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Abstract
In this deliverable we provide a thorough explanation of how the SELFBACK intervention has been developed by following the stepwise planning approach of Intervention Mapping.

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List of abbreviations

BCT = behaviour change technique
CBT = cognitive behavioural theory
HCP = health care professional
IM = Intervention mapping
LBP = low back pain
NPT = normalization process theory
RCT = randomized controlled trial
SME = small and medium-sized enterprise
TDF = theoretical domains framework

1 Introduction

In this deliverable we give a thorough explanation of how the SELFBACK intervention has been developed by following the stepwise planning approach of Intervention Mapping (IM). The process is both cumulative (each step informs the next) and iterative (program planners move back and forth between steps). Therefore, knowledge and experience gained through implementing the SELFBACK app in the pilot study (fall/winter 18/19) will give reason to re-evaluate the process and go through the steps again. Thus, the product (the app) will likely continue to develop until the randomized controlled trial (RCT) starts in M38 (February 2019).

In the following chapters, the development of the intervention is described.

2 Development of interventions using the Intervention Mapping process

IM is a six-step process where each step consists of several tasks, which once completed, inform the next step as detailed by Bartholomew et al. [1] and in Figure 1. The IM process aims to facilitate participation and consultation of all relevant stakeholders, and provides a structure for the integration of theory, empirical findings from the literature, and information collected from the target population. In SELFBACK, IM was used to guide the development of the content for the digital intervention delivered through the app.

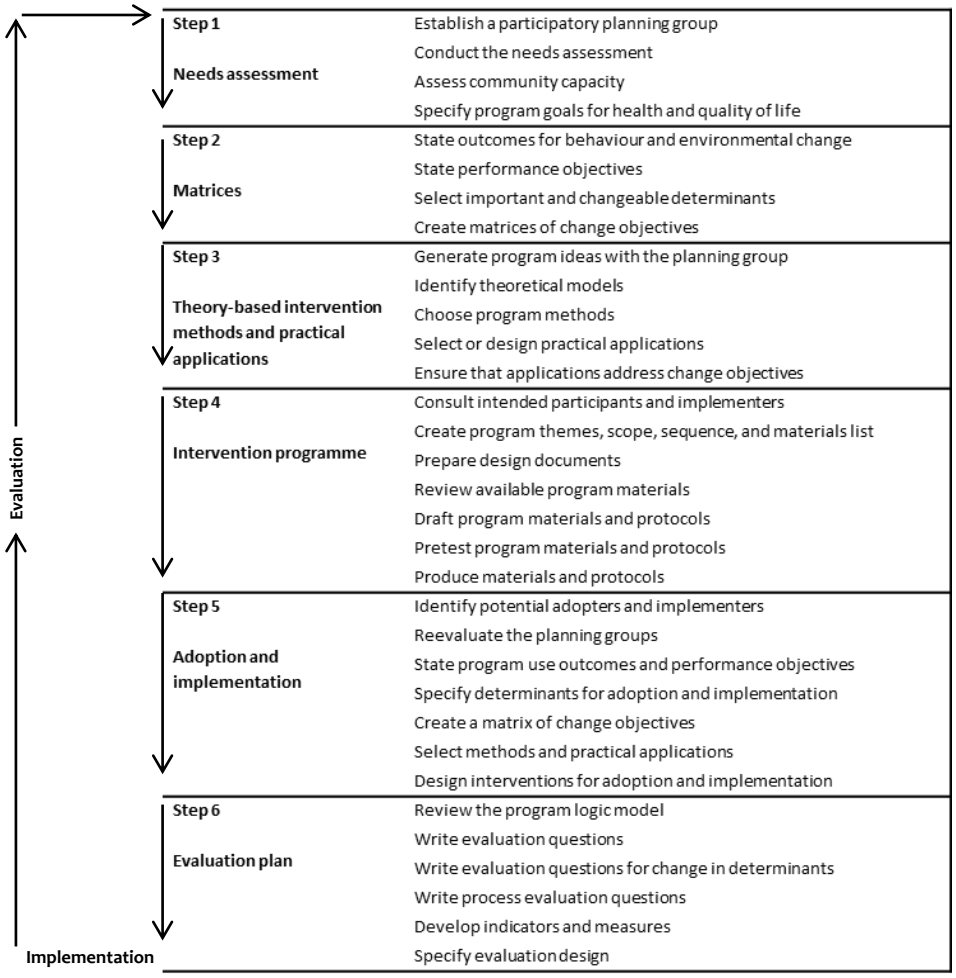

Figure 1 The Intervention mapping process as per Bartholomew et al [1] and resources available on the Intervention Mapping website (https://interventionmapping.com/)

2.1 Six steps of IM process

The six steps of the IM process are [1]:

Step 1 – Conduct a needs assessment
Step 2 – Create matrices of change objectives
Step 3 – Select theory-based intervention methods and practical applications
Step 4 – Organise methods and applications into an intervention programme
Step 5 – Plan for adoption and implementation
Step 6 – Generate an evaluation plan

2.1.1 Step 1 – Needs assessment

The aim of step one is to identify what, if anything, needs to be changed and for whom. This assessment results in a description of the health problem, its impact, causes and potential solutions.

2.1.2 Step 2 – Matrices

The aim of step two is to explain who and what will change as a result of the intervention, i.e. identification of outcomes, performance objectives (what do the participants in the programme need to learn to achieve the performance objective?) and change objectives (what needs to be changed related to an external determinant to accomplish the performance objective?). The product of this step is matrices of proximal programme objectives.

2.1.3 Step 3 – Theory-based intervention methods and practical applications

The goal of this step is to generate a list of intervention methods that match the proximal program objectives, and to identify practical and appropriate ways of conveying these methods to the target group.

2.1.4 Step 4 – Intervention programme

The fourth step aims to design and organise the intervention with components and content that matches the proximal change objectives and methods that were identified in the previous steps. This step includes pretesting of programme applications and materials.

2.1.5 Step 5 – Adoption and implementation

The fifth step aims to plan how the intervention will be adopted and implemented – although these considerations of course already begin as early as the needs assessment or even earlier. One of the tasks in this step is to create a matrix with programme use outcomes and performance objectives for adoption and implementation together with a detailed plan for how this should be fulfilled.

2.1.6 Step 6 – Evaluation plan

The goal of the sixth step is to finalise an evaluation plan, both in terms of effect and process.

3 Methods

The entire process of developing the SELFBACK intervention using the IM approach is documented in Appendix 1. Previously submitted deliverables and tasks are mapped to the process.

3.1 Step 1 – Needs assessment

The SELFBACK project is a response to a call from the Horizon 2020 program on "Self-management of health and disease and decision support systems based on predictive computer modelling used by the patient him or herself". Thus, a relevant topic for this should be a condition where self-management plays a vital role. To accommodate the call, we performed a needs assessment from a societal perspective and this first step was therefore primarily addressed in the grant application process. The establishment of a participatory planning group was therefore also given, as all partners in the consortium were participating in the intervention development process. The members brought their knowledge based on clinical experience, professional background, or scientific evidence and thus contributed to the final project description through several rounds of discussions and iterations.

The needs assessment was primarily informed by conducting literature reviews answering questions like 'What is the burden of different diseases?', 'What is the recommended treatment of different diseases?', and, 'How well does self-management fit into this?'. When it was decided that LBP should be the condition of interest, a literature review of clinical practice guidelines for LBP was conducted. In addition to the literature reviews conducted and the knowledge from the experienced researchers involved, people with LBP and health care professionals (HCPs) were interviewed and asked about their experience with treatment of LBP and how they usually self-manage their LBP/guide people to self-manage as well as their views on the need for an app to support self-management of LBP.

Another subtask of this step was to assess community capacity to carry out the intervention. As SELFBACK is an add-on to usual care, the community capacity was assessed by approaching clinics that could refer their patients to participation in trials (pilot and RCT). This was done by approaching research units or networks for target groups of HCPs (e.g. GPs) or by contacting potential clinics directly.

The overall programme goal was formulated based on recommendations from LBP literature and previous experiences with interventions to target LBP.

3.2 Step 2 – Matrices

We identified relevant pain- and function-related outcomes through a purposeful literature review of systematic reviews, overview papers and expert opinion papers of core outcome domains, and of outcome measures used in previous trials of patients with LBP (reported in D1.1 and 1.2). The main body of literature was identified by the medical partners in the consortium, who have in-depth knowledge of the existing literature on LBP management and first-hand experience with conducting trials for patients with LBP. A literature review on

behaviour change theory related to pain, pain-related disability and self-management was conducted to specifically identify the behaviour-related outcomes. In addition, two systematic reviews were conducted: the first review aimed to synthesize and critically appraise published evidence concerning the use of interactive digital interventions to support self-management of LBP [2]. The second review aimed to synthesize and critically appraise published qualitative literature to determine: 1) engagement strategies utilized in digital interventions aimed at supporting patient self-management of LBP, and 2) barriers and facilitators affecting patient uptake and utilization of digital interventions self-management of LBP (Kyle et al., submitted to BMC Musculoskeletal Disorders). Moreover, a non-systematic review was conducted on strategies to increase engagement in digital interventions for any behaviour change. Finally, discussions were carried out among the involved partners to develop the final matrices.

According to the Medical Research Council guidelines[1] on development and evaluation of complex interventions [3], we identified, selected and incorporated behaviour change theory to support the identification and selection of relevant determinants of behaviour for the intervention to target. The theoretical underpinning was chosen based on knowledge and experience of the medical partners together with literature reviews on theory-informed behaviour change interventions.

Through the reviewed literature, group discussions among medical partners, and information gathered from the interviews conducted in step 1, we formulated performance objectives and identified their changeable determinants (i.e. factors that have been found to be associated with performing/not performing the targeted behaviour). These include personal determinants (e.g., beliefs and perceptions or cognitive factors) and external determinants (e.g., social and structural factors). Matrices of performance objectives crossed with determinants and change objectives were created.

3.3 Step 3 – Theory-based intervention methods and practical applications

In step 3, the literature review on guidelines of self-management for LBP was updated together with studies on physical activity, exercise and patient education. The review served as inspiration for the content of each of the three components of the intervention. In addition, we reviewed the content of guideline-recommended patient leaflets and patient information delivered through webpages or mobile applications. The theoretical foundation for physical exercises and the education component was based on previously published evidence. The choice of physical exercises and educational content was determined in a parallel process with the GLA:D® Back project[2]. To further inform the process, people with LBP were interviewed about their experiences regarding physical exercises for LBP.

