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The engagement of healthcare providers in implementing the selfBACK randomised controlled trial – A mixed-methods process evaluation

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Abstract

Background: People with low back pain (LBP) are often recommended to self-manage their condition, but it can be challenging without support. Digital health interventions (DHIs) have shown promise in supporting self-management of LBP, but little is known about healthcare providers' (HCPs) engagement in implementing these.

Aims: We aimed to examine HCPs' engagement in patient recruitment for the selfBACK app clinical trial and explore their perceptions of the app.

Methods: In a mixed-methods design, we conducted a process evaluation alongside the selfBACK trial, triangulating quantitative data from trial recruitment logs and a vignette-based survey, and qualitative data from trial procedure documents, interviews with HCPs, and survey free-text responses. From 2019 to 2020, we recruited 57 HCPs from Norway and 39 health clinics in Denmark and collected quantitative and qualitative data in parallel. Results were integrated using displays.

Results: Overall, 825 patients were recruited by the HCPs. The vignette-based survey showed high agreement among HCPs (n = 62) with the self-management plans generated by the app (84.1–88.9%) but also highlighted concerns about tailoring and content. Interviews with HCPs (n = 19) revealed challenges with recruitment due to busy schedules, competing tasks, and varying levels of interest and engagement in the study.

Conclusions: The study identified factors that impact HCPs' engagement in recruiting patients for the selfBACK trial and highlighted overall positive views of the selfBACK app, although some concerns about the content and tailoring of the app were raised. Understanding HCP motivations and workload is crucial for the successful implementation of DHIs in clinical practice.

Keywords

Low back pain, self-management, mHealth, digital health, clinical trial, healthcare providers, primary health care

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Background

Low back pain (LBP) affects up to 80% of the global population at some point in their lifetime and is one of the leading causes of disability worldwide.[1] People with LBP are recommended to self-manage their symptoms[2,3] for example by undertaking education and exercise but this can be challenging without support.[4,5] Digital health interventions (DHIs) provide an opportunity to support self-management of LBP and there is some evidence to suggest such interventions can be effective in reducing pain and back pain-related disability.[6] Further, they may be important in reinforcing healthcare providers' (HCPs) advice on self-management.[7,8]

The implementation of DHIs for LBP has been studied from patients' perspectives.[9,10] However, less is known about HCPs' engagement in the implementation of DHIs and their views on using such tools in their clinical practice. This is important to understand since HCPs often signpost patients to DHIs, and HCP views can significantly influence patients' views on self-management activities.[10] Known barriers to recruitment in pragmatic trials are the recruiting HCPs' lack of experience with research procedures and high workloads or competing tasks. Whether similar or more complex barriers exist regarding the recruitment of patients to randomized controlled trials (RCTs) of DHIs and specifically a DHI for LBP remains unclear.

We evaluated the effectiveness of a knowledge-based artificial intelligence-based app (selfBACK) in an RCT in primary care settings in Denmark and Norway.[11] The selfBACK app was developed to support individually tailored and evidence-based self-management of LBP.[12,13] Results of the RCT indicated a small but favourable effect of the app-based intervention compared with usual care on LBP-related disability among patients receiving primary care.[11] A process evaluation was conducted alongside the RCT to understand the implementation of selfBACK viewed from the perspective of both patients[10] and HCPs who recruited patients to the study.

Aims

This mixed-methods process evaluation aims to examine HCPs' engagement in patient recruitment for the selfBACK app clinical trial and explore their perceptions of the app.

Methods

Overall approach

We used a mixed methods design with data triangulation, allowing for the simultaneous independent collection of both quantitative and qualitative data, with integration in the interpretation. Data was collected during the selfBACK RCT conducted from March to December 2019.[14] We undertook separate analyses of the quantitative and qualitative data and then contrasted and compared the results while giving equal weight to each type of data (Figure 1). Quantitative data was collected using RCT recruitment logs and an online, vignette-based survey (which included self-management plans) of HCPs in the primary care sector (general practitioners [GPs], physiotherapists [PTs], and chiropractors) who had agreed to participate in the RCT. Qualitative data were collected in the form of documents on RCT procedures, interviews with HCPs and free-text response options in the survey. The analyses were underpinned by Normalization Process Theory (NPT), a theory frequently used to examine implementation processes. An overview of the aims, NPT constructs, and qualitative and quantitative data is provided in Supplementary File A. The quantitative data are reported in accordance with the reporting of a cross-sectional design following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE, Supplementary File B) guidelines, while the qualitative data are reported following the criteria of the Consolidated Criteria for Reporting Qualitative Research (COREQ, Supplementary Files B).

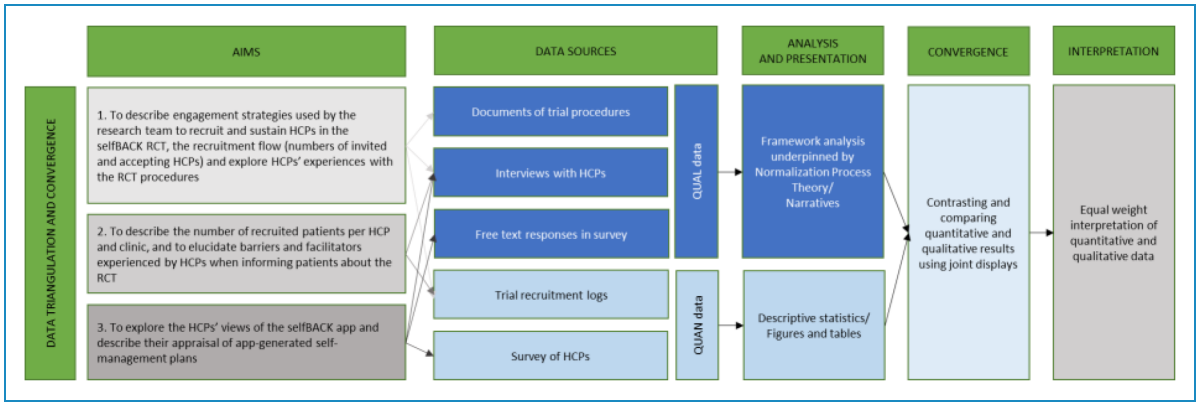


Figure 1. Data sources and triangulation using a mixed-methods convergence model

Settings and participants

All GPs, PTs and chiropractors practising within the primary healthcare setting in the Region of Southern Denmark or Trondheim Municipality in Norway were eligible for the RCT. All three HCP groups act as first-entry contact points for patients with LBP into the healthcare system. Overall, the Danish and Norwegian healthcare systems are comparable with universal, tax-funded healthcare systems and fair similar organisations and roles of the HCP in this study.[15]

