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Individually tailored self-management app-based intervention (SELFBACK) versus a self-management web-based intervention (e-Help) or usual care in people with low back and neck pain referred to secondary care: protocol for a multiarm randomised clinical trial

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ABSTRACT

Introduction Low back pain (LBP) and neck pain (NP) are common and costly conditions. Self-management is a key element in the care of persistent LBP and NP. Artificial intelligence can be used to support and tailor self-management interventions, but their effectiveness needs to be ascertained. The aims of this trial are (1) to evaluate the effectiveness of an individually tailored app-based self-management intervention (SELFBACK) adjunct to usual care in people with LBP and/or NP in secondary care compared with usual care only, and (2) to compare the effectiveness of SELFBACK with a web-based self-management intervention without individual tailoring (e-Help).

Methods and analysis This is a randomised, assessor-blind clinical trial with three parallel arms: (1) SELFBACK app adjunct to usual care; (2) e-Help website adjunct to usual care and (3) usual care only. Patients referred to St Olavs Hospital, Trondheim (Norway) with LBP and/or NP and accepted for assessment/treatment at the multidisciplinary outpatient clinic for back or neck rehabilitation are invited to the study. Eligible and consenting participants are randomised to one of the three arms with equal allocation ratio. We aim to include 279 participants (93 in each arm). Outcome variables are assessed at baseline (before randomisation) and at 6-week, 3-month and 6-month follow-up. The primary outcome is musculoskeletal health measured by the Musculoskeletal Health Questionnaire at 3 months. A mixed-methods process evaluation will document patients' and clinicians' experiences with the interventions. A health economic evaluation will estimate the cost-effectiveness of both interventions' adjunct to usual care.

Ethics and dissemination The trial is approved by the Regional Committee for Medical and Health Research Ethics in Central Norway (Ref. 2019/64084). The results of the trial will be published in peer-review journals and presentations at national and international conferences relevant to this topic.

Trial registration number NCT04463043.

Strengths and limitations of this study

► This randomised clinical trial will provide novel knowledge about the effectiveness of digital interventions to support self-management among patients with low back and neck pain in secondary care.

► A three-arm design will be used to compare individually tailored self-management support delivered via an app (SELFBACK) with usual care only and with a self-management website (e-Help) without individual tailoring.

► A mixed-methods process evaluation targeting both patients and clinicians will be carried out to elucidate barriers and facilitators for engaging with digital self-management interventions in secondary care.

► The effect of digital interventions might be limited to patients who have regular access to the internet and a smartphone and adequate digital literacy skills to engage with the intervention.

► The length of time needed to complete web-based questionnaires to collect outcome measures (ie, 15–30 min) may represent a potential barrier for participant's engagement.

INTRODUCTION

Self-management is a key element in the care of low back pain (LBP) and neck pain

(NP).[1–3] Self-management is commonly defined as the process in which individuals actively engage to manage a health condition, adapt to physical and psychological challenges, and adhere to lifestyle changes.[4 5] Current best evidence recommends that self-management is tailored to individual needs and capabilities and includes elements such as education, exercise programmes, and advice to stay active.[3 6 7] In primary care, general practitioners commonly lack time, resources and training for delivering evidence-based self-management support,[8] while access to specialist care for patients with more complex symptoms is generally limited and requires long waiting time. Digital interventions provide a viable option for supporting self-management across care pathways as they can be accessible to patients at any time and at low cost.

Despite the growing body of research on digital self-management interventions for chronic pain, their effectiveness still needs to be ascertained. Two recent systematic reviews with a focus on LBP concluded that there is large heterogeneity between studies in terms of type of delivery, content, theoretical underpinnings and outcome measures.[9 10] In addition, most digital interventions have been tested in the community or primary care settings, and their role as an adjunct to secondary care has not yet been explored.

Based on the case-based reasoning methodology,[11] we have developed an evidence-based decision support system (DSS)—selfBACK—designed to facilitate, improve and reinforce individually tailored self-management of LBP.[12–14] The selfBACK intervention is delivered via a smartphone app and its effectiveness among patients with LBP in primary care is currently under investigation.[15] In the current study, we adapted and extended the content of the selfBACK app to target both patients with LBP and NP.

While tailoring is recognised as an important element in the delivery of self-management interventions,[16] there is large variability on the level of tailoring carried out in previous studies,[9] and the added benefit of a tailored over a non-tailored approach is currently unclear. Given this gap in knowledge, we used a three-arm design where, besides the control group of usual care only, we developed an additional intervention arm consisting of a website—e–Help—that mimics the content of the selfBACK app, but without individual tailoring.