[1] The Medical Research Council (UK) published in 2000 a 'Framework for the development and evaluation of RCTs for complex interventions to improve health' to help researchers and research funders to recognize and adopt appropriate methods. This guidance has later been revised and updated. The key elements of the process are: Development – Feasibility/piloting – Evaluation – Implementation as an iterative process https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/

[2] GLA:D® Back project is a national Danish project aiming at developing a treatment regime for people with back pain. The content of GLA:D® Back and SELFBACK are very much alike since both are based on the same theoretical foundation. Some members of the SELFBACK consortium are involved in the GLA:D® Back project thus information obtained in GLA:D® Back is also used in SELFBACK and vice versa.

The practical applications of digitally supported behaviour change were selected by mapping the determinants identified in step 2 to theories for behaviour change and engagement in digital health interventions as well as identifying behaviour change techniques (BCTs) to underpin the intervention with. This process was supported by literature and the experience among the medical partners from previous self-management trials with a focus on behaviour change.

3.4 Step 4 – Intervention programme

The SELFBACK intervention materials were designed in this step, e.g. the app content, the technical systems supporting the app and the protocol for the pilot and RCT.

For the physical exercises, we created a matrix including all exercises and progressing difficulty levels. Members of both the SELFBACK planning group (medical partners) and members of the GLA:D® Back project group participated in a workshop to compile and organize, discuss and finalise guidelines for composition of exercise targets and progression/regression in difficulty levels. Likewise, the educational component was also developed together with members of the GLA:D® Back project group. A psychologist employed at the UoSD was consulted to provide feedback, in particular for the cognitive behavioural theoretically informed content. All of the intervention content was developed in close collaboration between partners in the planning group during a period of almost two years to ensure uniformity, consistency and thoroughness.

Partner TRX developed a design scheme to match the intention of the intervention, i.e. to deliver trustworthy, evidence based information supporting people with LBP to self-manage their condition. The design was firstly presented to the consortium who then gave feedback. Secondly, consortium members presented the design documents to colleagues and research groups to get further feedback. A user journey test was also conducted with three LBP sufferers (D4.6). A literature review on engagement strategies like gamification and notification systems in digital interventions was conducted and the results implemented. The process of designing and revising the app, including several iterations and steps, is further described in D4.6.

Two feasibility studies with people with LBP, one in Aberdeen (UK) and one in Trondheim (NO) were conducted. The UK feasibility study was conducted to explore feasibility and acceptability of the baseline questionnaire, physical activity monitoring and feedback strategies with a prototype app (reported in D2.5). The NO feasibility study included all main components of the SELFBACK app (physical activity monitoring, exercise module and educational module). Both feasibility studies were evaluated quantitatively and qualitatively and the information informed the development of the intervention. Simultaneously, app prototypes were tested among both consortium members and external users (mainly colleagues). User tests were carried out both as group sessions and as real time test of app usage in consecutive periods of time. In September 2018, the pilot trial has started using a complete version of the app. Results from the evaluation of this trial will inform refinement and revision of the app prior to the RCT.

3.5 Step 5 – Adoption and implementation

The goal of this step was to plan how the intervention will be adopted and implemented. The adoption plan for identification and recruitment of participants by HPCs at the recruitment sites is described in D5.1. Information obtained from the interviews with both HCPs and people with LBP from step 1 was coded using a theoretical framework for how a digital intervention can be implemented, embedded and integrated into routine or not. This information was then specified as determinants for adoption and implementation. A matrix crossing the determinants with performance objectives, practical applications and BCTs for this was created through group discussions among the medical partners.

3.6 Step 6 – Evaluation plan

In the final step, the evaluation plan was programmed. Evaluation plans were decided upon simultaneously with developing the intervention and were primarily planned during group discussions informed by both the literature reviewed in previous steps as well as the knowledge and experience that consortium members brought with them entering the project. The results from the work in this step are reported in D5.1.

4 Results

4.1 Step 1 – Needs assessment

The participatory planning group consisted of all members of the consortium. The consortium members represent a range of highly relevant professions, including HCPs with clinical experience (physiotherapists, medical doctors, chiropractors and exercise physiologist) and technical partners with extensive experience in developing patient-centred technical solutions. The members brought in clinical experience, professional backgrounds, and scientific evidence through several rounds of discussions and iterations.

According to the recent global burden of disease study, LBP is the most significant contributor of years lived with disability [4] and disability-adjusted life years [5]. Moreover, nonspecific LBP is the fourth most common diagnosis (after upper respiratory infection, hypertension, and coughing) seen in primary care [6]. Every year, about 1 in 15 people in the European population will consult their general practitioner with LBP, and it is one of the most common reasons for activity limitation, sick leave, and work disability [7, 8]. Cost of illness studies in different European countries such as Sweden, Belgium, the Netherlands, and the United Kingdom indicate that the total annual cost of LBP per capita range between 116 EUR and 399 EUR [9], amounting to a total annual cost in Europe at 85 to 291 billion EUR. This equals 0.4- 1.2% of the gross domestic product in the European Union. Thus, in addition to the suffering of affected individuals, LBP poses an enormous economic burden [10, 11] which is expected to increase with the aging population [9]. This presents a huge challenge for the future sustainability of the health care systems.

International clinical guidelines on LBP consistently endorse promotion of self-management for people with LBP as an integral component of care [12-15]. They consistently recommend patient education about the condition, consequences, and management, and the facilitation of evidence-based self-management behaviours, such as discouragement of bed rest, reassurance about the favourable prognosis, advice to stay active, and strength and/or stretching exercises [12-15].

Consistent delivery of self-management interventions in health care settings presents a challenge as implementation of interventions often require some variation and local adaptations [3], which can have a negative impact on the effect of the intervention [16]. Therefore, new ways to support self-management are needed. Digital interventions, such as those that can be provided by smartphone apps, have been proposed as a promising means of supporting self-management in people with chronic conditions [17]. However, in a systematic review on the use of interactive digital interventions to support self-management of LBP (reported in D1.1 and 1.2), we found that previous studies were extremely heterogeneous and the evidence base to support the use weak, making it difficult to understand what might work best, for whom, and under what circumstances. Moreover, comprehensive descriptions of the interventions' development and use of theory were either brief or completely lacking [2] (reported in D1.2). More promising conclusions were drawn from a systematic review on web-based interventions to support individuals with LBP [18]. In

particular, interventions that offer an interactive support component and elements from cognitive behavioural therapy (CBT) seem to be beneficial.

Pain-related disability is a major concern for patients with LBP, and one of the defining aspects of the condition. International expert groups consistently recommend pain-related disability as either a primary or secondary outcome in LBP interventions [19-21].The programme goal was formulated based on recommendations from LBP literature and previous experience with trials for LBP, and, thus, the overall programme goal of the SELFBACK project is:

To improve self-management of non-specific LBP to reduce pain-related disability

An assessment of the community capacity to recruit patients for the trials was done both in Denmark and Norway. In Denmark, four potential resources for patient recruitment were identified and approached. 1) GPs; the research unit for general practice at UoSD was approached and the Danish College of General Practitioners were invited to endorse the project. Hereafter, GP practices in the Odense area were identified and invited to take part in the recruitment. 2) Physiotherapy clinics; potential clinics were identified from a list of clinics drawn from a Danish physiotherapy clinic register. 3) Chiropractor clinics; the Nordic Institute of Chiropractic and Clinical Biomechanics, Odense identified potential clinics from their existing research network. 4) The Spine Centre of Southern Denmark (secondary sector outpatient clinic); the Spine Centre was approached and a collaboration for recruitment established. In Norway, similar approaches to identify and approach potential recruitment sites were used. This process included applying to the Danish Patient Safety Authority (DPSA) for transmission of patient information and the Spine Centre for use of data in a research project. The application to the DPSA is pending and once approved, the second application will be processed. In Norway, the trials were approved by the regional ethics committee and data security authority.

4.2 Step 2 – Matrices

In this step, we created the matrices specifying the intended behavioural change resulting from the SELFBACK intervention.

Based on the overall programme goal, the specific behavioural objectives for the self-management intervention are: 1) to increase the use of evidence-based self-management strategies, i.e. increase the understanding of LBP (the condition, consequences, and management), and increase capability to handle LBP (e.g. physical exercises and cognitive and behavioural strategies), and 2) to increase physical activity level.

For pain-related behaviour, several factors will affect the gap between intention and behaviour, i.e. the determinants of behaviour change. Fear-avoidance has been demonstrated to impact the activity levels of people with chronic LBP; however more recently it has been suggested that self-efficacy may be more important than fear-avoidance in mediating the relationship between pain and functional disability [20], and it has been recognised as one of the main drivers towards positive outcomes [21]. Pain self-efficacy refers to beliefs regarding the ability to carry out certain activities even when experiencing

pain [22]. Our literature reviews further revealed other examples of determinants of the outcome of self-management interventions in people with LBP such as knowledge/awareness, skills, and behaviour regulation, catastrophizing and motivation/attitude [12-15, 23-28]. The SELFBACK intervention should therefore target these determinants as outlined in Table 1.