Recruitment strategy and logs

While trial procedure documents were similar in Norway and Denmark, due to slight differences between the Norwegian and Danish settings, minor modifications to the recruitment strategies were applied to each setting. The differences are described in detail in Supplementary File C. Generally, the recruitment strategy included an introductory meeting or visit from the research team at the clinic explaining the recruitment procedures. During the recruitment period, regular visits were made to all clinics, including bringing chocolate and handing out mugs with the selfBACK logo. As part of the RCT procedures, HCPs had to identify potentially eligible patients using a short list of inclusion and exclusion criteria (e.g., non-specific LBP of any duration), briefly inform them about the RCT, and ask for their permission to be contacted by the research team. The HCPs also had to register the patient's name and phone number either on a weekly list (Denmark) or by taking a photo and sending it by multimedia messaging service (MMS) to the research team (Norway). A member of the research team would then contact the patient, provide information and screen for eligibility (including a score of 6 or above on the Roland-Morris Disability Questionnaire [RMDQ]).[16] The clinics and HCPs were financially compensated for their time (Supplementary File C). Detailed recruitment logs of patients accepting and declining (with reasons) were kept in both Denmark and Norway. Due to the differences in recruitment procedures and settings, we registered the number of recruited patients by individual HCPs in Norway and by clinics in Denmark. In Denmark, 224 patients were recruited from a secondary care spine centre, and 16 patients self-referred to the project using contact information on flyers. Due to a lack of time and funding, results regarding the recruitment of these patients are not included in this report.

Vignette-based survey

To explore the HCPs' view on the self-management plans created by the app, we conducted a cross-sectional online survey showcasing five vignettes of fictitious selfBACK patients in March 2020. The patient profiles were constructed using cluster analysis on real patient data from the selfBACK database. We pre-selected patient characteristics to be included in the cluster analysis (demographics and pain characteristics [i.e., intensity, duration, and disability]). A simulated self-management plan developed by the selfBACK system to match the patient profile was provided alongside each vignette. For each vignette, five statements on the appropriateness and relevance of the plan were presented and the HCPs were asked to indicate their level of agreement on a 5-point Likert scale with response options from "Completely agree" to "Completely disagree" (Supplementary File D). In addition, we queried HCPs' characteristics and their use of LBP clinical guideline recommendations on physical activity, patient education, and physical exercises. The questionnaires were developed for this study in Danish and piloted by a GP and a chiropractor in Denmark with no connection to selfBACK, and minor revisions were made. Next, it was translated into Norwegian and distributed via email in both Denmark and Norway to HCPs who had actively recruited patients for the RCT.

Data were analysed descriptively using STATA© vs.18, reported as frequencies and proportions, and tested for differences across nationalities and professions using Chi2-test.

Interviews with healthcare providers

Study population. The study population consisted of the primary care HCPs (GPs, chiropractors and PTs), who had agreed to recruit for the RCT. We used a purposive sampling strategy to recruit HCPs from all three professions by balancing recruitment from clinics that recruited the most patients (*high recruiters*) and the least patients (*low recruiters,* based on the recruitment logs). The HCPs were invited to participate in an interview via phone and email. In Denmark, 14 HCPs were contacted via phone, whereafter an email with information about the study was sent. In Norway, invitations were sent via email to 19 HCPs. In total, 19 HCPs (12 in Denmark, 7 in Norway) agreed to participate.

Data collection. Exploratory, descriptive interviews were conducted in the native tongue of the HCP (Danish and Norwegian) by two female research assistants from the selfBACK team from January to March 2020. A pilot-tested, fixed interview guide was used including questions relating to HCPs': (1) reasons for participating in the selfBACK project, (2) selection of patients to the RCT, (3) views on how the selfBACK app may have supported patient self-management, (4) in-clinic procedures for referral of patients to the RCT, (5) experiences with recruitment of patients, and (6) the impact of the selfBACK RCT on daily clinical practice. The interview guide is presented as

Supplementary File E. The 19 interviews each lasted approximately 20 min and were audio recorded and transcribed verbatim.

Data analysis. Qualitative data were analysed using Ritchie's framework analysis.[17] This method is particularly suitable for recognizing and visualizing patterns of themes, within and across individual interviews. Table 1 shows the analytic steps. In the second step (identifying a thematic framework), we used NPT and a structured coding framework to analyse data in a deductive manner,[18] but also inductively to allow for the development of themes that fell outside the coding framework. Transcripts were analysed in the original language. Quotes were translated into English and the correctness of these translations was confirmed by the Danish and Norwegian co-authors.[6]

NPT was then applied to understand the implementation process further. It consists of four main constructs (*coherence* (making sense of the work involved in the app and RCT); *cognitive participation* (engaging with the app and RCT); *collective action* (operationalization work, investment of resources to complete required tasks); and *reflexive monitoring* (appraisal work, evaluation and reflection on the app and processes)) and helps understand the process by which the selfBACK RCT was operationalised and sustained in clinical practice.[19–22]

Integration of quantitative and qualitative results

Integration of quantitative and qualitative data is a unique attribute of mixed methods research.[23,24] In this study, we used joint displays to converge results from the different data sources. Joint displays are tables or figures that can organize mixed data collection and analysis. Juxtaposing results enables contrasting and comparison of data and may reveal novel patterns and relationships that would have been masked without the mixed methods design, thus, broadening both the scope and depth of understanding.[24] In the presentation of the convergence of findings, we have mapped the quantitative findings onto the themes identified in the interviews and defined agreement as those who have answered "agree" or "completely agree" in the survey.

Ethical considerations

The selfBACK RCT, including the qualitative process evaluation, was registered with ClinicalTrials.gov (NCT03798288) and approved by national ethical committees in Denmark (S-20182000-24) and Norway (2017/923-6). All HCPs provided written signed informed consent for participation in the study and were informed that interviews would be recorded before arranging the interview. Clinics and HCPs were reimbursed for recruiting participants to the trial (Supplementary File C), but no reimbursement was given for participation in the interview or survey.

