CONSORT-EHEALTH Checklist V1.6.2 Report	Manuscript Number	14236
(based on CONSORT-EHEALTH V1.6), available at [http://tinyurl.com/consort-ehealth-v1-6].		
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by		
Sarah Eichler		
Telerehabilitation as a supplement to usual aftercare in patients after total knee or hip replacement - A randomized controlled study for the effectiveness of a telemedical assisted movement therapy in orthopaedic rehabilitation		
TITLE		
1a-i) Identify the mode of delivery in the title		
Telerehabilitation		
1a-ii) Non-web-based components or important co-interventions in title		
1a-iii) Primary condition or target group in the title		
patients after total knee or hip replacement		
ABSTRACT		
1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT		
Telerehabiliation		
1b-ii) Level of human involvement in the METHODS section of the ABSTRACT		
patients after total knee or hip replacement		
1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT		
rehab center		
1b-iv) RESULTS section in abstract must contain use data		
111		
1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials		
equivalent to usual aftercare		
INTRODUCTION		
2a-i) Problem and the type of system/solution		
The aim of this randomized controlled trial was to examine the previously developed telemedical assisted movement therapy regarding functional parameters, quality of life and pain as well as return to work compared to usual aftercare.		
2a-ii) Scientific background, rationale: What is known about the (type of) system		
In this regard, telerehabilitation seems predestined since it can be performed regardless of location and time. Therefore, it has the potential to increase both utilization and therapy adherence. The telemedical offers should be adapted to the individual and indication specific needs of the patients and should enable contact with the supervising therapists. However, this could not be adequately investigated with the systems available so far[14-20] as they are either not specific enough to the indication or do not have the opportunity to communicate with a therapist. The system MeineReha® [21, 22] combines these components and also provides real-time visual feedback. After development and validation, the system MeineReha® was supplemented with an individualized and therapist controlled telemedical assisted movement therapy consisting of 38 available training exercises for patients after knee as well as after hip replacement.		
Does your paper address CONSORT subitem 2b?		

The telemedical offers should be adapted to the individual and indication specific needs of the patients and should enable contact with the supervising therapists. However, this could not be adequately investigated with the systems available so far.		
METHODS		
3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio		
were included in the randomized controlled trial		
3b) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons		
not applicable, no changes		
3b-i) Bug fixes, Downtimes, Content Changes		
4a) CONSORT: Eligibility criteria for participants		
Patients were eligible for inclusion if a total hip or knee replacement was done after idiopathic, posttraumatic or congenital osteoarthritis, they were aged between 18 and 65 years and insured by the national or regional German Pension Insurance.		
4a-i) Computer / Internet literacy		
4a-ii) Open vs. closed, web-based vs. face-to-face assessments:		
in three inpatient rehabilitation centers		
4a-iii) Information giving during recruitment		
4b) CONSORT: Settings and locations where the data were collected		
in three inpatient rehabilitation centers, study site University of Potsdam		
4b-i) Report if outcomes were (self-)assessed through online questionnaires		
not applicable		
4b-ii) Report how institutional affiliations are displayed		
rehab centers, University of potsdam		
5) CONSORT: Describe the interventions for each group with sufficient details to allow replication, including how and when they were actually administered		
5-i) Mention names, credential, affiliations of the developers, sponsors, and owners		
5-ii) Describe the history/development process		
5-iii) Revisions and updating		
5-iv) Quality assurance methods		
5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used		
5-vi) Digital preservation		
5-vii) Access		
randomized		
5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework		

individual training therapy, set up by physiotherapists		
5-ix) Describe use parameters		
three times a week		
5-x) Clarify the level of human involvement		
technical support, University of Potsdam		
5-xi) Report any prompts/reminders used		
messages from the physiotherapists		
5-xii) Describe any co-interventions (incl. training/support)		
voluntary use of usual aftercare		
6a) CONSORT: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed		
primary endpoint (improvement in the 6-minute walk test)		
6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed		
6a-ii) Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored		
6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained		
6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons		
in three inpatient rehabilitation centers, study site University of Potsdam		
7a) CONSORT: How sample size was determined		
7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size		
see published study protocol		
7b) CONSORT: When applicable, explanation of any interim analyses and stopping guidelines		
primary endpoint (improvement in the 6-minute walk test)		
8a) CONSORT: Method used to generate the random allocation sequence		
using block randomization in the ratio of 1: 1, based on randomization lists drawn up in advance by the biometric institute. Written consent was obtained from all patients.		
8b) CONSORT: Type of randomisation; details of any restriction (such as blocking and block size)		
using block randomization in the ratio of 1: 1, based on randomization lists drawn up in advance by the biometric institute. Written consent was obtained from all patients.		
9) CONSORT: Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		
not applicable		
10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions		
biometrical institute		
11a) CONSORT: Blinding - If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		
11a-i) Specify who was blinded, and who wasn't		
Blinding of the patients was not possible dur to the nature of the trial...Another limitation of the study design is the lack of blinding of study participants and investigators. As a result, a possible influence on the participants during the investigations cannot be excluded.		
11a-ii) Discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator"		