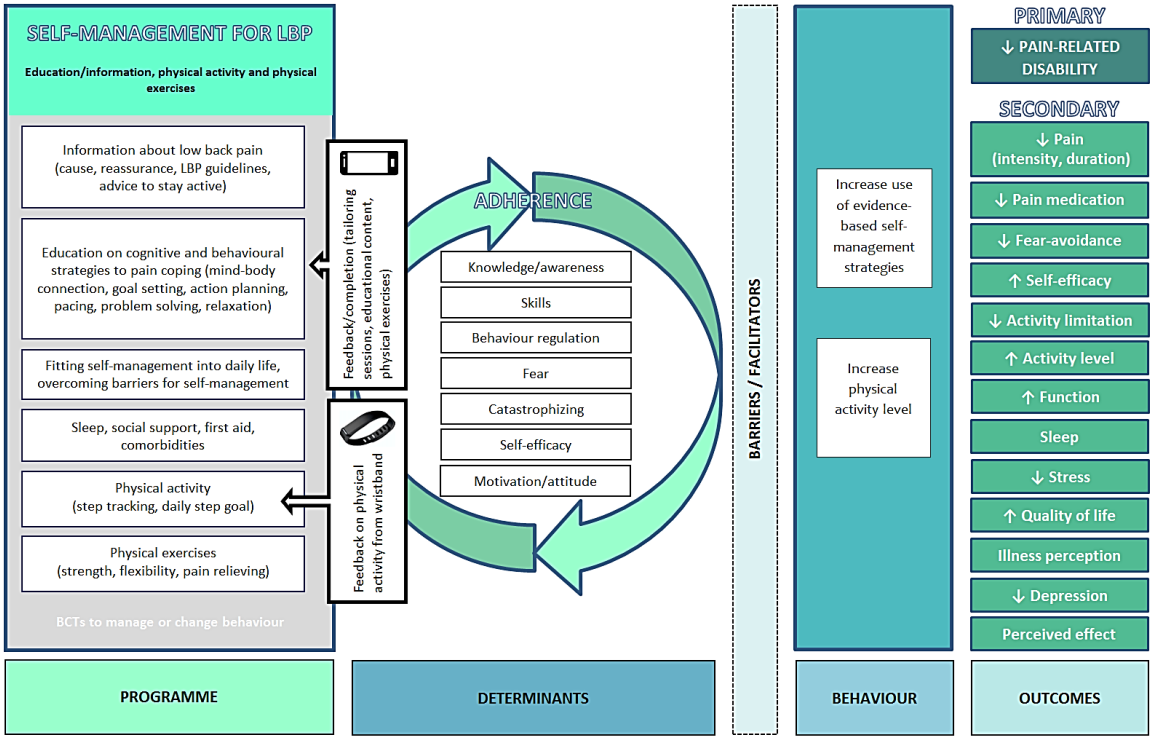

Figure 2 Programme logic model for the SELFBACK intervention

The programme logic presented in Figure 2 describes the mechanistic pathway from the intervention to the reduction in LBP. Moreover, the programme logic helps guide both the effect evaluation and process evaluation.

To theoretically underpin the participants' uptake and engagement in the SELFBACK intervention and support the further development of the intervention, the determinants were mapped to domains from Normalization Process Theory (NPT) and Theoretical Domains Framework (TDF) as presented in Table 1. These behaviour change theories are presented in more detail in step 3 (section 4.3).

Table 1 Determinants of self-management behaviour mapped to NPT and TDF domains

Determinants of self-management behaviour	Evidence of the determinant	NPT domain as per [29, 30]	TDF domain as per [31]
Knowledge/awareness	Literature review of guidelines for LBP [12-15, 24, 25] Literature review of behaviour change theory including mediators of behavioural outcomes and LBP outcomes [23] Conceptual definition of self-management [32] LBP patient interviews on (barriers to) self-management of LBP	Coherence	Knowledge To increase participants' knowledge for each self-management behaviour
Skills	Literature review of guidelines for LBP [12-15, 24, 25] Literature review of behaviour change theory including behavioural outcomes [23] Conceptual definition of self-management [32]	Cognitive Participation, Collective Action	Skills To develop participants' ability to uptake each self-management behaviour
Behaviour regulation	Literature review of guidelines for LBP [13-15] Literature review of behaviour change theory including behavioural outcomes [23]	Cognitive Participation, Collective Action	Behavioural regulation Strategies to manage or change objectively observed or measured self-management behaviour of participants
Fear	Literature review of guidelines for LBP [12-15, 24, 25] Literature review of behaviour change theory including behavioural outcomes [23, 26, 28]	Coherence	Emotion To reduce fear of specific self-management behaviours
Catastrophizing	Literature review of guidelines for LBP [12] Literature review of behaviour change theory including behavioural outcomes [23, 26, 27]	Coherence	Beliefs about consequences To reduce negative expectancies about consequences of engaging in specific self-management behaviours
Self-efficacy	Literature review of behaviour change theory including behavioural outcomes [20-23, 26-28]	Coherence, Cognitive Participation	Beliefs about capabilities To improve participants' perceived competence to

	LBP patient interviews on (barriers to) self-management of LBP		uptake and engage in each self-management behaviour
Motivation/attitude	Literature review of guidelines for LBP [12-15, 24, 25] Systematic review of barriers and facilitators for patient uptake and utilization of digital interventions (Kyle et al, submitted) Literature review of behaviour change theory including behavioural outcomes [23, 33] LBP patient interviews on (barriers to) self-management of LBP	Coherence Cognitive Participation	Intentions; Goals To improve autonomous motivation and goal setting of participants to engage in each self-management behaviour

Two matrices crossing change objectives with determinants and performance objectives were made (Table 2 and Table 3); one for each target behaviour. For example, for the target behaviour "increase use of evidence-based self-management strategies", the performance objective "uses specific exercises for pain condition" was linked to the determinant "fear" and resulted in the change objective "reduce fear related to engaging in selected specific exercises".

Table 2 Matrix of change objective 'Increase use of evidence-based self-management strategies' with determinants and performance objectives

			WHY?						
WHO?	Target group; Target behaviour **Patients with LBP; Increase use of evidence-based self-management strategies**		Determinants						
			Knowledge/ awareness	**Skills**	**Behaviour regulation**	**Fear**	**Catastro-phizing**	**Self-efficacy**	**Motivation/ attitude**
			Increase participants' knowledge for each self-management behaviour	Develop participants' ability to uptake each self-management behaviour	Strategies to manage or change objectively observed or measured self-management behaviour of participants	Reduce fear of specific self-management behaviours	Reduce negative expectancies about consequences of engaging in specific self-management behaviours	Improve participants' perceived competence to uptake and engage in each self-management behaviour	Improve autonomous motivation and goal setting of participants to engage in each self-management behaviour
WHAT? Performance objectives	**Performance objective 1** Uses the selfBACK app	Change objectives	Develop an understanding of how app works etc.	Can use the app					
	Performance objective 2 Accepts self-management as treatment		Develop an understanding of the rationale for self-management						Increase autonomous motivation to self-manage their pain condition
	Performance objective 3 Uses appropriate evidence pain management strategies to self-manage pain condition		Develop an understanding of evidence-based pain management strategies relevant to their pain condition	Develop skills to try and use evidence-based pain management strategies relevant to their pain condition	Develop ability to monitor pain condition to select and apply evidence-based pain management strategies relevant to their pain condition	Reduce fear associated with pain condition by using pain coping strategies	Reduce pain catastrophizing beliefs' associated with pain condition by using pain coping strategies	Increase self-efficacy to use evidence-based pain management strategies relevant to their pain condition	Increase autonomous motivation to use evidence-based pain management

Performance objective 4 Uses pain coping strategies	Develop an understanding of pain coping strategies	Develop skills to select and use pain coping strategies	Develop ability to monitor pain condition to select and apply appropriate pain coping strategies	Reduce fear associated with pain condition by using pain coping strategies	Reduce pain catastrophizing beliefs' associated with pain condition by using pain coping strategies	Increase self-efficacy in ability to use coping strategies	Increase autonomous motivation to use pain coping strategies
Performance objective 5 Getting appropriate sleep	Develop an understanding of appropriate and healthy sleep patterns		Develop ability to monitor sleep patterns				Increase autonomous motivation to apply appropriate and healthy sleep patterns
Performance objective 6 Integrates self-management into daily activities	Develop an understanding of the rationale for self-management	Develop skills to try and use evidence-based pain management strategies relevant to their pain condition					Increase autonomous motivation to self-manage their pain condition
Performance objective 7 Uses specific exercises for pain condition	Develop an understanding of how to perform selected specific exercises	Develop physical skills to engage in specific exercises	Develop ability to incorporate and monitor effects of specific exercise in daily life	Reduce fear related to engaging in selected specific exercises	Reduce pain catastrophizing beliefs' related to consequences of engaging in specific exercises	Improve self-efficacy in ability to engage in specific exercises	Increase autonomous motivation to engage in selected specific exercises

Table 3 Matrix of change objective 'Increase physical activity level' with determinants and performance objectives

WHO?	Target group; Target behaviour		WHY?						
			Determinants						
	Patients with LBP; Increase physical activity level		**Knowledge/awareness**	**Skills**	**Behaviour regulation**	**Fear**	**Catastro-phizing**	**Self-efficacy**	**Motivation/attitude**
			Increase participants' knowledge for each self-management behaviour	Develop participants' ability to uptake each self-management behaviour	Strategies to manage or change objectively observed or measured self-management behaviour of participants	Reduce fear of specific self-management behaviours	Reduce negative expectancies about consequences of engaging in specific self-management behaviours	Improve participants' perceived competence to uptake and engage in each self-management behaviour	Improve autonomous motivation and goal setting of participants to engage in each self-management behaviour
WHAT? Performance objectives	**Performance objective 8** Accepts the benefit of physical activity	Change objectives	Develop an understanding of the benefits of physical activity						Increase autonomous motivation to engage in physical activities
	Performance objective 9 Selects PA(s) relevant to lifestyle/pain condition		Develop an understanding of recommended types and levels of physical activity				Reduce pain catastrophizing beliefs' related to consequences of engaging in physical activity	Improve self-efficacy in ability to perform selected physical activities	Increase autonomous motivation to engage in selected physical activities
	Performance objective 10 Performs selected PA(s)		Develop an understanding of how to perform selected physical activity	Develop physical skills to engage in physical activity	Develop ability to incorporate and monitor effects of physical activity into daily life	Reduce fear related to engaging in selected physical activities	Reduce pain catastrophizing beliefs' related to consequences of engaging in physical activity	Improve self-efficacy in ability to engage in selected physical activities	Increase autonomous motivation to engage in selected physical activities

	Performance objective 11 Uses goal setting for the selected PA(s)	Develop an understanding of goals and its relevance for physical activity	Develop skills to apply relevant goal setting to selected physical activity		Improve self-efficacy in ability to use goal setting	Increase autonomous motivation to use goal setting
	Performance objective 12 Uses pacing to support selected PA(s)	Develop an understanding of pacing and its relevance for physical activity	Develop skills to apply pacing to selected physical activity	Develop ability to incorporate and monitor effects of physical activity into daily life	Improve confidence in ability to use pacing	Increase autonomous motivation to use pacing

4.3 Step 3 – Theory-based intervention methods and practical applications

In the following section, the theoretical basis of the intervention is described. First, the overall theoretical underpinning for behaviour change and engagement in the SELFBACK intervention is presented. Second, the evidence for the specific intervention components is presented.

