



# BMJ Open Effectiveness of the eVISualisation of physical activity and pain intervention (eVIS) in Swedish Interdisciplinary Pain Rehabilitation Programmes: study protocol for a registry-based randomised controlled clinical trial

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## ABSTRACT

**Introduction** Living with chronic pain often involves negative consequences. Interdisciplinary Pain Rehabilitation Programmes (IPRP) is considered superior to single-treatment measures in patients with chronic pain. Despite this, effects emerge suboptimal and more than 20% of patients deteriorate in patient-reported physical health outcomes after IPRP. A novel e-Health intervention, eVISualisation (eVIS) of physical activity and pain, was systematically developed to facilitate individualisation of physical activity levels. By adding elements of data collection, visualisation and communication of objectively measured physical activity and patient-reported outcomes (pain intensity, interference of pain, pharmaceutical consumption) to existing treatment modalities in IPRP, the IPRP team acquires prerequisites to adapt advice and physical activity prescriptions and to evaluate set activity goals. The overall aim is twofold. First, the aim is to evaluate the feasibility of the subsequent registry-based randomised controlled clinical trial (R-RCT). Second, the aim is to prospectively evaluate the effectiveness of the eVIS-intervention as a supplement to IPRP on our defined primary (physical health) and secondary outcomes.

**Methods and analysis** In the R-RCT, recruitment of 400 patients with chronic pain will be performed at 15 IPRP units. A random allocation to either IPRP + eVIS or to control group that will receive IPRP only will be performed. Data from the initial 30 participants completing the study period (6 months) will be included in a pilot study, where key feasibility outcomes (recruitment, randomisation, implementation, treatment integrity, data collection procedure, preliminary outcome measures) will be evaluated. Outcome variables will be extracted from the web application Pain And TRaining ON-line (PATRON) and from six national registries. Multivariate statistics and repeated measure analyses will be performed. Quality-adjusted life years and incremental cost-effectiveness ratio will be calculated for cost-effectiveness evaluation.

## Strengths and limitations of this study

- A preceding pilot study will enable improvements of design and feasibility of a subsequent randomised controlled clinical trial.
- The eVISualisation intervention has been developed, evaluated and improved, based on data provided from patients, clinicians and researchers in different fields.
- The intervention targets physical activity modalities in Interdisciplinary Pain Rehabilitation Programmes (IPRP) and is designed to enable a more individualised IPRP treatment.
- The intervention is based on objectively measured physical activity levels, patient-reported clinical outcomes and mechanisms that facilitate behaviour change, in accordance with current guidelines that are provided by authorities in the chronic pain management field.
- The nature of the intervention precludes blinding of patients and the IPRP team.

**Ethics/dissemination** The Swedish Ethics Review Board granted approval (Dnr 2021/02109). Results will be disseminated through peer-reviewed journals.

**Trial registration number** NCT05009459. Protocol V.1.

## INTRODUCTION

Chronic musculoskeletal pain (>3 months), including neck/shoulder/back pain or widespread pain, is a major global health and socioeconomic burden.<sup>1,2</sup> Living with chronic pain is often associated with reduced levels of well-being, and the health-related quality of life of this group has been reported to be among the lowest of any medical condition.<sup>3</sup> To date, physical activity (ie, any bodily



movement that requires energy expenditure) and exercise (ie, structured and planned physical activity aimed to increase fitness)<sup>4</sup> have been shown to prevent and/or treat several of our non-communicable diseases, including chronic pain,<sup>5</sup> due to their beneficial effects on general health, pain intensity, physical and psychological functioning and health-related quality of life.<sup>5–8</sup> Despite the growing evidence of health benefits related to physical activity, participation and adherence to physical activity recommendations, such as WHO's physical activity guidelines, are often low in patients living with chronic pain.<sup>9–12</sup> This may partly be explained by the indicated association between high pain scores and low patient-reported activity levels among patients with chronic pain and/or the documented reports of the negative impact of depression on physical activity levels.<sup>13</sup> In addition, it is well known that behaviour change is difficult, and that each individual's own participation is essential.<sup>14</sup> It has been shown that behaviour change towards a beneficial physical activity level may be facilitated by individuals self-monitoring their physical activity.<sup>15</sup> The use of objective measures increases the likelihood of the effectiveness of interventions designed to promote physical activity.<sup>15</sup> By adding goal setting, feedback and a focus on achieved goals, effectiveness can be further improved.<sup>15–18</sup>

Interdisciplinary Pain Rehabilitation Programme (IPRP) (described as a subset of interdisciplinary treatment) is defined as 'multimodal treatment provided by a multidisciplinary team (at least three professions), collaborating in assessment and treatment using a shared biopsychosocial model and goals'.<sup>19</sup> The IPRP approach adopts the principles of behavioural therapy and incorporates besides physical activity and exercise, also psychological measures, pharmaceutical treatment and patient education.<sup>20</sup> Physical activity and exercise are central measures in IPRPs as it targets the physical deconditioning by improving levels of physical activity and also reduces pain severity and improved physical function and quality of life, without causing any severe adverse events.<sup>5</sup> IPRPs are considered to be superior to single-treatment measures (eg, physical treatments, education interventions, surgery, etc) for patients with chronic pain supporting positive effects on pain intensity and activity disability.<sup>20–21</sup> However, IPRP effectiveness is only slightly better, and in the majority of cases, only a small effect is seen.<sup>21–25</sup> In addition, up to 25% of patients report deterioration in physical health after completing IPRP and after 12-month follow-up, regardless of duration of IPRP.<sup>20–25–26</sup> Sustainable treatment affects seem to vary according to patient clinical features at baseline, such as poor employment status, high pain levels and low functioning, all of which predict low physical health at follow-up.<sup>23–27</sup> Many efforts have been made to find effective interventions that improve the health of chronic pain patients. To facilitate individualised physical activity levels within the Swedish IPRP setting, an eVISualisation (eVIS) of physical activity and pain intervention has been systematically developed according to the Medical Research Council's recently updated framework for development

