Protocol for a non-randomized clinical intervention study- Concentrated Cross-disciplinary Group Intervention for Common Health Complaints (Including Post COVID-19 Fatigue)

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Introduction

An ageing population with a growing burden of chronic, complex diseases seriously challenges our ability to deliver adequate health services [1–3]. Adding to this, the ongoing COVID-19 pandemic has resulted in a new group of patients, who, having recovered from the acute infection may suffer from a range of long-lasting symptoms. This hitherto unknown condition is frequently termed post-COVID 19 syndrome (or long COVID) and may also affect people in which the primary infection was mild [4,5]. If we do not succeed in delivering treatment that enables the patients to deal effectively with their long-lasting illnesses, the public health care system is unlikely to cope with the upcoming demographic challenges [6,7].

Although patients with chronic illnesses suffer from a wide range of symptoms, pain and fatigue are among the most common [8,9]. Medical advice typically encourages the patient to be as active as possible, to eat healthily, get enough sleep and avoid stress [10–12], and to monitor improvement or worsening by using medical diaries and symptom logs [13]. Since the patient's main concern is to prevent worsening of the condition, activities that might increase symptoms are typically avoided [14]. Examples of such behavior patterns can be to restrict physical activity upon muscle pain, to stand, walk or move carefully, to rest or sleep whenever feeling exhausted or tired, and rest before or after engaging in activities. Over time, such coping strategies are likely detrimental and might contribute to a conservation or worsening of the symptoms. This is especially the case when the first indication of improvement might be a temporary worsening of symptoms, such as muscle pain or tiredness after increased physical activity.

Based on extensive experience with concentrated treatment formats [15–19], we have developed a comprehensive trans-diagnostic rehabilitation for chronic illnesses, characterized by a systematic focus on how to initiate and maintain change. In the presently described protocol, this intervention will be piloted on patients suffering from a diversity of chronic health challenges; chronic low back pain, post-COVID-19 symptoms, anxiety and depression, and diabetes type 2. These conditions were chosen as they collectively represent major personal and societal costs [20]. Furthermore, their inherent disparities allow us to maximize the knowledge gained in this pilot study.

Finally, by including patients with post-COVID-19 symptoms (fatigue, dyspnea, problems with concentration, diurnal pattern and/or nutrition), we may be able to further advance this field, as there presently are large knowledge gaps concerning the long-term prognosis and natural development of the complaints [21].

One of the main features of this novel, cross-disciplinary concentrated intervention (lasting less than a week) is a shift in focus from targeting symptoms to targeting and monitoring everyday micro-choices that facilitate increased levels of functioning. The intention of these micro-choices is to break inflexible patterns of symptom regulation by "doing something different" whenever tempted to be guided by the symptoms. This approach enables the patient to systematically increase flexibility and their level of functioning when the symptoms and health challenges are present. In addition, a focus on deliberate behavior instead of symptoms, implies that change is within reach and possible to control.

In order to ensure a safe setting in which participants may challenge their current coping strategies, they will work together with an interdisciplinary team and each patient will design individually tailored plans for the most relevant micro-choices. To ensure that the patients are prepared to initiate change, they are thoroughly introduced to the program prior to treatment, and if reluctant, they are encouraged to postpone participation until ready. After the concentrated intervention, the patients will be prepared to integrate the changes as part of their everyday living.

The aim of this pilot study is to explore the acceptability of the concentrated interdisciplinary group rehabilitation for patients with chronic low back pain, post-COVID-19 symptoms, anxiety and depression, and diabetes type 2, and describe basic changes in functional status. Based on our experiences with other concentrated treatment formats, we expect the intervention to be highly acceptable and to have significant effects on functional impairment [15–19].

Main hypotheses

- The treatment will be acceptable for the patients, regardless of illness, and they will complete the treatment
- Patients will be satisfied with the treatment

- There will be a significant reduction in how much the illness affects the patients' life
- The patients' level of functioning will be improved at follow-up.

Methods

This pilot study is part of the "Project Development of Smart Health Solutions" (PUSH project), a collaboration between Haukeland University Hospital (Bergen, Norway) and Helse i Hardanger (Øystese, Norway). The overall aim of the PUSH project is to develop more efficient and cost-effective treatments to be integrated as part of the public health care. The project is headed by a steering committee at Haukeland University Hospital, whereas the interventions and study data collection are primarily done at Helse i Hardanger, a health care research facility located outside Bergen.

Study design and participants

This study is designed to test the acceptability of the concentrated interdisciplinary group rehabilitation in an open pre-post follow-up design, for four groups of patients with chronic illnesses: chronic low-back pain, post-COVID-19 symptoms, chronic obstructive pulmonary disease, anxiety and depression, and diabetes type 2. The treatment will be delivered in groups of 6-10 patients, and the initial pilot study will include between 40 and 50 patients for each illness (4-6 treatment groups for each illness). For inclusion and exclusion criteria, please refer to Table 1, and for an overall study flowchart, Figure 1.

Procedures and patient flow

Although patients themselves may initiate the process, all potential participants need to be referred by their general practitioner or other physician responsible for the treatment of the relevant condition. If the patient fulfils the inclusion criteria, they will be invited to sign the informed consent, and offered participation in the project successively upon availability in the groups.

