

NKR - 02 for Udredning og behandling af diabetiske fodsår

Review information

Authors

Sundhedsstyrelsen¹¹[Empty affiliation]

Citation example: S. NKR - 02 for Udredning og behandling af diabetiske fodsår. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Characteristics of studies

Characteristics of included studies

Eraydin 2018

Methods	Study design: Randomized controlled trial Study grouping: Parallel group
Participants	<p>Baseline Characteristics</p> <p>Intervention</p> <ul style="list-style-type: none"> ● <i>Age, mean (SD):</i> 61.03 (9.97) ● <i>Female, N (%):</i> 15 ● <i>BMI, mean (SD):</i> 31.36 (7.6) ● <i>HBA1C, mean (SD):</i> 10.36 (1.91) ● <i>Wound area (cm²), mean (SD):</i> 12.63 (14.43) <p>Kontrol</p> <ul style="list-style-type: none"> ● <i>Age, mean (SD):</i> 65.76 (8.57) ● <i>Female, N (%):</i> 8 ● <i>BMI, mean (SD):</i> 28.58 (4.66) ● <i>HBA1C, mean (SD):</i> 10.02 (1.68) ● <i>Wound area (cm²), mean (SD):</i> 24.67 (20.70) <p>Included criteria: Diagnosed with type 2 DM, and classified as Wagner grade 1 or 2 DFU. Additional inclusion criteria were age between 20 and 80 years</p> <p>Excluded criteria: Not having dementia and mental problems; having no systemic diseases such as musculoskeletal disorders, heart diseases, or neurological diseases that can hinder ability to participate in the study; undergoing the standard wound care protocol (cleaning the wound with saline, covering it with gauze dressing); not receiving other treatments that could affect wound healing (negative-pressure wound treatment, hyperbaric oxygen treatment, a special wound care product, special wound dressing, or growth factor); and not using an-other complementary treatment method (herbal wound care products). Exclusion criteria were ulcer developed secondary to acute trauma; ulcer developed secondary to burns; ulcer advanced to Wagner grade 3, 4, or 5; a surgical operation other than debridement was to be applied to the existing ul- cer; impaired general health status; wound treatments other than standard care deemed to be required by the physician for wound care; and starting a complementary treatment method such as a herbal wound care product.</p>
Interventions	<p>Intervention Characteristics</p> <p>Intervention 1</p> <ul style="list-style-type: none"> ● <i>Description:</i> Instructions to patients with DFU were provided that included the following information: (1) avoid exercises that require weight bearing 23 ; (2) complete the exercise program in a sitting position at first and in a standing position after the wound heals 24 ; (3) exercises include range-of-motion movements of plantar flexion, dorsiflexion, inversion, eversion, circumduction, and plantar and dorsal flexion of toes; (4) exercise series should include, at minimum, 5 to 10 exercises with 10 to 15 repeats 23,24 ; (5) exercise 1 hour after taking insulin and before refreshments; (6) blood glucose level should be 100 to 125 mg/dL before the exercise; (7) defer exercises if the blood glucose level is more than 300 mg/dL and the blood pressure is more than 180 mm Hg before the exercise; and (8) discontinue exercises if the patient feels nausea, dizziness, or drowsiness during the exercise. 23 Participants completed 18 exercises with 10 repeats. Patients in the study intervention group were taught the diabetic foot exercises over 20 to 30 minutes in the clinic setting by the researcher without putting weight on the feet, including the movements of plantar flexion, dorsiflexion, inversion, eversion, circumduction, and plantar and dorsal flexion of toes using a demonstration method. Subjects in the study intervention group were asked to exercise twice daily for 12 weeks. The patients were given the diabetic foot exercise log, including the pictures of the exercises, to support the education. The patients recorded the exercises they did on an exercise log. The markings on the exercise logs and the DFU measurements were assessed in the 4th, 8th, and 12th weeks. ● <i>Duration:</i> 12 weeks <p>Kontrol 1</p> <ul style="list-style-type: none"> ● <i>Description:</i> Patients in both groups received standard wound care. The DFU measurements of the control group were assessed in the beginning, in the 4th week, the 8th week, and the 12th week. The researcher evaluated the extent to which the patients remembered the foot exercise information during the course of the study. ● <i>Duration:</i> 12 weeks
Outcomes	<p><i>Underekstremitets amputationer, længste follow-up</i></p> <ul style="list-style-type: none"> ● Outcome type: Adverse Event ● Reporting: Not reported <p><i>Sårheling (total sårlukning(ja/nej)), efter endt behandling</i></p> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Fully reported ● Unit of measure: Patients ● Direction: Higher is better ● Data value: Endpoint (12 weeks) <p><i>Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling</i></p>