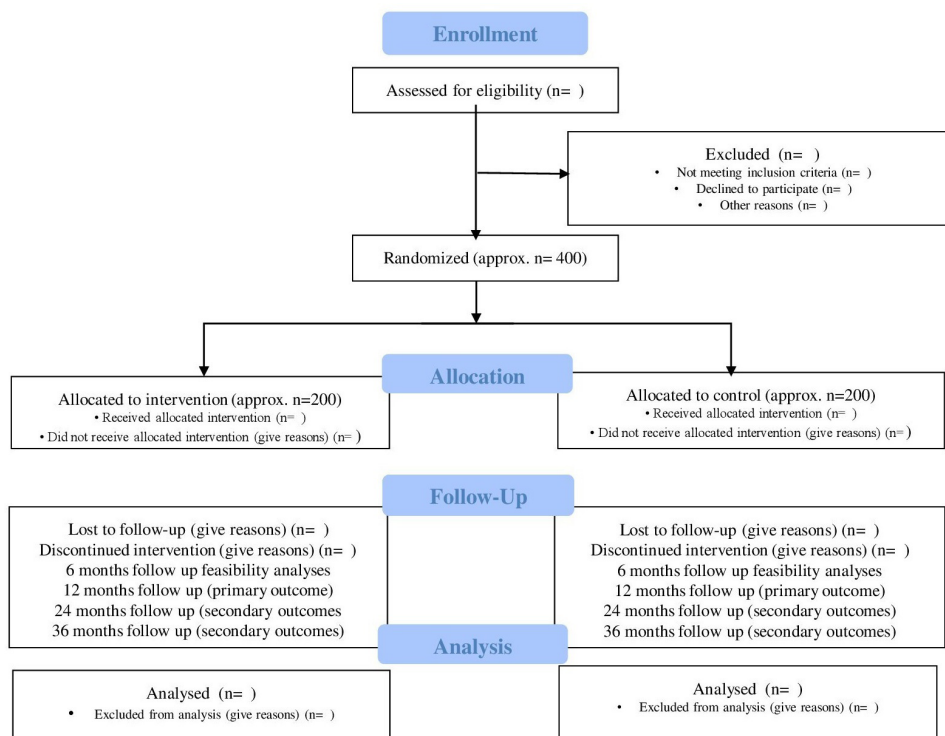
and evaluation of complex interventions.<sup>28–29</sup> In accordance with the framework, the eVIS-interventions was designed and planned in close collaboration with stakeholders. eVIS is designed to target facilitating mechanisms for behaviour change, such as outcome expectations, self-monitoring, self-evaluation and self-efficacy,<sup>30–32</sup> which are theoretically framed by the social cognitive theory.<sup>32</sup> In eVIS, objectively measured physical activity tracking using a wrist-worn activity tracker<sup>33</sup> (Fitbit Versa 2), is combined with a daily activity goal (steps/day) and daily patient reports of known important clinical outcome assessments: pain intensity and its interference on daily activities<sup>34–38</sup> and pharmaceutical consumption. Data are collected and visualised in a purpose-developed web application, Pain And TRaining ON-line (PATRON), which can be used by the patient and the IPRP team to follow and adjust individual physical activity levels. Despite interventions of this kind having highly promising potential to relieve pain and improve disability in this patient group,<sup>39</sup> interventions are rarely systematically developed and validated specifically for their target patient group, leaving crucial information of feasibility and true effectiveness unknown. Therefore, the overall aim of this study is twofold. First, the aim is to evaluate the feasibility (recruitment capability, eligibility screening procedure, randomisation, implementation process, response rate, compliance rate, changes in primary and secondary outcomes from start to end of study period, differences between treatment groups in primary outcome) of a subsequent registry-based randomised controlled clinical trial (R-RCT) within the IPRP setting in order to gain knowledge of population variation, increase robustness and to avoid underpower.<sup>40–43</sup> Second, the aim is to prospectively evaluate the effectiveness of the eVIS-intervention as a supplement to IPRP on our defined primary (physical health) and secondary outcomes, 12 months after completed IPRP compared with IPRP as usually provided. In addition, the aim is to evaluate the cost-effectiveness of eVIS supplementing IPRP at 12 and 36 months follow-up after completed IPRP and to prospectively evaluate differences in opioid consumption at start of IPRP compared with 6 months after completed IPRP.

In this trial, the UK National Institute for Health Research's definitions of the terms *pilot study* (ie, 'a smaller version of the main study') and *feasibility study* (ie, 'evaluation of pieces of research done before the main study') are applied.<sup>44</sup> The aim of this paper is to transparently clarify and report on study designs, aims, outcome assessments and procedures for a planned R-RCT (including an randomised pilot study), which prospectively will evaluate clinical effectiveness and cost-effectiveness of eVIS as a supplement to IPRPs for patients living with chronic pain compared with standard IPRPs.