One of the clinicians will call the patients upon referral and check the inclusion/exclusion criteria. During this phone call, the patients will be informed about the PUSH project and that the intervention is a concentrated, interdisciplinary group treatment that will take place in Øystese, outside Bergen. If they fulfil the inclusion criteria and none of the exclusion criteria, an appointment for screening will be made. Before they answer the online questionnaires, they will be asked to watch

videos describing the program, to ensure that all participants receive the same information (at the homepage www.helseihardanger.no) [22]. For low-back pain and diabetes type 2 the informed consent will be signed online, while patients with post-COVID-19 symptoms or anxiety/depression will sign at baseline testing, when the first face-to-face meeting takes place. For low-back pain and diabetes type 2, participants will be invited in groups to an approximately two-hour meeting 1-3 weeks before the treatment to make sure that they are prepared for the intervention. For patients suffering from anxiety and depression, or post-COVID-19 symptoms, the same information will be provided individually during the screening. All patients will be contacted by a therapist during the week prior to the treatment to confirm that they have received all necessary information and are ready to start their concentrated rehabilitation.

Outcomes

Assessments will be performed before and one week after the concentrated rehabilitation program, and after 3, 6 and 12 months. An overview of the measurement tools and the respective assessment times are presented in Table 2. The outcomes are selected with the aim of describing the overall experiences with the concept of the concentrated treatment format. More detailed, disease-specific outcome measures are also assessed, but will not be presented in this generic protocol paper, as they pertain to other aspects than the concentrated treatment format per se. The initial results will be published following 3 months of follow-up, whereas final results are to be published upon 12 months of follow-up.

Primary outcome measures

Acceptability: The acceptability of the treatment will be measured by the following variables: 1) The proportion of patients accepting to participate in the treatment of those fulfilling inclusion criteria and offered participation, 2) The proportion of patients offered participation that start treatment, and 3) The proportion completing the treatment program (on-site).

The Client Satisfaction Questionnaire (CSQ-8) is an 8-item questionnaire that measures patient satisfaction with health services, where the items are rated from 1 (very low satisfaction) to 4 (very high satisfaction) [23]. The total score ranges from 8-32, with higher scores indicating higher degree

of satisfaction. The CSQ-8 has good psychometric properties, with high internal consistency (Cronbach's α = .93), and high inter-item correlation [24].

The Brief Illness Perception Questionnaire (Brief IPQ) is a 9-item questionnaire designed to assess cognitive and emotional representations of illness [25]. Questions are graded from 1 to 10. The last item deals with perceived cause of illness, in which respondents list the perceived three most important causal factors in their illness. For this questionnaire, the general word 'illness' can be replaced by the name of a particular illness. The word 'treatment' in the treatment control item can be replaced by a particular treatment such as 'surgery' or 'physiotherapy'. The scale has good psychometric properties according to a recent review [26].

The Work and Social Adjustment Scale (WSAS) is a short questionnaire measuring the impact of the illness on aspects of work and social activities [27]. The scale consists of five items rated from 0 (not at all) to 8 (very severe), and higher score indicates higher impairment (maximum score is 40). The scale is regarded as reliable and valid, with good psychometric properties.

Trans-diagnostic secondary outcome measures: At pre- and post-treatment and the follow-up assessments the patients will be asked to rate on a scale from 0-100 to what extent they use the following strategies when trying to handle the symptoms:

a) Wait to start an activity until I feel up to it

b) Wait to start an activity until I am certain that I will succeed

c) Ensure that the symptoms will not get worse

d) Ensure that I am prepared to handle challenges

e) When I get anxious I try to calm down before I proceed

f) Spend a lot of time on worrying and ruminating

g) Avoid socializing if I do not feel up to it

h) Ensure that I get enough rest

i) Try to not let others see how I feel

j) Try to have a positive mindset

k) Follow my gut feeling

The intervention

The intervention consists of three equally important phases (see Figure 1): 1) Preparing for change, 2) The concentrated intervention, 3) Integrating change into everyday living. Throughout the intervention, the focus is on how to initiate and maintain change by utilizing discomfort as a guide to break inflexible patterns of symptom regulation. By intention, the topics introduced in the different phases overlap considerably. In order to incorporate the central aspects of a given health challenge, minor illness-specific adaptations are made to the intervention.

Phase 1: Preparing for change

It is essential that the patients are thoroughly informed and prepared prior to the rehabilitation, and that they have made an active choice to initiate change. During the pretreatment information meeting, the following topics will be covered using non-technical terms and easily understandable metaphors (with slight illness-relevant modifications):

a. *Improved everyday functioning*. The goal of this program is to help the participant to live a life where the symptoms/ health challenges do not decide how the person behaves. Thus, it is a program focused on change, with the goal of a better life and improved everyday functioning.
b. *Challenge patterns of symptom regulation*. Living with a chronic illness implies that patients are continuously trying to prevent their health from getting worse, which makes sense. However, one of the consequences might be that the patients develop patterns of symptom regulation that might contribute to a conservation – or even in some instances exacerbate - the problem. Typically, the patient finds it hard to know when to be cautious and when to challenge a given strategy to deal with the symptoms. In our experience, people with chronic illnesses typically have an adequate understanding of their problems, but this does not necessarily lead to change. Rather it may increase the feeling of helplessness because they do not know how to initiate and sustain change. The concentrated treatment is a practical, deliberate approach focused on how to identify and break unhelpful patterns of symptom regulation.
c. *Therapist-assisted behavior activation.* In line with the above, the illness is frequently a composite of health challenges that might require expertise from a number of specialized professions. During

four consecutive days (three for post-COVID-19 symptoms), a highly qualified interdisciplinary team will provide practical information and hands-on coaching while the patients challenge the way symptoms are handled. Patients referred to the program for anxiety and depression are prior to treatment expected to provide suggestions regarding unhelpful patterns of regulation which they are willing to start changing during the concentrated treatment days, e.g. avoidance of specific situations, social withdrawal etc.

