematic review. However, from the identified trial protocols it seems there is consistency in reporting pain-related disability as either a primary or secondary outcome. This is consistent with previous recommendations on preferred outcomes in LBP as suggested by Deyo et al [35] and Chiarotto et al. [36].
- Compliance to key elements in the intervention content should be quantified to allow for a dose response evaluation and thereby evaluate the program theory.
- A thorough description on the intervention's content and theoretical underpinning should be prioritised.
- The description of the intervention should be consistent with reporting guidelines for mHealth or eHealth.

5 Conclusion

We identified six completed RCT reports and three papers describing future RCTs using interactive digital self-management interventions to manage LBP. There was great variation in the detail provided concerning the characteristics, components and theories underpinning the digital interventions. Surprisingly, physical activity, which is considered one of the mainstays of the treatment of LBP, was only included as a key component in one study. Consequently, no evidence was presented to support effect on physical activity behavioural changes from digital self-management for LBP. The populations within the identified studies were predominantly female, white, well-educated and middle-aged and so the wider applicability of digital self-management interventions remains uncertain.

We identified large variation in the choice of primary and secondary outcomes to describe the intervention effects. In only one of the six completed RCT studies did the authors report a between-group difference in favour of the digital intervention over a passive waiting list, whereas there was no evidence to support differences in effects in the other five studies. There is no information available about the effects of such digital interventions on health care utilisation or their cost effectiveness, and no reports of obvious negative effects of such interventions. Consequently, while digital self-management interventions for LBP show promise, at present, there is little evidence of beneficial effects on outcomes.
References


Part B: CBR and Decision Support Systems

1 Introduction

Decision support systems have a long history in the medical field, but they often target the clinician rather than the patient. Often such systems are used for knowledge sharing and experience management, or in the interpretation of multidimensional data. In the course of the SELFBACK project, we are aiming at developing a predictive decision support system that provides recommendations for the patient. Therefore, this literature search is focusing on related work covering patient-centered decision support systems.

The underlying methodology for building the SELFBACK decision support system is Case-Based Reasoning (CBR). CBR uses old experiences to understand and solve new problems. Therefore, a new problem is compared to a case base containing previous experiences in order to find the most similar case. A case traditionally consists of a problem and a solution description. While the problem description is used to find the most similar case, the solution is presented to the user to give advice on how to solve the problem. Sometimes also the outcome after the solution has been applied is included in the case description. The main reference architecture for CBR system was introduced by Aamodt & Plaza [1]. This architecture describes a CBR system in four consecutive processes: retrieve, reuse, revise and retain.

In the retrieve process the new case’s problem description is compared to a case base in order to find the most similar case (or a set of most similar cases). Next, in the reuse step, derivations between the new case and the existing case are aligned in order to fit the retrieved case to the current problem. Subsequently, the adapted case is revised to quality check the solution and if necessary update it to make it coherent and suitable for the current problem. Once the new case has been applied, a CBR system retains it in its case base and the next time this or a similar situation occurs, the learned case will be available.

The focus within SELFBACK is the overall development of different factors (pain, function, activity, etc.), and the aim is to compare patients based on summaries and abstractions from collected raw data. Cases contain temporal information at the feature level only, the temporal data is piecewise interpretations of time-series which are compared using edit distance. The temporal features are piecewise interpretations of the patient activity stream over a day. The overall development of the patient over larger time spans will be solved through temporally connected cases at the case history level.

Within this literature review we are focusing on the following criteria for applications to be included: All systems should be CBR systems and match at least one of the following sub-categories:

- **Personalized Support** is provided by systems that target at a user who is not an expert in the field. In a medical domain it is the patient rather than a clinician or in a service support domain it is the user who gets help to master a complex problem.
- **Time Series** aspects are taken into account for comparing cases and making suggestions. This might be time sequences and series as well as abstractions from them.
- **Health Domain** is the core application area of the system.