## METHODS AND ANALYSIS

### Trial design and setting

This two-armed pragmatic multisite R-RCT will be conducted in specialised and primary IPRPs in Sweden



**Figure 1** CONSORT 2010 flow diagram chart of study design and enrolment. CONSORT, Consolidated Standards of Reporting Trials.

and include approximately 400 ( $n=200$ ,  $n=200$ ) patients (number will be definitively determined after the pilot study is finalised) with chronic musculoskeletal non-malignant pain. As indicated, a randomised controlled pilot study ( $n=15$ ,  $n=15$ ) will be incorporated as the initial phase of the main trial in order to evaluate the intervention's methodology and design.<sup>29 41 45</sup> This trial will comply with the Consolidated Standards of Reporting Trials<sup>40</sup> and with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).<sup>46</sup> A completed SPIRIT 2013 Checklist can be found in the additional files. See [figure 1](#) for study design and enrolment details.

### Eligibility criteria

In this trial, the patient-related, care process and caregiver-related inclusion criteria for receiving Swedish IPRP will be applied, as patients entering the trial must be accepted for IPRP. Principal IPRP inclusion criteria are patients in working age with persistent or intermittent musculoskeletal and or generalised pain lasting  $\geq 3$  months with pain affecting daily activities to a large extent, completed systematic assessment (including screening for psychosocial risk factors and differential diagnosis) and non-pharmacological optimisation. Inclusion criteria for Swedish IPRPs are outlined in detail elsewhere.<sup>47</sup> Due to the nature of the intervention, patients must be able to hear, see and comprehend spoken and written Swedish and have daily access to a computer, smartphone or tablet. Patients who need to use a walking aid indoors will be excluded.

### Recruitment

#### Interdisciplinary pain rehabilitation units

Approximately, 15 IPRP units in primary and specialised care in Sweden will be included in the trial. IPRP units reporting to the Swedish National Quality Registry for Pain Rehabilitation (SQRP) have been approached by email with study information (aim, rationale, methods, etc) and an invitation to participate in one of several online digital information meetings that will further present the study (initiated August 2021). Study representatives will approach healthcare staff at potential IPRP units by telephone or email to formally offer participation. Operation managers at each unit will be asked to provide written consent by e-mail.

### Participants

In order to give potential participants, additional time to consider taking part in the trial before they visit the IPRP unit, healthcare staff at the units will be encouraged to provide a general information sheet about the trial in the summon to the IPRP assessment. Members of IPRP teams (not only primarily physiotherapists but also occupational therapists, physicians, nurses, etc) will identify potential participants selected for IPRP based on outlined criteria and provide them with verbal and written details of the study (information sheets and the project's web address). All participants will provide written informed consent (see online supplemental file 1) prior to joining the study, which will be managed by the IPRP team. Detailed verbal and written information about the voluntary nature of





**Figure 2** Schematic illustration of the eVIS-intervention's three elements: (i) the data collection element of physical activity level (steps/day), patient reports of interference of pain on daily activities, pain intensity and pharmacological consumption, (ii) the visualisation element of collected data in different graphs and compilations of data and (iii) the communication element. eVIS, eVISualisation.

participation and the indisputable right to discontinue participation in the trial at any time will be provided. Detailed checklists and forms will support these procedures, and these will be easily accessible on the project website.

### Intervention

Participation in the intervention group involves regular IPRP supplemented with eVIS for a coherent time span of 6 months, IPRP time included. As the duration and intensity of IPRPs greatly vary from a couple of weeks up to 4 months,<sup>25</sup> a 6-month study period ensures time of independent use of eVIS after completed IPRP. Participants are not prohibited to take part of other healthcare during study period. IPRPs vary in interventions, duration, composition, intensity<sup>24 25</sup> and can be performed either individually or in group format. In this trial, participation in an IPRP will be supplemented by eVIS, a health-promoting intervention containing three elements designed to facilitate individualised physical activity level (figure 2).

#### The data collection element

Outcome assessments of physical activity level (steps/day) will be objectively collected by a wrist-worn activity tracker, Fitbit Versa 2. This device has been population-specifically validated and the measurement of step rate is indicated as valid for measurement in this population.<sup>33</sup> Data on patient's physical activity level, quantified as steps/day, will be automatically synchronised to the web application PATRON, where pain intensity (0–10),<sup>48</sup> interference of pain on daily activities (0–10),<sup>49</sup> pharmaceutical consumption (name, dose, number and form) and (optional) free-text comments will be reported by the patient daily. The web application can be accessed via computer, smartphone or tablet. A daily activity goal (steps/day) is formulated by the patient in close collaboration with the IPRP team and revised accordingly. The daily activity goal in eVIS is individually set based on patient's individual prerequisites and re-evaluated regularly as part of the communication element (described below). In the process of setting a daily activity goal, the

IPRP team is encouraged to consider international guidelines of step rate as a quantification of beneficial physical activity levels<sup>50</sup> as well as patient's personal barriers and resources to perform physical activity. The data collection element is designed to target facilitating mechanisms for behaviour change, such as outcome expectations, self-monitoring, self-evaluation and self-efficacy.<sup>30–32</sup>

#### The visualisation element

Objectively measured physical activity levels, patient report on pain intensity and interference of pain on daily activity are graphically visualised separately or alongside each other, in relation to the daily activity goal. Three different graphs (1/7/28 days) are available. The visualisation element provides additional prerequisites for increased knowledge acquisition, self-monitoring and self-evaluation as data are visualised over time and in relation to each other and to the individual daily activity goal in order to improve patient self-efficacy.

#### The communication element

The graphs in the visualisation element together with compiled data on pharmacological consumption will provide a novel decision basis for the patient and the IPRP team. This addition to existing treatment modalities traditionally provided in Swedish IPRP (eg, physical activity, cardio training, weight training, mobility training, stability training, motivating conversation education, advice, etc) enables prerequisites for the IPRP team to integrate behavioural changing techniques (eg, reinforcement, knowledge acquisition, self-monitoring, self-efficacy) into the existing treatment options. By such integration, knowledge of patient's personal barriers and resources in factors important in pain rehabilitation may be visualised and, if necessary, assessed. The IPRP team as well as the patients are encouraged to explore the visualisation element of eVIS at each visit at the IPRP unit. This is in order to use data into the treatment by adjusting advise or prescriptions.