	<ul style="list-style-type: none"> ● Outcome type: Continuous Outcome ● Reporting: Not reported <p><i>Patientrapporteret funktionsevne målt med standardiseret spørgeskema, efter endt behandling</i></p> <ul style="list-style-type: none"> ● Outcome type: Continuous Outcome ● Reporting: Not reported <p><i>Sårareal, efter endt behandling</i></p> <ul style="list-style-type: none"> ● Outcome type: Continuous Outcome ● Reporting: Fully reported ● Unit of measure: Wound size ● Direction: Higher is better ● Data value: Change from baseline (12 weeks) <p><i>Recidiv af sår, længste follow-up</i></p> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Not reported <p><i>Behandlings adherence/kompliance, i interventionsperioden</i></p> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Fully reported ● Unit of measure: Patienter ● Direction: Higher is better ● Data value: Endpoint (12 weeks) <p><i>Bivirkninger, i interventionsperioden, infektion</i></p> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Fully reported ● Unit of measure: Patients ● Direction: Lower is better ● Data value: Endpoint (12 weeks) <p><i>Tid til heling, efter endt behandling</i></p> <ul style="list-style-type: none"> ● Outcome type: Continuous Outcome ● Reporting: Not reported <p><i>Frafald, alle årsager, efter endt behandling</i></p> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Partially reported ● Unit of measure: Patients ● Direction: Lower is better ● Data value: Endpoint (12 weeks)
Identification	<p>Sponsorship source: no funding</p> <p>Country: turkey</p> <p>Setting: Patients in the intervention group received standard wound care and performed daily foot exercises for 12 weeks; the control group received standard wound care but no exercises.</p> <p>Comments: This study shows evidence of dose response relationship between exercise dose and decrease total ulcer area.</p> <p>Authors name: Sahizer Eraydin</p> <p>Institution: Nursing Department, Faculty of Health Sciences, Gaziosmanpas_a University, Tokat, Turkey</p> <p>Email: sahizer.eraydin@gop.edu.tr</p> <p>Address: Nursing Department, Faculty of Health Sciences, Gaziosmanpas_a University, Tokat, Turkey</p>
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "No differences were found between the demographic characteristics of the control and study intervention groups when age, marital status, diabetes onset, and laboratory results were compared (P > .05; Table 1)." Quote: "Randomization was based on the order of patients' referral to the clinic." Quote: "Th is study used a randomized controlled study design." Judgement Comment: Baseline difference in Ulcer area (p=0.008).
Allocation concealment (selection bias)	High risk	Quote: "Blinding was not employed in this study (Figure 1)." Judgement Comment: no allocation concealment
Blinding of participants and personnel (performance bias)	High risk	Quote: "Blinding was not employed in this study (Figure 1).
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: No blinding. Self-reported exercise logs. Other objective outcome unlikely influenced to lack of bias.
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: <10% drop outs from groups. Balanced drop outs.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol available.
Other bias	Low risk	Quote: "The authors declare no confl icts of interests." Judgement Comment: No reasons to suspect other sources of bias.