Results

Recruitment

Table 2 summarises the recruitment into the RCT through the 57 Norwegian HCPs and 39 Danish clinics that participated. This study considers the recruitment of 825 patients from GPs, chiropractors and PTs. Not included in this report are 224 patients recruited from a secondary care spine centre in Denmark, and 16 patients self-referred to the project using contact information on flyers

Vignette study

Sixty-two HCPs (9 GPs, 28 chiropractors and 25 PTs) responded to the vignette-based survey (Supplementary File F). The distribution of HCPs' responses is presented in Figure 2 using vignette 4 as an example. Vignettes 1–5, the suggested self-management plans, and the distribution of HCPs' responses are represented in Supplementary File D.

HCPs showed high agreement (84.1–88.9%) with the suggested self-management plans with GPs exhibiting the highest agreement (75.0–100%) and PTs the least (76.5–88.9%).

Agreement with the individual content components was also high (41.7–93.8%), with over 50% of HCPs agreeing with 17 out of 20 content components. Exceptions were steps in vignettes 1 (41.7%) and 4 (42.2%) and exercises in vignette 5 (48.9%). Free-text responses indicated some concerns about the low recommended number of exercises.

Agreement was highest in vignette 2 (63.0–89.1%), and lowest in vignette 4 (42.2–73.3%). In vignette 4, some PTs and chiropractors suggested alternative exercises. In vignette 4, all three groups of HCPs pointed to the relatively low recommended number of steps, but many also indicated that the patient's type of job (walking many steps) was important for determining a relevant number of recommended steps. Finally, some comments from the HCPs indicated that the provided information was insufficiently tailored and too general for the patient, although no alternatives were suggested.

Across the self-management plans, educational content had the highest agreement (73.3–93.8%), while the number of exercises received the least agreement (48.9–71.1%). GPs consistently agreed the most, followed by chiropractors, and PTs the least. Suggestions for alternative exercises were provided in the free text, particularly by PTs. Except for 3 variables out of 30, we did not observe any statistically significant differences across nationalities (data not shown).

Table 1. The analytic steps of the interviews with healthcare providers.

	Step 1	Step 2	Step 3	Step 4	Step 5
Analytic steps	Familiarisation	Initial thematic framework	Indexing and sorting	Charting and summarizing	Interpretation and abstraction
Analytic process	Familiarising with data and identifying preliminary themes	Constructing an initial thematic framework for organising data	Identifying, labelling, and sorting data into the themes	Summarising and displaying data in framework matrices	Synthesising the findings and offer explicit and implicit explanations of findings.
Conducting the analysis	MJS read the transcripts and noted initial impressions.	MJS operationalised the May 2022 coding framework to the interviews with healthcare providers assisted by BN and FM	MJS read each sentence and paragraph of the transcripts in fine detail and labelled and sorted it deductively. Uncoded text/text falling outside the coding manual was scrutinised for relevance to the topic, and if deemed relevant, inductive labelling was applied.	MJS extracted framework matrices, wrote summaries and identified detected elements. MJS, BN, KW and FM discussed and re-organised detected elements and identified key elements according to the HCPs' level of recruitment.	MJS wrote initial narratives describing the key elements and selected quotes. BN, KW and FM discussed and commented on the narratives.
Analytic tool used	Electronic and paper files of transcripts	Literature search	NVivo	NVivo Excel Word	Word
Units of analysis	19 transcripts	5 initial themes with 20 subthemes	10 themes with 20 subthemes	9 themes with 15 subthemes	2 themes and 8 subthemes

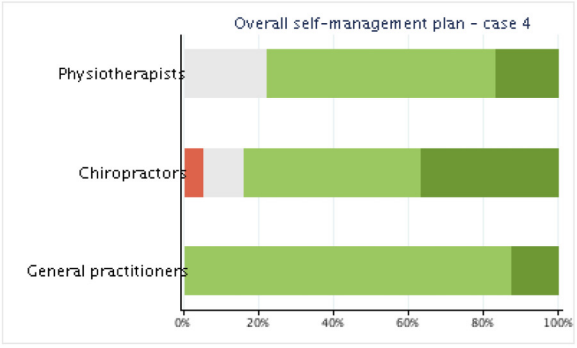
Table 2. Numbers of healthcare providers (Norway) and clinics (Denmark) and the number of patients they recruited to the selfBACK RCT.

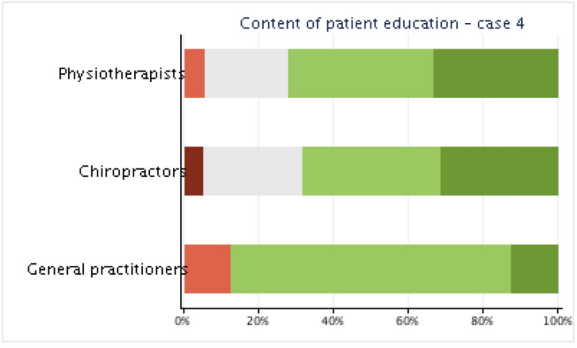
	Norway (healthcare providers)				Denmark (clinics)				
	GP	Chiro	PT	Total	GP	Chiro	PT	Mixed	Total
Participated in local meetings, n	31	18							
Signed up after the meeting, n	15	18							
Contacted after the meeting, n	51	23	38	112	18	13	33	12	76
Accepted participation, n (% out of those contacted)	41 (80)	21 (91)	29 (76)	91 (81)	4 (22)	11 (85)	19 (58)	8 (67)	42 (55)
Declined participation*, n (%)	6 (12)	0	8 (21)	14 (13)	14 (78)	2 (15)	14 (42)	4 (33)	34 (45)
No answer, n (%)	4 (8)	2 (9)	1 (3)	7 (6)	0	0	0	0	
Actively recruited, n (% out of those who accepted)	22 (54)	17 (81)	18 (62)	57 (62)	3 (75)	11 (100)	18 (95)	7 (88)	39 (93)
Recruited patients**, n [range]	96	83	94	273	18 [2;14]	318 [1;129]	216 [2:35]	-	552
Mean recruitment per type of HCP/ clinic	4.4	4.9	5.2	4.8	6	28.9	12	-	

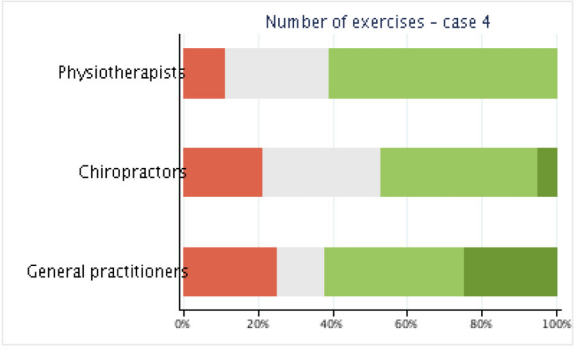
*HCPs' reasons for declining participation:
In Norway, 5 out of 8 PTs declined due to time constraints. Even though selfBACK seemed interesting, they had recently been involved in another research project.
In Denmark, GPs from clinics who declined told us it related to being too busy/too much work. PTs who declined said they were not interested, their patients were not eligible for selfBACK (specialised clinics), or they did not have the time to be involved in the project.
** Patients recruited from the mixed clinics were recorded as patients from chiropractic clinics.
Abbreviations: GP = general practitioner, Chiro = chiropractors, PT = physiotherapists, HCP = Healthcare provider.