d. *Group setting*. The concentrated treatment is delivered in groups of 6-10 patients. The participants will work side by side and challenge their own expectations regarding what they are capable of doing. In the group setting, each participant will need to take responsibility for making the treatment sessions relevant for their specific problems.

e. *Basic bodily rhythms*. An important aspect of the treatment is a focus on the practical implications of bodily rhythms such as sleep-wakefulness, activity-rest, and meal habits.

f. *Substantial self-effort*. All participants are expected to stay at the adjacent hotel throughout the treatment week, to dedicate full days to the treatment and engage in all parts of the program from 8:30 am to 4:00 pm. The last day, the program will be finished after lunch. From 4:00 to 7:00 pm, each participant will practice on their own based on what they learned during the treatment. This means that there will not be room for other appointments during the concentrated intervention period and their full focus will be on changing their unhelpful behavior patterns.

g. *Start planning life after the concentrated intervention.* Since the focus is to increase the level of functioning, it is necessary that each participant, prior to the intervention, decides upon how to practice the changes and integrate them into their lives, starting directly after the intervention. This includes specific plans to increase participation at work/school or other activities that will lead to better daily functioning.

h. *Not participate until you are ready.* No treatment or medicine works if the patient is not willing to take it – this even goes for penicillin. If the patients are reluctant to participate, we recommend them to wait until they are ready to make a change.

An adapted version of the Borkovec and Nau (1972) *Reaction to treatment scale* is used to explore the patients' readiness for treatment [28]. A low rating (<70%) on any of the four questions "How much does this approach make sense?"; "How likely is it that you would recommended this treatment to a friend with similar problems?"; How likely is it that you will be fully engaged in the program?"; "How likely do you think it is that you will benefit from the program?" will serve as an opportunity to clear up any misunderstandings, and together with the patient, decide if it might be better to postpone treatment initiation.

Phase 2: The concentrated group intervention

The program starts with patient education, and the most important points will be repeated throughout the week. At the first session, rules of confidentiality will be established. During the first part of day one, each participant will provide some information about his/her health problem based on the following: "How long have you struggled with this health challenge?", "What does it prevent you from doing?", "What are you looking forward to do when this is no longer a problem?". The participants will use 2-3 minutes each. Patient education will be interspaced with physical activity, brief mindfulness sessions, and practical training sessions focused on breaking problematic patterns of symptom regulation

Trans-diagnostic elements of the group intervention:

a. Patient education on how to initiate and maintain relevant change and at the same time accept those things that cannot be changed or controlled [e.g. history, thoughts and feelings (for post-COVID-19 symptoms and diabetes type 2: getting the infection / having the illness)]. It will be underscored that change starts with an active decision, and that the goal of the treatment is to increase flexibility and to live a life where the symptoms do not decide.

b. *Micro-choices* will be used as a term which refers to the moments when you discover specifically how and where in your everyday life the symptoms are making choices on behalf of you, and where you have an option to choose differently. Participants will be encouraged to do things they have avoided in fear of symptoms worsening. It will be emphasized that change is measured in behavior;

what you do, and *not* in reduction of symptoms. Symptom reduction on the other hand, will be described as a positive and valuable side effect of behavioral change. This shift in focus, from symptoms to deliberate behavior implies that change is within reach. Furthermore, participants will be challenged to do a value-based micro-choice each day, e.g. call a friend or relative whom they had neglected due to the health problems. During patient education, this concept is introduced and explained (i.e. having health problems and symptoms may make people more self-centered and to lose perspective, making them lose track of who they were. Value-based actions may help them get back on track and widen their focus).

c. Individually tailored practice in discovering micro-choices and "breaking problematic patterns" in as many relevant settings as possible will be the cornerstone of each day.

d. Feedback and coaching. Each morning, at lunchtime, and at the end of the joint program, everyone will be asked to share their self-evaluation on how successful they have been in identifying their own patterns of symptom regulation, and to what extent they have attempted to break the patterns. A scale from 1-6 will be used. If they rate themselves lower than a 6, the group leader will explore the reasons for this, with the aim of helping them to find the moments of "micro-choices" and to identify what they can do to break the pattern. Throughout these sessions, symptoms will not be given attention, but rather described as being important in order to be able to identify targets where it might be possible to break the patterns of regulation.