4.3.1 Theories for behaviour change and engagement in a digital intervention

Self-management interventions can be characterized as behaviour change interventions, in that they are designed to help the patient learn and adopt a set of health behaviours. The patients can use the new set of health behaviours in everyday life to reduce or manage their symptoms and, thus, benefit their condition [34]. The TDF is an overall framework encompassing 33 behaviour change theories [35]. TDF was developed using an expert consensus process, and has been refined and validated for use in behaviour change and implementation research [31]. To facilitate the application of BCTs [36], matrices have been created by expert consensus mapping BCTs and theoretical constructs such as those used in TDF [37, 38]. BCTs are observable and replicable components of an intervention and can be used in complex interventions [36].

NPT theoretically underpins the strategies for uptake and adherence to the intervention. NPT is a sociological theory that has been widely promoted as a means to understand the factors that influence how new technologies or therapies become implemented, embedded and integrated into routine or not. Within the SELFBACK intervention, NPT is used to help understate and evaluate the factors that promote or inhibit uptake, utilisation and sustained use of SELFBACK (i.e., adoption and implementation). The theory has four main constructs: 1) coherence, the sense making work that participants undertake that influences whether they are willing to embed a new practice in their lives; 2) cognitive participation, the work that participants undertake to engage with the new practice; 3) collective action, the work that participants do to enact a new practice; 4) reflexive monitoring, the appraisal work that participants undertake to determine whether the new practice is worth sustaining or how it must be reconfigured to fit their needs [29, 30, 39]. See Figure 3.

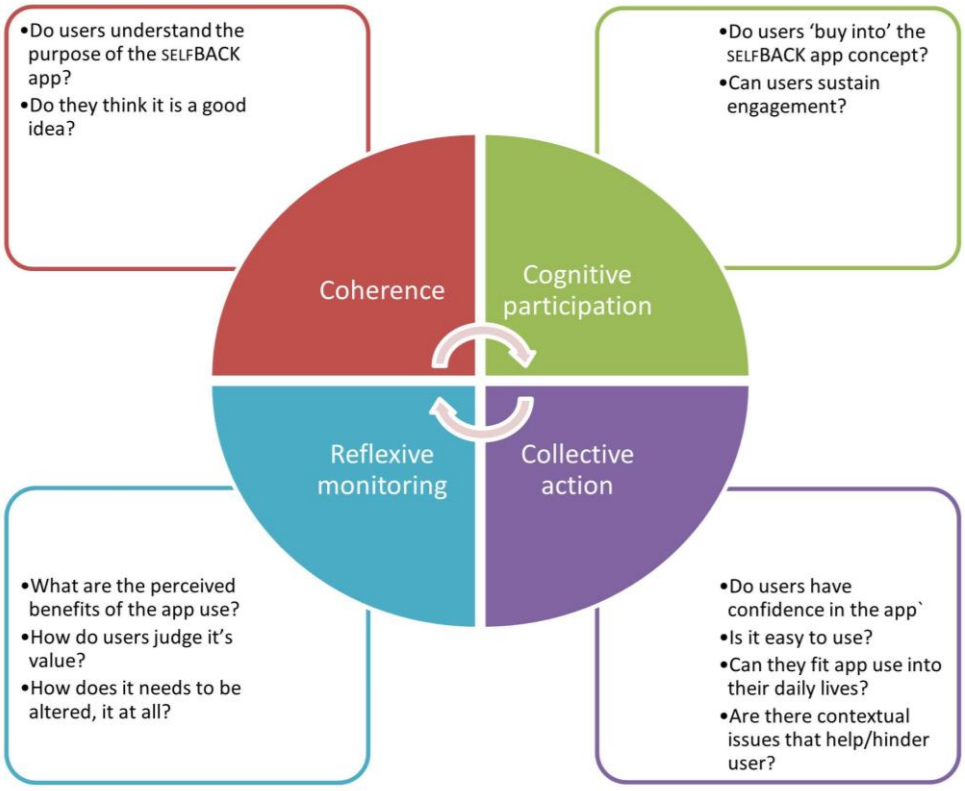

Figure 3 Four constructs of NPT and associated question from the process evaluation (from D5.1)

The determinants targeted by the SELFBACK intervention are mapped to TDF and NPT domains in Table 1. All intervention content is mapped to specific BCTs in Appendix 2, Table 7.

4.3.2 Evidence for specific intervention content

The extent of descriptions of intervention content in the literature reviewed in steps one and two varied across studies, but the level of detail provided was generally sparse. Most studies only report the overall themes of the content but not the details or information about sequences of content [2]. Therefore, we searched patient leaflets and other patient information delivered through websites or apps and reviewed them for content on self-management of LBP.

From our literature reviews on guidelines and studies on (self-)management of LBP as well as patient leaflets and pain management websites, it was clear that self-management of LBP can be grouped into three overall themes: 1) education, 2) physical activity and 3) physical exercises. In the following, the theoretical foundation for each as well as the theoretical basis of strategies for engaging users (barriers and facilitators for engagement and gamification) will be presented.

4.3.3 Education

The guidelines recommend educating patients with a cognitive behavioural approach [13, 14], evolving around teaching or promoting pain coping skills like activity pacing and progression guidance, goal setting and action planning and relaxation techniques [15], which resembles the core of BCTs [40]. The process of patients assimilating BCTs to self-manage their LBP is supported in the app by incorporating interactive tools, quizzes and support to develop practical pain management skills. The educational component of the intervention is mapped to relevant BCTs in Appendix 2, Table 7.

The most recurrent themes of education in the guidelines and patient leaflets were: Information about the nature of LBP; Reassurance; Understanding and accepting pain; Changing thought patterns to avoid catastrophizing and negative thoughts; and Encouragement to stay physically active and continue with normal activities including work [13-15, 41]. From the pain management websites that were reviewed, the themes about self-management of LBP were in line with what was recommended in the guidelines. That is, they advise patients to take an active role in managing their LBP by learning skills that help them to take control over their pain. This should include being physically active; having a positive, confident attitude and taking ownership of the pain; being a problem solver and taking action; and knowing how to fit in self-management in the daily life including overcoming barriers when it is a struggle. The websites and patient leaflets also suggested supplementary themes for supporting patients' self-management of LBP like what to do if a flare-up occurs; information about comorbidities and red flags; encouragement to seek social support from family, friends and work; as well as help to sleep better with LBP [42-59].

The educational content was organised as shown in Table 4. Two planning group members from medical partners worked together on creating the table and content. Continuously throughout the process, clinicians and other experts experienced within the field of LBP and patient education provided feedback.

Table 4 Main themes and sub themes of the educational content

Main theme	Sub theme
Information about LBP	Cause of LBP
	Guidelines LBP
	Imaging
	Pain rating
	Reassurance
	Start exercise
	Stay active
	Structure of back
Understanding mind-body therapy	Mind-body connection
Self-management for LBP	Encouragement to self-management
Thoughts, behaviour, attitude and feelings	Accepting pain
	Anxious thoughts and feelings
	Attitude
	Changing negative thoughts
	Distraction
	Distress
	Fear-avoidance
	Stress
	Thoughts
Fitting in self-management in a busy life	Daily activity
	Me time
First Aid when your back hurts	First Aid reassurance
	First Aid stay active
LBP and comorbidities	Anxiety
	Depression
	Musculoskeletal pain
	Sleep disorders
Goal setting and action planning	Action planning
	Goal setting
Pacing and progression guidance	Pacing
Problem solving	Problem solving
Relaxation	Relaxation
Sleep and LBP	Sleep
Social support	Family and friends
	Work
Overcoming barriers for self-management of LBP	Barrier facilities
	Barrier family and work
	Barrier time
	Barrier tiredness
	Barrier support
	Barrier weather

4.3.4 Physical activity

The importance of physical activity has been recognised as a prime strategy in European guidelines for the management of LBP [24, 25]. Advice to stay active, early and gradual activation and discouragement of bed rest are all key features of LBP management guidelines [12, 13, 24, 25]. This has to a large part been based upon the deconditioning model

of LBP [60]. That is, patients with LBP may be restricted in the performance of everyday physical activities. As a consequence, they risk developing a hypoactive lifestyle and a vicious circle may then gradually develop: hypoactivity leading to a reduction in physical fitness (deconditioning), leading to further hypoactivity. In addition, various changes in physical functioning in patients with LBP have been seen [61], as well as neuromuscular changes [62], decreases in physical fitness [63], alterations in the patterns [64] and levels of activity [65]. General recommendations of physical activity will be applied to guide users to set a daily step count goal. The lowest step count goal possible will be 3000 steps per day. The limits of the step count are based on previous studies on comparable populations in a workplace pedometer intervention (average ~6000 steps) [66] and home-based pedometer intervention in older adults with knee problems (average ~3500 steps) [67]. The minimum step count goal of 3000 per day was chosen to reflect that participants in the trial have functional disability that may also affect their physical activity level. Optimally, users should reach 10.000 steps/day [68].

4.3.5 Physical exercises

The physical exercises included into the SELFBACK system are based on studies included in international guidelines for treatment of LBP [69, 70], and systematic reviews on the effect of exercise in LBP treatment [71-77]. A recent review concluded that there is strong evidence that exercise relieves pain and improves function in both acute and chronic back pain with moderate to large effect sizes [78]. The review also states that there is little empirical evidence in favour of any particular type of exercise (i.e. dynamics, static exercises, flexibility, strength, etc.) or in how the exercise is delivered. In any case, exercise is as effective as other treatment modalities and should be considered a first line intervention.

Strength training and motor control exercise were the most common interventions in a review from 2005 where exercise therapy was explored for acute, sub-acute and chronic LBP [79]. Exercise therapy was superior in reducing pain and improving function when compared to no treatment or other treatments in patients with chronic LBP and as effective as other interventions in acute and sub-acute populations. *Strength training*, where certain muscle groups are exercised with an intensity of > 70% of one repetition max (RM) and relatively few repetitions (3-12 repetitions) are well known to facilitate neuromuscular adaptions such as improved neural drive, change in the local chemical environment, muscle fibre hypertrophy and increased muscle strength [80, 81]. A particular type of these exercises are *core exercise* that aim to support the spine through balanced simultaneous contractions of the abdominal wall, quadratus lumborum; latissimus dorsi; and the back extensors of longissimus, iliocostalis, multifidus and pelvic floor muscles [82]. Strength training improves muscle strength, functional ability, pain and in some studies also quality of life [83]. A systematic review on strength training for people with chronic LBP showed that strength exercise was more effective than no exercise at long term follow-up, and that more intensive training had better outcomes than lower intensities [84].