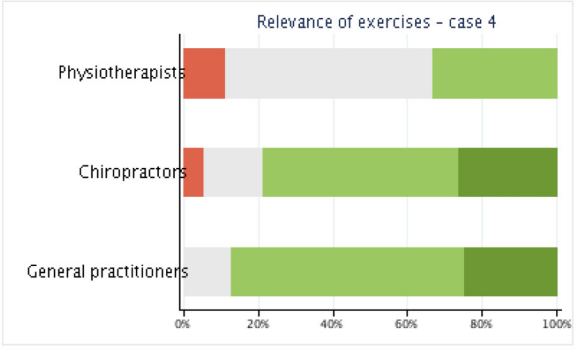
Case 4
62-year-old male, full-time employed in a position that primarily consists of walking. More than 13 years of education. Low back pain for more than 3 months. Pain intensity is constant at 6 out of 10. No problems with falling asleep but awakes repeatedly during the night several times a week. He changes position often to relieve symptoms. He has to lie down often to rest during the daytime and thinks that physical activity aggravates pain. He has reduced his work and leisure time level of activity during the past year and takes pain medication daily. No stress, nervousness, or depression. He also suffers from upper back pain and osteoarthritis. BMI=25.5.

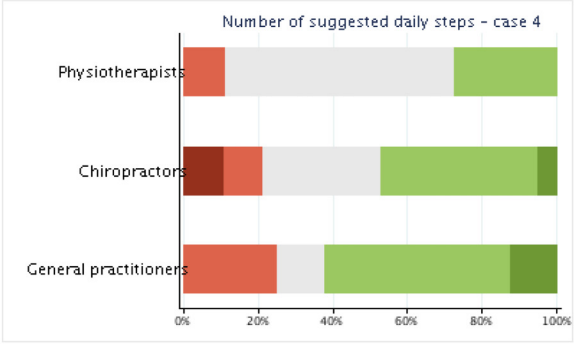
Suggested plan*
Steps: Recommended 3500 daily steps
Exercises: 15 minutes (3 exercises), including core stability (level 1), stretching, and pelvic tilt/lift (level 1)
Patient education: 8 messages focusing on increasing physical activity, pain management, problem-solving, and reassurance.











Extract from free text responses:
Agreement between GPs, chiropractors and PTs about lack of exercise relevance, but suggested alternatives varied greatly (including strength, stretch, cardiovascular, and functional exercise). Too few were recommended, but depends on the type steps of job, job exposures and number of steps taking during work hours. The patient education not sufficiently tailored and perhaps too general for the patient.

Figure 2. The distribution of the healthcare providers' responses in the vignette-based survey using vignette 4 as an example.

Table 3. Overview of themes and sub-themes

Theme 1. Shaping HCPs' motivation and willingness to participate in the RCT
1.1 The Societal needs for digital interventions
1.2 Current situation in the primary healthcare sector
1.3 Alignment with HCPs' beliefs and practice
1.4 Value for patients
1.5 Legitimacy and acceptability of an app as a means to promote self-management
Theme 2. Enacting the procedures of a research project
2.1 Working together to implement new procedures
2.2 Autonomous eligibility criteria govern recruitment
2.3 Sustaining engagement with the RCT

Interviews with HCPs

Interviews were undertaken with four GPs, eight chiropractors and seven PTs (n = 19) with 9 to 31 years of clinical experience. The interviews led to the identification of two main themes with eight subthemes (Table 3). Throughout, NPT constructs are noted *(in brackets)* to aid the understanding of the implementation process at play, and supporting citations from the interviews are used to illustrate results. The labelling of the participants indicates their profession and nationality (e.g *Chiro2_No* is a Norwegian chiropractor)

Theme 1: shaping HCPs' motivation and willingness to participate in RCT recruitment

The societal need for digital interventions. HCPs acknowledged the increasing use of smartphones in society and the high levels of trust in digitally conveyed information, especially by younger people. However, concerns were expressed about the increased prevalence of musculoskeletal pain and LBP in society at large together with the need for people to exercise to stay healthy and the necessity of finding viable solutions to promote physical activity and healthy lifestyles.

> Chiro2_No: "But they all sit with a smartphone and everybody wants easy solutions."

Several HCPs expressed the need for HCPs to join in with the trend of using digital solutions, as expressed by a chiropractor:

> Chiro1_No: "In a way, it is an important study, because, with the general increase in musculoskeletal disorders and back pain, I think, we need to find out more about what we can do and everybody knows that physical activity, movement and exercise is healthy and good."

Current situation in the primary healthcare sector. GPs in particular felt that people with LBP were a large part of their workload but with few treatment options available.

> GP1_No: "… I think it is a really large group of patients, so I think it would be really good… because we need tools. I don't always feel we have much time to go through all the exercises, and then it would be great if we had something concrete, and perhaps… it might become an alternative to the prescription pad or referrals…"

Busy schedules and time constraints were also expressed by PTs and chiropractors. However, another issue, unique to GPs, was that available treatment options might not always be acceptable to patients or GPs. GPs described the appeal of an alternative app-based solution to initiate self-management and exercise for LBP patients.

> GP1_DK: "Also, there are some patients who can't afford physiotherapy, but most have a smartphone."

Alignment with HCPs' beliefs and practice. The HCPs' willingness to participate in the RCT was strongly linked to their beliefs about the importance of patient self-management and exercise when experiencing LBP and how that can be achieved.

> PT4_DK: "But it is the self-understanding that you [the patients] need to take responsibility when something needs to be done".

Advising on self-management, providing information about LBP and instructing about exercises were important parts of HCPs' usual practice, with the app perceived to complement this practice *(NPT construct: Coherence)*.

> PT2_No: "The thing about educating the patients in pain and understanding how they affect the pain, and how pain affects your behaviour, is something that emphasize a lot when I talk to my patients."