e. Physical activity. These sessions will vary across illnesses, however, common for all participants will be instructions to attempt making the physical activity relevant for their own challenges and fit into their projects of "breaking patterns of symptom-regulation". For some, this might mean to refrain from the temptation to overdo, for others, it might imply to be more active, – or active in a different way. For patients with anxiety/ depression the task during the physical activity will be to "surprise themselves" by doing a little more when they feel they have reached their limit. Patients with low-back pain will follow the validated ready-to-use program "GLA:D® Back", integrating patient education and exercise therapy [29,30]. For post-COVID 19 patients, the physical training will be a mix of high- and low-intensity training, focusing on increased exercise capacity and the restoration of

trust in one's own body. In the diabetes type 2-group, the main aim will be to experience how a diverse range of activities can be useful in order to maximize the effect of the body's available insulin.

f. Mindfulness. Each day will contain 1-3 brief sessions of detached mindfulness where the task will be to focus on the breathing, while at the same time observe (and accept, without trying to change), wandering thoughts, bodily sensations etc [31].

g. Food and meal habits. One of the patient education sessions will be focused on useful dietary choices. For patients with post-COVID-19 symptoms affecting diet and/or nutrition, the focus will be on useful dietary choices with a focus on helping the body to recover. In patients with anxiety and depression, the focus is on the establishment of good mealtime habits as a way of restoring diurnal rhythms. For patients with diabetes type 2, the emphasis will be to explore how to get the maximum out of the available insulin (i.e. their beta-cell capacity or their insulin injections). During this session, they will also test different "forbidden" (carbohydrate-rich) food items and evaluate the consequences on their blood glucose levels. This will be followed by physical activity, to experience the restoration of habitual glucose levels. The aim is to recognize that no food is forbidden, but that there are consequences of the choices, with various possible compensatory actions.

h. Pharmacist. For all participants, a pharmacist reviews the individual medication lists, focusing on potential harmful interactions. In the low-back pain group, two sessions of patient education are provided. First on various types of formulations and medications in general, followed by an illness-specific session focusing on risks of combining pain medication, potential impact on driving capabilities and an overall emphasis on minimizing the use of opioid-based and other pain-relief symptom treatment. Individual advice on the downsizing and discontinuation of medication is provided in cooperation with the study physician. Following the same pattern, the diabetes type 2 group also have two interactive educative sessions with the pharmacist. Here, the second session deals specifically with diabetes medications; – use, effects, and most common side-effects. For patients with Post-COVID-19 symptoms, a short patient education is followed by a brief counseling session with a pharmacist on proper use of inhalators.

i. Afternoon practice. Before the group split at 4:00 pm each day, individual practice plans for each afternoon and evening will be made, focusing on implementing micro-choices in terms of physical activity, social/value-based activity, self-reflection etc.

j. Individual consultation. During the program, all patients will receive an individual consultation with the group leader or one of the psychologists or psychiatrists who are experts on the concentrated treatment format. This consultation will be focused on how to integrate the change into everyday living.

k. Preparing for life after the treatment. By the end of the program, all patients will have made a specified plan addressing how to integrate the change into normal living using the concept of SMART goals (Specific, Measurable, Achievable, Relevant, Time-bound) [32,33]. Also, they will start answering the following daily questions on-line: "To what extent did you allow the symptoms to decide today" (0-10) and "To what extent did you make use of the principle of 'doing something else'" (0-10).

Phase 3: Integrating the change into everyday living

Daily online reports. For three weeks after the concentrated program, through a digital solution, all patients will answer the two daily questions (described above) pertaining to the maintenance of the change. This will be done without feedback from the program. Helse i Hardanger is in the process of developing a smart-phone application through which the patients are expected to answer questionnaires, store their SMART-goals and provide feedback. The program will facilitate contact with the clinic if needed.

Individual video or phone consultation. Ten days after the concentrated treatment, an individual phone or video consultation is performed, focusing on how to maintain the change. Additionally, patients with low back pain follow the program for GLA:D® Back, with bi-weekly training for eight weeks at certified local GLA:D® Back facilities.

Further follow-up and data gathering. All patients will answer questionnaires at 3-, 6- and 12-months follow-up. Further disease-specific examinations and/or data may also be gathered, however, the description of these are outside the scope of this generic protocol paper.

Competency in the concentrated treatment format

A psychologist with extensive experience with concentrated treatment formats will lead all groups for patients with anxiety/depression, and these groups will be used for hands-on training in the format for clinicians working with the other illnesses. The content of all manuals (Standard Operating Procedures) is supervised and approved by the originator of the format (GK), and all groups will receive hands-on supervision daily from GK.

Statistical analysis plan (SAP) and data handling

Data will be analyzed with Stata version 16.1 (StataCorp LLC 2019, College Station, TX, USA). For the initial pilot study, linear mixed models will be used to evaluate changes in the trans-diagnostic primary outcome measures from pre-treatment to post treatment and 3-months follow-up. Between illness differences in measured change will be explored by including interactions between time (pre-treatment, post-treatment, and 3-month follow up) and illness. Statistically significant interactions will be followed by examination of simple effects. Within-group effect sizes will be calculated on complete data using Glass´ Δ, with pretreatment SD as denominator. Glass's Δ is the recommended effect size for intervention studies in which there are reasons to believe that the treatment will influence the standard deviation as well as the mean [34]. An effect size is commonly interpreted as small (0.2), moderate (0.5), and large (0.8)

Following the principle of intention-to-treat, all participants will be included in the analyses, irrespective of missing data at any of the assessment points. Mixed models do not assume balanced data and are able to account for missing data on the outcome variable by using all available data on each participant. Under the *missing at random* (MAR) assumption, these models provide unbiased estimates [35].