#### Control

Participation in the control group involves taking part in regular IPRP plus making daily ratings of pain intensity, interference of pain on daily activities and pharmaceutical consumption (corresponding as in intervention group) in PATRON for 6 months, including the time that the IPRP is being carried out. The control group will not use the wrist-worn activity tracker as this may affect their physical activity behaviour.<sup>51</sup> Nor will they have access to PATRON's visualising or communication features.

#### Patient and public involvement statement

In an early developing phase, stakeholders (patients living with chronic pain, representatives from patient organisations and clinicians experienced in pain rehabilitation) were invited to contribute to the intervention development. In this phase, the web application PATRON and the eVIS-intervention were presented and carefully discussed with stakeholders as well as with web application

developers and researchers. Several needs for improvement were identified, such as a need of an addition of pharmaceutical report function, designated web pages and graphical changes in planned interfaces.

### Outcome assessments

According to the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials, physical health, emotional health and pain intensity are three of six identified core outcome domains that should be considered when designing research studies aiming to evaluate effectiveness of chronic pain treatments.<sup>35–37</sup> It is specifically recommended that a health survey such as RAND-36 should be incorporated into treatment as a clinical outcome assessment of physical health in clinical trials.<sup>36 37</sup> Outcome assessments for evaluating feasibility will be performed on data from the IPRP baseline and after the study period is completed (6 months) for the first 30 participants (n=15+, n=15). In the main trial, assessments of effectiveness will be performed on data from the IPRP baseline and from the 12-month follow-up. The cost-effectiveness assessments will be based on data from the IPRP baseline, from the 12-month IPRP follow-up and again 24 and 36 months after the IPRP is completed. A detailed overview of outcome assessments can be found in [table 1](#).

### Feasibility outcomes, pilot study

The trial will be initiated as a full-scale registry-based randomised controlled pilot study. In this initial step, feasibility will be evaluated from data provided from the first 30 participants completing the study period and in the following key areas: the unit's recruitment capabilities, the randomisation process, implementation process, participant response to intervention which is outlined in [box 1](#). In addition, the data collection procedure and the preliminary outcome measures (standardised effect size, sample size estimation with Cohen's d, characteristics (mean, SD)) in main trial will be evaluated.<sup>41 45</sup> In addition to feasibility outcomes, characteristics of the IPRP units will be collected

### Primary outcome, main trial

The R-RCT will prospectively evaluate the *clinical effectiveness* of eVIS supplementing IPRPs regarding improvements in our primary outcome assessment *physical health* collected by the physical health domain in RAND-36 health survey<sup>3 52</sup> at the 12-month IPRP follow-up after completing the IPRP. The RAND-36 is, for this population, a valid health survey measuring health-related quality of life in two dimensions, physical health (PCS) and mental health (MCS), mediated by eight subscales.<sup>52</sup>

### Secondary outcomes, main trial

In the main trial, secondary outcomes will be extracted from Fitbit Versa 2, PATRON and collapsed with data from six national registries (all listed below) at 12, 24, 36 months after the IPRP is completed.

### Objectively measured secondary outcomes collected using Fitbit Versa 2

Objectively measured physical activity levels will be collected daily during the study period using a wrist-worn activity tracker (Fitbit Versa 2). The Fitbit device measures and estimates a range of physical activity outcomes such as number of steps, heart rate, energy expenditure, floors climbed, physical activity level and sleep.<sup>33 53</sup> In this trial, participants' step count per day will automatically be synchronised to PATRON during the study period (6 months). The use of steps per day is considered to be a valid quantification of physical activity levels and this is acknowledged by the Swedish Health Authority.<sup>54</sup>

### Patient-reported secondary outcomes collected through PATRON

Data on physical and mental health collected by RAND-36 health survey will be collected through PATRON at 6, 12 and 24 months after IPRP. Pain intensity ('rate your average pain during the last 24 hours') will be measured daily using the Numeric Rating Scale (NRS, 0=no pain at all to 10=pain as bad as it could be), a 11-point Likert scale<sup>48</sup> incorporated in the web application PATRON. Pain interference on daily activities is a recommended outcome domain.<sup>35</sup> In PATRON, assessments of interference of pain on daily activities will be measured by the question 'rate how much your daily activities are affected by pain' using an 11-point Likert Scale (0=not at all to 10=to a very large extent). This question in PATRON has been modified based on the Multidimensional Pain Inventory Swedish version and its items on pain interference<sup>49</sup> and validated in our previous study (in manuscript). Data on daily pharmaceutical consumption will be collected in PATRON (name, dose, number and form). Voluntary free text comments will supplement patient reporting by providing additional information regarding perceived MCS and physical health (only in the intervention group).