In particular, PTs and chiropractors elaborated on the potential of the app as an extension of their current practice. A chiropractor explained how having "*as many different tools as possible*" (Chiro5_DK-1) in the toolbox was necessary to target different types of patients - the app might target patients that would otherwise not be easily supported.

> PT4_DK: "I think there is a nice connection [between usual practice and selfBACK]. They [the patients] get the sense of how important is to do something themselves and find out what is good for them, what is the right direction to take. And the constant reminder, that is also a part of our job, to try to pass on the responsibility, because one thing is the visit here once a week or whatever, but we are only a tiny fraction of what needs to be done."

The HCPs felt the app helped to reinforce their advice by repeating information given during the consultation. HCPs' understanding of their professional roles and responsibilities concerning self-management influenced HCPs' willingness to participate. One chiropractor perceived themselves as a guide, while the key to health mainly relied on the patient's work between consultations.

They described chiropractors as "*motivators*" with the obligation to "*stimulate*" *(Chiro3_NO)*, while a PT articulated their role as "*give them [the patients] the responsibility" (PT4_DK)* for their health. However, one PT also recognized that many patients struggle to self-manage when treatment ends.

> PT1_DK: "They are often left somewhat on their own when they leave"

Finally, a few HCPs described an aspect of altruism in their professional roles by expressing an obligation to contribute to research and the development of their professions. A focus on their professions and practice and not specifically on their patients was described by two HCPs:

> PT3_DK: "We think it is interesting to be part of such projects and to be in developing the profession. We have students for the same reason, and because we have a responsibility when having a clinic as large as ours."

Value for patients. Some HCPs' motivation and perception of the potential value of the RCT was positively influenced by the possibility that the patient would be offered a specific treatment element (the app) when participating in the RCT, and that the content did not conflict with treatment already offered by the HCP *(NPT construct: Coherence).*

> PT5_DK: "There is a lot of research for the sake of research, and not so much [direct benefit] for the patient. In this project, they [the patients] would benefit continuously… and it is a supplement to what we do."

The HCPs had been briefly introduced to the app and shown its' features but had not had the opportunity to use the app themselves yet they were overwhelmingly positive about the perceived benefits for patients *(NPT construct: Coherence)*. The app was recognized as a tool that was immediately available for patients (as opposed to waiting for a clinical appointment) and allowed patients to revisit information in their own time. Behaviour change components of goal setting, monitoring, feedback, rewards, and motivational messaging were recognized as engaging and motivating. Information in the app was praised as educational, reassuring and with the potential to change the patient's mindset about LBP. It was perceived by many as an extension of their consultation with repetition of the information provided verbally.

Legitimacy and acceptability of an app as a means to promote self-management

The familiar content and perceived timeliness of the app as an innovative, assistive technology for patients, shaped HCPs' agreement with the intervention as a means to promote self-management and value as a supplementary tool in clinical practice *(NPT construct: Cognitive participation)*. Provided patients were informed about symptoms indicative of a serious pathology like cauda equina, HCPs approved of the app as safe to use. The scientific foundation and evidence-based content added to the perceived quality and trustworthiness of the app.

> GP2_No: "Back pain is rarely dangerous in any way, so I think it is safe for the patient. And it is so that there is always the possibility of adding red flags too, and if that happens, you [the patients] can contact a GP."

However, one GP voiced their concern about self-monitoring potentially leading to over-vigilant attention to variation in health and, thus potential over-use of health services.

> GP2_NO: "But I'm against going around and over-registering all values during a day…if it is blood pressure, heart rate and so on, then, people become too occupied with health, and the slightest deviation can lead to horror and anxiety and over-use of health services at worst."

When asked what could have been done differently, several HCPs would have liked to know more about how the selfBACK system tailored content to individual patients or would have liked to be able to follow up on or add content to the app.

> Chiro2_DK: "I use apps for almost all patients, so I'm used to guiding people through the app… I go in and adjust the exercises the apps suggest, when I have them [the patients] in my consultation, so that I can find the threshold for what they can tolerate, but that is difficult [with the selfBACK app]."

These findings suggest that, although HCPs were generally positive about the app as a supplement to clinical care, it may also potentially infringe on clinical autonomy and decision-making.

Theme 2: enacting the procedures of a research project

Working together to implement new procedures. The HCPs commended the research team for setting up very easy-to-follow RCT procedures but described difficulties getting into new working habits *(NPT construct: Cognitive participation)*. Further, the team was praised for being consistent and persistent in their contact with the clinics and HCP personnel. Frequent, personal follow-up visits created a sense of ownership of the project and kept the project at the forefront.

> "I think the personal contact was good, that everything isn't done by email or telephone, but you actually meet…you probably have a little more, that is a deeper relationship to it [the RCT] and a little more ownership" (Chiro5_1_DK)

While low recruiters described difficulty in fitting new procedures into their busy clinical schedules, high recruiters described a range of active strategies to overcome these barriers.

A chiropractor *(Chiro3_DK)* had delegated the responsibility of handling patient lists and following up on the HCPs' work to the clinic secretary who regularly "poked" the HCPs for patients. At another clinic, recruitment was discussed at weekly staff meetings, and a competition was created to recruit the most patients.

High recruiters often described extra efforts or strategies that they had implemented to facilitate or sustain recruitment, which were not mentioned by low recruiters. For example, using visual cues (post-its or recruitment documents within eyesight, mugs) or making notes in patient files, to remind themselves to inform patients about the RCT. Often patient leaflets were distributed in multiple places in the clinics and in one PT clinic, electronic information screens in the waiting area were used to inform the patients about the RCT.

> "We actually had some [leaflets] all over the place, also in the office where we sit by the computer. And that was intentional so that we would remember." (PT4_DK)

One chiropractic clinic (part of a practice-based research network) had previous experience with research projects and participated in the selfBACK pilot study, which facilitated organizational readiness to implement active strategies.

> "We have a maximum number of projects that we can handle in the clinic, both in relation to us [the HCPs] and the secretaries who are also involved in providing information" (Chiro1_DK)

Working together with other staff members and creating communities of practices beyond what was requested by the research team increased buy-in to drive recruitment procedures forward and contrasted with low recruiters who were less likely to mention specific strategies or did not get around to implementing intended initiatives.

Autonomous eligibility criteria govern recruitment. In addition to the RCT eligibility criteria, most HCPs added a layer of their own criteria when recruiting patients *(NPT construct: Cognitive participation)*. The individual criteria differed between high and low recruiters and were sometimes conflicting in nature.