Clinically significant change will be assessed using the criteria of Jacobson and Truax (1991). These specify that 1) The patients' pre-post (pre-follow-up) change score on the primary outcome measures is larger than the measurement error (Reliable Change Index) and 2) The post-treatment (follow-up) score is outside of the patient sample's pre-treatment distribution (defined as M - 2SD) or within the normal group's distribution (defined as M + 2SD).

Data collection and monitoring:

For each illness, a centralized team will be established. This team will have monthly contact with one designated researcher for each illness in order to monitor inclusion and data collection. Most of the data will be collected electronically and all sensitive data stored on an encrypted server at Helse Vest IKT. Once the patients are included, all data entered by participants are monitored by the Study Administrative Team.

Adverse events

If an acute condition should occur, patients will receive the necessary care, and patients might be excluded from the study if there are concerns about safety. Such patients will be thoroughly described and accounted for, in line with the illness-specific Standard Operating Procedures.

User involvement

The project has established a broad user panel with representatives recruited through HUS and HiH. The following organizations are represented: Norwegian Asthma and Allergy Association, Norwegian Rheumatics' Association, Mental Health Norway, Breast Cancer Association, Norwegian Diabetes Association, Norwegian Association for Lung and Heart Disease, "Grannehjelpa" («Neighbors' help»). The panel has given feedback throughout the development of the protocol and approved the final version.

Ethical considerations

The PUSH project as well as the web application is approved by the Research ethical board, Helse Vest 2020/101638 and will be conducted in accordance with the Helsinki Principles.

Gender perspectives

The inclusion as well as all interventions are gender neutral. However, in order to ensure adequate external validity and proper representation we have no absolute limits in terms of minimum inclusion rates of one gender. For all illnesses, the project will aim for at least 30-70 representation of the genders.

Discussion

In this paper, we describe a protocol for the establishment and initial evaluation of a novel, concentrated interdisciplinary group rehabilitation for patients with chronic low back pain, post-

COVID-19 symptoms, COPD, anxiety/depression or diabetes type 2. To our knowledge, this will be the first study to evaluate concentrated interdisciplinary group rehabilitation for such a diverse range of chronic health issues. Based on previous experiences with the short, concentrated treatment format, we hypothesize that the intervention described will be positively received by the participants, will reduce the impact of the illness on their lives, and will improve the level of daily functioning.

The study is designed with participants as their own controls (pre-post comparisons) with a 12-month follow-up. Although this allows for summarizing the experiences and findings as described above, causal conclusions on the effects of the intervention may not be drawn. However, in our mind, this is an essential first step enabling subsequent separate controlled trials where such research questions – as well as the cost-effectiveness issues – may be addressed. Still, the modest labor factor (ten patients, two group leaders) compared to traditional rehabilitation projects clearly benefit our concentrated treatment format, if shown to be efficacious.

If the intervention is followed by meaningful improvements for the participants, we will be able to help large groups of patients with chronic illnesses to adhere to choices in their daily living that eventually will enhance their functional status. Due to the concentrated format, the fact that participants need only 3 or 4 days of sick leave to take part in the intervention, with the continued rehabilitation process at home is another clear advantage. Existing rehabilitation programs for chronic illnesses often have a duration of 3-4 weeks or longer, and therefore requires longer time away from home and for those who are working, longer sick leave. Another benefit of our intervention is the focus on implementing micro-choices in everyday life, with guided practice during the intervention and the assisted introduction into the life at home and work. Although this needs to be investigated, the aim is to ensure the long-term maintenance of the new life trajectory.

Considering the methodology, dropouts and poor adherence to the intervention can threaten the internal validity. Although proper information aims to limit this problem, we cannot be sure that the participants will participate for the whole period or whether they will complete digital and clinical

examinations at 3- 6- and 12-month follow-ups. A notice will be sent to the patients about two to three weeks before the assessments will take place. Participants who are not answering the questionnaires online, or meet to the clinical examinations, will be contacted by telephone. Impact of missing data will be assessed with appropriate statistical methods, e.g., linear mixed models, multiple imputations, and sensitivity analysis.

This protocol describes a novel trans-diagnostic rehabilitation approach, and the illnesses in focus are clearly disparate. Hence, if the intervention in the described study appears effective, this could also trigger new studies investigating the effects on other chronic diseases or health challenges. In line with this, and to facilitate potential dissemination of the concentrated rehabilitation format, a training program for relevant health professionals will be made available.

Conclusion

We present a protocol for the establishment and evaluation of a novel, concentrated treatment to be investigated on patients with chronic low back pain, COPD, post-COVID-19 symptoms, anxiety/depression and diabetes type 2. The treatment focuses on how to initiate and maintain change, with a shift away from monitoring symptoms towards an active approach to daily health-promoting micro-choices. This short intervention has the potential of fundamentally changing the way we deliver health care to these patient populations, and hence could be a useful addition to the treatment armamentarium of the health care system, in the face of the coming socio-demographic challenges.