Specific *exercises for flexibility* have also been suggested to be effective to alleviate LBP and improve function [71, 72, 77]. The aim of this type of exercises is to restore or improve

range of motion for the lumbar spine. The theory behind flexibility exercises is that pain leads to protective muscle spasm that can be released by movement to end-range and stretching of the affected muscles [85]. Flexibility exercises should be performed to end range in all directions with acceptable pain. In case of non-acceptable pain in a given direction, this direction can be omitted. Unfortunately, none of the included reviews reported the results of flexibility exercises alone but rather as a component of an exercise package [71, 72, 77].

Another group of therapeutic exercise can be classified as *pain relieving exercises,* where the patient is encouraged to explore strategies for movement that can be done with less pain or resulting in pain reduction. These exercises consist of movements performed in midrange and without strong muscle contractions and exercises of low-level muscle contractions to facilitate relaxed movements. As with exercise for flexibility, this type of exercises are hidden within an exercise package, but the reviews on motor control exercise support this type of exercise as being effective to support management of pain [71, 74, 76, 77, 86].

The dose of exercise in primary randomised controlled trials included in the reviews is not always clearly described. Although inconclusive, it appears that longer durations of exercise periods and heavier training is more effective in reducing back pain compared to shorter periods and lighter loads [84]. The American College of Sports Medicine recommends 2-3 weekly sessions for muscle training at 60-70% of one repetition max (RM) for novice trainers and 80% or 1RM for experienced people, sets of 8-12 repetitions for strength and power and >15 for endurance [87]. To maintain good range of motion, flexibility exercises to end range are recommended 2-3 days a week, held for 30 seconds and repeated 2-4 times [87].

Since there is no clear indication of which exercises are the most effective, an exercise program should be individually tailored to the patient by e.g. symptoms, preference or fitness level, and comprise exercises for pain control or pain reduction, improving motor control, strength and flexibility. Consequently, exercises included in the SELFBACK catalogue were categorized within six different targets. The organization of exercises by their target was guided by consensus discussions among experienced clinicians and researchers. The targets are 1) flexibility exercises, 2) pain relieving exercises in addition to strength exercises for 3) back extensors, 4) gluteal and hip muscles, 5) abdominal muscles and 6) core muscles. Once organized by target, the exercises were ordered into difficulty levels. Rules for progression or regression between exercise levels were guided by physiological reasoning and clinical experience.

4.3.6 Barriers and facilitators for engagement in a digital intervention

In both our systematic and non-systematic literature reviews concerning barriers/facilitators for engaging in digital interventions (both LBP and other conditions), we found that a variety of themes either enhance or inhibit engagement. Lack of human interaction [88], too much information or conflicting information [89]; (Kyle et al., submitted), lack of practical support (Kyle et al., submitted) and lack of feedback/evaluation (Kyle et al., submitted) were all identified as barriers for engagement. Conversely, tailoring of content to the individual

patient [88, 90]; (Kyle et al., submitted), interactive elements like gamification [89], short texts [90], simple layout and navigation [90], feedback [91]; (Kyle et al., submitted), user-friendliness (Kyle et al., submitted), trustworthiness (e.g., evidence-based content and trustworthy source) (Kyle et al., submitted), reminders, prompts and updates [89]; (Kyle et al., submitted), use of images [90], use of different media types (e.g., text, audio and video) (Kyle et al., submitted), emotional support (Kyle et al., submitted) and evidence of improvements from other users (Kyle et al., submitted) were found to enhance engagement in digital interventions.

Additionally, a study combining a literature review and a survey among 519 university students found that rewards, personalisation, tracking features, positive feedback and alarms, prompts or reminders were facilitators of engagement in mHealth (mobile health technology) apps [92]. A systematic review on smartphone apps for self-management of LBP by Machado et al. [93] rated apps available in the iTunes and Google Play stores using the MARS scale[3]. They found that the overall quality of the included apps (n = 61) was low because they lacked engaging features, presented unattractive layouts, and provided questionable and low-quality information [93]. The lowest scoring domain was 'engagement', and the authors recommend that future apps should incorporate strategies to increase engagement by stimulating repeated use, e.g. through gamification or reward systems [93].

Some identified barriers and facilitators affecting engagement may be difficult to target by the intervention per se but do give valuable insight in patient utilisation and therefore informed the planning of the process evaluation in step 5. Technical concerns like lack of affinity with computers or smartphones, concerns regarding battery consumption, issues with registering or logging in, lack of practical support staff, or device malfunction due to incorrect use [88, 90]; (Kyle et al., submitted), as well as personal concerns like preference for personal contact, privacy concerns, and perception that health problem is too complex to be managed digitally [88]; (Kyle et al., submitted), were all found to be barriers for engagement. Conversely, we identified that engagement in digital interventions was facilitated because digital interventions allow patients to proceed at their own pace and take all the time needed to comprehend [89]; (Kyle et al., submitted), give patients an opportunity to acquire words about their health condition that makes it easier to discuss this with their HCP [89];(Kyle et al., submitted), and develop patients' self-efficacy/confidence in ability to self-manage LBP [89].

4.3.7 Gamification for increased engagement

Based on the reviews on facilitators for engagement in digital interventions, all three main components of the SELFBACK app intervention incorporate some sort of interactive element or gamified interaction. Gamification, the concept of applying game mechanics to non-game

[3] MARS = The Mobile App Rating Scale, a 23-item questionnaire on five domains: *1) engagement* (fun, interesting, customizable, inteactive and well-targeted to audience, *2) functionality* (functioning, easy to learn, navigation, logic flow, and gestural design of app), *3) aestethics* (graphic design, overall visual appeal, color scheme, and stylistic consistency), *4) information quality* (quality and quantity of information, credibility of developer), and *5) general, overall quality*

contexts, has been shown to enhance user engagement in eHealth[4] [95, 96], by employing many different techniques, e.g. points, badges, leader boards, feedback, rewards, avatars, progress elements, quizzes, challenges, quests and levels. Additionally, gamification in eHealth offers other advantages like enhancing motivation, making health activities fun, enjoyable and understandable as well as improving users' ability to self-manage their condition [96]. Therefore, it is thought to greatly contribute to behaviour change due to the resemblance with established health BCTs [97]. Edwards et al. [97] identified appropriate BCTs in gamified health promotion apps and found that all apps (n = 64) included at least five BCTs. However, the employed BCTs were of great variation and the effectiveness of individual techniques was difficult to determine. Edwards et al. [97] recommend app developers to use BCTs to develop more effective apps. A step on the way is to plan interventions to include BCTs and code them using a standard taxonomy [36]. All intervention components of the SELFBACK app are coded for BCTs in Appendix 2, Table 7.

4.4 Step 4 – Intervention programme

In this step we created the content of the intervention, the theoretical and practical ways of applying content to function as a digital intervention for behaviour change, worked on the design features of the intervention, and created the participant documents (e.g. invitation letter and letter of consent) to be used in the intervention. All of these tasks and items were continuously reviewed, evaluated and revised, e.g. by consortium members, potential end users (people with LBP), external reviewers, external researchers and stakeholders. The development of the back-end and front-end systems that is an integral part of the intervention is described in D1.3, D1.4, D1.5, D1.6. D2.1, D2.2, D2.3, D2.4, D3.1, D3.2, D3.3, D3.4, D3.5, D3.6, D3.7, D4.1, D4.2, D4.3, D4.4, D4.5, D4.6, D4.7, D4.9, D4.10.
To ensure participants' engagement with the intervention, all written content in the app was first completed in English and then translated to the native languages of the sites for conducting both the pilot and RCT studies (i.e., Danish and Norwegian) (D4.10).

4.4.1 Intervention content

The weekly self-management plans consist of the three main components that are tailored to the individual participant. An overview of the available content is presented in Figure 4. Each component is described in the following sections.

[4] The difference between eHealth and mHealth (which is used as a term in the 4.3.4 section) is explained by Quiñonez et al. (2016) like this: "The concept of eHealth (electronic health) has been described as the use of the Internet and related technologies to deliver health-related information and interventions. […] mHealth refers to the delivery of health messages and interventions via mobile phones or tablets by making use of telecommunication and multimedia technologies."
94. Gomez Quinonez, S., et al., *mHealth or eHealth? Efficacy, Use, and Appreciation of a Web-Based Computer-Tailored Physical Activity Intervention for Dutch Adults: A Randomized Controlled Trial.* J Med Internet Res, 2016. **18**(11): p. e278.(2016)

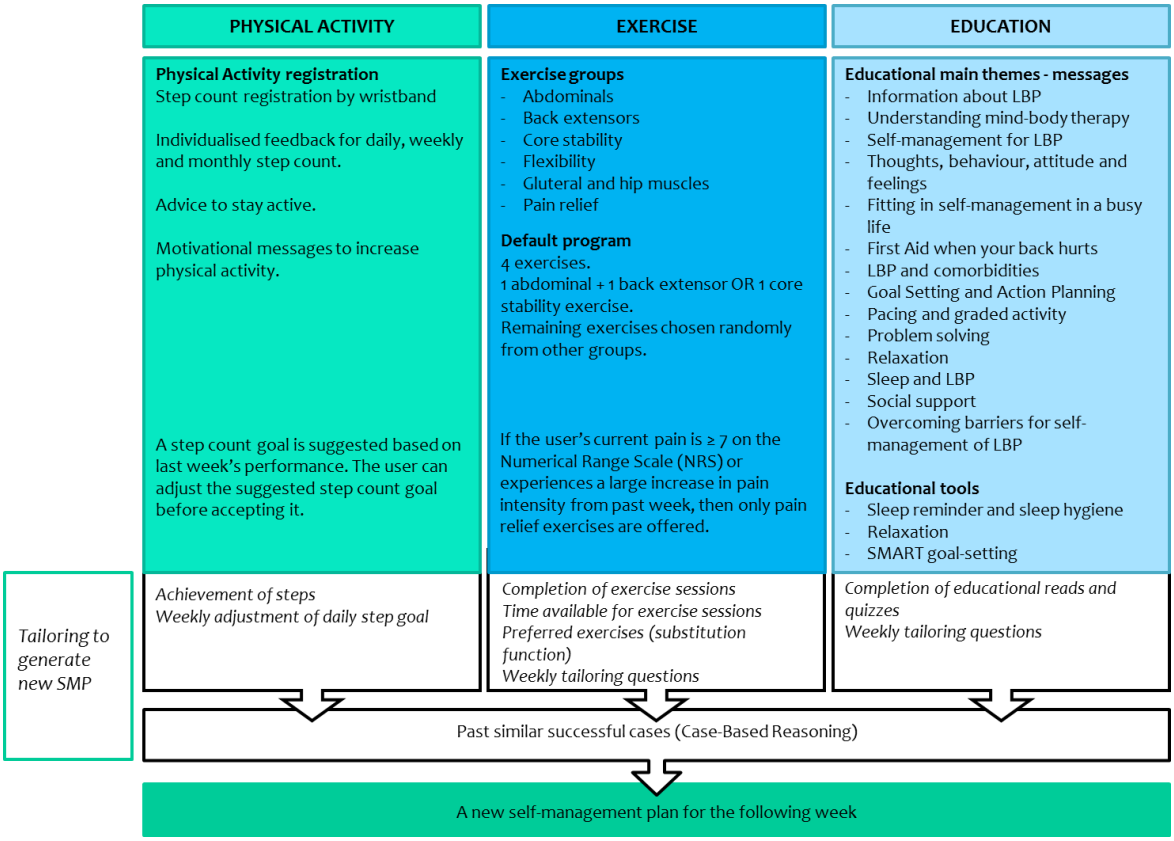

Figure 4 Overview of available content, tailoring and generation of new self-management plans