High recruiters generally found it easy to decide which patients to include, and a GP *(GP2_No)* stated that s/he simply informed all LBP patients about the RCT. The GP mentioned telling the patients about the project briefly and letting the research team do the rest. Most HCPs described striving to find "the right" patients. Several high recruiters selected patients with more LBP episodes and longer duration of pain as eligible candidates, while not recruiting those with short duration of LBP and few symptoms. Other criteria mentioned were patients who were perceived to need structure, self-management tools and exercise, those with little time to exercise and those who are tech-savvy. Some high recruiters mentioned not recruiting patients who were perceived to be demotivated for self-management or not committed to treatment in general.

> "So, there might have been some that I excluded as I was thinking, this is never going to… you will never live up to this anyway. I also think people had to deserve it a little." (Chiro3_DK)

Several low recruiters expressed difficulty in deciding which patients were eligible and having few eligible patients but also talked about the importance of evaluating the patient's life situation, motivation, time, room and general attitude towards self-management and the app.

> "You get a feel of how positive in general they are, while others are more like life is a struggle and things are a burden, and to saddle someone with an extra task, I think that becomes too much overload on a person in a way. So, kind of the entire life situation, perhaps also." (Chiro1_No)

To be able to evaluate these criteria, some low recruiters described needing to know the patient well and often waiting until later in a course of treatment, at which point

the patient had improved and become ineligible for the RCT.

When discussing their personally defined criteria, HCPs did not agree about the relevance of the RCT and the app for patients with more severe or longstanding problems, with low recruiters applying stricter personally defined criteria. Low recruiters were highly selective in whom they would offer the RCT to and, thus, continuously made decisions on behalf of their patients.

Sustaining engagement with the RCT. Most patients accepted the invitation, which spurred HCPs to continuously support the RCT and recruit more patients *(NPT construct: Collective Action).* Further, HCPs explained that it was easier to "sell" the RCT to patients who already "bought into" the self-management concept or were positive about self-monitoring and exercise – this reinforced their continuous support for the RCT. Some would even have liked the eligibility criteria to be broader so more patients would have received the offer.

> "We have a lot of those NOT eligible, unfortunately. And the only downside was that we were sorry, we couldn't simply send a bunch [of patients] to you. Because, if it had been everybody with back pain, we would have bombarded you [with patients]."

For many HCPs, their busy clinical life would trump RCT procedures, but several explained that a constant flow of eligible patients helped to keep focus on the RCT whereas with a short supply and irregular flow of patients, procedures were forgotten. Both high and low recruiters mentioned uncertainty of the RCT outcome as a barrier to continued support. Several explained that patients had been excluded by the research team for being "too good", or described the risk of ending up in the control groups which would make them hesitant to inform patients about the RCT. Finally, a few recognized that the real effect of the app was unknown.

Integration of quantitative and qualitative results and interpretations

The convergence of the quantitative and qualitative findings and meta-inferences are presented in Table 4. Areas of complementarity showed that the HCPs' motivation to participate and recruit patients was shaped by a balance between recognizing the need for change in clinical practice and society and the daily challenges of high workload and stress. The urgency of the study was linked to the volume of LBP patients, and HCPs' confidence and perceived treatment options, which varied by profession. While there was overall enthusiasm for the self-management app and patient education, survey results revealed HCPs questioning specific app components, potentially due to perceived infringement on traditional professional roles. Professional identities influenced RCT procedures, with some clinicians displaying an authoritarian approach, while others embraced innovation and collaboration, fostering a sense of ownership in the project and commitment to recruitment.

Discussion

We have examined the engagement of HCPs with the recruitment of potential selfBACK RCT participants and the HCPs' perception of the selfBACK app. While many clinicians displayed high interest in the study, believing it was relevant and timely, recruitment was still challenging because of busy schedules and competing tasks. This was despite the study procedures being perceived as easy to follow, and the engagement and effort of the study teams being appreciated. Consequently, there was a large variation in the number of patients recruited by different HCPs, reflective of different flows of LBP patients, with chiropractors seeing many more LBP patients, but also by approaches to engagement with the study and hesitancy by some HCPs. Importantly, we have shown that HCPs were generally positive (84–89%) about the self-management advice given by the app and so this seems likely to facilitate future uptake and utilization. While there was overwhelming enthusiasm for the concept and potential of the selfBACK app and overall satisfaction with the app's self-management plans, there were still some questions relating to the app content, particularly relating to concerns about insufficient tailoring or a belief that the app could challenge patients to do more.

Previous investigations have indicated that HCPs have various motivations, experiences and personal preferences regarding DHIs that significantly influence their endorsement of DHIs for patients with chronic pain conditions in clinical practice.[7] HCPs' added workload and shortage of resources are further barriers to the implementation of DHIs in routine healthcare practice across a large range of conditions.[8,25] These findings are in line with ours, and it would therefore appear that such views also translate to clinical trial studies. By inviting HCPs to both recruit patients and engage in a novel type of treatment, we increased the workload considerably. Having had designated research staff to undertake the recruitment and reduce the burden for the HCPs, the HCPs' perception of the app might have been different.

In concordance with traditional professional roles, education and exercise prescription was mainly employed by PTs and chiropractors.[26] These two professions, and especially PTs, expressed a preference for maintaining control over planning patient care programs, including the flexibility to adapt or modify the app content. The overall high agreement with the educational components suggests that the content was perceived to have some universal validity.

Table 4. Comparison and contrasts of quantitative and qualitative findings and interpretations.