Flahr 2010

Methods	Study design: Randomized controlled trial Study grouping: Parallel group
Participants	Baseline Characteristics Intervention 1 <ul style="list-style-type: none"> ● Age, mean (SD): 61.9 ● Female, N (%): 2 Kontrol 1 <ul style="list-style-type: none"> ● Age, mean (SD): 74.25 ● Female, N (%): 4 Comment: Substantial between group age difference. Included criteria: 8 years of age or older with diabetes, ulceration, sensory neuropathy, and the ability to provide informed consent in English. Excluded criteria: The exclusion criteria were cognitive impairment (cognition was not formally assessed — if patients were able to answer questions and demonstrate an appropriate understanding, they were included in the study); infection (measured by greater than four pathogens by Gram stain); and ischemia. The latter was assessed clinically and patients who did not have palpable pulses were excluded from study participation.
Interventions	Intervention Characteristics Intervention 1 <ul style="list-style-type: none"> ● Description: The exercise protocol was established as a result of the literature search. Exercises demonstrating, in cross-sectional trials, an increase in blood flow and that did not involve weight-bearing, included simple ankle inversion, eversion, flexion, and extension were prescribed. The researcher had participants demonstrate the exercises before leaving the clinic to ascertain their ability to complete them without pain or other obvious limitations. No time frame was established for completion of the exercise routine and because the study was home-based and entirely voluntary, there were no restrictions placed on performance. An exercise journal with self-completion information also was provided. Participants were asked to perform four ankle exercises 10 times each twice a day and note the frequency in the exercise journal. They were asked to bring the journal back with them for review on subsequent clinical visits. The exercise program used in this project was designed to be self-supervised. ● Duration: 12 weeks Kontrol 1 <ul style="list-style-type: none"> ● Description: Protocols of wound care were not standardized. It was assumed that involving podiatry patients would limit variability in practitioner approach to wound care, permitting evaluation of the effects of exercise or no-exercise between groups. The use of this directional hypothesis is an attempt to reduce one of the confounding variables: the differences in approach to diabetic foot ulcer management among different health care service providers. The use of a single group of health care providers across both the control and experimental groups should allow for comparison of the proposed difference — ie, exercise — between the two groups ● Duration: 12 weeks
Outcomes	<i>Underekstremitets amputationer, længste follow-up</i> <ul style="list-style-type: none"> ● Outcome type: Adverse Event ● Reporting: Not reported <i>Sårheling (total sårlukning (ja/nej)), efter endt behandling</i> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Fully reported ● Unit of measure: Patients ● Direction: Higher is better ● Data value: Endpoint (12 weeks) <i>Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling</i> <ul style="list-style-type: none"> ● Outcome type: Continuous Outcome ● Reporting: Not reported <i>Patientrapporteret funktionsevne målt med standardiseret spørgeskema, efter endt behandling</i> <ul style="list-style-type: none"> ● Outcome type: Continuous Outcome ● Reporting: Fully reported ● Scale: The Dartmouth COOP Functional Assessment Charts/WOCNA ● Unit of measure: Points ● Direction: Lower is better ● Data value: Change from baseline (12 weeks) <i>Sårareal, efter endt behandling</i> <ul style="list-style-type: none"> ● Outcome type: Continuous Outcome ● Reporting: Fully reported ● Unit of measure: Wound size ● Direction: Higher is better ● Data value: Change from baseline (12 weeks) <i>Recidiv af sår, længste follow-up</i> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Not reported <i>Behandlings adherence/kompliance, i interventionsperioden</i> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Fully reported ● Unit of measure: Patient ● Direction: Higher is better ● Data value: Endpoint (12 weeks) <i>Bivirkninger, i interventionsperioden, infektion</i> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Fully reported

	<ul style="list-style-type: none"> ● Unit of measure: Patients ● Direction: Lower is better ● Data value: Endpoint (12 weeks) <p><i>Tid til heling, efter endt behandling</i></p> <ul style="list-style-type: none"> ● Outcome type: Continuous Outcome ● Reporting: Fully reported ● Unit of measure: Weeks ● Direction: Lower is better ● Data value: Endpoint (12 weeks) <p><i>Frafald, alle årsager, efter endt behandling</i></p> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Partially reported ● Unit of measure: Patients ● Direction: Lower is better ● Data value: Endpoint (12 weeks)
Identification	<p>Sponsorship source: no funding</p> <p>Country: canada</p> <p>Setting: Nineteen patients were recruited. Of those, 10 (88.9% men) were randomized to ankle exercise treatments and nine (50% men) continued their previous care regimen.</p> <p>Authors name: Donna Flahr</p> <p>Institution: Skin and Wound with the Saskatoon Health region</p> <p>Email: donnaflahr@hotmail.com</p> <p>Address: 266 Highbury Court, Saskatoon, SK, S7H4W3, Canada</p>
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Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "The assignment process involved including every other person who fit the study inclusion criteria."
Allocation concealment (selection bias)	Low risk	Quote: "Before initiating the data collection process, numbered envelopes starting with the experimental arm and alternating with the control arm of the study were prepared. The envelopes contained the data collection tools specific to the participant's assignment."
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No blinding described
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: Patients not blinded (not feasible) (potentially affecting self-reported COOP/WOCNA and training log).
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: 1 drop out from each group. Poor exercise adherence reporting.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol available.
Other bias	High risk	Quote: "were excluded from study participation. Protocols of wound care were not standardized. It was assumed that involving podiatry patients would limit variability in practitioner approach to wound care, permitting evaluation of the effects of exercise or no-exercise between groups. The use of this directional"
		Judgement Comment: No standardisation.

