Telemedicin for Diabetiske fodsår

Review information

Authors

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Characteristics of studies

Characteristics of included studies

Rasmussen 2015

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age, mean (SD)*: 68.6 (13.0) ● *Female, N (%)*: 42 (22) ● *BMI, mean (SD)*: 28.96 (6.2) ● *Type 2 diabetes, N (%)*: 31 (85) ● *Current smoker, N (%)*: 74 (26) Kontrol 1 ● *Age, mean (SD)*: 66.7 (12.8) ● *Female, N (%)*: 52 (29) ● *BMI, mean (SD)*: 28.9 (6.0) ● *Type 2 diabetes, N (%)*: 127 (84) ● *Current smoker, N (%)*: 62 (20) **Included criteria:** Inclusioncriteria were adults with diabetes aged.18 years residing in the RSD andhaving a diabetic foot ulcer and referralto an outpatient clinic by a general prac-titioner or a hospital department. We ex-cluded individuals with conditions thatwould affect compliance (i.e., psychiatricdisease, dementia, alcohol abuse), com-peting conditions suspected to be thecause of the ulcer (i.e., gout, rheumatoidarthritis, uremia requiring dialysis), pastinclusion in the project, and expected ul-cer healing within 4 weeks. **Pretreatment:** The baseline demographics showed equal distribution of selected variables in the two groups (Table 1).
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: The per-protocol telemedical monitoring con-sisted of two consultations in the patient'sown home using telemedicine and oneconsultation at the outpatient clinic. Stan-dard treatment comprised three outpa-tient clinic visits. The three-visit cycle wasrepeated as necessary for each patient un-til study end point. If a patient presentedwith two or more foot ulcers, one ulcerwas selected as the treatment or interven-tion focus (index ulcer) before randomiza-tion. In a few cases, an index ulcer was notdefined before randomization; thus, wedefined the ulcer meeting one of the endpointsfirst as the index ulcer. The ulcersnot included as an index ulcer were trea-ted according to recommended guidelines,but these were disregarded in this study.Patients monitored with telemedicinewere treated according to the algorithmshowninFig.1.No frequency of telemed-icine consultations or clinic visits was predefined by the protocol but was drivenby clinical judgment at every consultationbe it telemedical or control. Municipalnurses provided standard daily care undersupervision of a nurse specialized in ulcercare. The telemedical consultations wereconducted by telephone or online writtenconsultations between the specializedmunicipal nurse and physicians at the out-patient clinic. These consultations weresupplemented by an uploaded image ofthe ulcer and a detailed written assess-ment through the online database (25).If needed, the treatment strategy was re-vised, and the next consultation (telemed-ical or standard) and the indication forfurther images were agreed on by thenurse and physician. If the treatment orthe patient's health condition neededcloser supervision by a hospital specialist(i.e., physician, podiatrist, nurse special-ist), deviation from the workflow algo-rithm was allowed. Kontrol 1 ● *Description*: outpatient monitoring: Patients randomized to standard carefollowed the usual practice and treat-ment provided by the outpatient clinic.All visits and consultations took place inthe outpatient clinics. Patients stayed inthe study until ulcer healing, amputation,or death. If a patient did not meet any ofthe end points within 1 year (365 days),their condition was considered chronic,1724 Telemedicine and Diabetic UlcersDiabetes CareVolume 38, September 2015and they were terminated from thestudy.OutcomesThe primary outcome of the overall studywas the number of hospital admissions,including the number of inpatient days re-lated to ulcer treatment and surgical pro-cedures. These data will be publishedelsewhere. We report here the study endpoints of ulcer healing, amputation, anddeath. All end points reported in this studywere thefirst to occur for each patient.Amputations below the ankle were classi-fied as minor and those from the ankle andabove as major.Sample Size CalculationA previous study showed a reduction in theproportion of patients using the emer-gencydepartmentfrom73% inthecontrolgroup to 42% in the telemedical monitoringgroup (26). Similarly, the average numberof emergency department visits was re-ducedfrom2.05to0.84duringa2-yearperiod. The samplesize estimate for the present study was 180 patients in eachgroup based on the proportion of patientsusing the emergency department. Wechose to include 400 patients (200 ineach group) to adjust for an estimated10% dropout rate.Randomization ProcedureThe participants were included and evalu-ated by the clinical staff at the participating outpatient clinics. Eligible patients werescreened for inclusion and exclusion crite-ria, and the cause of noneligibility wasnoted. The clinical staffs were suppliedwith checklists of the procedures requiredfor each patient. When a patient hadprovided written consent for participationin the trial, manual randomization was car-ried out using sealed, sequentially num-bered envelopes containing a letterassigning the patient to either the telemed-ical monitoring or the control group. Ran-domization was performed in blocks of12 patients (6 to telemedical monitoringand 6 to control). The 12 letters of assign-ment were placed in separate envelopes,which were sealed and scattered twice in arandom order and then assigned a serialnumber. The 12 envelopes were thengrouped in one block (in one large envelope).Grouped letters of assignment were pre-pared and distributed to the participatingclinics from the Department of Quality and Research/Health Technology Assessmentat Odense University Hospital. Staff at theoutpatient clinic opened one envelopein sequential order at the time of patientinclusion.
Outcomes	*Helbredsrelateret livskvalitet, efter endt behandling* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: PAID-20 ● **Range**: 0-100 ● **Direction**: Lower is better ● **Data value**: Endpoint *Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: AdverseEvent ● **Reporting**: Fully reported ● **Unit of measure**: n/N