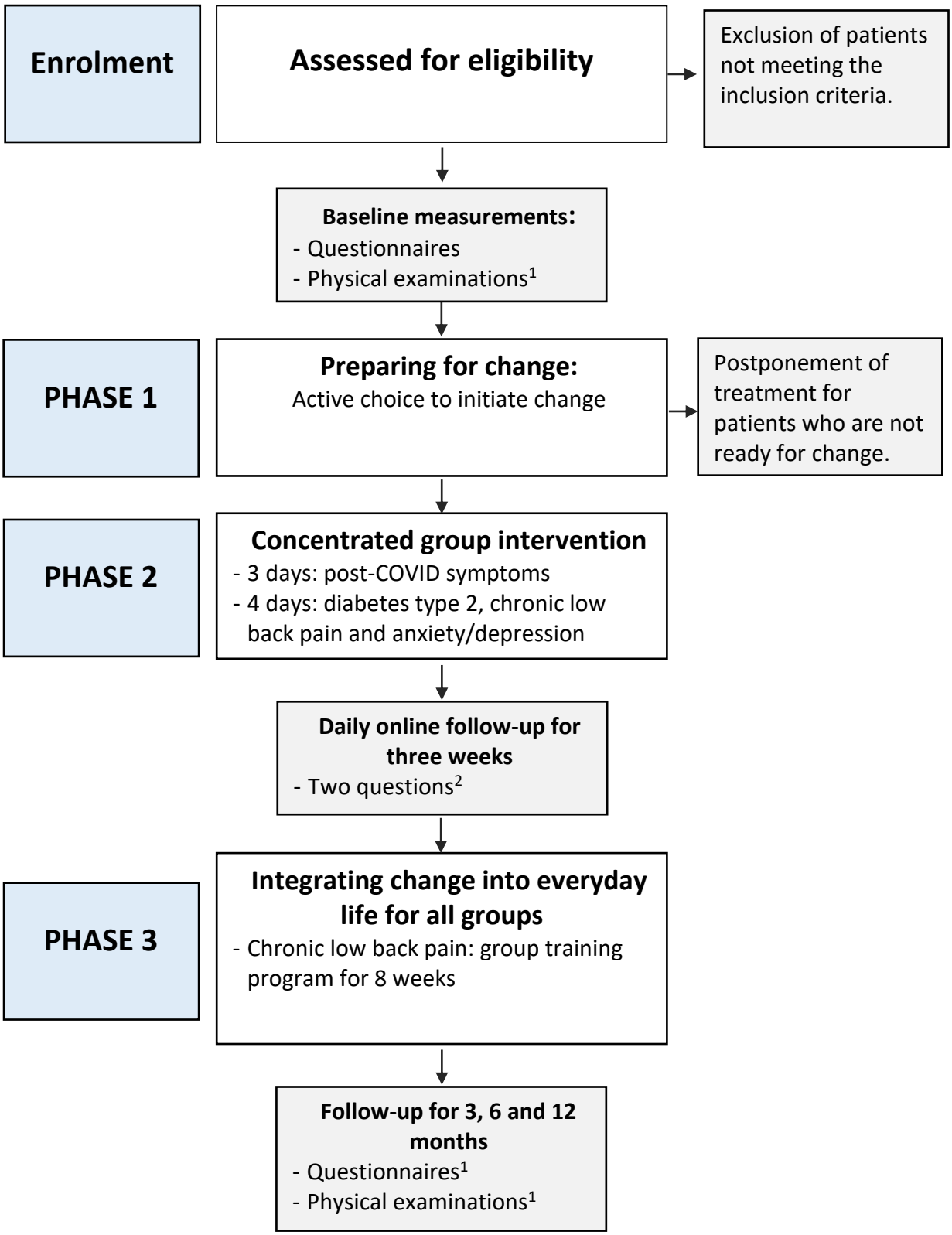

Figure 1: Flowchart of the study

[1] Illness-specific physical exercise test and examinations. Evaluation with questionnaires at pre-treatment one week and 3-, 6- and 12-months follow-up.
[2] 1) *To what extent did you allow the symptoms to decide to-day* (0-10) and 2) *To what extent did you make use of the principle of 'doing something else'* (0-10).

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
For all diagnoses	
• Fluent in oral and written Norwegian • Access to smartphone and sufficient digital competence to handle online questionnaires • Negative COVID-19 PCR test	• Cognitive failure • Lack of self-reliance in daily routine • Severe mental health problems preventing engagement in the rehabilitation program • Conditions that inhibit physical activity
Chronic low back pain	
• Low back pain with or without radiculopathy • Age between 18–70 years old • Low back pain >3 months, and at least 4 months of sick leave • Able to participate at a group based post-treatment physical training in Bergen, Voss or Kvam municipalities	• Surgery during the last 8 weeks • Available alternative rehabilitation therapy for low back pain
Diabetes type 2	
• Type 2 diabetes • Age >18 years • Have at least one of the following complications/ challenges: - Dysglycemia - Frequent or severe hypoglycemia - Weight gain - Diabetes complications - Diet, physical activity and/or medical treatment challenges	• Type 1 diabetes • Monogenic diabetes • Secondary diabetes (pancreatogenic or any other forms of secondary diabetes). • Ongoing pregnancy
Post-COVID-19 Symptoms	
• Age between 18–67 years • >2 months since the COVID-19 infection • Impaired ability to work full-time • Substantial post-COVID-19 related physical and/or mental health problems • Fatigue • Dyspnea • Concentration difficulties • Sleeplessness, diurnal disturbances • Nutritional deficiencies	• Exercise contraindicated
Anxiety or depression	
• Age between 18- 47 years • Fulfilling ICD-11 criteria for one of the following disorders: - Mixed anxiety and depressive illness - Other mixed anxiety illnesses - Unspecified anxiety illness - Generalized anxiety illness - Depressive episode - Recurrent depression - Unspecified recurrent depression	• Bipolar illness • Psychosis • Ongoing substance abuse/dependence • Ongoing suicidal ideation