### Secondary outcomes collected through the Swedish National Quality Registry for Pain Rehabilitation

In Sweden, 90% of IPRP units routinely collect patient-reported data from standardised questionnaires and report to SQRP, a database initiated in 1998 that contains data from chronic non-malignant pain patients participating in IPRPs.<sup>24 55</sup> The registry consists of two parts; the primary care SQRP (SQRP-PC) and the specialised SQRP (SQRP-SC). The SQRP-PC is supplied with data from affiliated primary care IPRP units (n=42, reported data from 505 patients in 2020). The specialised care SQRP, receives data from affiliated specialised care IPRP units (n=45, reporting data from 7427 patients in 2020). Data in both registries are collected at baseline, when the IPRP is completed and at 12-month follow-ups, the content of data collected in the registries differs somewhat. In this trial, registry data from both registries will be collected used to describe demographics such as age, sex, height, weight, education level and work.<sup>24 55</sup> Participants partaking in an IPRP in SC will also routinely complete the RAND-36 health survey at baseline and at

**Table 1** Overview of study period, measurement time points, outcome assessments (*bold and italics*), instruments and data sources (*italics*)

	Study period						
	Enrolment	Allocation	Post allocation				
	-t <sub>1</sub>	0	Baseline	t1	t2	t3	t4
Enrolment	X						
Written and verbal study information	X						
Eligibility screen	X						
Informed consent	X						
Allocation/randomisation		X					
Interventions							
Intervention, eVIS (6 months)			X	X			
Control (6 months)			X	X			
Outcome assessments							
<b><i>Personal characteristics</i></b>							
Sex, age, country of origin, family composition, beliefs of restored health ( <i>SQRP, SS</i> )			X				
Disposable-, earned- and net income ( <i>SS</i> )			X		X	X	X
Education level and education orientation ( <i>SPR, ITR</i> )			X		X	X	X
Diagnosis ( <i>NPR</i> )			X		X	X	X
Volume and reason for inpatient care ( <i>NPR</i> )			X		X	X	X
<b><i>Pain characteristics</i></b>							
Pain intensity (last 7 days), NRS ( <i>SQRP-PC and SC</i> )			X		X		
Pain intensity (today), NRS ( <i>PATRON</i> )			X	X			
Pain type, location, duration ( <i>SQRP-PC and SC</i> )			X				
Pain interference ( <i>PATRON</i> )			X				
<b><i>Multidimensional measures</i></b>							
Physical health, RAND-36 PCS health survey ( <i>PATRON</i> )			X	X	X	X	X
Physical health, RAND-36 PCS health survey ( <i>SQRP-SC only</i> )			X		X		
Emotional health, RAND-36 MCS health survey ( <i>PATRON</i> )			X	X	X	X	X
Emotional health, RAND-36 MCS health survey ( <i>SQRP- SC only</i> )			X		X		
Overall emotional distress, HAD(S) ( <i>SQRP-PC and SC</i> )			X		X		
Pain catastrophising, PCS ( <i>SQRP-PC and SC</i> )			X		X		
Psychosocial consequences, MPI-S ( <i>SQRP-PC and SC</i> )			X		X		
Pain acceptance, CPAQ-8 ( <i>SQRP-PC only</i> )			X		X		
Perceived life satisfaction, LiSat ( <i>SQRP-PC and SC</i> )			X		X		
Functional level, FRI ( <i>SQRP-SC only</i> )			X		X		
<b><i>Physical activity</i></b>							
Objective measures of steps per day ( <i>Fitbit Versa 2</i> )			X	X			
Patient-reported measures ( <i>SQRP- PC and SC</i> )			X		X		
<b><i>Work</i></b>							
Return to work (partially or full time) every month ( <i>SSIA</i> )					X	X	X
Number of days with sick benefit during study period ( <i>SSIA</i> )					X	X	X
Number of days in work before new sick leave during study period ( <i>SSIA</i> )					X	X	X
Length of total sick leave during study period ( <i>SSIA</i> )					X	X	X
Perceived work ability, WAI ( <i>SQRP-PC and SC</i> )			X		X		
<b><i>Sleep quality</i></b> , ISI ( <i>SQRP-SC only</i> )			X		X		
<b><i>Pharmaceutical consumption</i></b>							
Name, dose, size, prize of prescribed pharmaceuticals ( <i>SPDR, PATRON (not size, prize)</i> )					X	X	X

Continued

Table 1 Continued

	Study period						
	Enrolment	Allocation	Post allocation				
	-t <sub>1</sub>	0	Baseline	t1	t2	t3	t4
Prescribed pharmaceuticals collected from pharmacies, (SPDR)					X	X	X
Cost of prescribed pharmaceuticals included in benefit programme (SPDR)					X	X	X
<b>Healthcare consumption (NPR)</b>					X	X	X
<b>Feasibility outcomes, Questionnaire</b>				X			
<b>Treatment integrity, Questionnaire</b>				X	X		

CPAQ-8, The Chronic Pain and Acceptance Questionnaire; eVIS, eVISualisation of physical activity and pain intervention; FRI, Functional Rating Scale; HAD(S), Hospital Anxiety and Depression Scale; ISI, Insomnia Severity Index; LiSat, Life Satisfaction Scale; RAND-36 MCS, mental health domain; MPI-S, Multidimensional Pain Inventory—Swedish Version; NPR, National Patient Register; NRS, Numeric Rating Scale; PATRON, Pain and Training Online (web application); PCA, Pain Catastrophizing Scale; RAND-36 PCS, physical health domain; SPDR, Swedish Prescribed Drug Register; SPR, Swedish Population Register; SQRP, Swedish National Quality Registry for Pain Rehabilitation; SQRP-PC, Swedish National Quality Registry for Pain Rehabilitation Primary Care; SQRP-SC, the Swedish National Quality Registry for Pain Rehabilitation Specialised Care; SS, Statistics Sweden; SSIA, Swedish Social Insurance Agency's Registry; -t<sup>1</sup>, prerecruitment period; t<sup>1</sup>, completed study period (6 months); t<sup>2</sup>, follow up 12 months after completed Interdisciplinary Pain Rehabilitation Programme (IPRP); t<sup>3</sup>, 24 months after completed IPRP; t<sup>4</sup>, 36 months after completed IPRP; WAI, Work Ability Index.