Morgan 2018

Methods	<p>Study design: pilot RCT</p> <p>Study grouping: Parallel group</p>
Participants	<p>Baseline Characteristics</p> <p>Intervention 1</p> <ul style="list-style-type: none"> ● <i>Female, N (%)</i>: 43% ● <i>Age, mean (SD)</i>: 59.7 <p>Kontrol 1</p> <ul style="list-style-type: none"> ● <i>Female, N (%)</i>: 45% ● <i>Age, mean (SD)</i>: 55.6 <p>Included criteria: 18 or more years of agediagnosis of type 2 diabetesundergoing treatment for a Wagner grade II, III, or IV diabetic foot ulcerable to attend regular exercise classes and two data collection sessions</p> <p>Excluded criteria: medical conditions where aerobic or resistance exercise is contraindicated(e.g., uncontrolled cardiovascular problems)a score of less than 18 on the Montreal Cognitive Assessment indicatingmoderate cognitive impairmentresponse from primary physician requesting that the participant not engage inexercisecurrent participation in a regular exercise program (more than 30 minutes, morethan 2 times a week)</p>
Interventions	<p>Intervention Characteristics</p> <p>Intervention 1</p> <ul style="list-style-type: none"> ● <i>Description:</i> The first group attendedEnhanceFitnessclasses (3x/wk, 12 weeks). Physicianswere consulted about exercise eligibility. ● <i>Duration:</i> 12w ● <i>Dose:</i> 3x/w <p>Kontrol 1</p> <ul style="list-style-type: none"> ● <i>Description:</i> The second group was asked not to exercise ● <i>Duration:</i> 12w

Outcomes	<p><i>Frafald, alle årsager</i></p> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Fully reported ● Direction: Lower is better ● Data value: Endpoint <p><i>Bivirkninger, i interventionsperioden</i></p> <ul style="list-style-type: none"> ● Outcome type: Adverse Event ● Reporting: Fully reported ● Direction: Lower is better ● Data value: Endpoint <p><i>Underekstremitets amputationer, længste follow-up</i></p> <ul style="list-style-type: none"> ● Outcome type: Adverse Event ● Reporting: Fully reported ● Direction: Lower is better ● Data value: Endpoint <p><i>Behandlings adherence/kompliance, i interventionsperioden</i></p> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Fully reported ● Direction: Higher is better ● Data value: Endpoint
Identification	<p>Sponsorship source: N.A, unclear Country: USA Setting: Participants with ulcers were recruited from local wound care clinics and randomly assigned to two groups. The first group attended Enhance Fitness classes (3x/wk, 12 weeks). Physicians were consulted about exercise eligibility. The second group was asked not to exercise. Authors name: Sara Morgan, PhD, CPO Institution: Department of Rehabilitation Medicine, University of Washington Email: sjmorgan@uw.edu Address: 1959 NE Pacific St, Box 356490, Seattle, WA 98195</p>
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Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Participants with ulcers were recruited from local wound care clinics and randomly assigned to two groups."
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: From protocol: Open label, no masking
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: From protocol: Open label, no masking
Incomplete outcome data (attrition bias)	High risk	Quote: "both groups was low (attrition=8/group). Reasons for leaving the study included scheduling challenges (exercise=4;control=2); ineligibility in baseline screen (exercise=2;control=1); lost interest (exercise=2); and preference for the exercise group (control=5)" Quote: "Thirty-four participants were randomized (exercise=15;control=19). Retention in both groups was low (attrition=8/group)." Quote: "Group differences were assessed with 2x2 repeated measures ANOVA" Judgement Comment: Per protocol analysis.
Selective reporting (reporting bias)	Unclear risk	Quote: "(trial registration: NCT03002155)." Judgement Comment: Unable to properly evaluate (only abstract available).
Other bias	Low risk	Judgement Comment: No reasons to suspect other sources of bias.