The primary aim of this randomised clinical trial is to evaluate whether the selfBACK app is an effective adjunct to usual care for patients with LBP and/or NP in secondary care, compared with usual care only. The second aim is to compare the effectiveness of the selfBACK intervention with the e-Help intervention.

METHODS
Trial design
This is a randomised clinical trial with three parallel arms aiming to determine the effectiveness of digital self-management interventions in patients with LBP and/or NP in a secondary care setting. Participants will be followed for 6 months after randomisation and outcomes will be collected at 6-week, 3-month and 6-month follow-up. The primary outcome is musculoskeletal health measured by the Musculoskeletal Health Questionnaire (MSK-HQ)[17] at 3 months. A process evaluation using a mixed-methods approach and a health economic evaluation is planned as part of the trial. The trial commenced in July 2020 and is expected to terminate in June 2022.

This protocol was developed in accordance to the Standard Protocol Items: Recommendation for Intervention Trials 2013 Statement[18 19] and the Consolidated Standards of Reporting Trials 2010 guidelines.[20 21] The Pragmatic-Explanatory Continuum Indicator Summary-2 tool was used to guide the trial design with the aim of enhancing the applicability of the interventions to clinical practice.[22]

Eligibility criteria
All participants will meet the following inclusion criteria: (1) reporting LBP and/or NP; (2) referred and accepted to a secondary care multidisciplinary outpatient clinic; (3) owning and using a smartphone with internet access. Exclusion criteria are: (1) under 18 years of age (no upper age limit); (2) 'red flags' indicating possible malignancy, fracture, cauda equina syndrome, infection or other conditions prioritised for urgent treatment or examination (expected waiting list period <4 weeks *at time of referral*); (3) unable to take part in exercise or physical activity (eg, non-ambulatory patients, use of walking aids, unable to get up and down the floor independently); (4) unable to speak and/or read Norwegian; (5) unable/unwilling to complete the baseline questionnaire; (6) already enrolled in the ongoing selfBACK trial in primary care.

Recruitment and screening
The recruitment is carried out at the multidisciplinary outpatient clinic for back, neck and shoulder rehabilitation at St Olavs Hospital in Trondheim, Norway. The clinic receives approximately 3500 referrals for LBP and/or NP from primary care each year. Nearly 50% of referred patients are admitted to the clinic upon assessment of referral by a consultant physician.