We do not aim at an exhaustive review of applications and research approaches. Instead, we are focusing on systems that have some relevance for the SELFBACK approach.
Table 1: Overview of CBR systems related to selfBACK

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Ref.</th>
<th>CBR</th>
<th>Health Domain</th>
<th>Time Series</th>
<th>Personalized Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bichindaritz et al. 1998</td>
<td>[2]</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Juarez et al. 2011</td>
<td>[3]</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Montani &amp; Portinale 2005</td>
<td>[4]</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Nilsson &amp; Funk 2004</td>
<td>[5]</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Schlaefer et al. 2001</td>
<td>[6]</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Schmidt &amp; Gierl 2002</td>
<td>[7]</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Schmidt &amp; Gierl 2005</td>
<td>[8]</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Bach et al. 2010</td>
<td>[9]</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
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<tr>
<td>Marling et al. 2011</td>
<td>[10]</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Bareiss et al. 1990</td>
<td>[11]</td>
<td>x</td>
<td>x</td>
<td></td>
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<tr>
<td>Bichindaritz 1996</td>
<td>[12]</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Bell et al. 1994</td>
<td>[13]</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Kolodner &amp; Kolodner 1987</td>
<td>[14]</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
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<tr>
<td>Koton 1988</td>
<td>[15]</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
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<tr>
<td>Bergman et al. 2015</td>
<td>[16]</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
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<tr>
<td>Chang et al. 2009</td>
<td>[17]</td>
<td>x</td>
<td>x</td>
<td></td>
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<tr>
<td>Gundersen et al. 2013</td>
<td>[18]</td>
<td>x</td>
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<td>Hansen 2007</td>
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<tr>
<td>Jære et al. 2002</td>
<td>[20]</td>
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<td>Leake &amp; Kendall-Morwick 2008</td>
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<td>Olsson et al. 2004</td>
<td>[22]</td>
<td>x</td>
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<tr>
<td>Ram &amp; Santamaria 1997</td>
<td>[23]</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Bridge &amp; Healy 2012</td>
<td>[24]</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Craw et al. 2015</td>
<td>[25]</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
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<tr>
<td>Cordier 2009</td>
<td>[26]</td>
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<td>x</td>
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<tr>
<td>Hanft et al. 2010</td>
<td>[27]</td>
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<td>Müller &amp; Bergmann 2015</td>
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<tr>
<td>Ontañón et al. 2012</td>
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<td>Quijano-Sánchez 2014</td>
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<td>Smyth et al. 2009</td>
<td>[31]</td>
<td>x</td>
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</tbody>
</table>

Table 1 gives an overview of applications and approaches we will look into within this review paper. While the selfBACK system will cover all of the four categories, the review of applications published by the CBR community did not include such a system. However, the challenges we are addressing when developing the selfBACK system can be related to these systems to some degree.

In the following we are looking into these systems by first focusing on health care approaches that (a) focus on patients and (b) include abstractions and reasoning about time series. In the second part we look into applications that target time series and user interaction outside the healthcare domain.

2 Health Care Domain

The first description of a CBR decision support system in health care was introduced by Janet and Robert Kolodner [14]. The system, SHRINK, was never fully implemented. The idea was that the system was supposed to aid with psychiatric diagnosis and treatment. Many of the ideas described in by Janet and Robert Kolodner were, however, implemented in the decision support system MNAMOMIA [12]. Two of the most well-
known early CBR systems, PROTOS [11] and CASEY [15], were designed for diagnosis of diseases. PROTOS diagnosed hearing disorders into 15 distinct categories (diagnoses). Casey diagnosed cardiac patients. The suggested diagnosis was the cause of the patient’s heart failure. One interesting variant of a CBR system in the health care domain, the Sickle Cell Counselor [13], is an educational system. It teaches museum visitors about the sickle cell disease by covering the disease itself as well as the genetic inheritance of the sickle cell trait. The Sickle Cell Counselor puts the visitor in the role of an expert that is supposed to give virtual couples advice about the sickle cell disease. The system then presents the result of the counselling for the museum visitor by presenting the results of your advice for the virtual couple after a virtual year. Compared to control subjects that were only given written instructional material, the visitors using the Sickle Cell Counselor, learned more about the disease and its genetic inheritance.