	● **Direction**: Lower is better ● **Data value**: Endpoint *Mortalitet, længste follow-up (op til 1 år)* ● **Outcome type**: AdverseEvent ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Change from baseline *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Higher is better ● **Data value**: Change from baseline *Sårareal, efter endt behandling* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Partially reported ● **Unit of measure**: Weekly healing rate ● **Direction**: Higher is better ● **Data value**: Endpoint *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Not reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Not reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Tid til heling, efter endt behandling* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: Days ● **Direction**: Lower is better ● **Data value**: Endpoint *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** The study was funded by the ABTFund (Applied Citizen Technology) from theDanish Ministry of Finance, ABT funds fromthe Region of Southern Denmark, and the EUproject Renewing Health. **Country:** Denmark **Comments:** Clinical trial reg. no. NCT01608425, clinicaltrials.gov **Authors name:** Benjamin S.B. Rasmussen **Institution:** Department of Medical Endocrinology, **Email:** Corresponding author: Knud B. Yderstraede, knud.yderstraede@rsyd.dk **Address:** Department of Medical Endocrinology, OdenseUniversity Hospital, Odense, Denmark
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "When a patient had provided written consent for participation in the trial, manual randomization was car- ried out using sealed, sequentially num- bered envelopes containing a letter assigning the patient to either the telemed- ical monitoring or the control group. Ran- domization was performed in blocks of 12 patients (6 to telemedical monitoring and 6 to control)."
Allocation concealment (selection bias)	Low risk	Quote: "The 12 letters of assign- ment were placed in separate envelopes, which were sealed and scattered twice in a random order and then assigned a serial number. The 12 envelopes were then grouped in one block (in one large envelope)."
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Blinding not feasible. It is judged that the critical outcomes deaths and amputations is not affected by lack of blinding. Hiogh risk for PROMs (quality of life, critical outcome)
Blinding of outcome assessment (detection bias)	Low risk	Judgement Comment: No information of blinding of outcome assessors. It is judged that the critical outcomes deaths and amputations is not affected by lack of blinding of outcome assessors, thus Objective measures
Incomplete outcome data (attrition bias)	Low risk	Quote: "401 were randomized as eligible partici- pants, and 374 were included in the final analysis (193 [52%] in the telemedical monitoring group and 181 [48%] in the control group) (Fig." Judgement Comment: Available case analysis. 12/206 were excluded from the analyses in the intervention group and 12/195 in the control group.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: protocol at clinical trials https://clinicaltrials.gov/ct2/show/NCT01608425. The criticial outcome death is not stated in the protocol
Other bias	Low risk	Judgement Comment: The study appears to be free of other sources of bias

Santamaria 2004

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age, mean (SD)*: 63.5 ● *Female, N (%)*: 26 (52%)

	Kontrol 1 ● *Age, mean (SD)*: 49.5 ● *Female, N (%)*: 16 (37.21%) **Included criteria:** Inclusion criteria●Documented diagnosis of chronic ulcer of the lowerextremity.●Treated as a wound care outpatient at one of the trial sitehospitals●Informed consent. **Excluded criteria:** Exclusion criteria●Under 18 years of age.●Disorientation or mental impairment.●Unstable medical comorbidity. **Pretreatment:** Table 1 reveals that control group subjects were younger thanintervention subjects and that there was a greater number ofmales in the control group. There were also less leg woundsin the control group, but identical numbers of foot woundsbetween the groups.Of note in the aetiology of the chronic ulcers found in thestudy was the very high incidence of diabetic ulcers in theintervention group (Table 2).
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: Intervention group subjects also had their wound photographed and measured at each clinicattendance; however, these images and measurements wereelectronically transferred every 2 weeks to a wound careconsultant (KC) located in Perth. Wound care nurses at the two intervention sites used theAMWIS remote consultation function to transmit patient filesin encrypted form to the wound care consultant every 2weeks for the duration of the patients' care. The consultantreviewed the wound progress depicted in the electronicAMWIS file of each patient and then transferred the file backto the originating site with comments on the management ofthe wound entered into the AMWIS 'consultant advice'screen. Below is an example of the AMWIS measurementscreens and associated wound management advice providedfor one of the intervention group patients with a diabeticneuropathic foot ulcer (Figures 2-4). The consultant also oftentelephoned the local clinicians to discuss the images, progressof the wound and management options. ● *Dose*: 2 weeks ● *Duration*: 12 month Kontrol 1 ● *Description*: Control group subjects received standard wound care asdetermined by the local wound care clinician and had theirwound photographed and measured at each clinicattendance ● *Duration*: 12 month
Outcomes	*Helbredsrelateret livskvalitet, efter endt behandling* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: PAID-20 ● **Range**: 0-100 ● **Direction**: Lower is better ● **Data value**: Endpoint *Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: AdverseEvent ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint *Mortalitet, længste follow-up (op til 1 år)* ● **Outcome type**: AdverseEvent ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Change from baseline *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Higher is better ● **Data value**: Change from baseline *Sårareal, efter endt behandling* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Partially reported ● **Unit of measure**: Weekly healing rate ● **Direction**: Higher is better ● **Data value**: Endpoint *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Not reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Not reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Tid til heling, efter endt behandling* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: Days ● **Direction**: Lower is better ● **Data value**: Endpoint *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** The study was funded through a research grant from theWestern Australian Department of Health, TelehealthDevelopment Unit **Country:** Australia **Setting:** four sites in the Kimberley region of Western Australia **Comments:** None of the authors hold a financial interest in the AMWIS.

	Authors name: Nick Santamaria **Institution:** The Alfred Hospital Melbourne & University of Melbourne **Email:** n.santamaria@alfred.org.au **Address:** Commercial Rd, Melbourne, VIC 3004
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "four sites in the Kimberley region of Western Australia (Broome, Derby, Wyndham and Kununurra) between October 2002 and October 2003. The unit of randomisation was the clinical site; this was in order to avoid the potential for confounding the results due to changes in clinician knowledge level stemming from consultation with the wound care expert." Judgement Comment: Cluster randomised trial. No information of sequence generation
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Blinding not feasible.
Blinding of outcome assessment (detection bias)	Low risk	Judgement Comment: No information. outcomes reported were jugded not to be affected by lack of blinding (death and amputations)
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: Dropout is not clearly described but 2 person died in the control vs 0 in intevention group and 6 got amputations vs. 1.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No reference to a protocol. Only healing rates and costs are stated as outcomes in the methods section. The study reports on several other otucomes eg. death and amputations
Other bias	Unclear risk	Judgement Comment: No information of inclusion criteria for the clusters.