Overarching themes	Categories	Quantitative findings*	Qualitative findings	Comparison and contrasts	Interpretations
Theme 1: Shaping HCPs' motivation and willingness to participate in the RCT.	1.1 The societal needs for MSK digital interventions	80% of GPs, 91% of chiros and 76% of PTs in Norway accepted the invitation to participate in the trial. 84% of chiro clinics in DK accepted the invitation.	*Chiro1_No: "In a way, it is an important study, because with the general increase in musculoskeletal disorders and back pain, I think, we need to find out more about what we can do and everybody knows that physical activity, movement and exercise is healthy and* *PT1_No: "In a way, it is the modern way of living"* *Chiro4_DK: "It is interesting to create more knowledge about what we do, and I'm a big supporter of research, and I want to be a part of it when possible."*	**Convergence**: The acceptance rate was generally high in Norway and among Danish chiros. **Expansion**: HCPs felt the study was highly relevant at a societal level giving reference to public health concerns and the digitalization of society. Some expressed the importance of participation in research for the continued development of their profession.	**Complementarity**: Both the motivation and willingness to participate and recruit patients appear to be shaped by two contrasting perspectives: 1) the perceived need for change in the clinic and society at large and 2) a daily work-life situation of high workload and stress.
	1.2 Current situation in the primary healthcare sector	22% of GP clinics and 56% of PT clinics in DK accepted the invitation.	*All declining GPs in DK declined due to too much work.* *GP2_No: " But, then suddenly a week passed by, then it was perhaps more difficult to remember because there is so much, so much multi-tasking in general practice, a lot of considerations and phones, enquires, as I said, the challenge is simply to remember."* *PTs declining said they were not interested, their patients were not eligible for selfBACK, or they did not have enough energy for such a project.*	**Convergence**: The acceptance rate was relatively low among GPs and moderate among PTs in Denmark. **Expansion**: Reasons for declining participation were mainly centred around the perceived workload in the clinics.	
		78% of GPs and 64% of PTs in the survey saw 10 or fewer patients with LBP per week. 93% of chiros saw 20 or more patients with LBP per week.	*GP1_DK: Now, unfortunately, it's not like we have had many patients in this period, back pain patients that is.* *PT1_No: But sometimes there was perhaps a month without any new ones [back pain patients]* *Chiro1_DK: But it was all those non-specific [LBP patients], but there are so many of them... But there were quite many of those we saw, so in that sense, it became a natural part of how you think in some way.*	**Convergence**: Interviews reflect the variation between professions in the number of LBP patients that present to them. GPs and PTs see fewer than chiros. **Expansion**: Lack of a steady flow of patients impedes recruitment as HCPs tend to forget to recruit. Easier to integrate in daily routines, with a high and steady flow of relevant patients.	**Complementarity**: The sense of importance of study seems to be influenced by the volume of LBP patients seen by the HCPs, and by extension, the skills, knowledge and perceived treatment options with GPs feeling less confident/having fewer relevant treatment offers. HCPs' beliefs about the importance of self-management and educating patients to become masters of their own lives aligned very well with the general idea of apps for self-management.
	1.3 Alignment with HCPs' beliefs and practice	95% of HCPs agreed that they recommend physical activity to their LBP patients. 86% of HCPs agreed that they recommend exercises to their LBP patients. 90% of HCPs agreed that they use patient education with LBP patients. 22% of GPs did not agree that they use patient education with LBP patients.	*GP1_No: I believe a lot in self-management for back patients, that there is much they can do if only they are provided with instructions, and it is not always necessary to see a physiotherapist, either, to get instructions.* *GP2_NO: "It [the content of the consultation] becomes more concrete than simply saying "you [the patient] must seek a physiotherapist".* *GP survey: "As a GP, I don't have enough knowledge about exercise intensity."*	**Convergence**: HCPs had strong beliefs in the importance of self-management and physical exercise for LBP patients. Education is also used by most, but less among GPs. **Expansion**: GPs expressed concerns about the content and adequacy of the information and advice they provide to LBP patients	

(continued)

Table 4. Continued.

Overarching themes	Categories	Quantitative findings*	Qualitative findings	Comparison and contrasts	Interpretations
	1.5 Legitimacy and acceptability of an app as a means to promote self-management	84–87% of HCPs overall agreed with the 5 plans. >50% agreed with 17 out of 20 content components. 41.7–93.8% agreed with the content components. 61–72% of PTs did not agree with the relevance of the exercises in the 5 vignettes. Up to 31% of HCPs did not agree with the educational content. 42–76% of HCPs agreed with the recommended number of steps.	*GP1_No: one [the patients] always have an alternative. If you become unsure…you can always seek a healthcare professional. And as long as it has been carefully laid out, that if they experience such and such symptoms, they can contact someone, then it should be safe".* *PT4_DK: I think there is a good connection [between app and consultation] because they [the patient] get an understanding of how important is to do something… We…try to give them some responsibility. We are only a tiny fraction of what needs to be done* *Chiro4_DK: There is a little control [over the exercises in the app], so it is not like the Wild West as it might be if you go into YouTube and search for exercise there.* PT survey: *If the patient prefers pre-defined exercises (and there are no contra-indications in the clinical examination), I think the exercises are really good.* *PT survey: Uncertain which exercises match – for example, some [patients] experience aggravation of pain with extension – therefore, it is difficult to give general, individually non-tailored exercise.* *PT survey: Based on my experience, many patients experience aggravation with symptoms with extension exercises.* *PT survey: "Choice of exercise seems a little random… In my experience, exercise 2 may increase pain with for example hypermobile back patients, and there I have chosen a dynamic rotation exercise."* *PT1_NO: When the patients started to use this app, very many of them came back and said "Yes, there were many of the exercises that you gave me that the app also suggested" … And then we adjusted a little to what level they should choose when they had to do that.* *GP survey: "As a GP, I don't have enough information about exercise intensity ".* *PT survey: Patient information is perhaps not adjusted to him [patient in vignette], too general* *GP survey: Too few steps* *Chiro survey: Think he could walk more steps.*	**Convergence**: HCPs are overall in agreement with the plans and the content provided to the patients, and the perceived trustworthiness and safety of using an app is high. **Divergence:** The largest disagreement with the plans related to the exercise content. The survey findings are somewhat in contrast to the perceived acceptability and usability of app-based exercising expressed in the interviews in which the potential was highly praised. **Expansion**: HCPs mostly agree that their contribution to the patient´s improvement was minor compared to what the patient could achieve him-/herself by engaging in self-management. They drew on their own experience to suggest alternatives in exercises and highlight the importance of a clinical evaluation.	**Complementarity**: Despite the overall very high enthusiasm for the app and the importance of educating the patient to become masters of their own lives expressed in the interviews, the survey results indicate that when put into action, some HCPs question the individual, app components and lean on their role as experts in assessing and guiding the patient. This may be interpreted as a sign of infringement of the app on traditional professional roles.

(continued)

Table 4. Continued.