Nwankwo 2014

Methods	<p>Study design: Randomized controlled trial Study grouping: Parallel group</p>
Participants	<p>Baseline Characteristics</p> <p>Intervention 1</p> <ul style="list-style-type: none"> ● Age, mean (SD): 69.06 ± 4.79 ● Female, N (%): 15 ● BMI, mean (SD): 27.66 ± 5.44 ● Wound area (cm²), mean (SD): 26.45 ± 9.46 <p>Kontrol 1</p> <ul style="list-style-type: none"> ● Age, mean (SD): 68.50 ± 5.01 ● Female, N (%): 15 ● BMI, mean (SD): 22.96 ± 3.23 ● Wound area (cm²), mean (SD): 17.70 ± 7.23 <p>Included criteria: They were recruited for the study based on meeting certain inclusion criteria which is as follows: eligible subjects were sedentary for at least 6 months prior to the study. All the subjects had diabetic foot ulcers as a result of type 1 or 2 with at least 1cm²(greatest length x greatest width) and at least foot ulcer of 30 days duration. The protocol was designed according to the fundamental treatment principal of the expert panel to the 2004 American</p>

	<p>Diabetic Association [13]consensus development conference on diabetic foot wound care</p> <p>Excluded criteria: Subjects with congestive heartfailure, uncontrollable cardiac arrhythmias, severe valvular heart diseases, individuals with uncontrolled BP (systolic BP>165/mmHg), extreme claustrophobia, Hematological disease that affects mobility, impaired knee flexion of <1900 and severe illness that precluded them from exercising, were excluded from the study</p> <p>Pretreatment: Baseline wound size difference. Also difference in BMI, however not sig.</p>
<p>Interventions</p>	<p>Intervention Characteristics</p> <p>Intervention 1</p> <ul style="list-style-type: none"> ● Description: Subjects reported to the exercise clinic 3times a week. Initial aerobic exercise intensity was based on 60% of max. HR achieved on a stress test.Each subject was progressed to 85% of the value over 12weeks. All subjects were engaged in an aerobic warm-up of at least 5minutes with perceived rating in the light range of Borg's rating of perceived exercise scale [15],following the warm up, the subjects were instructed to start with a ten minutes exercise which was increased until the exercise intensity gets to the range of target heart rate and rate of perceived exertion (RPE) to commensurate with "somewhat hard"(4 point), HR and RPE were monitored to ensure subjects were exercising at their prescribed intensity throughout the study. Subjects were encouraged to increase their exercise time by 5minute each two weeks until they reach 50minute at the ninth week, which was maintained until the end of the 12weeks program [15].Each of the subjects were exercising under supervision throughout the study and rode on a bicycle ergo meter with foot interaction kept constant with a standard gym pedal and a specializedoff-loading insole padding to relieve pressure on the ulcer ● Duration: 12w ● Dose: 3 times per w <p>Kontrol 1</p> <ul style="list-style-type: none"> ● Description: Subjects reported to the exercise clinic 3times a week. While the group two subjects were placed on the normal wound dressing, diet control, counselling and medication without any form of exercise. ● Duration: 12w ● Dose: 3 times per w
<p>Outcomes</p>	<p><i>Underekstremitets amputationer, længste follow-up</i></p> <ul style="list-style-type: none"> ● Outcome type: Adverse Event ● Reporting: Not reported <p><i>Sårheling (total sårlukning(ja/nej)), efter endt behandling</i></p> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Fully reported ● Unit of measure: Patients ● Direction: Higher is better ● Data value: Endpoint (12 weeks) <p><i>Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling</i></p> <ul style="list-style-type: none"> ● Outcome type: Continuous Outcome ● Reporting: Not reported <p><i>Patientrapporteret funktionsevne målt med standardiseret spørgeskema, efter endt behandling</i></p> <ul style="list-style-type: none"> ● Outcome type: Continuous Outcome ● Reporting: Not reported <p><i>Sårareal, efter endt behandling</i></p> <ul style="list-style-type: none"> ● Outcome type: Continuous Outcome ● Reporting: Fully reported ● Unit of measure: Wound size ● Direction: Higher is better ● Data value: Change from baseline (12 weeks) <p><i>Recidiv af sår, længste follow-up</i></p> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Not reported <p><i>Behandlings adherence/kompliance, i interventionsperioden</i></p> <ul style="list-style-type: none"> ● Outcome type: DichotomousOutcome ● Reporting: Fully reported ● Unit of measure: Patienter ● Direction: Higher is better ● Data value: Endpoint (12 weeks) <p><i>Bivirkninger, i interventionsperioden, infektion</i></p> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Fully reported ● Unit of measure: Patients ● Direction: Lower is better ● Data value: Endpoint (12 weeks) <p><i>Tid til heling, efter endt behandling</i></p> <ul style="list-style-type: none"> ● Outcome type: Continuous Outcome ● Reporting: Not reported <p><i>Frafald, alle årsager, efter endt behandling</i></p> <ul style="list-style-type: none"> ● Outcome type: Dichotomous Outcome ● Reporting: Partially reported ● Unit of measure: Patients ● Direction: Lower is better ● Data value: Endpoint (12 weeks)
<p>Identification</p>	<p>Sponsorship source: no sponsorship</p> <p>Country: Nigeria</p> <p>Setting: Sixty one (61) subjects including 31 males and 30 females with diabetic foot ulcers were recruited to the study and were randomized using the pitcher bowl method to either receive the aerobic exercise with bicycle ergometer (Group One) or not (Group Two) but placed on their routine treatment alone</p>