Smith-Strøm 2018

Methods	**Study design:** Cluster randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age, mean (SD)*: 67.2 (16.7) ● *Female, N (%)*: 24 (25.5) ● *Type 2 diabetes, N (%)*: 81/94 (86.2%) ● *HBA1C, mean (SD)*: 62 (18.6) ● *Current smoker, N (%)*: 14 (18.4) ● *Peripheral neuropathy, N (%)*: 63/94 (72.4%) Kontrol 1 ● *Age, mean (SD)*: 65.5 (16.5) ● *Female, N (%)*: 23 (26.1) ● *Type 2 diabetes, N (%)*: 63 (71.6) ● *HBA1C, mean (SD)*: 63 (18.6) ● *Current smoker, N (%)*: 14/88 (18.0%) ● *Peripheral neuropathy, N (%)*: 57/88 (70.4%) Overall ● *Age, mean (SD)*: 66.4 (16.6) ● *Female, N (%)*: 48 (25.8) ● *Type 2 diabetes, N (%)*: 144 (79.1) ● *HBA1C, mean (SD)*: 62 (18.6) ● *Current smoker, N (%)*: 28 (18.2) **Included criteria:** We included patients with DFUs from theendocrinology unit at Stavanger Univer-sity Hospital, from the orthopedics or en-docrinology unit at Haukeland UniversityHospital, and from the surgical unit at Stordcounty hospital. Inclusion criteria were thatpatients have type 1 or type 2 diabetes andbe aged 20 years or older, presenting witha new DFU to the clinical site. A DFU wasdefined as a skin lesion below the ankle.Exclusion criteria were as follows:1)anul-cer on the same foot treated during thelast 6 monthsin specialist health care,2)adiagnosis of mental disorders or cognitiveimpairment (including schizophrenia,other psychotic disorders, and dementia),3) inability to complete questionnaires inNorwegian, or4) life expectancy,1year(19). The difference in inclusion criteria be-tween our study and the Danish RCT study(6), which did not show superiority of theintervention, was that we included onlypatients who had not been treated forany DFU in the last 6 months before in-clusionNo informations of the including criterias of the clusters **Excluded criteria:** Exclusion criteria were as follows:1)anul-cer on the same foot treated during thelast 6 monthsin specialist health care,2)adiagnosis of mental disorders or cognitiveimpairment (including schizophrenia,other psychotic disorders, and dementia),3) inability to complete questionnaires inNorwegian, or4) life expectancy,1year(19). **Pretreatment:** Overall, baseline characteristics were well matched between the two groups (Table 1). However, there was a significant difference between the two groups in type of diabetes (P= 0.016) and localization of ulcer (P= 0.009). A higher proportion of patients in the TM group had type 2 diabetes compared witht he SOC group: 86.2% vs. 71.6%, respectively. A higher proportion of patients in the TM group had ulcers in the toe area compared with the CG: 60.6% vs. 38.6%, respectively.
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: telemedicine (TM) follow-up TM Follow-up. The TM application consisted of an inter-active Web-based ulcer record and amobile phone, enabling counseling andcommunication between the communitynurses and specialist health care. The keyingredient was the close integration be-tween the levels of the health care ser-vices. Patients in the intervention groupreceived TM follow-up care in the com-munity with consultations at the outpa-tient clinic every 6 weeks until an endpoint occurred. During follow-up in thecommunity, the community nurses pro-vided care under supervision of the spe-cialist nurses at the outpatient clinics andcommunicated at least weekly with thespecialist nurses at the outpatient clinic.The TMconsultationsconsisted ofwrittenassessment of the ulcer and images sentvia the mobile phone through the onlineWeb-based ulcer record for assessmentand feedback and further follow-up pro-cedures. If the community nurse hadquestions regarding the feedback, discus-sion between the community nurse andthe specialist was conducted by phoneor e-mail. All diabetes specialist nursesand/or podiatrists and community nursesreceived training in the use of the Web-based ulcer record and mobile phoneaftera standardizedprocedure.Individua eaching and training of the nursing staffin primary care were offered at the spe-cialist clinic or in primary care to ensureequivalent andcompetenthandlingofpa-tients. In addition, nurses in the commu-nity were encouraged to visit the hospitalclinic to improve their practical skills ● *Dose*: follow-up care in the com-munity with consultations at the outpa-tient clinic every 6 weeks until an endpoint occurred. ● *Duration*: follow-up care in the com-munity with consultations at the outpa-tient clinic every 6 weeks until an endpoint occurred.