Figure 1 shows the participant flow through the trial. The administrative staff at the clinic identify potential study participants based on the available patient information (ie, age, primary pain site and language barrier) and send them an invitation text message with a link to a registration form. The form includes information about the study along with contact details of study personnel, two eligibility questions, two questionnaires (the Keele STarT MSK tool[23] and the Fibromyalgia Survey Questionnaire[24]), and a digital consent form to participate in the study. Up to three reminders about submitting the registration form are scheduled to ensure adequate participation rate. If eligible and interested in the study, participants are required to provide a digital informed
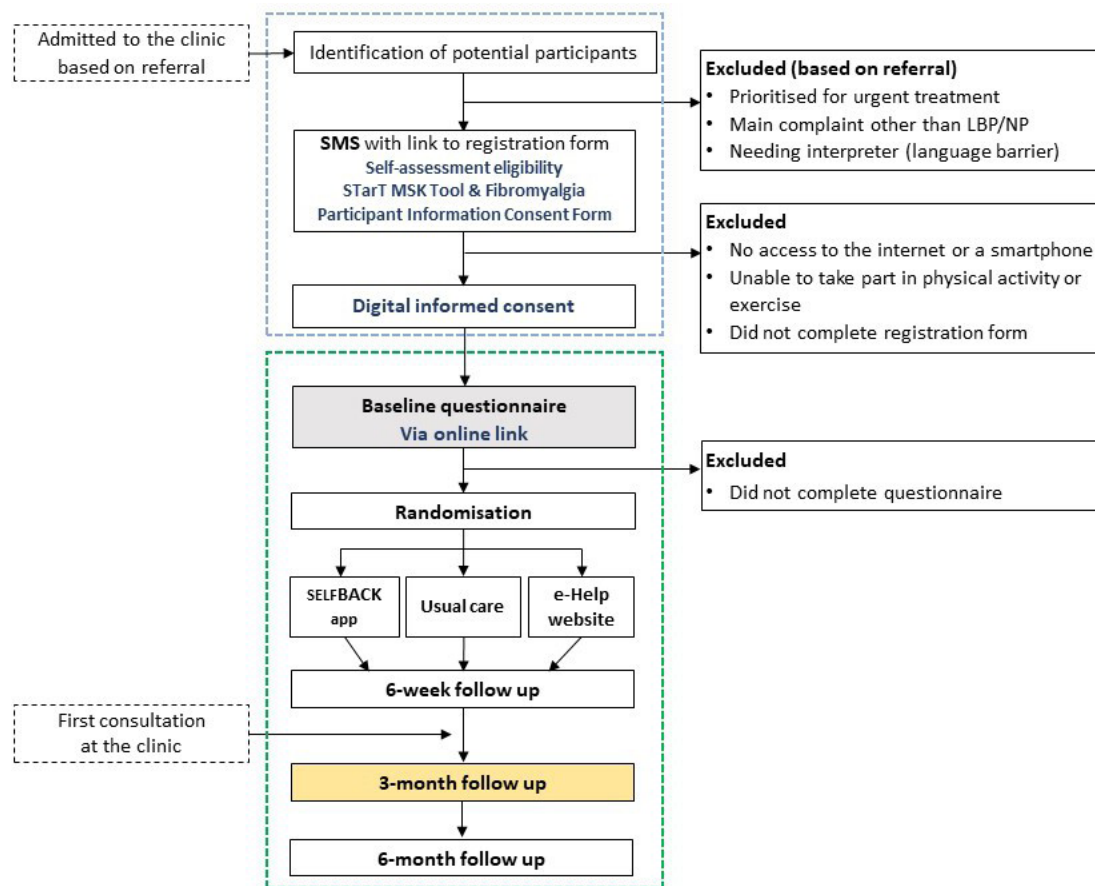
Figure 1 Participants' flow chart. Actions in the blue and green dashed line boxes are performed by the staff at the clinic and by researchers, respectively. LBP, lower back pain; MSK, musculoskeletal; NP. neck pain; SMS, short message service.

consent. Participants are given the opportunity to contact a study staff member either by email or phone to clarify any concerns before consenting to the study. Once the consent process is finalised, participants are assigned a study username and invited by email to complete an online baseline questionnaire after which they will be randomised to one of the three groups.

Randomisation and blinding

Participants are randomly assigned to (1) the SELF-BACK app adjunct to usual care or (2) the e-Help website adjunct to usual care, or (3) usual care only, using a permuted block randomisation with blocks of random size and 1:1:1 allocation. The randomisation is performed in a web-based trial management system (Web Case Report Form, WebCRF) administered by the Unit of Applied Clinical Research, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology (NTNU), Trondheim, Norway. To ensure allocation concealment, the block sizes are not disclosed to study personnel, and the randomisation code is automatically generated by the software and released after participants are enrolled into the trial. Participants are informed about their group allocation via a text message containing the link to the intervention.

This trial is single blinded. Participants and healthcare personnel at the clinic are not blinded to group allocation, whereas researchers performing the analysis and the interpretation of the results are blinded to group allocation. Once the study is completed, the data will be extracted from the database in an anonymised form for statistical analysis. The randomisation key, that is, document entailing information on group allocation, is kept at the Unit of Applied Clinical Research (NTNU). They will provide the randomisation key to the research team once a blinded interpretation of the results is finalised. Primary and secondary outcomes will be collected directly from participants via online questionnaires.

Interventions
Usual care
Participants randomised to usual care will continue to follow any diagnostic or treatment-related pathways as indicated by healthcare practitioners they may consult during the study period. All patients on the waiting list will undergo a clinical examination at first consultation at the outpatient clinic. Based on this first consultation, a suitable treatment is offered to the patient at the clinicians' discretion in accordance with current evidence-based guidelines. Treatment options include: no further treatment, adjusted recommendations for primary care

treatment, outpatient multimodal rehabilitation, surgery and referral to other medical specialists (eg, orthopaedic, neurosurgery, neurology or rheumatology department). Therefore, the type, modality and length of treatment are expected to vary between patients.