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Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	SUPPORTING ANNOTATIONS: "The study was a pretest-posttest randomized control trial design without single or double blinding of the participants. Sampling Technique The subjects were recruited using purposive non-probability sampling technique." COMMENTS: randomized using the pitcher bowl method. Unclear random sequence generation. Baseline wound size and BMI difference.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information about allocation concealment. No blinding of participants nor personnel.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No blinding
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: No blinding of personnel however, only "objectively" measured outcomes
Incomplete outcome data (attrition bias)	Low risk	Judgement comment: Likely no attrition.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: No protocol
Other bias	Low risk	Judgement comment: No reason to suspect other sources of bias.

Footnotes

Characteristics of excluded studies

Bolton 2019

Reason for exclusion	Wrong study design
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Dufour 2018

Reason for exclusion	Wrong study design
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Eraydin 2017

Reason for exclusion	dublet
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Joergensen 2020

Reason for exclusion	Wrong intervention
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McCarthy 2020

Reason for exclusion	Wrong study design
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Mutlak 2018

Reason for exclusion	Wrong patient population
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Otterman 2011

Reason for exclusion	Wrong study design
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Footnotes

References to studies

Included studies

Eraydin 2018

Eraydin, S.; Avsar, G.. The effect of foot exercises on wound healing in type 2 diabetic patients with a foot ulcer: a randomized control study. *Journal of Wound, Ostomy, and Continence Nursing* 2018;45(2):123-130. [DOI:]

Flahr 2010

Flahr, Donna. The effect of nonweight-bearing exercise and protocol adherence on diabetic foot ulcer healing: a pilot study. *Ostomy/wound management* 2010;56(10):40-50. [DOI:]

Morgan 2018

Morgan, Sara. Effects of a Exercise Program on Health Outcomes in People With Diabetic Foot Ulcers Status: Completed. 2018;(Web Page). [DOI:]

Nwankwo 2014

Nwankwo, M. J.; Okoye, G. C.; Victor, E. A.; Obinna, E. A.. Effect of Twelve Weeks Supervised Aerobic Exercise on Ulcer Healing and Changes in Selected Biochemical Profiles of Diabetic Foot Ulcer Subjects. 2014;3(3):41-48. [DOI:]

Excluded studies**Bolton 2019**

Bolton, Laura. Exercise and Chronic Wound Healing. Wounds : a compendium of clinical research and practice 2019;31(2):65-67. [DOI:]

Dufour 2018

Dufour, Emilie; Duhoux, Arnaud. Re: The Effect of Foot Exercises on Wound Healing in Type 2 Diabetic Patients With a Foot Ulcer: A Randomized Control Study. J Wound Ostomy Continence Nursing. 2018;45(2):123-130. Journal of wound, ostomy, and continence nursing : official publication of The Wound, Ostomy and Continence Nurses Society 2018;45(6):492-493. [DOI: <https://dx.doi.org/10.1097/WON.0000000000000484>]

Eraydin 2017

Eraydin, Sahizer; Avsar, Gulcin. The Effect of Foot Exercises on Wound Healing in Type 2 Diabetic Patients With a Foot Ulcer. Journal of wound, ostomy, and continence nursing : official publication of The Wound, Ostomy and Continence Nurses Society 2017;(Journal Article). [DOI: <https://dx.doi.org/10.1097/WON.0000000000000405>]