	Kontrol 1 ● *Description*: standard outpatient care (SOC). SOC Patients randomized to SOC followed theSOC and treatment provided by the out-patient clinic. The treatment procedureswere evidence based in agreement withthe clinics. Consultations at the outpatientclinic were normally scheduled to takeplace every second week. For some pa-tients in the SOC group, follow-up by thecommunity nurse between the consulta-tions at the outpatient clinics was neces-sary but without use of TM follow-up ● *Dose*: Consultations at the outpatientclinic were normally scheduled to takeplace every second week ● *Duration*: until an endpoint occurred.
Outcomes	*Helbredsrelateret livskvalitet, efter endt behandling* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: PAID-20 ● **Range**: 0-100 ● **Direction**: Lower is better ● **Data value**: Endpoint *Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: AdverseEvent ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint *Mortalitet, længste follow-up (op til 1 år)* ● **Outcome type**: AdverseEvent ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Change from baseline *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Higher is better ● **Data value**: Change from baseline *Sårareal, efter endt behandling* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Partially reported ● **Unit of measure**: Weekly healing rate ● **Direction**: Higher is better ● **Data value**: Endpoint *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Not reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Not reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Tid til heling, efter endt behandling* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: Days ● **Direction**: Lower is better ● **Data value**: Endpoint *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** Funding.The Norwegian Directorate of Healthand Innovation Norway, the Western NorwayRegional Health Authority (911716 and 911605),the Norwegian Diabetes Association, and West-ern Norway University of Applied Sciencesfunded the trial. This study was also fundedbyagrantfromtheNorwegianResearchCouncil(Norges Forskningsr˚ad), project number 221065 **Country:** Norway **Setting:** three clinical sites in west-ern Norway. outpatient clinics **Comments:** Clinical trial reg. no. NCT01710774 **Authors name:** Hilde Smith-Strøm **Institution:** Department of Health and Social Science, Cen-tre for Evidence-Based Practice, Western NorwayUniversity of Applied Sciences, Bergen, Norway **Email:** miv@hvl.no **Address:** Faculty of Health and Social Sciences, Department of Health and CaringSciences, Western Norway University of Applied Sciences, N-5020 Bergen,Norway
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A person independent of the study performed the randomization sequences using SPSS, version 21, statistical software (IBM Corporation) (19)." Judgement Comment: computer generated allocation sequence. Rogaland and Hordaland counties inwestern Norway were divided into 42 clusters based on the municipalities or districtswithin the municipalities. The clusterswere matched in 21 pairs according topopulation size and rural/urban characteristics in the municipalities or districtsand randomized to either the TM or SOCgroup. A person independent of the studyperformed the randomization sequencesusing SPSS, version 21, statistical software(IBM Corporation) (19).

Allocation concealment (selection bias)	Unclear risk	Quote: "At the initial visit to the clinic, the study nurse screened patients for eligibility and informed them about the study." Quote: "The health care professionals, patients, and researchers were not blinded to the patients' group allocation." Judgement Comment: No information of whether the nurse including participants were blinded for the allocation sequence. If this nurse treating other patients in the trial she is not blinded for which cummunities belongs to which treatment groups
Blinding of participants and personnel (performance bias)	High risk	Quote: "follow-up. The health care professionals, patients, and researchers were not blinded to the patients' group allocation." Judgement Comment: No blinding of participants and personel. All participants are informed by the study nurse about the allocated type of treatment after enrollment in the study and after providing baseline data. The intervention is designed to evaluate a change in health service provision; therefore blinding of the intervention is not possible.
Blinding of outcome assessment (detection bias)	High risk	Quote: "deathdup to a maximum of 12 months of follow-up. The health care professionals, patients, and researchers were not blinded to the patients' group allocation." Judgement Comment: No blinding. High risk for self-reported outcomes (quality of life) which i a critical outcome. Low risk for amputation and death (also critical outcomes)
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: No dropouts, all participants included in the analyses (intention to treat analyses. Except for data for the critical outcome "quality of life" (from Iversen which is per protocol analysis). Data were analyzed according to the initial group allocation (intention to treat).In total 156 participants (78/78) reported on secondary endpoints: self-reported health, well-being andquality of life evaluated by generic and disease-specific patient-reported outcome measures (e.g. Euro-QOL, theHospital Anxiety and Depression Scale (HADS), Problem Areas in Diabetes (PAID), Neuropathy and Foot Ulcer–SpecificQuality of Life Instrument (NeuroQOL))
Selective reporting (reporting bias)	Unclear risk	Quote: "Clinical trial reg. no. NCT01710774, clinicaltrials .gov." Judgement Comment: The study has been registered with ClinicalTrials.gov [NCT01710774].https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4969550/From protocol: "The time elapsing before a new foot ulcer appears" This is an important outcome of interest, but not reported in article.
Other bias	Unclear risk	Judgement Comment: a cluster randomised trial with 3 sites and 42 communities, The communities were the randomised clusters.

Teot 2020

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age, mean (SD)*: 72 ● *Female, N (%)*: 44 ● *Type 2 diabetes, N (%)*: 8 (9%) (DFU) Kontrol 1 ● *Age, mean (SD)*: 72.8 ● *Female, N (%)*: 50 ● *Type 2 diabetes, N (%)*: 5 (5,32 %) (DFU) **Included criteria:** > 18 year old living in the languedoc rousillion regionhaving at least one wound qualified as complex and considered healable
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: Group 1 did not leave their residence and their medical examinations were conducted by telemedicine by a wound care expert ● *Duration*: 6 months Kontrol 1 ● *Description*: Group 2a patients who did not leave their residence for wound treatment received home wound care from a trained wound care nurse and group 2b were examined at a wound clinique by a physician. Group 2 patients were placed into group 2a instead of 2b if they haf potential difficulties with mobility due to age, comorbidities or other factors. ● *Duration*: 6 months
Outcomes	*Mortalitet, længste follow-up (op til 1 år)* ● **Outcome type**: AdverseEvent ● **Reporting**: Fully reported ● **Unit of measure**: Death ● **Direction**: Lower is better ● **Data value**: Change from baseline *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Higher is better ● **Data value**: Change from baseline *Tid til heling, efter endt behandling* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Partially reported ● **Unit of measure**: Days ● **Direction**: Lower is better ● **Data value**: Change from baseline *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** funded by the french government **Country:** France **Setting:** patients received either at home telemedicine care or at home face to face care or at the clinique face to face care **Authors name:** Luc Teot **Institution:** department of wound healing, university hospital montpellier **Email:** l-teot@chu-montpellier.fr **Address:** CHU de Montpellier Hospital la columbiere pavillon 41 38 avenue, charled flahault 34955 montpellier cedex s france
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement Comment: "Patients were randomized into one of the groups either by the call center or by the consulting expert in the clinic. A clinical research assistant was employed to formally enroll patients, start the randomization process and centrally organize collection of the data."Unclear sequence generation.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: "A clinical research assistant was employed to formally enroll patients, start the randomization process and centrally organize collection of the data."Unclear
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Not feasible to blind participants and NI about blinding of personnel
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: No information about blinding, likely unblinded.
Incomplete outcome data (attrition bias)	High risk	Judgement Comment: 183/220 completed the study. 16.82 % attrition. Per protocol analysis. No sensitivity analysis.
Selective reporting (reporting bias)	High risk	Judgement Comment: https://clinicaltrials.gov/ct2/show/NCT02545374. Secondary outcomes from protocol: "Result to the questionnaire on the quality of life: EQ-5D [Time Frame: Six months after inclusion]" "The total healing time [Time Frame: Six months after inclusion]" "The decrease in centimeters of the wound surface to 6 months [Time Frame: Six months after inclusion]" "The response time between making an appointment and support [Time Frame: Six months after inclusion]" These outcomes are not reported in article. Also not pre-specified that control group were split post randomization and results reported seperately. Time to heal only reported for all patients and for patients in group 2b.
Other bias	Low risk	Judgement Comment: No reasons to suspect other sources of bias.