Since then, many CBR systems in health care have emerged. An extensive review and comparison of these is described by Bichindaritz & Marling [32] as well as an overview of current developments is given by Bichindaritz & Montani [33].

2.1 Patient Interaction

While CBR has been used very often in developing decision support systems for experts, there are only a few systems targeting the layman. Moreover, supporting patients by providing tailored information for increasing their health is a research field, which is rarely touched. To our knowledge, only the two CBR systems, presented in this section, are providing healthcare advice to the patient in the same manner as SELFBACK will do.

The docQuery system [9] supports travellers by giving scientifically proven, up-to-date, pharmaceutical company independent information for free. The provided information covers vaccination, clarification of threats, medicament information, hospital location information, regional epidemics, general guidelines and governmental travel advice. Each of these topics is collected in separate case bases and once a traveller’s query is received, the information collected from each topic case base are assembled into one information leaflet. Thereby the system provides tailored advice for a traveller.

4DSS [10] is a system supporting insulin-dependent diabetes mellitus patient management. A previous version (T-IDDM [34]), when tested against a panel of clinicians specialized in diabetes, the system managed to correctly identify the problem 77.5% of the time (remaining distribution was 15% mixed feelings and 7.5% disagree). During use, the patient added daily glucose levels and life event data to the system through a Web browser. The system then searched for 12 possible problems in blood glucose control. Next, the problems were detected and the advice was displayed for a clinician. The current version (4DSS) displays advice directly to the patient. The case structure consists of three parts: the problem, the solution and the outcome that is the resulting patient state after following the solution of the case. The system matched physician ratings 85% of the time during testing and evaluation.

2.2 Time Series Data

When reasoning with time in CBR, the temporal information can be dealt with at the feature level, the case level or a combination of these two. This idea was introduced by Montani and Portinale [4]. At the case level, history is described using temporally connected cases while at the feature level, the features of the cases contain temporal information. A combination of these two are temporally connected cases that contains temporal features. Temporal features could be of different types:

1. Raw time series (Ram [23]),
2. Sequences of events (Juarez et al. [3], Gundersen et al. [18]),
3. Graphs (Jære et al. [20]) and
4. Piecewise interpretations of raw time-series (Montani et al. [35]).

The type of feature that represents temporal information directly influences which type of similarity metric that can be used to compare local similarity of the temporal features. In order to compare raw time series, the types of similarity metrics that are used include Euclidian Distance metrics, Fourier coefficient metrics, auto-regressive models, dynamic time warping, edit distance, time-warped edit distance and minimum jump cost dissimilarity metrics. Serra and Arcos [36] gives a review and empirical evaluation of these. Variants of these similarity metrics are used for both sequences and piecewise interpretations. Montani [37] applies the Discrete Fourier Transform when comparing the similarity of time-series. In the work of Montani and Leonardi [35], time series are converted to temporal abstractions that describe the state or trend of a time-series. These temporal abstractions are organized in a tree based on the granularity of the abstractions and similarity computations are conducted based on the distance in the tree structure. Fritsche et al. [38] compares the similarity of time-series using dynamic time-warping, and Gundersen et al. [18] uses edit distance on sequences of events. For a discussion on measuring the similarity of sequences of complex events, see Gundersen [39].

The selfBACK system uses both static and temporal data for its case representation and during case retrieval. Contrary to the selfBACK system, many CBR systems in the health care domain that operate on temporal data, only use temporal data in their case representation and their case retrieval. Also, compared to selfBACK, which uses a multitude of different types of attributes, many of the existing systems only use variations of one single attribute in their case descriptions. For example, the systems by Schmidt et al. [7] and Schlaefer et al. [6] only use variations of creatinine values for case comparisons.

