PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	An evidence-based digital support during one year after an Interdisciplinary Pain Rehabilitation Program for persons with chronic musculoskeletal pain to facilitate a sustainable return to work: a study protocol for a registry-based multicentre randomized controlled trial.
AUTHORS	Turesson, Christina; Liedberg, Gunilla; Vixner, Linda; Lofgren, Monika; Björk, Mathilda

VERSION 1 – REVIEW

REVIEWER	Raquel Leirós-Rodríguez Universidad de Leon - Campus de Ponferrada
REVIEW RETURNED	07-Jan-2022

GENERAL COMMENTS	Dear Authors: Congratulations on the research conducted. This is a well-developed study of clinical impact for the scientific and professional community. However, the manuscript has some limitations and/or errors that need to be resolved before acceptance. ABSTRACT: Abbreviations should be removed from this section. They are not formally correct. The subsections in this section are also inappropriate. Please respect the rules for authors of the journal. No mention of Conclusions and their clinical impact. INTRODUCTION This section (and/or Discussion) should link this research to the current context of the COVID-19 pandemic and the impact of socio-health measures on the incidence and prevalence of chronic pain: Doi: 10.3390/ijerph18010031 Doi: 10.3390/jcm9124053 There are some spelling and punctuation mistakes that need to be corrected. MATERIAL AND METHODS The organisation of the information and the arrangement and number of subsections should be reconsidered (authors should consult other relevant articles published in this Journal and the Instructions for Authors of this Journal). Authors should adequately reference and justify the sample size calculation described. Statistical analysis should be improved to increase the power of the reported results. At a minimum, effect sizes should be included.

	DISCUSSION The lack of this section is worrying and alarming. If an adequate section discussing the results obtained by this research is not included, this manuscript should be rejected. Discussion with reference manuscripts for the intervention of chronic pain patients is recommended: Doi: 10.1186/s13102-021-00361-6 Doi: 10.1186/s13102-021-00313-0 Kind regards

REVIEWER	Jeannie Bailey UCSF
REVIEW RETURNED	07-Mar-2022

GENERAL COMMENTS	This protocol looks great. My only two inquiries are: 1) I would like some more information on the state and symptoms of the low MSK patients that may be enrolled in this study. Will you have info on the chronicity of their pain? 2) I am concerned by the lack of 'sham' for the control group. If patients are consented into this study, they will know it is a digital care invention. Won't the controls be aware they are not in the intervention when they don't get access to an app? Can you provide some limited/basic form of the intervention to the control group? Like some education only? Lastly, there are some spelling mistakes, primarily with the word enroll (misspelled 'enrol') and enrollment (misspelled 'enrolment') throughout. Please check.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Dr. Raquel Leirós-Rodríguez, Universidad de Leon - Campus de Ponferrada Comments to the Author:

Dear Authors:
Congratulations on the research conducted. This is a well-developed study of clinical impact for the scientific and professional community. However, the manuscript has some limitations and/or errors that need to be resolved before acceptance.

ABSTRACT:
Abbreviations should be removed from this section. They are not formally correct.
Response: We have removed the abbreviations from the abstract.
The subsections in this section are also inappropriate. Please respect the rules for authors of the journal. No mention of Conclusions and their clinical impact.
Response: The sections we have included are in line with the journal's instructions regarding abstracts for study protocols in BMJ Open (https://bmjopen.bmj.com/pages/authors/#protocol)

INTRODUCTION
This section (and/or Discussion) should link this research to the current context of the COVID-19 pandemic and the impact of socio-health measures on the incidence and prevalence of chronic pain:
Doi: 10.3390/ijerph18010031
Doi: 10.3390/jcm9124053
Response: Despite the interesting content of the proposed articles, we cannot see a direct connection to our manuscript. Our manuscript has a focus on return to work where the persons also have a diagnosed chronic pain. We have now developed a digital application for facilitating the cooperation and dialogue between the employer and the employee with chronic pain and the content of the proposed articles doesn't seem in line with the focus of our study. We have not made any connections

to the pandemic since it hasn't influenced our work and we have therefore not included the proposed articles in this manuscript.
There are some spelling and punctuation mistakes that need to be corrected.
Response: Thank you for bringing this to our attention. We have reviewed the manuscript regarding spelling and punctuation.

MATERIAL AND METHODS
The organisation of the information and the arrangement and number of subsections should be reconsidered (authors should consult other relevant articles published in this Journal and the Instructions for Authors of this Journal).
Response: We have worked through the method section and re-organised the subsections according to instructions for authors.
Authors should adequately reference and justify the sample size calculation described.
Response: As there is no defined minimal clinical important difference regarding sick leave and as sick leave is a complex outcome, the sample size calculation was inspired by and partially based on findings from previous research. It has been shown that the distribution of sick leave for persons with chronic pain change over time for example from full-time to partial sick leave after IPRP and that sick leave are reduced with approximately 16 net days from one year before to two years after IPRP. Therefore, we estimated a difference between the groups of 20 net days with a standard deviation of 60 and an effect-size of 0.333 was set for rejection of the null hypothesis. This has been clarified in the manuscript.
Statistical analysis should be improved to increase the power of the reported results. At a minimum, effect sizes should be included.
Response: We have added that we intend to calculate and report effect-size and perform repeated measures analyses of data from SWEPPE.

DISCUSSION
The lack of this section is worrying and alarming. If an adequate section discussing the results obtained by this research is not included, this manuscript should be rejected.
Discussion with reference manuscripts for the intervention of chronic pain patients is recommended:
Doi: 10.1186/s13102-021-00361-6
Doi: 10.1186/s13102-021-00313-0
Response: We have followed the instructions for authors and the inclusion of a discussion section is optional. We have therefore chosen not to include a discussion as strengths and limitations of the study is summarized in bullet points in a separate section after the abstract.

Kind regards

Reviewer: 2
Dr. Jeannie Bailey, UCSF

Comments to the Author:
This protocol looks great. My only two inquiries are:
1) I would like some more information on the state and symptoms of the low MSK patients that may be enrolled in this study. Will you have info on the chronicity of their pain?
Response: Regarding stratification of participants into high/low sick leave, this will be done due to sick leave being a strong predictor for future sick leave. It has been shown that patients with low sick leave history to a larger extent are younger, have an employment, higher education and are more confident regarding recovery. We have added information regarding this in the section Allocation/randomization. We will collect patient characteristics from the SQRP and supplementary questionnaires regarding for example age, employment and education as described under the heading Outcomes.

2) I am concerned by the lack of 'sham' for the control group. If patients are consented into this study, they will know it is a digital care invention. Won't the controls be aware they are not in the intervention when they don't get access to an app? Can you provide some limited/basic form of the intervention to the control group? Like some education only?
Response: Thank you for your point. We agree with you that it is a limitation that the control group will be aware of not receiving any intervention which could affect self-reported outcomes. However,

primary outcome of the study is sick leave days collected from the Swedish Social Insurance Agency. Your valuable suggestion with a sham intervention to the control group is unfortunately not feasible due to the nature of the intervention with SWEPPE as a tool for facilitating communication and interaction with the employer. We also want to stay as close as possible to real world conditions where persons with CMSP do not receive any support after completing rehabilitation. We have added a sentence regarding blinding to treatment allocation not being feasible to the section describing the control group. We have also added a bullet point regarding the lack of blinding to treatment allocation to the section Strengths and limitations of the study.

Lastly, there are some spelling mistakes, primarily with the word enroll (misspelled 'enrol') and enrollment (misspelled 'enrolment') throughout. Please check.
Response: Thank you for bringing this to our attention. We have worked through the manuscript regarding spelling.