Footnotes

Characteristics of excluded studies

Armstrong 2007

Reason for exclusion	Wrong patient population

Dobke 2008

Reason for exclusion	Wrong outcomes

Fasterholdt 2018

Reason for exclusion	dublet

Iversen 2019

Reason for exclusion	dublet

Iversen 2020

Reason for exclusion	dublet

Jecht 2018

Reason for exclusion	Wrong study design

Kolltveit 2018

Reason for exclusion	Wrong study design

Lavery 2004

Reason for exclusion	Wrong patient population

Lavery 2007

Reason for exclusion	Wrong patient population

Rasmussen 2015a

Reason for exclusion	dublet

Skafjeld 2015

Reason for exclusion	Wrong patient population

Smith Strom 2016

Reason for exclusion	dublet

Smith Strom 2018

Reason for exclusion	dublet

Wilbright 2004

Reason for exclusion	Wrong study design

Footnotes

Summary of findings tables

Additional tables

References to studies

Included studies

Rasmussen 2015

Rasmussen, B. S.; Froekjaer, J.; Bjerregaard, M. R.; Lauritsen, J.; Hangaard, J.; Henriksen, C. W.; Halekoh, U.; Yderstraede, K. B.. A Randomized Controlled Trial Comparing Telemedical and Standard Outpatient Monitoring of Diabetic Foot Ulcers. Diabetes care 2015;38(9):1723-1729. [DOI: 10.2337/dc15-0332 [doi]]

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Smith-Strøm 2018

Iversen, M. M.; Igland, J.; Smith-Strøm, H.; Østbye, T.; Tell, G. S.; Skeie, S.; Cooper, J. G.; Peyrot, M.; Graue, M.. Effect of a telemedicine intervention for diabetes-related foot ulcers on health, wellbeing and quality of life: secondary outcomes from a cluster randomized controlled trial (DiaFOTo) . 2020;20(157):8 s.. [DOI:]

Smith-Strøm, H.; Igland, J.; Østbye, T.; Tell, G. S.; Hausken, M. F.; Graue, M.; Skeie, S.; Cooper, J. G.; Iversen, M. M.. The Effect of Telemedicine Follow-up Care on Diabetes-Related Foot Ulcers: A Cluster-Randomized Controlled Noninferiority Trial. Diabetes care 2018;41(1):96-103. [DOI: 10.2337/dc17-1025 [doi]]

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Teot L.; Geri C.; Lano J.; Cabrol M.; Linet C.; Mercier G.. Complex Wound Healing Outcomes for Outpatients Receiving Care via Telemedicine, Home Health, or Wound Clinic: A Randomized Controlled Trial. International Journal of Lower Extremity Wounds 2020;19(2):197-204. [DOI: http://dx.doi.org/10.1177/1534734619894485]

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Armstrong 2007

Armstrong, D. G.; Holtz-Neiderer, K.; Wendel, C.; Mohler, M. J.; Kimbriel, H. R.; Lavery, L. A.. Skin temperature monitoring reduces the risk for diabetic foot ulceration in high-risk patients. The American Journal of Medicine 2007;120(12):1042-1046. [DOI: S0002-9343(07)00739-5 [pii]]

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Iversen M.M.; Igland J.; Smith-Strom H.; Ostbye T.; Tell G.S.; Skeie S.; Cooper J.G.; Graue M.. Effect of a telemedicine diabetic foot ulcer intervention on health and well-being: A cluster randomized controlled trial. Diabetes 2019;68(Journal Article). [DOI: http://dx.doi.org/10.2337/db19-175-LB]

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Lavery 2004

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Rasmussen 2015a

Rasmussen, Benjamin S. B.; Froekjaer, Johnny; Bjerregaard, Mads R.; Lauritsen, Jens; Hangaard, Joergen; Henriksen, Claus W.; Halekoh, Ulrich; Yderstraede, Knud B.. A Randomized Controlled Trial Comparing Telemedical and Standard Outpatient Monitoring of Diabetic Foot Ulcers. Diabetes care 2015;38(9):1723-9. [DOI: https://dx.doi.org/10.2337/dc15-0332]

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Skafjeld, A.; Iversen, M. M.; Holme, I.; Ribu, L.; Hvaal, K.; Kilhovd, B. K.. A pilot study testing the feasibility of skin temperature monitoring to reduce recurrent foot ulcers in patients with diabetes--a randomized controlled trial. BMC endocrine disorders 2015;15(Journal Article):55-015-0054-x. [DOI: 10.1186/s12902-015-0054-x [doi]]

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Smith-Strom, Hilde; Iversen, Marjolein M.; Graue, Marit; Skeie, Svein; Kirkevold, Marit. An integrated wound-care pathway, supported by telemedicine, and competent wound management-Essential in follow-up care of adults with diabetic foot ulcers. International journal of medical informatics 2016;94(Journal Article):59-66. [DOI: https://dx.doi.org/10.1016/j.ijmedinf.2016.06.020]