Abbreviations: PCR: polymerase chain reaction; ICD: International Classification of Illnesses

Table 2. Questionnaires, clinical and physical examinations

Questionnaires and assessments	Assessment point
• Client Satisfaction Questionnaire	• One week post rehabilitation
• Brief Illness Perception Questionnaire	• Baseline, one week, 3-, 6- and 12-months post rehabilitation
• Work and Social Adjustment Scale	• Baseline, 3-, 6- and 12-months post rehabilitation
• Strategies for handling symptoms, rating 0-100 and two questions[1]	• Daily reports for 21 days post rehabilitation
	• Baseline, one week, 3-, 6- and 12-months post rehabilitation
• Patient Activation Measure	• Baseline, one week, 3-, 6- and 12-months post rehabilitation
• Consumption of health care	• Baseline, 3-, 6- and 12-months post rehabilitation
• Medication lists	• Baseline, 3-, 6- and 12-months post rehabilitation
• Body weight/body mass index	• Baseline, 3-, 6- and 12-months post rehabilitation
	• Baseline, 3-, 6- and 12-months post rehabilitation

[1] To what extent did you allow the symptoms to decide today" (0-10) and "To what extent did you make use of the principle of 'doing something else'" (0-10).

References

1. Forouzanfar MH, Afshin A, Alexander LT, Anderson HR, Bhutta ZA, Biryukov S, et al. Global, regional, and national comparative risk assessment of 79 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. Lancet 2016 Oct;388(10053): 1659-1724 [doi: 10.1016/S0140-6736(16)31679-8]
2. WHO Noncommunicable diseases. URL: https://www.who.int/health-topics/noncommunicable-diseases#tab=tab_1 [accessed 2021-07-20]
3. Mathers CD, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. PLoS Med 2006;3(11). [doi: 10.1371/journal.pmed.0030442]
4. Blomberg B, Mohn KG-I, Brokstad KA, Zhou F, Linchausen DW, Hansen B-A, et al. Long COVID in a prospective cohort of home-isolated patients. Nat Med 2021; epub ahead of print [doi: 10.1038/s41591-021-01433-3]
5. Salamanna F, Veronesi F, Martini L, Landini MP, Fini M. Post-COVID-19 syndrome: The persistent symptoms at the post-viral stage of the disease. A systematic eeview of the current data. Front Med 2021;8(May) [doi: 10.3389/fmed.2021.653516]
6. Waters H, Marlon G. The costs of chronic disease in the U.S. Milken Institute 2018. URL: https://milkeninstitute.org/report/costs-chronic-disease-us [accessed 2021-07-20]
7. Holman HR. The relation of the chronic disease epidemic to the health care crisis. ACR Open Rheumatol 2020;2(3):167–173. [doi: 10.1002/acr2.11114]
8. Menting J, Tack CJ, Bleijenberg G, Donders R, Droogleever Fortuyn HA, et al. Is fatigue a disease-specific or generic symptom in chronic medical conditions? Heal Psychol 2018 Jun;37(6): 530-543 [doi: 10.1037/hea0000598]
9. Hara KW, Borchgrevink PC, Jacobsen HB, Fimland MS, Rise MB, Gismervik S, et al. Transdiagnostic group-based occupational rehabilitation for participants with chronic pain, chronic fatigue and common mental disorders. A feasibility study. Disabil Rehabil 2018 Oct

9;40(21): 2516-2526 [doi: 10.1080/09638288.2017.1339298]

10. Bennett JE, Stevens GA, Mathers CD, Bonita R, Rehm J, Kruk ME, et al. NCD Countdown 2030: worldwide trends in non-communicable disease mortality and progress towards Sustainable Development Goal target 3.4. Lancet 2018 Sep;392(10152): 1072-1088 [doi: 10.1016/S0140-6736(18)31992-5]
11. McPhee JS, French DP, Jackson D, Nazroo J, Pendleton N, Degens H. Physical activity in older age: perspectives for healthy ageing and frailty. Biogerontology 2016 Jun 2;17(3): 567-580 [doi: 10.1007/s10522-016-9641-0]
12. Depner CM, Stothard ER, Wright KP. Metabolic consequences of sleep and circadian disorders. Curr Diab Rep 2014 Jul 10;14(7) [doi: 10.1007/s11892-014-0507-z]
13. Menchaca D. 5 diary apps for tracking symptoms (Teamscope). URL: https://www.teamscopeapp.com/blog/5-diary-apps-for-tracking-symptoms [accessed 2021-07-20]
14. Stussman B, Williams A, Snow J, Gavin A, Scott R, Nath A, et al. Characterization of post–exertional malaise in patients with myalgic encephalomyelitis/chronic fatigue syndrome. Front Neurol 2020 Sep 18;11 [doi: 10.3389/fneur.2020.01025]
15. Stubhaug B, Lier HO, Aßmus J, Rongve A, Kvale G. A 4-day mindfulness-based cognitive behavioral intervention program for CFS/ME. An open study, with 1-year follow-up. Front Psychiatry 2018 Dec 20;9 [doi: 10.3389/fpsyt.2018.00720]
16. Hansen B, Kvale G, Hagen K, Havnen A, Öst L-G. The Bergen 4-day treatment for OCD: four years follow-up of concentrated ERP in a clinical mental health setting. Cogn Behav Ther 2019 Mar 4;48(2):89–105 [doi: 10.1080/16506073.2018.1478447]
17. Kvale G, Hansen B, Björgvinsson T, Børtveit T, Hagen K, Haseth S, et al. Successfully treating 90 patients with obsessive compulsive disorder in eight days: the Bergen 4-day treatment. BMC Psychiatry 2018 Dec 4;18(1):323 [doi: 10.1186/s12888-018-1887-4]
18. Launes G, Hagen K, Sunde T, Öst LG, Klovning I, Laukvik IL, et al. A randomized controlled trial of concentrated ERP, self-help and waiting list for obsessive-compulsive disorder: The Bergen 4-day treatment. Front Psychol 2019 Nov 15;10 [doi: 10.3389/fpsyg.2019.02500]