their 12-month follow-up after they have completed their programme. Data on pain intensity ('last 7 days') (NRS 0–10)<sup>48</sup> will be retrieved from SQRP-PC and SQRP-SC alongside other pain characteristics including pain location (36 anatomical predefined areas, 18 on the left

side, 18 on the right side), pain duration and pain type (intermittent or continuous). Data on self-rated physical and mental health are collected by the RAND-36 health survey<sup>3 52</sup> in SQRP-SC and the EuroQol-5 dimensions collected routinely in SQRP-PC and SQRP-SC will be used. The EQ-5D is a standard instrument used in health economic evaluations and contains five items each with three-ordered response categories, and a 0–100 index.<sup>56</sup>

Measures of self-rated physical activity are collected in SQRP-PC and SC using the National Board of Health and Welfare's three questions on physical activity (0 to >300 min/week), exercise (0 to >120 min/week), and sedentary behaviour (0–15 hours/day),<sup>57</sup> and in SQRP-PC by the Godin-Shepard leisure-time physical activity questionnaire (number of times/week that strenuous/moderate/light exercise).<sup>58</sup> Data on overall emotional distress (0–3), pain catastrophising (0–4) and psychosocial consequences (0–6) of living with pain are collected in SQRP-PC and SQRP-SC using the Hospital Anxiety and Depression Scale,<sup>52 59</sup> the Pain Catastrophizing Scale (PCS)<sup>60</sup> and the Multidimensional Pain Inventory Scale Swedish (V.0–6).<sup>49</sup> Level of pain acceptance (0–6) is collected in SQRP-PC using the Chronic Pain and Acceptance Questionnaire-8).<sup>61</sup> Perceived life satisfaction (1–6) is collected by the Life Satisfaction Scale (LiSat)<sup>62</sup> in both registries. Data on perceived work ability (0–10) are collected by the Work Ability Index<sup>63</sup> and functional levels (0–4) by the Functional Rating Scale<sup>64</sup> are collected in SQRP-SC only. Data on patient-reported sleep quality (0–4) are collected by the Insomnia Severity Index<sup>65</sup> in SQRP-SC.

#### Secondary outcomes collected through other national registries

Data will be collected from the Swedish Social Insurance Agency's registry on diagnosis, reasons for sick leave, type of financial compensation, number of sick days and sickness benefit (days and hours) during the study period. In

### Box 1 Overview of key feasibility outcomes in pilot study.

#### Key feasibility outcomes

##### Recruitment capability

- ▶ Volume of total eligible patients.
- ▶ Number recruited/week.

##### Eligibility screening procedure

- ▶ Proportion accepted/declined
- ▶ Personal characteristics of accepted and declined participants.
- ▶ Pain characteristics of accepted and declined participants.
- ▶ Procedure of collecting consent.

##### Randomisation process

- ▶ Delivery envelopes.
- ▶ Storage of envelopes.
- ▶ Procedure of opening envelopes.
- ▶ Patients' reaction to allocation.

##### Implementation process

##### Response rate RAND-36 PCS.

##### Compliance rate (use of Fitbit Versa 2, intervention group only).

##### Compliance rate (patient-reported outcomes in PATRON).

##### Treatment integrity.

##### Reported adverse events.

##### Data collection procedure.

- ▶ Access to PATRON data.
- ▶ Access to registry data.
- ▶ Access to RAND-36 data.

##### Preliminary outcome measures

- ▶ Characteristics, mean (SD).
- ▶ Missing data.
- ▶ Changes from baseline to finalised study period.

RAND-36 PCS, physical health domain in RAND-36; PATRON, Pain and training online (web application).



addition, data on days in work (partial or full time) per month in total before new sick leave period and length of total sick leave during the study period will be retrieved from the registry. Data will be retrieved from the National Patient Register on diagnosis and healthcare consumption (total number of days in care, etc). Retrieved data from the Swedish Prescribed Drug Register will provide information on prescribed pharmaceutical names, doses, sizes and prices that have been collected from pharmacies, their costs and whether the pharmaceutical is included in the subsidised pharmaceutical programme. Data on disposable and earned income as well as net income will be retrieved from Statistics Sweden. In addition, demographic data such as sex, age, marital status, citizenship, education level and number of children in the family will be collected. From the Population registry, data on education level and education orientation (focus) in addition to limited demographic data (sex, age) will be collected.

### Sample size

A sample size for the pilot study of at least  $n=30$  is considered sufficient for planned feasibility analyses since it will not involve hypothesis testing and sample size calculation per se.<sup>43 66 67</sup> For the main trial, a preliminary power calculation is based on assumptions from previous research reporting on proportions of patients who report a clinically meaningful difference of  $\geq 3$  points in the physical health domain in RAND-36, 12 months after completed IPRP.<sup>25</sup> The calculation was performed in R, using a calculation method for simple randomisation and for independent observations. The preliminary power calculation allows a dropout rate of 20% and requires a total sample size of approximately  $n=400$  to have an 80% power to detect a 15% difference ( $\geq 3$  p) between the groups in the outcome physical health. Physical health is measured by the RAND-36 health survey at the 12-month follow-up measurement point after the completion of the IPRP. The significance level is set to 0.05 and is two tailed. The sample size calculation may be recalculated after the pilot study is completed. In this trial, the null hypothesis is that there will be no difference between the intervention group and the control group ( $<15\%$  with  $\geq 3$  points improvement) with regards to proportional improvement in the PCS domain of RAND-36 health survey when assessed at the 12-month follow-up after the completion of the IPRP.