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Wilbright 2004

Wilbright, W. A.; Birke, J. A.; Patout, C. A.; Varnado, M.; Horswell, R.. The use of telemedicine in the management of diabetes-related foot ulceration: a pilot study. Advances in Skin & Wound Care 2004;17(5 Pt 1):232-238. [DOI: 00129334-200406000-00012 [pii]]

Other references

Additional references

Other published versions of this review

Classification pending references

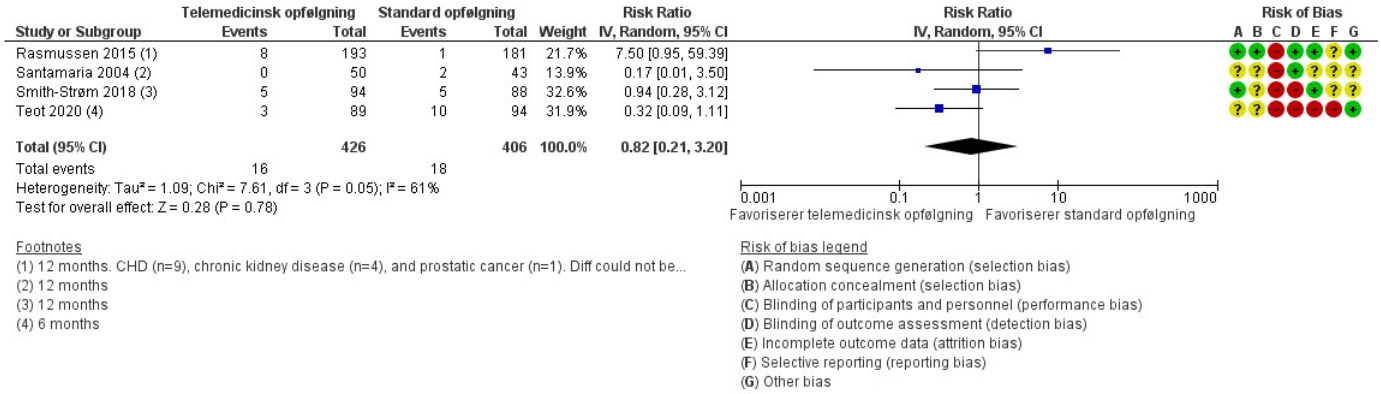
Data and analyses

1 Telemedicinsk opfølgning vs standard opfølgning

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Mortalitet, længste follow-up (op til 1 år)	4	832	Risk Ratio (IV, Random, 95% CI)	0.82 [0.21, 3.20]
1.2 Underekstremitets amputationer, længste follow-up (op til 1 år)	3	649	Risk Ratio (IV, Random, 95% CI)	0.54 [0.28, 1.05]
1.3 Sårheling (total sårlukning (ja/nej)), efter endt behandling	3	739	Risk Ratio (IV, Random, 95% CI)	1.01 [0.92, 1.10]
1.4 Frafald, alle årsager, efter endt behandling, risk ratio	3	802	Risk Ratio (IV, Random, 95% CI)	1.79 [0.22, 14.40]
1.5 Frafald, alle årsager, efter endt behandling, risk difference	3	802	Risk Difference (IV, Random, 95% CI)	0.05 [-0.05, 0.15]
1.6 Helbredsrelateret livskvalitet, efter endt behandling	1	112	Mean Difference (IV, Fixed, 95% CI)	3.10 [-3.97, 10.17]
1.7 Tid til heling, efter endt behandling	1	182	Mean Difference (IV, Fixed, 95% CI)	-0.40 [-1.36, 0.56]
1.8 Sårareal, efter endt behandling	0		Mean Difference (IV, Fixed, 95% CI)	No totals
1.9 Recidiv af sår, længste follow-up (op til 1 år)	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.10 Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden	0		Risk Ratio (IV, Fixed, 95% CI)	No totals

Figures

Figure 1 (Analysis 1.1)

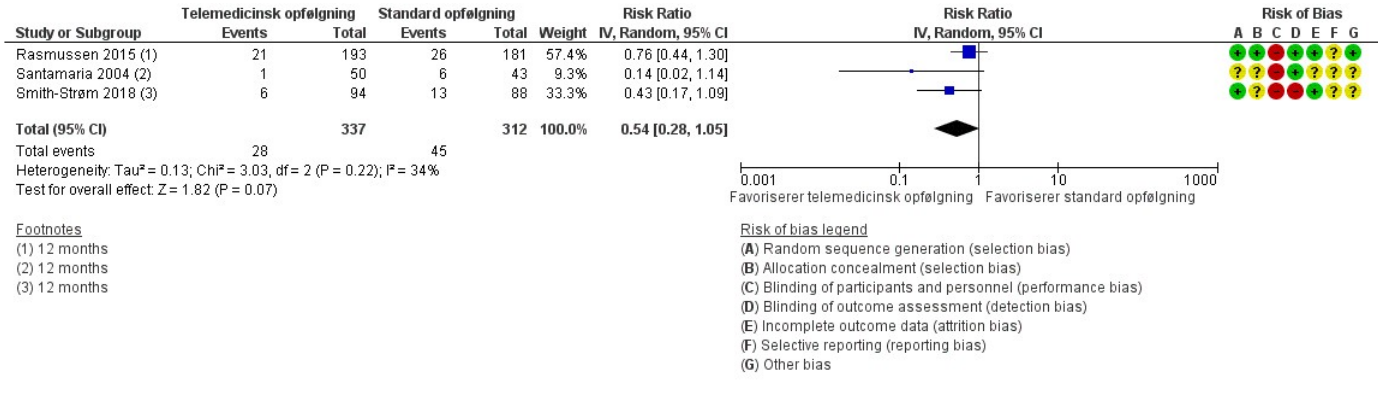


Footnotes
(1) 12 months. CHD (n=9), chronic kidney disease (n=4), and prostatic cancer (n=1). Diff could not be...
(2) 12 months
(3) 12 months
(4) 6 months

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Telemedicinsk opfølgning vs standard opfølgning, outcome: 1.1 Mortalitet, længste follow-up (op til 1 år).