Schmidt et al. [7] implement a system that supports a clinician in predicting kidney failure with CBR and temporal abstractions by monitoring a patient's kidney function. The case contains seven attributes derived from blood creatinine values: the kidney states from the current and last three weeks, a 3 week-, a 2 week- and a 1 week kidney function trend.

Schlaefer et al. [6] describe a case-based classification system to warn about rejection of transplanted kidneys. The classification is done on cases consisting of time series of patient creatinine levels. When compared, the sum of distances between the measured creatinine values describe the distance between cases. This advice is also targeted towards the clinician.

Another example of a system made for supporting a clinician is presented by Nilsson et al. [5]. The system is made for classifying respiratory sinus arrhythmia patterns. It combines a CBR system with a rule-based reasoning system. The rule-based reasoning system reduces the amount of cases that need to be retrieved from the case base. The case-based reasoning part of the system, then suggests the most similar case, to the observed electrocardiograph pattern, to the clinician.

T-CARE [3] is a decision support system for medical domains operating on temporal cases. Its practical implementation is presented in an intensive care burn unit. During retrieval, the search space is reduced by applying discriminative filters. The T-CARE cases are first classified depending on their completeness, author and the goal of the case into different categories (Complete, Solved, Contextualized, etc.). First then, is the similarity computed, and all attributes (both temporal and non-temporal) are used for the computation.
In the system described by Portinale et al. [40], search space reduction is performed by using the discrete Fourier transform on time series data and storing the first three coefficients as features for the time series. Each case is a haemodialysis session and the purpose of the system is to warn when a patient’s blood pressure gets dangerously low. During retrieval, the precomputed features are matched first and a most similar subset of the cases are retrieved. This set of cases is then used for a more expensive similarity assessment where time-series features are used as attributes. The approach of Portinale et al. also supports abstraction operations on the time series itself. The temporal data can be represented on different levels in a tree structure. For instance, one can change a time series represented by 30 minute intervals into a time series of 1 hour intervals.

3 Time Series and User Interaction outside Healthcare

3.1 Time Series

Decision support systems that perform case-based reasoning on temporal data have been developed for a diverse set of domains that include weather prediction [19], buy and sell points prediction for stocks [17], oil well drilling [18] and fault diagnosis of industrial robots [22] among many others.

Hansen et al. [19] describe a case-based reasoning system for weather prediction using domain specific fuzzy similarity metrics. The goal of the system is to predict the cloud ceiling and a complete case contains relevant parameters measured hourly over a period of seven hours and the cloud ceiling. The input case contains four hours of measurements and lacking relevant future measurements from the following three hours are predicted either by an expert or a weather model. These hypothetical values are then included in the case matching to predict the future cloud ceiling.

Chang et al. [17] present a system that predicts the buy and sell points of stocks on the basis of time series data from the Taiwan Economic Journal. The system, CBDWNN, is a hybrid and uses both CBR and an artificial neural network. The artificial neural network is used to identify the buy and sell points. In order to not waste money on transaction fees due to high level of fluctuations in buy/sell decisions, a case-based reasoning system is used to predict the stock’s fluctuations. CBDWNN uses the minimum Euclidean distance on the fluctuation parameters to retrieve similar cases.

DrillEdge [18] is a real-time decision support system that continuously monitors the oil well drilling process in order to identify symptoms of problems as well as derivations from best practices. DrillEdge supports the drilling engineer in monitoring and understanding the situation on the oil well drilling rigs and aims at supporting the rig crews when problematic stations occur. Cases capture previous critical situations and DrillEdge’s CBR engine matches these to the current situation based on abstractions of time series data [39]. Once they match significantly, the drilling engineer is alerted in order to take pre-cautious actions.

Olsson et al. [22] present a case-based reasoning system that preforms fault diagnosis on industrial robots using acoustic sound signals. The sound signals are divided into windows of discrete time steps and converted to a vector. The discrete wavelet transform is then used for feature identification. The features are then used in a Euclidean distance similarity metric for case retrieval.