Overarching themes	Categories	Quantitative findings*	Qualitative findings	Comparison and contrasts	Interpretations
Theme 2: Enacting the procedures of a research project	2.1 Working together to implement new procedures	54–81% of HCPs who accepted to participate in Norway actively recruited patients. Between 4.4 and 5.2 patients were recruited on average by the Norwegian HCPs. Between 1 and 129 patients were recruited by the Danish clinics.	*K2_DK: I haven't been good enough at recruiting people, I must admit.* *K1_no: Maybe it was a little harder to recruit than I had envisioned it would be, to talk to the people who were here.* *K1_No: Right when the patients were finished and perhaps had left, I would think of it, oh no, perhaps that was a candidate because it was something about having it at the top of your mind at any time in a hectic day and thinking of it while the patient was in the office.* *PT2_DK: It is busy and you run past this and that, and you forget sometimes.* *Gp2- DK: You [research team] have been very proactive when it comes to informing us, and you were easy to get hold of. I called you, and you immediately responded. Like, that is good collaboration.* *Chiro1_DK: It was a fairly easy project, you can say... It did not involve our clinical work. In that sense, it was a fairly simple project to be in.*	**Convergence**: The recruitment rates varied across professions and HCPs. **Expansion**: Recruitment rates were reflective of the volume of patients across the professions, and the perceived ease of engaging in the project versus the perceived business/workload in general. Some HCPs applied additional eligibility criteria other than the ones specified in the RCT, which limited the number of perceived eligible patients. Others worked as a team at the clinic to set up procedures that were easy to remember and enact.	Enacting the RCT procedures is in part influenced by professional identities and roles. Some clinicians made decisions on the part of their patients without consulting with them and confer a traditional, paternalistic professional identity. Others were innovative and collaborative. They internalised and adopted the project creating a sense of ownership, which made them invested in the recruitment.
	2.2 Autonomous eligibility criteria govern recruitment	No quantitative data	*Chiro1_NO: I tried a little to see it for me, and it's somewhat about getting an impression of some persons, who are, what to say, motivated and inspired and perhaps a little structured and so on. What I can say is, who wants to contribute? You kind of sense how positive they are in general if everything in life is a struggle and things are hard, and to saddle them with an extra task, I thought that would be too much.* *Chiro3_DK: So, there might have been some that I excluded as I was thinking this is never going to... you [the patient] will never live up to this anyway.*		
	2.3 Following through to the end	No quantitative data	*PT4_DK: We actually had some [leaflets] all over the place, also in the office where we sit by the computer. And that was intentional so that we would remember.*		

Areas of **convergence** between the two phases: describes the agreement between the quantitative and qualitative findings.
Areas of **divergence** between the two phases: describes when the quantitative and the qualitative findings demonstrate conflicting interpretations.
Areas of **expansion** where qualitative sources helped to expand the survey findings. The 'expansion' label also indicates instances where the qualitative and quantitative data addressed the same phenomenon but in a different and informative way.
Areas of **complementarity** are used when new insights or interpretations are illustrated by the integrated findings.
*Agreement is defined as those who have answered "agree" or "completely agree" in the survey.
Abbreviations: GP = general practitioner, Chiro = chiropractors, PT = physiotherapists, HCP = Healthcare provider.

In contrast, the lower agreement with the presented exercises may reflect the HCPs' personal preferences and idiosyncrasies regarding the choice of exercises. The desire for autonomy aligns with findings from various HCPs, who share concerns about maintaining authority in patient care when using digital tools.[27–29] Although not directly voiced, the interference of digital tools on the rapport and trust in the patient-provider relationships found in other studies, may also potentially have impacted the recruitment and perception of the app in the present study.[27,30,31]

We have identified important factors that align well with other literature on barriers to recruitment in RCTs,[32,33] and which need to be addressed if self-management apps and other types of DHI are to be implemented in clinical care. It is important to understand the motivation for HCPs to engage in DHIs and how the reality of their daily workloads is balanced against their beliefs and values. The HCPs' engagement was partly determined by their professional identity; the paternalistic, traditional authoritative figure, who made decisions on behalf of the patient or the innovator and collaborator who was invested in the potential of a DHI for LBP. Finally, DHIs, like the selfBACK app, may be perceived by some HCPs as compromising their professional autonomy, which may pose a significant barrier to implementation, something that needs to be considered when introducing DHIs into research projects and clinical practice.

This study has several strengths, including a mixed-methods approach and a large dataset consisting of results from five data sources that have been integrated using joint displays and NPT as a guiding theory for data collection and analysis. The study also has limitations. Due to the recruitment strategy in Denmark, we could not identify the number of actively recruiting individual Danish HCPs or calculate the Danish response rates in the survey, which may limit the generalisability of our recruitment results. Although we had high acceptance rates, and few HCPs declined to participate, the participating HCPs were self-selected and likely more enthusiastic about the topic than clinicians in general. Thus, we have not heard the voices of those declining participation, particularly Danish GPs, nor the secondary spine centre personnel. Further, the voices of patients are not included here, but have been reported elsewhere.[10] Interviews with HCPs were in a few instances short and conducted by interviewers with moderate experience in interviewing. The qualitative data collecting finished as the time and funding for the selfBACK study concluded, and we did not formally assess saturation, although, from analysis, it is our impression that saturation was reached. The results are specific to the contexts that apply to the primary care sector and the three groups of HCPs in Denmark and Norway, and other conclusions may have been drawn if the study had been conducted elsewhere. We used an outcome-based honorarium to compensate the participating clinics and HPCs for their time and effort in recruiting patients, which may have impacted their decision-making process in the recruitment process and incentivized them to put undue pressure on the patients.[34] However, we did not see any indication of this. Rather, the HCPs restricted their recruitment by adding their own inclusion criteria aligned with their beliefs and values.

Conclusion

We have identified factors that impact HCPs' engagement in recruiting patients for the selfBACK RCT and demonstrated strong approval of the app content, albeit with some concerns about the content and tailoring of the app content. The study focus triggered high interest among HCPs, and that along with easy-to-follow trial procedures and engaged research teams supported the HCP in recruiting patients. Nonetheless, recruitment of patients was still challenging for some due to competing tasks and workload. The selfBACK app and other similar DHIs must be considered both useful and trustworthy by HCPs for them to recommend such tools to their patients. Thus, understanding HCPs motivations and workload is crucial for the successful implementation of DHIs in clinical practice. To ensure buy-in from HCPs and trust in future DHIs, we recommend using a robust, theory-driven development process that takes into consideration clinicians' input at the early stage and throughout the development and implementation phases.

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Availability of data and materials: The data is available (in original language) from the corresponding author upon reasonable request.

Competing interests: All authors declare that they have no competing interests. After ending the RCT study, selfBACK was licensed to the Norwegian University of Science and Technology's Technology Transfer Office and a third party. The researchers do not have any personal financial benefits from working with the study.

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