Figure 2 (Analysis 1.2)

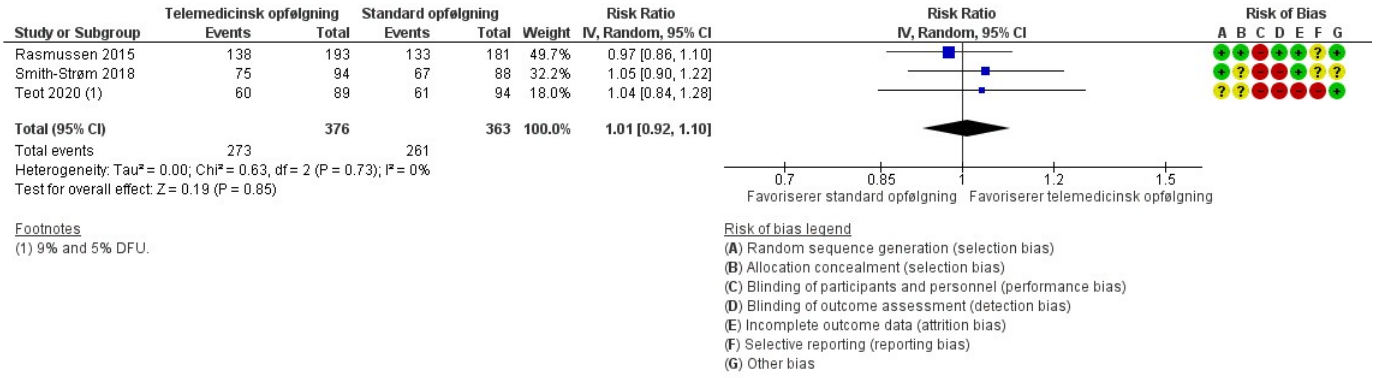


Footnotes
(1) 12 months
(2) 12 months
(3) 12 months

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

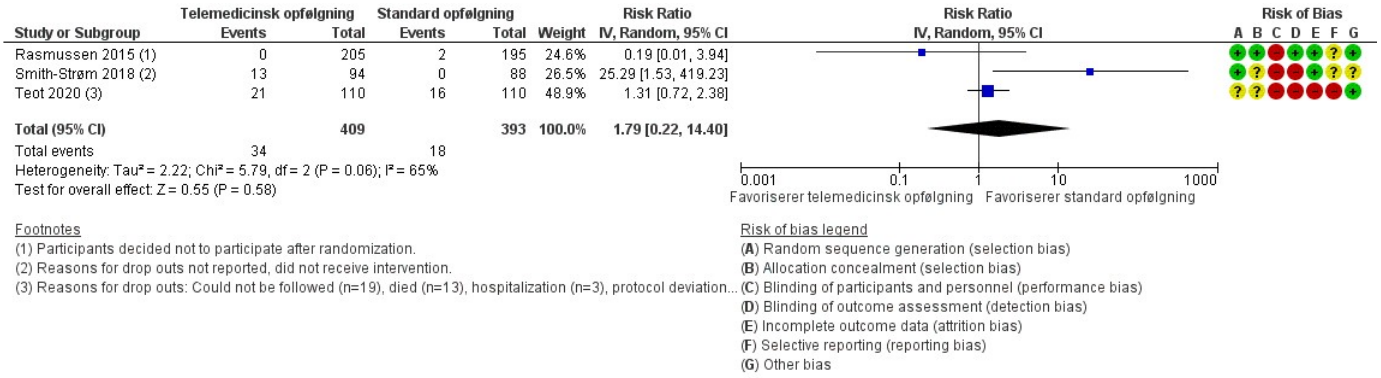
Forest plot of comparison: 1 Telemedicinsk opfølgning vs standard opfølgning, outcome: 1.2 Underekstremitets amputationer, længste follow-up (op til 1 år).

Figure 3 (Analysis 1.3)



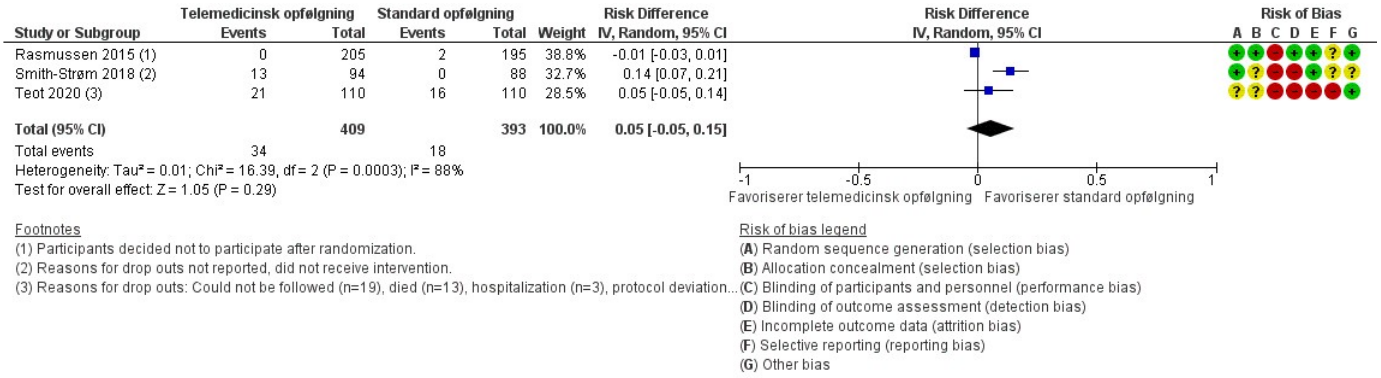
Forest plot of comparison: 1 Telemedicinsk opfølgning vs standard opfølgning, outcome: 1.3 Sårheling (total sårlukning (ja/nej)), efter endt behandling.