The SELFBACK app adjunct to usual care

In addition to usual care, participants in this group will have access to the SELFBACK intervention throughout the study period. A detailed description of the SELFBACK DSS including its theoretical underpinning,[12] as well as results from pilot and feasibility testing, is available elsewhere.[13 14] In short, the SELFBACK DSS uses case-based reasoning to provide users with weekly individually tailored self-management plans. Case-based reasoning is a methodology that uses knowledge about previous patient cases along with data about the current patient case, to tailor the recommendations to the current patient. This enables a patient-centred intervention based on what has or has not been successful in previous patient cases.[11]

The SELFBACK app was developed using an intervention mapping process involving patients, researchers and clinicians and the content is based on current best evidence for the management of LBP.[25] On a weekly basis, tailoring questions are asked via the app and used to revise the self-management plan for the upcoming week. The weekly plans generated encompass three main components: (1) advice on physical activity based on step counting, (2) educational messages based on a cognitive–behavioural approach, and (3) recommendations on strength and flexibility exercises. Additional resources, such as general information about LBP/NP, mindfulness audios, goal-setting tool and pain relief exercises, are also available in the app. For the current trial, the content and functionality of the SELFBACK DSS have been adapted to broaden the applicability to patients with NP by extending the bank of strength and flexibility exercises as well as adapting the educational material.

The e-Help website adjunct to usual care

In addition to usual care, participants randomised to this group will have access to the e-Help intervention. The e-Help is a web-based resource offering evidence-based support and advice on self-management of LBP and NP. Participants access the intervention via their own devices, for example, smartphone, personal computer and tablet, throughout the study period. The SELFBACK theoretical framework and content was used to build the e-Help website. Clinicians and a patient representative were involved in the development process to maximise its relevance and applicability to patients treated at the clinic. The e-Help website is structured in four sections: (1) homepage describing the purpose and how to use e-Help, (2) educational messages organised by topic and based on a back school cognitive–behavioural approach, (3) strength and flexibility exercise videos organised by difficulty level and target area along with guidelines on how to build weekly exercise programmes, and (4)

educational tools and resources (ie, goal setting, pacing techniques, sleep hygiene, mindfulness instructions along with practice audio files and useful external links). The content in sections 2–4 is identical to the one shown in the SELFBACK app, for example, same bank of exercises, with minor adaptations to fit the website format. No individual tailoring of the content is provided in the e-Help solution but instructions in the first section emphasise self-tailoring techniques based on pacing and goal-setting strategies.

Delivery of the interventions and concomitant care

Table 1 summarises the characteristics of delivery of the SELFBACK and e-Help interventions.

The digital interventions in this trial are intended to supplement usual care and, as such, their delivery is integrated into the clinical workflow, though without interfering with usual practice or any usual care procedure received by the patient. The interventions are first offered to patients during the waiting time period, that is, before any usual care procedure has started, and will be available to them throughout the study period. A study webpage is available to participants together with a telephone hotline for any questions related to the use of the SELFBACK app or e-Help website. Clinicians treating patients taking part in the study were provided with adequate knowledge about the interventions through workshops and regular clinical team discussions, enabling them to address any concerns or questions patients might have about the interventions when attending the clinic. The clinical treatment strategy on whether/how to integrate the use of the digital interventions within the clinical practice for the individual patient was left to the discretion of each clinician.

Adherence strategies

The first login to the SELFBACK app and e-Help website will be monitored to check if participants accessed the allocated intervention. Up to two reminders will be made within 2 weeks from allocation either via text message or phone call to prompt participants to access the intervention. Participants who do not access the intervention after the reminders or want to discontinue its use will be followed up as usual.

Data analytics on usage and interaction with the app/web interventions will be used as an indirect measure of adherence. The SELFBACK app provides individually tailored support and, as such, it has built-in functions to promote engagement such as personalised messages to encourage self-management behaviours, rewards when a goal is achieved, and push notifications reminding participants to open the app and view their new self-management plan.[12] It is therefore anticipated that people assigned to the SELFBACK group might show higher adherence compared with people in the e-Help group. No additional measures are in place to improve adherence.