The **educational material** contains content arranged under 14 main themes as shown in Table 4. Sub themes have up to 14 variations, resulting in 184 unique short messages (e.g. cause of LBP 1, 2 and 3) and 49 quizzes. For all sub themes a tree structure of content in six different forms ranges under: 1) short messages, 2) quizzes with yes/no answering options followed by 3) the correct answer with a brief explanation, 4) long messages elaborating the short messages, 5) additional information texts supplementing the long message, and 6) interactive tools (e.g. goal setting). The content structure has three variations as shown in Figure 5. Only one short message or quiz is presented to the user each day but after completion (i.e. having read it/answered), the educational material will be put in the user's library where previous messages and tools can be accessed anytime. After the current day's educational material has been completed, completion is shown both as a circular progression bar and a fractional number.

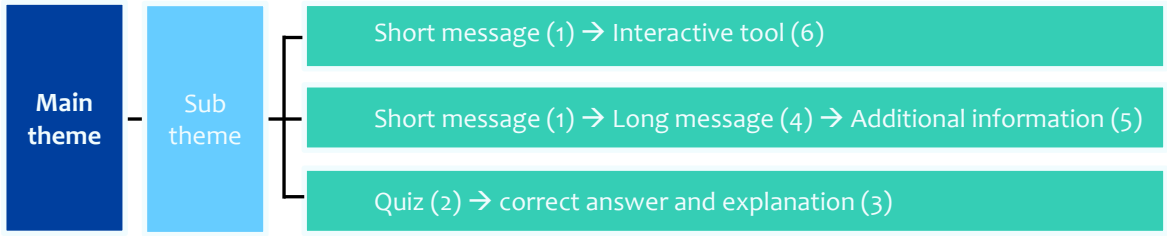

Figure 5 Structure of educational content

All short messages and quizzes are linked to a specific answering category for all tailoring questions. A library of all previously received educational materials is available to the user to access anytime. Additionally, three supportive tools are included; one for relaxation (mindfulness session for either 4 or 16 minutes), one for SMART[5] goal-setting, and one for sleep with a bedtime reminder.

Physical activity is tracked by users wearing a wristband detecting steps. Within the SELFBACK app the user sets a goal for their level of physical activity, to progress the level of physical activity a gradual increase in daily step count is suggested, if the goal was achieved within the past week. A 10% increase is suggested, until a goal of 10000 steps per day is reached. The user is allowed to adjust the suggested goal before accepting it. The achievement of daily steps is shown in the app as circular progression bars as well as the immediate step count alongside the daily goal. The user also has the opportunity to monitor the daily, weekly and monthly achievement of steps. In order to promote physical activity, notifications are sent to the user with encouraging messages for achieving the daily step goal and incorporating physical activity in daily life. To educate on the beneficial effects of physical activity for LBP patients and to motivate users to be physically active, the educational content of the app covers extensive aspects of these themes.

The user is presented with a **physical exercise** programme tailored to the individual patient. The recommended and default duration is 20 minutes 3-5 times weekly and includes 4 exercises performed in three sets with ten repetitions each or 3x30 seconds for each side for flexibility exercises. The number of exercises is adjustable to the user's time available for exercise and to the anticipated level of difficulty defined by the baseline questionnaire. An exercise programme is composed of either 1) one strength exercise for the abdominal and one for back extensor muscles, or 2) one strength exercise for the core muscles. Additionally, exercises targeting strength in the hip abductors and gluteal muscles, flexibility around the spine and pain-relieving exercises can be included into the programme. The exercises for each individual user are chosen from an exercise bank containing 70 exercises. The exercises are grouped as described in Figure 4, and comprise up to 6 levels of difficulty. Reports of acute pain flares or high pain ratings from a user will result in only pain-relieving exercises being offered. The level of difficulty within the exercise is progressed based on the volume of performed exercise as reported by the users themselves. The process for progression or regressing in level of difficulty is automated by the decision support system. Users also have the opportunity to substitute exercises based on personal preference (i.e. if the user dislikes an exercise an alternative exercise will be presented). The exercise instructions are video shots with a written instruction underneath. The video shows the exercise being performed in one set with ten repetitions. After completing an exercise, the user is asked to report how many sets and repetitions were completed. For flexibility exercises, the report on completion is a yes/no answer to a question "Did you perform the exercise?" Completion of exercise sessions is shown in the app as circular progression bars and a fractional number of exercises

[5] SMART is an acronym for Specific, Measurable, Attainable, Realistic and Timely. Goal-setting with the SMART model provides a structure for the user to consider all important aspects of setting a goal (and reaching it).

completed. Execution of exercise sessions are also promoted in the educational content. The user has the opportunity to access all previously received exercises anytime through the library. The exercise catalogue was linked to the tailoring question on average pain to monitor any development in pain that would lead to the users being offered pain relieving exercises only.

Additionally, a top bar panel presents the user with a daily summed completion for the three intervention components. If all three components are fully completed, a trophy (reward) is gained. In addition, a Statistics panel keeps track of other trophies achieved by the user. Trophies are achieved by completing daily goals for step count, exercise, education and general (overall) goals. Examples of these are: "Completed all exercises for the first/third/seventh/fourteenth day" (physical exercises), "Reached an average of 5000 steps/day in a week" (physical activity), "Reached your daily step goal for the first/third/seventh/fourteenth time" (physical activity), "Reached 10.000 steps in one day" (physical activity), "Completed the education read for the first/third/seventh/fourteenth day" (education), "Set a goal using the Goal Setting tool for the first time" (education), "Completed your first relaxation session using the Relaxation tool" (education), and "Completed all three activities on the same day for the first/third/seventh/fourteenth time" (general).

The app includes other supportive functions, e.g., longer texts about pacing and progression for physical activity and exercises; what self-management for LBP is, general information about LBP; a disclaimer section with information about what to be aware of and when to seek clinical care; and a First Aid Kit section for acute pain relief. Lastly, a Settings panel allows the user to adjust the app's settings for notifications and find technical support information.

4.4.2 Tailoring of content to create new self-management plans

The self-management plans will be generated using CBR, as described in D3.1-3.7. This technology utilises knowledge about previous patient cases along with data about the current patient case enabling a tailored intervention regime based on successful past cases of similar patients [98-100]. In addition to CBR, elements of model- and rule-based reasoning are applied to capture and utilise generalised knowledge. The data source for the CBR engine comprises all available data from the individual user. The weekly tailoring session entails 2-5 questions from a pool of eligible questions on pain intensity, functional ability, fear-avoidance, workability, sleep, self-efficacy, stress, overall health-belief and experience of barriers when self-managing LBP. The frequency of each question varies between one and eight weeks.

As users complete their weekly self-management plans they become new cases in the data storage if the outcome was successful (i.e. their pain level is at 2 or below or there was a decrease in pain of 2 or more). Since the plans are grounded in the system's growing experience of the effect of plans and the accompanying symptom progression, the prediction quality of SELFBACK will increase over time. In order to have initial cases in the data storage to match the initial participants, cluster analysis was performed on existing patient

data from the FYSIOPRIM and DPhacto cohorts (D1.3, D1.4, D1.5) to create seed cases (n = 6) that would have a distinct set of characteristics representative of different subtypes of LBP patients (defined by cluster analyses). A week 1 self-management plan was constructed for each seed case: the exercise program was drafted to match the specific case and revised by experienced physiotherapists. The educational content was also chosen based on the seed case's data and revised by an experienced clinician. Since plans for physical activity level are based on the participant's actual step count (to suggest a goal for the following week), this was not possible for the seed cases.

The self-management plan for the initial intervention week is generated from the participant's answers to the baseline questionnaire and similar successful cases by the CBR-system. During the initial week, the daily step count is tracked by the wristband and completion of exercises and educational sessions is reported by the user. After following the plan for seven days, the user is required to complete the tailoring questionnaire. The answers from these, together with information from the user, e.g., time available to exercise and preferred exercises, is put into the CBR engine to generate a new self-management plan for the second week (Figure 4). In order to ensure a relevant self-management plan for the users, they are recommended to use the SELFBACK app daily or at least once a week. Also, the app will send push-messages reminding the user to launch the app and complete their self-management plans.

4.5 Step 5 – Adoption and implementation

In this step, a plan for adoption and implementation was made – although the planning was carried out simultaneously with the previous steps. As stated in section 2.5, most of this work is reported in D5.1, although the protocol does not describe the theoretical underpinning for how recruitment sites adopt the SELFBACK intervention or how patients implement the SELFBACK app into daily life.

As stated in D5.1, adopters were identified as potential recruitment sites, i.e. clinics (GP, physiotherapy, chiropractor and outpatient hospital). The potential implementers are all the eligible patients from these clinics. The potential clinics were approached as described in section 4.1.

A matrix for adoption and implementation programme use outcomes and performance objectives was mapped to determinants informed by the NPT framework as described in section 4.3.1., and is presented in Table 5. The determinants are coherence, cognitive participation, collective action and reflexive monitoring. The practical applications for targeting the specified performance objectives were mapped to BCTs (Table 6). The practical strategies for adoption and implementation also included producing manuals for operation (e.g. project information leaflets to give to the HCPs as "advertisement" of the project, how HCPs practically recruit participants, and how the SELFBACK app is installed on a participant's smartphone etc.).