Figure 4 (Analysis 1.4)



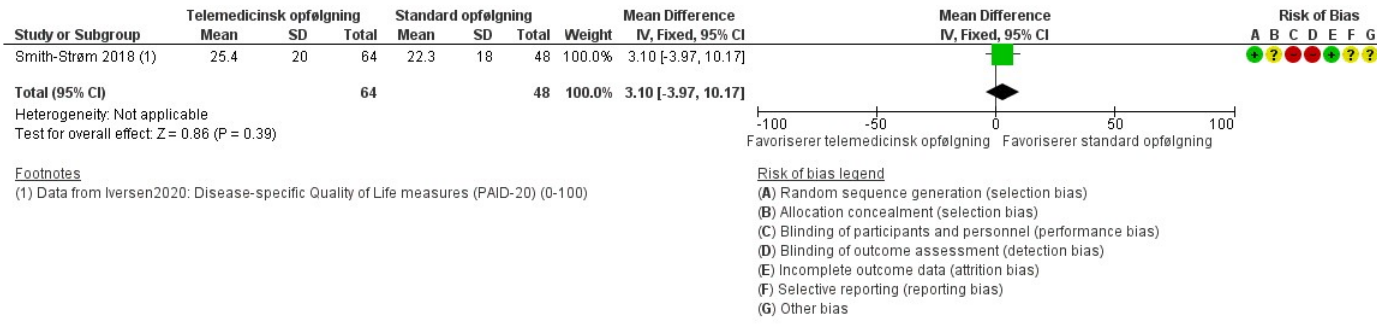
Forest plot of comparison: 1 Telemedicinsk opfølgning vs standard opfølgning, outcome: 1.4 Frafald, alle årsager, efter endt behandling, risk ratio.

Figure 5 (Analysis 1.5)



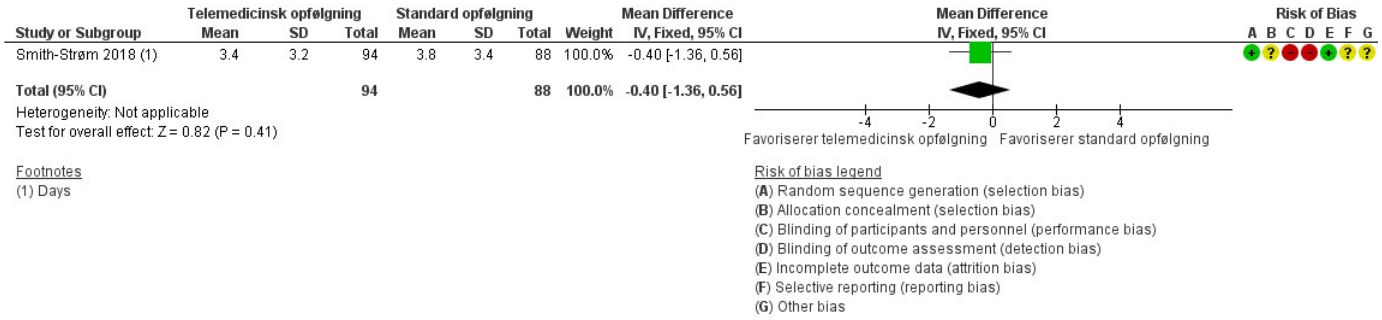
Forest plot of comparison: 1 Telemedicinsk opfølgning vs standard opfølgning, outcome: 1.5 Frafald, alle årsager, efter endt behandling, risk difference.

Figure 6 (Analysis 1.6)



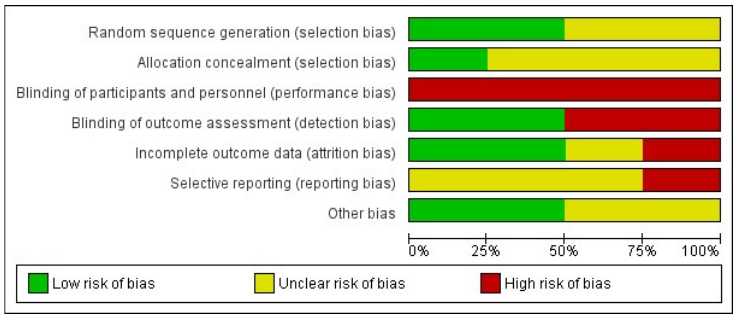
Forest plot of comparison: 1 Telemedicinsk opfølgning vs standard opfølgning, outcome: 1.6 Helbredsrelateret livskvalitet, efter endt behandling.

Figure 7 (Analysis 1.7)



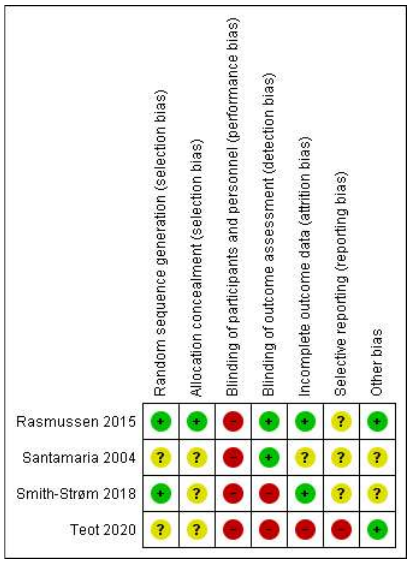
Forest plot of comparison: 1 Telemedicinsk opfølgning vs standard opfølgning, outcome: 1.7 Tid til heling, efter endt behandling.

Figure 8



Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 9



Risk of bias summary: review authors' judgements about each risk of bias item for each included study.