Table 1 Summary of the characteristics of delivery of the interventions

	ꜱᴇʟꜰBACK app	e-Help website
Format and mode of delivery	Weekly self-management plans with tailored content accessible via smartphone app (ꜱᴇʟꜰBACK). Additional self-management content available as static elements.	Self-management content available as static elements and accessible via computer, handheld devices or smartphone internet browser.
Recommended frequency	Participants need to access the app weekly to see the new self-management plan. Recommendation to perform the exercises 2–3 times per week. Built-in push notifications, for example, reminding participants to open the app and view their new self-management plan.	Recommendation to visit and interact with the content of the website on a weekly basis by setting goals according to the SMART acronym (Specific, Measurable, Realistic, Time specific). No built-in push notifications.
Recommended duration of visit	No recommended duration for each visit provided. Participants select desired duration of weekly exercise session and a plan is generated accordingly.	No recommended duration for each visit provided. Participants are given instructions on how to build weekly exercise plans based on desired duration.
Tailoring	Baseline information and weekly Question and Answer (Q & A) session in app are used to tailor the self-management plan for the coming week. Q & A session includes up to nine items (eg, pain intensity, fear-avoidance belief, pain self-efficacy, work ability, sleep, stress, depression, perceived barriers, pain-related function). Full details are available in[12].	No tailoring provided.
Audio/video elements	Strengths and flexibility exercise videos; mindfulness audio files.	Introductory audio file about how to use the website delivered by a physician; strength and flexibility exercise videos; mindfulness audio files.
Interactive elements	Personalised messages to encourage self-management behaviours; rewards when a goal is achieved based on count steps, accomplishment of educational sessions and physical exercises; goal setting tool; sleep tool.	No interactive elements provided.
Intervention duration	Unlimited access for 6 months.	Unlimited access for 6 months.

Adapted from intervention characteristics described in Nicholl *et al.*[9]

Post-trial care
Access to the ꜱᴇʟꜰBACK app and the e-Help website will cease after the 6-month follow-up by disabling the participant's username in the system. No further post-trial care is planned.

Outcomes
Table 2 shows the primary and secondary outcomes along with time points for data collection.

The primary outcome is the mean difference in musculoskeletal health measured by the MSK-HQ[17] at 3-month follow-up from baseline. The MSK-HQ contains 14 items assessing severity of pain/stiffness, physical function, physical activity level, symptoms interference, sleep, fatigue, emotional health, understanding of the condition, confidence to self-manage, independence and overall impact of symptoms. Each item is scored from 0 to 4 and is summed to provide a final score (range 0–56), with higher scores indicating better musculoskeletal health. There is no consensus regarding the optimal measure to assess the effectiveness of self-management interventions and a wide variety of outcome measures were adopted in

previous studies.[26] MSK-HQ is a multidomain scale and was chosen in this trial as it was considered to capture changes in musculoskeletal health more comprehensively than single construct measures (eg, physical function, pain, pain self-efficacy).

A range of secondary and exploratory outcomes will be collected at all time points using Norwegian-translated versions of validated questionnaires, including pain-related disability,[27 28] the average and the worst pain intensity within the past week,[29] health-related quality of life,[30] pain self-efficacy,[31] illness perception,[32] fear avoidance beliefs,[33 34] stress and depressive symptoms,[35] patient-specific functional scale,[36] self-reported level of physical activity,[37] self-reported sleep[38] and work ability.[39] In addition, measures of satisfaction[40] with the intervention and the global perceived effect[41 42] will be collected at follow-ups. Demographic variables including age, sex, education and employment status, and clinical variables including duration of current pain episode and pain medication are recorded at baseline.

Table 2 Timeline of the study and data collection

Time points	Study period		Follow-up time points			
	Enrolment	Randomisation				
	—	0	6 weeks	3 months*	6 months	1 year
Study procedures						
Eligibility screening	X					
Informed consent	X					
Baseline assessment (via online questionnaires)	X					
Randomisation		X				
Process evaluation (mixed-methods)				X§		
Health economic evaluation						X
Interventions						
SELFBACK app		X	←————————————————→			X
e-Help website		X	←————————————————→			X
Usual care (waiting time +first consultation/ treatment)		X	←————————————————→			X
Outcome data collection						
Demographics and clinical variables						
Age, sex, higher education, employment status	X					
Duration of current pain episode	X					
Pain medication(s)	X					
Primary outcome						
Musculoskeletal Health Questionnaire	X		X	X	X	
Secondary and other clinical outcomes						
Roland Morris Disability Questionnaire	X		X	X	X	
Neck Disability Index	X		X	X	X	
Average pain intensity over last week	X		X	X	X	
Worst pain intensity over last week	X		X	X	X	
EuroQoL-5 Dimension	X		X	X	X	
Pain Self-Efficacy Questionnaire	X		X	X	X	
Brief Illness Perception Questionnaire	X		X	X	X	
Fear Avoidance Belief Questionnaire	X		X	X	X	
Perceived Stress Scale	X		X	X	X	