A workflow is a repeatable sequence of steps performed in a sequential manner over time. While time series are describing a high frequencies of input data are workflows used to represent sequences of more complex actions over time. Thus, workflows are a type of a temporal abstraction. In CBR, a two-phase retrieval approach is often applied in workflow based systems. It allows reducing the complexity of workflow data structure.
representation by applying filters. The resulting simplified data structure is then used for retrieval of similar cases in the first phase. In the second phase, a small amount of retrieved cases is compared by using more computationally expensive similarity metrics and without simplification of the data structure.

Leake et al. [21] filters workflows by considering workflow provenance (in workflows, provenance is captured as a set of dependencies between data objects). The system, Phala, suggests extensions to unfinished workflows. The goal of providing these suggestions is to inform users about data and services they might not have considered and make workflow components quickly accessible for reuse. After filtering out the non-relevant cases by use of provenance, Phala uses a more computationally expensive graph-based retrieval on the reminding cases to find the most similar ones.

Bergmann et al. [16] represents workflows as graphs and computes structural key features from the resulting graphs. The pre-computed structural features are then used during similarity assessment in the first retrieval phase. Then, a computationally more expensive graph-based retrieval is used. The system is tested in the cooking domain and scales up to case bases with 15000 cases.

In the SELFBACK system, a two-phase retrieval approach will also be used. The key difference between the workflow systems discussed above and the SELFBACK system, is that the SELFBACK cases are not abstracted into simpler data structures during the first retrieval phase. Instead only a subset of the attributes is compared. During the second retrieval phase the rest of the attributes, which require more expensive calculations, are compared.

3.2 User Interaction

Case-based recommendation and decision support systems that support laymen instead of experts [41] are applied in various disciplines such as music [25] or movie [30] recommendation, creation and personalization of cooking recipes (as done by the Taable [26], CookingCake [28] and CookII [27] systems), writing product recommendations [24], and audio-visual content generation [29].

The music recommendation engine by Craw et al. applies similarity-based matching of songs by combining user tags and the audio texture (timbre). By included crowd-sourced and song-specific, objective features in the similarity assessment; the recommender system does not only suggest the most popular, but also structural similar novel or unknown songs.

A different approach for creating recommendation has been presented by Quijano-Sánchez for group-based movie recommendations [30]. The presented system learns features about the users and projects these to movie preferences. Therewith a more personalized and user group-based recommender system has been created.

The creation and personalization of Cooking Recipes has been a continuous topics over the last years within the CBR community, but also beyond. Taable [26], CookingCake [28] and CookII [27] are some of the CBR systems that continuously participated in the competition and created recipes, menus and recipe variations using CBR underneath and targeting the hobby chef as well as day-to-day cooking rather than professionals.

Bridge et al. [24] introduced an interactive writing guide for product recommendations. The GhostWriter application guides the user through a given structure and makes topic suggestions in order to achieve complete product descriptions. It applies

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1 www.computercookingcontest.net
2 https://www.ibmchefwatson.com/community
conversational CBR and feature extraction from textual cases in order to retrieve most similar suggestions and map them to the user context.

The GENA system aims at creating audio-visual summaries from TV coverage of sports event as well as generating customized summaries of such videos [29]. A case in GENA is a finalized summary containing several parts of a summary (e.g. who are the playing teams in a football match, who scored, and which team won) and when a case is retrieved each part is replaced by the current content keeping the given structure.

The presented systems are only a subset of existing case-based decision support systems to illustrate the broad variety of applications CBR has been successfully applied.

3.3 Time Series and User Interaction

In our research of related work there was no concept or application that was based on CBR with underlying time series data, which is used by non-expert users. Especially the decision support and knowledge management applications were focusing on experts in the field.

4 Conclusion

The literature review provides an overview of previous research and application development in the field Case-Based decision support systems. It draws a particular focus on health science applications, temporal abstractions and patient or user-oriented implementations.