11b) CONSORT: If relevant, description of the similarity of interventions		
not applicable		
12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes		
The statistical analyzes were conducted according to the description in the previously published study protocol.[23] All analyzes were performed with the full analysis set of randomized patients (intention-to-treat). Patient characteristics and follow-up values were described descriptively with mean and standard deviation (metric variables) and absolute and relative frequencies (categorical variables). Group-specific changes in metric variables (trends) were tested for significance versus "no change" with one-factorial variance analyzes. The calculation of the number of cases (n = 84) was based on the comparison of the primary endpoint (improvement in the 6-minute walk test) between the groups. This comparison was carried out with an analysis of covariance (ANCOVA) with 22 baseline covariates at the 5 % level (two-sided). All metric secondary endpoints were tested analogously without multiple adjustment. The ANCOVA estimates of the group differences in the continuous endpoints are presented in a forest plot. The group difference of the return-to-work rate was tested with the Chi2-test.		
12a-i) Imputation techniques to deal with attrition / missing values		
see above		
12b) CONSORT: Methods for additional analyses, such as subgroup analyses and adjusted analyses		
not applicable		
RESULTS		
13a) CONSORT: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome		
At baseline, data of 92 patients (IG: n = 48, CG: n = 44, Figure 1) could be collected.		
13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons		
Figure 1		
13b-i) Attrition diagram		
14a) CONSORT: Dates defining the periods of recruitment and follow-up		
From August 2016 to December 2017,		
14a-i) Indicate if critical “secular events” fell into the study period		
14b) CONSORT: Why the trial ended or was stopped (early)		
not applicable		
15) CONSORT: A table showing baseline demographic and clinical characteristics for each group		
Table 1		
15-i) Report demographics associated with digital divide issues		
Table 1		
16a) CONSORT: For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups		
16-i) Report multiple “denominators” and provide definitions		
At baseline, data of 92 patients (IG: n = 48, CG: n = 44, Figure 1) could be collected.		
16-ii) Primary analysis should be intent-to-treat		
17a) CONSORT: For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)		
Table 2		
17a-i) Presentation of process outcomes such as metrics of use and intensity of use		

17b) CONSORT: For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
Table 2		
18) CONSORT: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		
not applicable		
18-i) Subgroup analysis of comparing only users		
19) CONSORT: All important harms or unintended effects in each group		
not applicable		
19-i) Include privacy breaches, technical problems		
19-ii) Include qualitative feedback from participants or observations from staff/researchers		
DISCUSSION		
20) CONSORT: Trial limitations, addressing sources of potential bias, imprecision, multiplicity of analyses		
20-i) Typical limitations in ehealth trials		
In the investigated sample, an above-average education level can be ascertained (43.5 % with polytechnic or university degree). Data from the Employment Agency in Germany show that in the total population only 20 % of the gainfully employed persons have a polytechnic or university degree.[35] Furthermore, the unemployment rate of the sample with a rate of 5.4 % is to be classified as low compared to the average in Berlin of 8.4 %.[36] In addition, a large proportion of the patients came from Berlin and the surrounding countryside. Therefore, in this study, the access route to the study site the patients had to do independently and twice may have been an obstacle to the participation of patients from structurally weak areas far off. Only a quarter of the screened patients participated in the study. Thus, the low participation rate and the discussed patient characteristics suggest a selection bias. Another limitation of the study design is the lack of blinding of study participants and investigators. As a result, a possible influence on the participants during the investigations cannot be excluded. It is known that in non-blinded studies greater intervention effects than in blinded ones can be shown.[37] All patients underwent inpatient rehabilitation and aftercare. It is not possible to determine which improvements can be directly traced back to the effect of telerehabilitation, as due to ethical reasons usual aftercare in this study were not replaced but were complementarily extended.		
21) CONSORT: Generalisability (external validity, applicability) of the trial findings		
21-i) Generalizability to other populations		
21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting		
22) CONSORT: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		
22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)		
The investigated telemedical assisted exercise therapy in patients after knee or hip replacement was equivalent to the usual aftercare regarding the difference achieved in the 6-minute walk test. In addition, equivalent increases in both groups were demonstrated as secondary endpoints for functional mobility, health-related quality of life and joint-related complaints. However, the patients of the intervention group were employed at a significantly higher rate at the end of the intervention.		
22-ii) Highlight unanswered new questions, suggest future research		
Other information		
23) CONSORT: Registration number and name of trial registry		
German Register of Clinical Trials (ID DRKS00010009).		

24) CONSORT: Where the full trial protocol can be accessed, if available		
Eichler, S., et al., Effectiveness of an interactive telerehabilitation system with home-based exercise training in patients after total hip or knee replacement: study protocol for a multicenter, superiority, no-blinded randomized controlled trial. Trials, 2017. 18(1): p. 438		
25) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders		
The study was funded by the German Pension Insurance Berlin-Brandenburg (grant number 10-40.07.05.07.007).		
X26-i) Comment on ethics committee approval		
The study protocol with the description of the methods was written and published in accordance with the ethical requirements of the current version of the Declaration of Helsinki (Revision 2013).[23] The Ethics Committee of the University of Potsdam gave a positive ethics vote (No. 15/2016).		
x26-ii) Outline informed consent procedures		
Written consent was obtained from all patients.		
X26-iii) Safety and security procedures		
X27-i) State the relation of the study team towards the system being evaluated		
The Authors declare no Competing Financial or Non-Financial Interests.		