Table 5 Programme use outcomes and performance objectives for adoption and implementation

Programme use outcomes	Performance objectives		Determinants for embedment of digital intervention to everyday routine as per NPT [29, 30]
Adoption use outcome: **Recruitment sites adopt the SELFBACK intervention and participant recruitment procedures**	Performance objective 1	Agree to participate in SELFBACK trials (pilot or RCT) as recruitment sites	Coherence, Cognitive Participation
Adoption use outcome: **HCPs at recruitment sites implement the SELFBACK intervention and participant recruitment procedures**	Performance objective 2	Agree to recruit patients to participate in SELFBACK trials	Cognitive Participation
	Performance objective 3	HCPs complete training in recruitment procedures (identification of eligible patients based on a description provided by the research team)	Coherence, Cognitive Participation
	Performance objective 4	HCPs encourage patients to participate in SELFBACK trials as an add-on to usual care during intervention period	Cognitive Participation, Collective Action
Implementation use outcome: **Recruited patients engage in the SELFBACK intervention by implementing SELFBACK app in daily routines**	Performance objective 5	Patients make sense of the selfBACK intervention	Coherence
	Performance objective 6	Patients build and sustain engagement in the SELFBACK intervention	Cognitive Participation
	Performance objective 7	Patients invest efforts and resources in engagement in the SELFBACK intervention	Collective Action
	Performance objective 8	Patients evaluate engagement in the SELFBACK intervention	Reflexive Monitoring

Table 6 Programme adoption and implementation linking performance objectives and change objectives to practical applications

Performance objective	Change objectives	BCT to address each change objective as per BCT taxonomy v1 [36]	Practical applications
P.O. 1	Managers at recruitment sites provide verbal agreement to allow their service to implement SELFBACK	1.8 Behavioural contract	Verbal agreement from each recruitment site manager to: i. Allow their clinic to implement SELFBACK trials ii. Support participant recruitment to SELFBACK trials
P.O. 1	Managers at recruitment sites allocate resources (time) to support recruitment	1.8 Behavioural contract	Recruitment site managers nominate HCPs to receive instruction in recruitment pathway from selfBACK researchers
P.O. 2	HCPs develop an understanding of purpose, structure and content of the SELFBACK intervention	5.1 Information about health consequences of the intervention	HCPs read information about SELFBACK trials and receive information from researchers if further questions
P.O. 3	HCPs develop understanding of who eligible patients are	5.1 Information about health consequences of the intervention	HCPs read information about SELFBACK trials and receive information from researchers if further questions
P.O. 3	HCPs develop skills to initiate recruitment (new patients in clinics)	4.1 Instruction on how to perform a behaviour	HCP recruitment pathway training hosted by SELFBACK researchers
P.O. 4	HCPs inform eligible patients about the SELFBACK intervention	4.1 Instruction on how to perform a behaviour	HCPs give written information (flyer) about SELFBACK to patient and promote participation verbally
P.O. 5	Patients develop understanding of purpose and potential of the SELFBACK app	8.1 Behavioural practice/rehearsal	*Patients explore the features of the SELFBACK app by using it (regularly) **
P.O. 6	Patients initiate regular use of the SELFBACK app	8.1 Behavioural practice/rehearsal	*Patients launches and uses the SELFBACK app regularly **
P.O. 7	Patients prioritise regular use of the SELFBACK app	8.1 Behavioural practice/rehearsal	*Patients launches and uses the SELFBACK app regularly **
P.O. 8	Patients appraise the SELFBACK app and decide to sustain engagement	5.1 Information about health consequences 5.6 Information about emotional consequences	*Patients deem SELFBACK app as effective or helpful **

*Practical application is desired scenario

The final details are not yet in place as they will be further developed based on the experiences from the pilot study beginning in M30.

4.6 Step 6 – Evaluation plan

The evaluation plans for effectiveness on outcome measures and process evaluation are reported in the RCT protocol (D 5.1).

5 Conclusion and future work

This report provides a detailed description of the application of the IM approach to the development of the theory-driven complex SELFBACK intervention designed to promote self-management for LBP patients.

As IM is an iterative and non-linear process, testing the intervention in the up-coming pilot study will give reason to revise the process and go through the steps again. Especially the tasks of steps 4 to 6 will be revised based on the information and experiences gained through the pilot study. The future work in step 4 will be to revise and refine the intervention content based on feedback from pilot study participants. Steps 5 and 6 will be revised based on our experiences in delivering and evaluating the intervention during and after the pilot, prior to the RCT study.

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7 Appendices

7.1 Appendix 1

Table 7 IM process table documenting the development of the selfBACK intervention

Step in IM process	Subtask	Method	Result	T #	D #
Step 1 **Needs assessment**	• Establish a participatory planning group	• Planning group is given due to project structure with consortium members from medical and technical partners and a SME working on the commercial business plan for SELFBACK	• Planning group comprises all medical and technical partners, n ≈ 35 • Many of the planning group researchers have clinical background (physiotherapists, chiropractors, physicians and exercise physiologists)		
	• Conduct the needs assessment	<u>Literature reviews conducted:</u> • Burden of different diseases (non-systematic) • Recommended treatment of different diseases (non-systematic) • How well self-management fits into treatment of these diseases (non-systematic) • Clinical practice guidelines for LBP (non-systematic) <u>Qualitative studies:</u> • Individual interviews with persons currently or previously dealing with LBP (n = 8) from different countries (n = 2) regarding experience with traditional treatment of LBP, self-management of LBP, and need for and wishes to potential app to support self-management of LBP • Individual interviews with health care professionals (n = 2, GP and physiotherapist) regarding experience with self-management for LBP patients	• LBP is the most significant contributor to years lived with disability • Self-management is vital in LBP management • Main elements of LBP self-management are education, physical activity and physical exercises • Diversities in opinions regarding treatment – if HCP can provide "cure" or patient must self-manage by doing exercises • Positivity towards potential app but uncertainties regarding sustained engagement • Appraisal of evidence-based app from trustworthy source; recommendation from HCP would encourage usage • Role of and need for self-management often comes as a surprise for patients – high number	T1.1 T1.2	D1.1 D1.2

			of patients who rely on HCPs in curing the pain • Many patients believe that physical activity will increase LBP • Many patients believe a gym is needed to do physical exercises
	• Assess community capacity	• Initial indication from potential recruitment sites in each country to assess possibility for collaboration and potential recruitment sizes	• Meetings with Research Units and networks, direct contact to potential clinics • Applications to transmission of patient information and data access
	• Specify program goals for health and quality of life	• Accommodation to Horizon 2020 call – condition needs to be one where self-management plays a vital role and include a decision support system based on predictive computer modelling used by the patient him or herself • Knowledge and experience within planning group	• Program goal is to improve self-management of non-specific LBP to reduce pain-related disability
Step 2 **Matrices**	• State outcomes for behaviour and environmental change	<u>Literature reviews conducted:</u> • Core outcome domains and outcome measures for LBP (systematic, [2])	• 2 self-management behavioural outcomes for change specified
	• State performance objectives	• Behaviour change theory including behavioural outcomes related to pain, pain-related disability and self-management (non-systematic)	• 12 performance objectives specified; related to use of evidence-based self-management strategies (n = 7) or physical activity (n = 5)
	• Select important and changeable determinants	• Digital support interventions for the self-management of low back pain (systematic, [2]) • Barriers and facilitators to patient uptake and utilization of digital interventions for the self-management of low back pain (systematic, submitted) • Strategies to increase engagement in digital interventions for	• 7 determinants of self-management behaviour selected; knowledge/awareness, skills, behaviour regulation, fear, catastrophizing, self-efficacy, motivation/attitude
	• Create matrices of change objectives		• 12 performance objectives were mapped to the 7 determinants to create matrix of change objectives

		behaviour change (non-systematic) • Knowledge and experience among planning group members • Group discussions and workshops in planning group			
Step 3 **Theory-based intervention methods and practical applications**	• Generate program ideas with the planning group	Literature reviews conducted: • Updated - Clinical practice guidelines for LBP management (non-systematic) • Patient information and leaflets from guidelines (non-systematic) • LBP patient support websites (non-systematic) • Planning group reviewed program ideas and practical methods for the three main components of the intervention in consultation with behaviour change (i.e., CBT) experts	• Self-management of LBP should evolve around three main intervention components: education/information, physical activity and physical exercises		
	• Identify theoretical models	• Determinants of self-management behaviour mapped to theories for behaviour change and engagement in digital health interventions	• 8 TDF domains selected • 3 NPT domains selected	T2.4	D2.4
	• Choose program methods	• Planning group reviewed eligible program methods compatible with a digital intervention in consultation with technical partners • GLA:D® Back project planning group interviewed people with back pain (n = 8) and clinicians (n = 4) to get feedback on physical exercises included in SELFBACK intervention • GLA:D® Back project planning group hosted an additional feedback meeting for clinicians	• Advice to stay active and help to set a daily step goal, education on numerous aspects of low back pain self-management and specific exercises were chosen as main components of the intervention • Exercises were organised into six targets and then into difficulty levels		