Overall, this review shows that CBR has been used to build applications in the health sciences as well as research on temporal abstractions in CBR systems is an ongoing working area. However, we have also seen that health science applications targeting the patient are less common and none of the existing ones take the personal patient history into account. The approach for developing the SELFBACK system is going to combine temporal data and the core user of the decision support system is the patient, who is receiving tailored information to self-manage her/his disease. Previous work on temporal data will help to guide the development and design decisions, while related work in the health sciences shows how health science applications can be implemented.
References


Appendix 1

PROSPERO International prospective register of systematic reviews

Review title and timescale

1 Review title
Give the working title of the review. This must be in English. Ideally it should state succinctly the interventions or exposures being reviewed and the associated health or social problem being addressed in the review.
A Systematic Review of Digital Support Interventions for the Self-Management of Low Back Pain

2 Original language title
For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3 Anticipated or actual start date
Give the date when the systematic review commenced, or is expected to commence.
18/04/2016

4 Anticipated completion date
Give the date by which the review is expected to be completed.
30/06/2018

5 Stage of review at time of this submission
Indicate the stage of progress of the review by ticking the relevant boxes. Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. This field should be updated when any amendments are made to a published record.
The review has not yet started ✗

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<td>Formal screening of search results against eligibility criteria</td>
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<td>Data analysis</td>
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</table>

Provide any other relevant information about the stage of the review here.

Review team details

6 Named contact
The named contact acts as the guarantor for the accuracy of the information presented in the register record.
Barbara Nicholl

7 Named contact email
Enter the electronic mail address of the named contact.
barbara.nicholl@glasgow.ac.uk

8 Named contact address
Enter the full postal address for the named contact.
General Practice & Primary Care, Institute of Health & Wellbeing, University of Glasgow, 1 Horsehill Road, Glasgow, G12 9LX, UK

9 Named contact phone number
Enter the telephone number for the named contact, including international dialing code.
+44141 3308327

10 Organisational affiliation of the review
Full title of the organisational affiliations for this review, and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.
University of York
Centre for Reviews and Dissemination

Website address:
http://www.gla.ac.uk/researchinstitutes/healthwellbeing/

11 Review team members and their organisational affiliations
Give the title, first name and last name of all members of the team working directly on the review. Give the organisational affiliations of each member of the review team.

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<td>Jan</td>
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<tr>
<td>Dr</td>
<td>Per</td>
<td>Kjaer</td>
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</tr>
<tr>
<td>Professor</td>
<td>Frances</td>
<td>Mar</td>
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<tr>
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<td>Marianne</td>
<td>McCallum</td>
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<td>Professor</td>
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<td>Monk</td>
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</tr>
<tr>
<td>Dr</td>
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<td>Nicholl</td>
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<tr>
<td>Ms</td>
<td>Louise</td>
<td>Sandal</td>
<td>The University of Southern Denmark</td>
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<tr>
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<td>Karen</td>
<td>Sagaard</td>
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<td>Mette</td>
<td>Stokke</td>
<td>The University of Southern Denmark</td>
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<td>Suresh</td>
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</tr>
<tr>
<td>Professor</td>
<td>Ottar</td>
<td>Vasseljen</td>
<td>The Norwegian University of Science &amp; Technology</td>
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12 Funding sources/sponsors
Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Any unique identification numbers assigned to the review by the individual or bodies listed should be included.

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 689040. Project title: A decision support system for self-management of low back pain. Project acronym: SELFBACK.

13 Conflicts of interest
List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.
Are there any actual or potential conflicts of interest?
None known

14 Collaborators
Give the name, affiliation and role of any individuals or organisations who are working on the review but who are not listed as review team members.