Continued

Table 2 Continued

Time points	Study period		Follow-up time points			
	Enrolment	Randomisation				
	—	0	6 weeks	3 months*	6 months	1 year
Patient Health Questionnaire-2	X		X	X	X	
Patient Specific Functional Scale	X		X	X	X	
Saltin-Grimby Physical Activity Level	X		X	X	X	
Self-reported sleep problems	X		X	X	X	
Work Ability Index (1-item)	X		X	X	X	
Patient Acceptable Symptom State			X	X	X	
Patient Global Perceived Effect			X	X	X	
Process evaluation outcomes						
Virtual Care Climate Questionnaire				X§		
Usage/interaction data analytics		X	←———————————→		X	
Qualitative data via interviews†				X§		
Health economic outcomes						
Healthcare consumption‡						X
Sickness absence‡						X

Adapted from the SPIRIT Group template.[19]

*Primary endpoint.

†Barriers/facilitators and user experience with the interventions.

‡Based on objective registry data linked to social security number in Norway.

§Occurring at 4 months from baseline (after primary outcome data collection is completed)

SPIRIT, Standard Protocol Items: Recommendation for Intervention Trials.

Health economic evaluation

The health economic evaluation will entail cost-effectiveness analyses that compare the relative costs of achieving the same outcome by different interventions. Registry-based data linked to social security number in Norway will be accessed to explore differences in healthcare consumption and sickness absence between trial arms. The societal perspective will be evaluated, and two analyses will be conducted using two different direct outcomes of the interventions: number of sick-leave days and number of health service consultations. The main goal of the economic evaluation is to identify the treatment alternative that provides the greatest health for a given level of expenditure, or, equivalently, that has the lowest cost for a given level of health.

Process evaluation

A process evaluation involving participants in the intervention arms will be carried out after the 3-month primary outcome data collection to explore barriers and facilitators for using digital interventions in secondary care. A mixed-methods approach is used comprising of four data collection sources: (1) the Virtual Care Climate Questionnaire, which is a 15-item scale evaluating the user-perceived autonomy support for health behaviour changes offered by the digital interventions,[43] (2) three questions on overall impression of the app/website, ease of use of the app/website and recommendation to others (rated on a 5-point scale), (3) data analytics on usage and interaction with the app/web interventions, and (4) semi-structured qualitative interviews collected from a purposive sample of participants in the intervention arms. Participants with different levels of usage of the interventions based on the first 3-month period will be invited for the interview. Up to a total of 15 interviews will be conducted. The Normalisation Process Theory provided the framework for developing the interview guide.[44] The interviews will be undertaken via phone by a member of the research team with a Master Degree in clinical health

science. Focus groups with involved secondary care clinicians will be carried out via video call to investigate the acceptance of digital interventions in this clinical setting. Interviews and focus groups will be audio-taped with participants' consent and thereafter transcribed verbatim. Data analysis will be performed using thematic analysis.[45]

Sample size

Data on between-group differences in MSK-HQ have not been previously reported. A 5.5 point (95% CI 2.7 to 8.3) change in MSK-HQ was reported as minimally important change in four validation cohorts—community physiotherapy and secondary care orthopaedic cohorts—with mixed musculoskeletal conditions.[46] For this trial, a 4-point difference between the intervention groups and the usual care group was chosen as a meaningful difference since the interventions are intended to be an add-on to the usual care rather than standalone. The *sampsi* procedure within Stata was used to estimate the required sample size for repeated data with one baseline measure and two follow-up measures (6 weeks and 3 months). Assuming an SD of the MSK-HQ score of 10 points[46] and a correlation between repeated measures of 0.4, we estimated that a sample size of 213 (71 in each group) was necessary to detect a 4-point difference with 90% power and a two-sided alpha level of 0.05 when analyses adjusting for baseline values of the outcome were specified. Allowing for 30% loss to follow-up, the estimated total sample size is 279.

Three comparisons will be performed, SELFBACK versus usual care (primary analysis), e-Help versus usual care and SELFBACK versus e-Help. We will maintain the alpha level at 0.05 as multiple comparison correction is highly debated[47] and, in agreement with recent recommendation,[48] we will interpret our results based on the estimated effects and their precision rather than a specific p value threshold.