		(n = 11) Results from this process were reviewed by SELFBACK planning group			
	• Select or design practical applications	• Planning group reviewed eligible practical applications compliant with a digital self-management intervention	• Facilitating strategies (e.g., gamification, tailored feedback, trustworthiness, rewards, reminders and easy navigation) were selected and incorporated in program methods		
	• Ensure that applications address change objectives	• Intervention content of the three main intervention components mapped to NPT domains, TDF domains and behaviour change techniques (BCTs) selected from the Behaviour Change Technique Taxonomy v1	• 17 BCTs were identified as being directly mapped to target behaviours of the intervention		
Step 4 **Intervention programme**	• Consult intended participants and implementers	• Tested a preliminary version of app among test users to investigate how users approach the app (n = 5) • Evaluated participant documents (e.g., invitation letter and information sheet) with members of the NRS Primary Care Research Network Patient Public Involvement Group (UK) (n = 12) to gain knowledge from stakeholder for potential implementers	• Experiences gathered gave input to design of SELFBACK app and intervention • Participant documents refined according to feedback		
	• Create program themes, scope, sequence, and materials list	• Smaller divisions of planning group created intervention content and then reviewed this with the planning group continuously, e.g. by having workshops and frequent meetings over period of app. 24 months	• Physical activity: tracking of steps with Xiaomi Mi Band 2. Weekly adjustment of daily step goal • Exercises: default programme consists of 4 exercises performed in 3 sets with 10 repetitions each. Weekly adjustment and tailoring of programme • Education: individually tailored messages, quizzes and interactive	T3.1	D3.1

		tools. New message daily, weekly tailoring • Intervention is fitted to be delivered through an app • New weekly self-management plans created by CBR-system		
• Prepare design documents	• SELFBACK logo, app design and wireframes and website created, reviewed and revised	• Colour scheme, font and illustrations chosen and created to match evidence-based intervention content	T4.1 T4.3 T4.4	D4.1 D4.2 D4.3 D4.6 D4.7
• Review available program materials	• Consortium and planning group meetings to review all intervention content to ensure uniformity and consistency	• Materials revised and adjusted accordingly		
• Draft program materials and protocols	• Technical partners created front-end and back-end solutions with input from medical partners to end up with a full working digital intervention delivered through an app • Participant documents drafted	• Frontend – design, user friendliness and technical support etc. • Backend – secure data storage, web questionnaire, CBR-system, rule engine, trigger of notifications etc. • Participant documents revised after meeting with NRS Primary Care Research Network Patient Public Involvement Group (UK)	T1.3, T1.4, T1.5 T1.6 T2.1 T2.2 T2.3 T2.4 T3.2 T3.3 T3.4 T3.5 T4.2 T4.4 T4.5 T4.6 T5.2	D1.3 D1.4 D1.5 D1.6 D2.1 D2.2 D2.3 D2.4 D3.2 D3.3 D3.4 D3.5 D3.5 D3.7 D4.4 D4.5 D4.6 D4.9 D4.10
• Pre-test program materials and protocols	• Clinicians evaluated exercise plans generated by CBR system • Clinicians evaluated education plans generated by CBR system • App design and usability evaluated by consortium members, external researchers and potential end users (n = 20 + 12 + 3) • Several rounds (after revisions and releases of new versions) of testing app versions among consortium members and external	• Data and input collected through all user tests and feasibility studies used to review and refine intervention and decision support system • Results, experiences and feedback from pilot trial will be used to refine SELFBACK system and app prior to RCT	T2.5 T4.4	Avai-ting D2.5 for UK feasibility study D4.6

		test users over course of 6 months (n = 24 (int.) + 20 (ext.) • Feasibility study (UK, n = 16) to explore feasibility and acceptability of baseline questionnaire, physical activity monitoring and feedback strategies (quantitatively and qualitatively evaluated) • Feasibility study (NO, n = 10) to explore feasibility, acceptability and design of the SELFBACK app, including the physical activity monitoring module, the exercise module, and the education module (quantitatively and qualitatively evaluated) • Pilot trial to test intervention planned to start in Sep 2018			
	• Produce materials and protocols	• Continuous work on revising and refining intervention content to app prototypes with input from consortium, planning group, user tests and feasibility studies • RCT protocol conducted simultaneously • Ethics committees and data protection agencies applied for pilot and RCT	• Local ethics and data protection approvals for DK and NO	T5.1 T5.3	D5.1
Step 5 **Adoption and implementation**	• Identify potential adopters and implementers	• Potential adopters identified as recruitment sites • Potential implementers identified as patient groups from each recruitment site	• Adopters identified through diverse channels and approached to agree on participation in SELFBACK project as recruitment sites	T5.1	D5.1
	• Re-evaluate the planning groups	• N/A			
	• State program use outcomes and performance objectives	• Group discussions among medical partners • Programme for adoption and	• 3 program use outcomes and 8 performance objectives specified		

	• Specify determinants for adoption and implementation	implementation underpinned by Normalization Process Theory	• 4 determinants for adoption and implementation selected;		
	• Create a matrix of change objectives		• 8 performance objectives were mapped to the 4 determinants to create matrix of change objectives		
	• Select methods and practical applications		• 5 BCTs were mapped to performance objectives and described as practical strategies for adoption and implementation		
	• Design interventions for adoption and implementation		• Materials to support HCPs recruitment of participants created		
Step 6 **Evaluation plan**	• Review the program logic model	• Reported in D5.1	• Reported in D5.1	T5.1	D5.1
	• Write evaluation questions				
	• Write evaluation questions for change in determinants				
	• Write process evaluation questions				
	• Develop indicators and measures				
	• Specify evaluation design				

7.2 Appendix 2

Table 7 Programme matrix for the SELFBACK intervention mapping content, BCTs and NPT

Intervention component	Target	Intervention content	BCTs	NPT
Physical Activity	Reduce inactivity	Track activity level by step count from wristband	2.2 Feedback on behaviour	Collective Action/ Reflexive Monitoring
	Reduce inactivity	Notifications on progress towards goal	1.6 Discrepancy between current behaviour and goal 5.1 Information about health consequences 10.4 Social reward 7.1 Prompts/cues 7.3 Reduce prompts/cues	Collective Action/ Reflexive Monitoring
	Increase activity	Notifications on achievement of daily step count	7.1 Prompts/cues 7.3 Reduce prompts/cues 5.1 Information about health consequences 10.4 Social reward	Reflexive Monitoring
	Set goal for physical activity	Weekly goal setting for step count	1.1 Goal setting (behaviour) 1.5 Review behaviour goal(s)	Collective Action
	Increase use of evidence-based self-management strategies	Rewards for achievement of physical activity (steps)	10.4 Social Reward	Reflexive Monitoring
Exercise	Increase muscle strength	Tailored exercise programme with strength exercises with volume sufficient to obtain muscle strength	4.1 Instruction on how to perform the behaviour 6.1 Demonstration of the behaviour	Cognitive Participation/ Collective Action
	Increase flexibility	Inclusion of flexibility exercise in the exercise programme	4.1 Instruction on how to perform the behaviour 6.1 Demonstration of the behaviour	Cognitive Participation/ Collective Action
	Set goal for physical exercises	Weekly goal setting for exercise volume (choose preferred duration which then corresponds to a certain number of exercises and sets based on programme rules for exercises)	1.1 Goal Setting (behaviour) 1.5 Review behaviour goals	Collective Action/ Reflexive Monitoring
	Adjustment of exercise programme - participant	Possibility of skipping and/or alternating exercise(s) in exercise programme to match participant's preference	4.1 Instruction on how to perform the behaviour	Collective Action/ Reflexive Monitoring
	Adjustment of	Adjust exercise difficulty based on	8.7 Graded tasks	Reflexive

	exercise programme – SELFBACK system	reported performed volume		Monitoring
	Reduce focus on pain	Inclusion of pain relieving exercise in toolbox of app and in individual participants program upon report of high or increased pain	5.1 Information about health consequences 5.6 Information about emotional consequences 9.1 Credible source	Coherence/ Cognitive Participation/ Collective Action
	Increase muscle strength and flexibility	Prompts/reminders for physical exercises	7.1 Prompts/cues 7.3 Reduce prompts/cues 5.1 Information about health consequences	Cognitive Participation/ Collective Action
	Increase use of evidence-based self-management strategies	Rewards for achievement of physical exercises	10.4 Social reward	Reflexive Monitoring
Education	Increase knowledge	Information about LBP (cause, guidelines, imaging, structure of back)	5.1 Information about health consequences 5.6 Information about emotional consequences 9.1 Credible source	Coherence
	Increase knowledge	Information about comorbidities	9.1 Credible source	Coherence
	Increase knowledge	Information about red flags	9.1 Credible source	Coherence
	Increase knowledge	Explanations of beneficial effects of physical activity and exercise	9.1 Credible source	Coherence
	Improve coping strategies	Education about understanding and accepting pain	6.1 Demonstration of the behaviour 9.1 Credible source	Coherence
	Improve coping strategies	Promotion/encouragement of cognitive and behavioural pain coping strategies (e.g. goal setting, action planning, pacing, problem solving, relaxation, distraction)	1.1 Goal setting 1.4 Action planning 6.1 Demonstration of the behaviour	Coherence/ Cognitive Participation/ Collective Action
	Improve coping skills	Practical guidance (tool) to learn goal setting	6.1 Demonstration of the behaviour	Coherence
	Improve coping skills	Practical guidance (tool) to improve sleep	6.1 Demonstration of the behaviour 12.6 Body changes	Coherence
	Improve coping skills	Practical guidance (tool) to mindfulness exercises/relaxation techniques	6.1 Demonstration of the behaviour 12.6 Body changes	Coherence
	Reduce negative thoughts and	Education about changing thought patterns to avoid catastrophizing and negative thoughts	5.1 Information about health consequences	Coherence

	increase positive thoughts		5.6 Information about emotional consequences	
	Improve positive attitude and mind-set	Promotion of a positive and 'in control' attitude	11.2 Reduce negative emotions	Coherence
	Reduce avoidance behaviour	Encouragement to stay physically active and continue with normal/everyday activities	5.1 Information about health consequences 5.6 Information about emotional consequences	Coherence
	Reduce avoidance behaviour	Reassurance about the favourable prognosis	5.1 Information about health consequences 5.6 Information about emotional consequences	Coherence
	Reduce avoidance behaviour	Reassurance that pain does not mean harm	9.1 Credible source 5.1 Information about health consequences	Coherence
	Reduce avoidance behaviour	Reassurance that physical activity and physical exercises will not increase pain permanently but might do briefly	9.1 Credible source	Coherence
	Increase social support	Encouragement to ask for and accept help and support from family, friends and work	3.1 Social support	Cognitive Participation
	Increase use of evidence-based self-management strategies	Prompts/reminders to read educational messages	7.1 Prompts/cues	Cognitive Participation/ Collective Action
	Increase use of evidence-based self-management strategies	Rewards for achievement of educational materials	10.4 Social reward	Reflexive Monitoring
General	Increase use of evidence-based self-management strategies	Prompts/reminders to launch and explore SELFBACK app	7.1 Prompts/cues	Cognitive Participation/ Collective Action
	Increase use of evidence-based self-management strategies	Rewards for general achievements general (combined achievements for physical activity, physical exercises and education; tailoring sessions; introduction session)	10.4 Social reward	Reflexive Monitoring
	Increase use of evidence-based self-management strategies	Education and advice from trustworthy source	9.1 Credible source	Coherence
	Increase use of evidence-based	Pain relief (First Aid Kit)	9.1 Credible source	Coherence

	self-management strategies		5.1 Information about health consequences	
	Increase use of evidence-based self-management strategies	Disclaimer (what to be aware of and when to seek professional help	9.1 Credible source	Coherence