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<td>Ms</td>
<td>Ingrid</td>
<td>Ingelberg</td>
<td>The Norwegian University of Science &amp; Technology</td>
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Review methods

15 Review question(s)
State the question(s) to be addressed / review objectives. Please complete a separate box for each question.
The purpose of this systematic review is to synthesise the published evidence concerning the characteristics, components, and effects of digital interventions to support patient self-management of low back pain. The review will address the following questions:

1. What outcome measures have been used in trials of digital self-management interventions in low back pain and what effects, if any, have been reported?

2. What are the key characteristics and components of reported digital self-management interventions for low back pain, including theoretical underpinnings?
3. What are the key characteristics and components of digital self-management interventions for low back pain that appear to be associated with beneficial effects?

16 Searches
Give details of the sources to be searched, and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.

A systematic search of bibliographic databases including MEDLINE, Embase, CINAHL, PsycINFO, Cochrane Library (including CDSSR, DARE, CENTRAL, and HTA databases), DoPHER and TROPHI (both produced by the EPPI Centre), and Web of Science (Social Science Citation Index and Science Citation Index) will be undertaken. Reference and citation searching will also be undertaken for included articles. All databases will be searched from 2000 until March 2016. The search strategy will combine the following concepts and study-type filters: (1) low back pain, (2) digital intervention, and (3) self-management.

17 URL to search strategy
If you have one, give the link to your search strategy here. Alternatively you can e-mail this to PROSPERO and we will store and link to it.

I give permission for this file to be made publicly available
Yes

18 Condition or domain being studied
Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

Digital interventions aimed at supporting self-management of low back pain.

19 Participants/population
Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

Adults aged 18 years and older with low back pain.

20 Intervention(s), exposure(s)
Give full and clear descriptions of the nature of the interventions or the exposures to be reviewed.

The term "digital intervention" can relate to a number of different types of intervention. For the purpose of this review it will include any intervention accessed through a computer (work or home), mobile phone, or other handheld devices, and include a Web-based program, desktop computer program, or apps that provide self-management information. Intervention participants may input information or interact online or offline through the particular device used. The intervention must function without any directive input from health professionals, and be "interactive" in nature. We define "interactive" as requiring contributions from program users (e.g., entering personal data and making choices) that alter pathways within the program to produce feedback. Studies that only involved sending information about pain to a remotely located health professional and receiving advice directly from a health professional will be excluded from this review. Interventions that include face-to-face contact will only be included if this interaction is an add on to an automated, interactive component without direct health professional mediation (e.g., users report pain level interactively then receive automated messages advising them to increase/decrease activity levels). These features are termed characteristics of the digital self-management intervention. The components of the digital self-management intervention refer to the "ingredients" driving the intervention, e.g., behavior or cognition change theory, which will be related to the type of feedback or advice supplied, e.g. physical activity, cognitive coping strategies, or social support.

21 Comparator(s)/control
Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group).

Trials with a comparator group of usual care or non-digital self-management intervention or non-interactive digital self-management for low back pain will be included.

22 Types of study to be included initially
Give details of the study designs to be included in the review. If there are no restrictions on the types of study design eligible for inclusion, this should be stated.

Publications from randomized controlled trials, including trial protocols, that have been published in peer-reviewed journals will be considered.

23 Context
Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.
Studies in primary care, out patient, occupational or community settings will be eligible for inclusion, for example, studies originating in the community or primary or secondary care and other specialist contexts and also those that recruit via social media.

24 Primary outcome(s)
Give the most important outcomes.
The primary outcomes will be: a) Details of outcome measures used to determine the effects of interventions for self-management of low back pain b) Effects on pain related disability
Give information on timing and effect measures, as appropriate.

25 Secondary outcomes
List any additional outcomes that will be addressed. If there are no secondary outcomes enter None.
We are interested in all outcomes assessed in these trials in relation to self-management and low back pain. The most likely secondary outcomes identified will include: a) Effects on: - Pain intensity - Quality of life - Depression - Fear avoidance - Pain Catastrophizing - Physical activity - Medication use - Health care utilisation (e.g., primary and secondary care visits, emergency department visits) - Health care costs - Knowledge of LBP - Markers of self-care - Self efficacy b) A summary of the key characteristics and components reported as being present in the interventions including theoretical underpinnings.
Give information on timing and effect measures, as appropriate.