### Allocation

A permuted block randomisation design with a random block size of 4 and 6 and an 1:1 allocation ratio will be applied and evaluated in the pilot study in order to allocate participants to either the intervention or control group.<sup>68–70</sup> A computer-generated randomisation schedule will be created using a random number table to allocate participants to one of the two treatment arms; intervention group (IPRP supplemented by eVIS) or control group (IPRP with daily patient reports in PATRON). The schedule will be generated by an

experienced researcher, who is not directly involved in the trial. Sequentially numbered opaque sealed envelopes will be used to ensure allocation concealment. Allocation will take place at the IPRP unit and will be conducted by members of the IPRP team after initial assessment.

### Blinding/masking

Neither the IPRP team delivering the intervention nor participants will be blinded to allocation to either group due to the nature of the intervention.

### Data collection methods

Besides objectively measured data of physical activity level, patient-reported data will be collected from PATRON and from six Swedish registries at the IPRP baseline and at 6, 12 and 24 months after completed IPRP. In addition, patient-reported data regarding cost-effectiveness will be retrieved 36 months after the IPRP is completed. In this trial, data will be retrieved from SQRP, the Swedish social insurance agency's registry, the Patient registry, the Swedish Prescribed Drug Register, the Income and Taxation registry and the Swedish Population Register to enable a broad investigation into the intervention's effectiveness.

To enable sufficient pilot study analyses as well as assessment of the primary outcome Physical health (PCS) in RAND-36, members of the IPRP team will be asked to provide self-reported data on feasibility outcomes (outlined below) using a purpose-developed questionnaire with specific questions targeting the IPRP team perspective.<sup>41</sup> If deemed required, data collection will be supplemented by individual or group interviews. A detailed overview of assessments, time points, and data sources can be found in [table 1](#).

### Data management

In order to link individual-level data from different registries to PATRON data, we will seek assistance from the National Board of Health and Welfare who will provide a consecutive number key. This key will be stored at the National Board of Health and Welfare for 3 years (longer if needed). The procedure is initiated by sending PATRON data to the National Board of Health and Welfare and participants' social security numbers will be sent there by SQRP. The National Board of Health and Welfare creates the consecutive number key and connects ordered data with own registry data (the National Patient Register and the Swedish Prescribed Drug Register). The National Board of Health and Welfare will then send a data order to the remaining registries (the Swedish Social Insurance Agency's registry, Statistics Sweden, and the Swedish Population Register) and encoded data will be sent to the principal investigator to be stored in Dalarna University's secured server.

### Intervention fidelity

The following measures have been and will be taken to increase intervention fidelity: a systematical intervention development with a clarified theoretical base explaining



suggested mechanisms has been undertaken throughout the development process.<sup>29</sup> Healthcare staff at the IPRP units will be provided with comprehensive written information (easily accessed online) that includes step-by-step instructions on how to initiate and deliver the intervention while maintaining a high level of integrity. Before the study starts, all participating healthcare staff at the IPRP units will take part in a standardised provider training session online. Data on each participant's number of entries in PATRON will be available throughout the study in order to collect data on treatment fidelity. During the on-going study period, researchers will be automatically notified of non-wear time (Fitbit Versa 2) and any absence of patient reports in PATRON. In these cases, researchers will contact the relevant participant via email or telephone to ask if they need help or support. If a participant decides to discontinue the trial, he or she will be asked if they are willing to grant permission for the collected data up to that point to be used in the trial. Also, recurring web-based meeting opportunities will be provided, where IPRP team members will be encouraged to discuss experienced or perceived difficulties, and a questionnaire will be sent out after the study period with the aim of assessing treatment fidelity (treatment integrity and treatment differentiation) by gathering data on how treatment was delivered (manner vs treatment manual, intervention's alignment to intended theoretical base). This will allow results to be interpreted and will facilitate practical implementation.<sup>71 72</sup>

### Statistical methods

A statistical analysis plan will expand on statistical principles, statistical analyses, the planned handling of missing data, possible additional analyses (subgroups, etc) and interim analyses. In both the pilot study and the R-RCT, descriptive statistical analyses will be performed to provide transparent reporting of characteristics of both participants and participating IPRP units. In addition, IPRP units will be prompted to register the number of patients they ask to participate, those excluded based on eligibility criteria and those who decline participation. Analyses of pilot data (ratings of key feasibility outcomes) made by IPRP teams on a four-point Likert scale (ie, 1=strongly disagree, 2=disagree, 3=agree, 4=strongly agree) will be calculated as proportions in four categories for each item. Ratings  $\geq 3$  will be considered as acceptable feasibility. Analyses of primary and secondary outcomes in main trial will be performed based on PATRON data and registry data. The clinical effectiveness of eVIS will be analysed for each outcome using multivariate statistical and repeated measures analyses as a preliminary plan. Both the intention-to-treat and the per-protocol sample will be analysed, but the intention-to-treat analysis will be considered as the primary analysis. All p values will be presented. If a p value is  $\leq 0.05$ , the null hypothesis will be rejected and eVIS will be considered effective according to the outlined hypothesis. To perform cost-effectiveness calculations, data on health-related quality of life

measured by EQ-5D will be retrieved from SQRP. EQ-5D is the standard instrument used to evaluate health costs and cost-effectiveness. Calculations of quality-adjusted life years will be performed by multiplying health-state utility (measured using the EQ-5D Index score) by time spent in this specific health state.<sup>73 74</sup> In addition, calculations of the incremental cost-effectiveness ratio will be made as the difference in the cost of two interventions divided by their affect.<sup>75</sup>

### Data monitoring

Trial data will be monitored and regularly assessed for integrity and errors. All data monitoring will be performed completely independently from sponsors and competing interests. An independent data monitoring committee will be appointed to critically review data safety in the trial. VS will be responsible for the monitoring of all data collected in the pilot study. A data management plan will be outlined by the first author (VS) and implemented by the principal investigator (LV) to ensure sound data structure (folder structure, file naming, organisation) and data storing.