Data collection, storage and protection

The timeline for data collection is shown in table 2. Outcome measures will be collected directly from participants via web-based questionnaires. At each time point, participants are sent an email with the link to a web-based questionnaire that they access with a username and password received at the start of the trial. Two automated email reminders along with text messages are generated. For the primary endpoint at 3 months, if no response to the web-based questionnaire is registered, the research team will ask participants if they are willing to answer the primary outcome measure (MSK-HQ) by phone. Up to three attempts to reach the participants by phone will be made in this circumstance.

All outcome data are stored on secure and firewall-protected servers at NTNU. Data storage is compliant with national and European regulations on data protection.[49] The servers can only be accessed by authorised technical staff at NTNU's Department of Computer Science. Additional access can only be approved by the responsible technical staff. Researchers connected to the recruitment of participants, data collection and conduct of the trial are not allowed to add data, review, access or make changes in the original participant data. No information concerning the group allocation is held in the outcome database, but this information is kept separate in the WebCRF system. NTNU will have sole ownership of the collected data. All personal identifiable data will be kept for 5 years. Hereafter the data set will be fully anonymised. The anonymised full data set will be kept for 30 years for research purposes.

Statistical methods

The primary intention-to-treat analysis will estimate mean differences with 95% CI in MSK-HQ between the groups at 3-month follow-up using a linear mixed model. This model includes all available data for all participants at each time point, that is, baseline, 6 weeks and 3 months and specifies a random intercept for each individual to account for the within-subject covariance structure (ie, dependency across time points within each individual). The effect of group and time will be specified as fixed effects using a joint variable with a common baseline category (ie, to adjust for any baseline differences in MSK-HQ between the groups). This approach will be used for all three comparisons: (1) SELFBACK versus usual care, (2) e-Help versus usual care and (3) SELFBACK versus e-Help. All associations will be adjusted for important predictors of the outcome (eg, age, sex, education). Similar analyses will be conducted to estimate mean differences of secondary outcomes. Additionally, we will use generalised estimating equations to estimate OR or relative risks for the effect on binary outcomes. A statistical analysis plan is available.[50]

Data monitoring

No serious adverse events are anticipated for this trial. However, a list of potential adverse events was comprised before commencing the study (see online supplemental file) and adverse advents will be monitored during the trial. Participants who contact the research team regarding any worsening of symptoms will be advised to seek care from their healthcare professional as they normally would if not included in the trial. All enquiries regarding potential adverse events will be recorded and discussed in an internal audit and reported within the study results. In the unlikely event of a serious adverse event, this will be recorded by the principal investigator and reported to the Norwegian health authorities. As serious adverse events are not expected, no interim analysis or a priori stopping rules are defined or implemented for this trial. The principal investigator will be responsible for a decision about premature suspension.

On a monthly basis, the principal investigator, a secretary at the clinic involved in patient recruitment, the chief physician assessing patient referrals, and members of the research team will review the recruitment, enrolment, data collection, conduct of the intervention, completion

of the trial, reported adverse events and discuss appropriate actions to any inconsistencies or unexpected events.

Patient and public involvement

A user representative (E-NK) participated actively by giving feedback on the study design, taking active part in the development of the e-Help website and in user testing of the procedure for piloting the trial. The patient and public involvement for the development of the SELFBACK app has been described previously.[12]

ETHICS AND DISSEMINATION

The trial is approved by the Regional Committee for Medical and Health Research Ethics in Central Norway (Ref. 2019/64084). For the SELFBACK intervention, approval of compliance with the relevant national regulations and European Union Guidelines on Medical Software Devices was obtained by the Norwegian Medicines Agency. Any amendment to the protocol that might impact on the conduct of the trial will be submitted for approval to the relevant ethical committees or data protection agencies prior to implementation and the clinical trial registry (ClinicalTrials.gov) will be updated.

Potential participants are provided with detailed information about the study and are given the opportunity to contact a study staff member should they need any clarification before consenting to take part in the study. They are also informed that participation in the study is voluntary, and that they can withdraw at any time without consequences for their current or future contact with the clinic. Participants consent to the study digitally via the online registration form including giving consent to access their social security number for obtaining linkage to national data registries.

The results of this trial will be published in peer-reviewed journals and at national and international conferences relevant to this research topic. The results and experiences from the trial may inform future development of DSSs aimed at supporting self-management. Results will be disseminated regardless of the magnitude or direction of the effect. Efforts will also be placed to disseminate the findings to patient representatives and the public, to guide further implementation if the interventions are shown to be effective.

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