26 Data extraction, (selection and coding)
Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted.
Two members of the team will independently screen titles and/or abstracts identified in the literature search for studies that potentially meet the inclusion and exclusion criteria. The full text of these articles will be retrieved and reviewed independently by two reviewers; any disagreement will be discussed with a third reviewer and a decision on eligibility made against the predetermined inclusion criteria. A pre-piloted form will be used to extract the required data from the included articles, which will then be used to assess study quality and to synthesise data. Data extraction will be carried out by two reviewers independently and any disagreements discussed and decided upon with a third reviewer, if required. Data to be extracted will include: study setting, details of study population, baseline characteristics, details of the intervention (key components, characteristics, and theory underpinning intervention) and comparison, recruitment and participation rates, outcome measures, timing of outcome measures, information for assessment of risk bias. The DistillerSR software (Evidence Partners, Ottawa, Canada) will be used to manage the duplicate references, data screening and extraction process.

27 Risk of bias (quality) assessment
State whether and how risk of bias will be assessed, how the quality of individual studies will be assessed, and whether and how this will influence the planned synthesis.
Two reviewers will independently assess the risk of bias in each of the included studies using the Cochrane risk of bias tool. Disagreements between reviewers will be discussed with a third reviewer, if required.

28 Strategy for data synthesis
Give the planned general approach to be used, for example whether the data to be used will be aggregate or at the level of individual participants, and whether a quantitative or narrative (descriptive) synthesis is planned. Where appropriate a brief outline of analytic approach should be given.
A meta-analysis will be conducted if there is sufficient data and the studies are sufficiently homogeneous with regard to outcomes studied. A narrative review will be conducted to describe the key characteristics, components and underpinning theory, including aspects of behaviour change, of the digital self-management interventions studied.

29 Analysis of subgroups or subsets
Give any planned exploration of subgroups or sets within the review. ‘None planned’ is a valid response if no subgroup analyses are planned.
If appropriate data is available, separate analyses will be conducted for age/gender, duration of chronic pain (acute, sub-acute, chronic).

Review general information
30 Type of review
Select the type of review from the drop down list.
Intervention

31 Language
Select the language(s) in which the review is being written and will be made available, from the drop down list. Use the control key to select more than one language.
English, Danish, Norwegian

Will a summary/abstract be made available in English?
Yes

32 Country
Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved. Use the control key to select more than one country.
Scotland, Denmark, Norway

33 Other registration details
Give the name of any organisation where the systematic review title or protocol is registered together with any unique identification number assigned. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here.

34 Reference and/or URL for published protocol
Give the citation for the published protocol, if there is one.
Give the link to the published protocol, if there is one. This may be to an external site or to a protocol deposited with CRD in pdf format.

I give permission for this file to be made publicly available
Yes

35 Dissemination plans
Give brief details of plans for communicating essential messages from the review to the appropriate audiences.
This review will form part of a report to funders; in addition, it will be published in a leading open-access, international peer-reviewed journal with a focus on musculoskeletal pain.

Do you intend to publish the review on completion?
Yes

36 Keywords
Give words or phrases that best describe the review. (One word per box, create a new box for each term)
low back pain

digital health

self-management

e-health

mhealth

37 Details of any existing review of the same topic by the same authors
Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

38 Current review status
Review status should be updated when the review is completed and when it is published.
Ongoing
39 Any additional information
   Provide any further information the review team consider relevant to the registration of the review.

40 Details of final report/publication(s)
   This field should be left empty until details of the completed review are available.
   Give the full citation for the final report or publication of the systematic review.
   Give the URL where available.
Appendix 2

MEDLINE search details

Ovid MEDLINE(R) 1946 to March Week 1 2016

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# Appendix 3

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D 1.1: Literature Review (LIT)  

Dissemination Level: PU