### DISCUSSION

This article describes a protocol for an R-RCT trial of a novel e-Health intervention. The trial will contribute to establish evidence for the effectiveness of individualised physical activity and exercise among patients living with chronic pain and participating in IPRP. The methodology and feasibility of the trial will be evaluated in an early phase by a pilot study, which will contribute to optimised robustness of the subsequent R-RCT trial and enable further refinement of the intervention. Despite many efforts have been taken to develop health-promoting interventions for this patient group, it is rare that such interventions are systematically developed and includes both objective and patient-reported outcomes. The potential measurement errors of self-reported constructs of physical activity are well known and this trial contributes to introducing objective measurement methods in a clinical context. The eVIS-intervention is developed according to MRC's framework for development and evaluation of complex interventions.<sup>29</sup> It consists of both objectively measured physical activity level (steps/day), and patients own reports on pain intensity, interference on daily activities and individual daily activity goal, all joint in the web application named PATRON. This enables known facilitating mechanisms for behaviour change (eg, as self-monitoring, etc)<sup>32</sup> while including several core outcome domains.<sup>34 76</sup> The agile development process has enabled continuous evaluation and improvement of the intervention based on data provided from patients, clinicians and researchers in different fields. Objectively measured constructs of physical activity by Fitbit devices have been criticised due to lack of accuracy of measurements of time spent in moderate to vigorous physical activity where various devices overestimate the measurement.<sup>77</sup> Preceding this study, our

research group performed an evaluation of Fitbit Versa's criterion validity of measuring energy expenditure, heart rate and step count among patients living with chronic pain. Results confirmed previous study results in adjacent patient groups reporting that Fitbit Versa systematically overestimated energy expenditure, however, measurements of step count both in laboratory and in free-living setting were valid.<sup>33</sup>

In this trial, participants will be recruited at IPRP units nationally distributed. All units adopt to core IPRP content regarding modalities, but it is well known that both duration and intensity greatly vary, which may limit generalisation of the results.<sup>25</sup> To achieve maximum external validity, we will collect data on the specific characteristics of all participating units and include this in the final analyses. Unknown engagement in other out-patient treatments under study period may be a potential source of bias, though data on in-patient engagement will be known through registry data from the National Patient register. Non-adherence to daily self-report in PATRON can be expected and may differ between intervention and control group (differential missing). Measures will be taken to optimise adherence in both groups such as regular auditing of registrations in PATRON followed by personal emails with encouragement to follow protocol. To minimise the risk of contamination between groups and to ensure that the study will be carried out in compliance with the study protocol, all participating staff at the IPRP units will participate in a study-specific course prior entering the trial. Results generated from the pilot study and the subsequent effectiveness trial will inform pain management field with new knowledge on eVIS's potential to increase pain rehabilitation programme's effectiveness by individualised physical activity levels among patients living with chronic pain.

### Harms and adverse events

Participating patients and healthcare staff at the participating IPRP units will be encouraged to report any adverse events such as unexpected side effects or symptom deterioration,<sup>78</sup> which will also be reported to the Swedish Ethical Board Review.

### ETHICS AND DISSEMINATION

The trial is prospectively registered in ClinicalTrials.gov and was approved by the Swedish Ethics Review Board in May 2021 (Dnr 2021/02109). The trial will be conducted in compliance to the Helsinki Declaration.<sup>79</sup> Important protocol modifications will be communicated to the Swedish Ethics Review Board as well as to all participating IPRP units and participants. To protect confidentiality, all data will be coded by an individual code, and the encryption key will be stored separately. Data will be stored at an intended project server at Dalarna University, which is secured by regular backups. No unauthorised persons will have access to data, for example, data will only be accessible by researchers in the trial after approval from

the principal investigator. Results of the pilot study and the main trial will be submitted for publication in peer-reviewed journals and communicated in national and international research networks as well as in relevant clinical settings, including patient associations.

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**Contributors** LV and BOÅ are responsible for the conception of the trial. LV is the principal investigator and was involved in all methodological decisions. VS, ET, AM, JW, RLM, BOÅ, MH, MB and LV all contributed to study design and were all involved in the development processes (the evaluation of criterion validity of the wrist-worn activity tracker and the evaluations of the content validity and clinical feasibility) of the intervention. RLM performed the preliminary power and sample size calculations and was involved in all associated decisions. VS wrote the first draft of the manuscript and was responsible for revising the manuscript's intellectual content based on all co-authors conscientious input as well as conducted manuscript revisions according to peer-reviewer's comments. All authors read and approved the final version of the manuscript. For this article, no ghost authors, guest authors or professional writers have or will be used. Author eligibility is and will be based upon the ICMJE Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly work in Medical Journals.

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HÖGSKOLAN  
DALARNA

Deltagarkod \_\_\_\_\_

### Samtycke till att delta i projektet

Jag har fått muntlig och skriftlig informationen om projektet och har haft möjlighet att ställa frågor. Jag får behålla den skriftliga informationen.

- Jag samtycker till att delta i projektet **Utvärdering av eVISualisering av fysisk aktivitet och smärta (eVIS) som tillägg till multimodal smärtrehabilitering**
- Jag samtycker till att Socialstyrelsen sammanför data från de i forskningspersonsinformationerna nämnda svenska register med den data som samlas in via forskningsprojektet (PATRON, aktivitetsklockan och hälsoenkäten RAND36)
- Jag samtycker till att uppgifter om mig behandlas på det sätt som beskrivs i forskningspersonsinformationerna.

**Ort och datum**

**Underskrift**

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