19. Haukebø K, Skaret E, Öst L-G, Raadal M, Berg E, Sundberg H, et al One- vs. five-session treatment of dental phobia: A randomized controlled study. J Behav Ther Exp Psychiatry 2008 Sep;39(3):381–390 [doi: 10.1016/j.jbtep.2007.09.006]

20. NAV. Norwegian national sick leave and disability statistics. URL: https://www.nav.no/no/nav-og-samfunn/statistikk/sykefravar-statistikk/sykefravar [accessed 2021-07-20].

21. Shah W, Hillman T, Playford ED, Hishmeh L. Managing the long term effects of covid 19: summary of NICE, SIGN and RCGP guideline. BMJ 2021;372:n136 [doi.org/10.1136/bmj.n136]

22. Helse i Hardanger homepage. URL: www.helseihardanger.no [accessed 2021-07-20]

23. Nguyen TD, Attkisson CC, Stegner BL. Assessment of patient satisfaction: Development and refinement of a Service Evaluation Questionnaire. Eval Program Plann 1983;6(3–4). [doi: 10.1016/0149-7189(83)90010-1]

24. Larsen DL, Attkisson CC, Hargreaves WA, Nguyen TD. Assessment of client/patient satisfaction: development of a general scale. Eval Progr Plann 1979;2:197–207. PMID:10245370

25. Broadbent E, Petrie KJ, Main J, Weinman J. The Brief Illness Perception Questionnaire. J Psychosom Res 2006 Jun;60(6):631–637. PMID:16731240

26. Broadbent E, Wilkes C, Koschwanez H, Weinman J, Norton S, Petrie KJ. A systematic review and meta-analysis of the Brief Illness Perception Questionnaire. Psychol Heal [Internet] Routledge; 2015;30(11):1361–1385. PMID:26181764

27. Mundt JC, Marks IM, Shear MK, Greist JH. The Work and Social Adjustment Scale: A simple measure of impairment in functioning. Br J Psychiatry 2002;180:461–464. PMID:11983645

28. Borkovec TD, Nau SD. Credibility of analogue therapy rationales. J Behav Ther Exp Psychiatry 1972;3(4): 257-260 [doi: 10.1016/0005-7916(72)90045-6]

29. Kjaer P, Kongsted A, Ris I, Abbott A, Rasmussen CDN, Roos EM, et al. GLA:D ® Back group-based patient education integrated with exercises to support self-management of back pain - Development, theories and scientific evidence. BMC Musculoskelet Disord 2018 Nov

29;19(1). [doi: 10.1186/s12891-018-2334-x]

30. Kongsted A, Ris I, Kjaer P, Vach W, Morsø L, Hartvigsen J. GLA:D® Back: implementation of group-based patient education integrated with exercises to support self-management of back pain - protocol for a hybrid effectiveness-implementation study. BMC Musculoskelet Disord 2019 Feb 18;20(1). PMID:30777049

31. Kabat-Zinn J, Lipworth L, Burney R. The clinical use of mindfulness meditation for the self-regulation of chronic pain. J Behav Med. 1985; 8(2): 163-90. [doi: 10.1007/BF00845519]

32. Bovend'Eerdt TJH, Botell RE, Wade DT. Writing SMART rehabilitation goals and achieving goal attainment scaling: A practical guide. Clin Rehabil 2009;23(4):352–361. PMID:19237435

33. Bowman J, Mogensen L, Marsland E, Lannin N. The development, content validity and inter-rater reliability of the SMART-Goal Evaluation Method: A standardised method for evaluating clinical goals. Aust Occup Ther J 2015;62(6): 420-427. [doi: 10.1111/1440-1630.12218]

34. Lakens D. Calculating and reporting effect sizes to facilitate cumulative science: A practical primer for t-tests and ANOVAs. Front Psychol 2013;4:863 [doi: 10.3389/fpsyg.2013.00863]

35. Schafer JL, Graham JW. Missing data: Our view of the state of the art. Psychol Methods 2002;7(2): 147-177 [doi: 10.1037/1082-989X.7.2.147]