Joergensen 2020

Joergensen, Tue Smith et al. A new passive movement model for the treatment of non-healing diabetic foot ulcers. A randomized clinical pilot study of wound healing (140920) Manuscript - ikke udgivet endnu.. 2020;(Journal Article). [DOI:]

McCarthy 2020

McCarthy, Matthew; Yates, Thomas; Webb, David; Game, Frances; Gray, Laura; Davies, Melanie J.. Health impacts of seated arm ergometry training in patients with a diabetic foot ulcer: protocol for a randomised controlled trial. BMJ open 2020;10(6):e039062. [DOI: <https://dx.doi.org/10.1136/bmjopen-2020-039062>]

Mutlak 2018

Mutlak, O.; Aslam, M.; Standfield, N.. The influence of exercise on ulcer healing in patients with chronic venous insufficiency. International Angiology 2018;37(2):160-168. [DOI:]

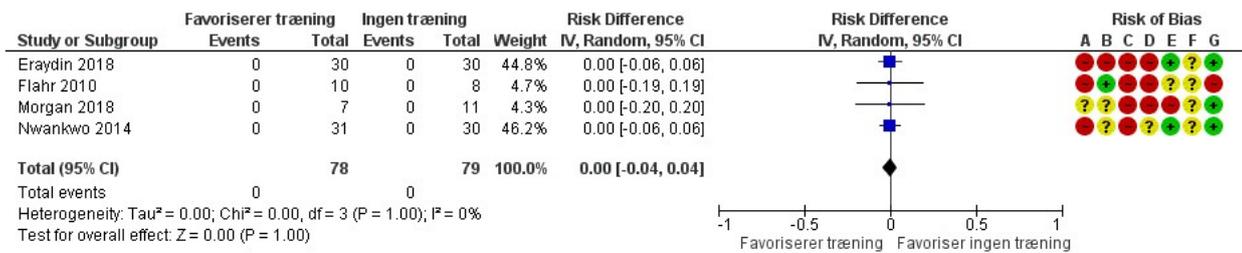
Otterman 2011

Otterman N.. An exercise programme for patients with diabetic complications: A study on feasibility and preliminary effectiveness. Physiotherapy (United Kingdom) 2011;97(Journal Article):eS950-eS951. [DOI: <http://dx.doi.org/10.1016/j.physio.2011.04.002>]

Data and analyses**1 Træning vs ingen træning**

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Underekstremitets amputationer, længste follow-up, risk difference	4	157	Risk Difference (IV, Random, 95% CI)	0.00 [-0.04, 0.04]
1.2 Sårheling (total sårlukning(ja/nej)), efter endt behandling	2	79	Risk Ratio (IV, Random, 95% CI)	1.50 [0.74, 3.02]
1.3 Behandlings adherence/kompliance, i interventionsperioden	3	97	Risk Ratio (IV, Random, 95% CI)	0.73 [0.61, 0.88]
1.4 Bivirkninger, i interventionsperioden, risk ratio	3	96	Risk Ratio (IV, Random, 95% CI)	0.83 [0.26, 2.67]
1.5 Bivirkninger, i interventionsperioden, risk difference	3	96	Risk Difference (IV, Random, 95% CI)	-0.05 [-0.14, 0.04]
1.6 Frafald, alle årsager, efter endt behandling	4	179	Risk Ratio (IV, Random, 95% CI)	1.27 [0.67, 2.39]
1.7 Patientrapporteret funktionsevne målt med standardiseret spørgeskema, efter endt behandling	1	18	Mean Difference (IV, Fixed, 95% CI)	-2.63 [-6.09, 0.83]
1.8 Tid til heling, efter endt behandling	1	6	Mean Difference (IV, Fixed, 95% CI)	-1.34 [-5.02, 2.34]
1.9 Sårareal, efter endt behandling	3	139	Std. Mean Difference (IV, Random, 95% CI)	-1.04 [-2.27, 0.19]
1.10 Recidiv af sår, længste follow-up	0		Risk Difference (IV, Fixed, 95% CI)	No totals
1.11 Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling	0		Mean Difference (IV, Fixed, 95% CI)	No totals

Figures**Figure 1 (Analysis 1.1)**

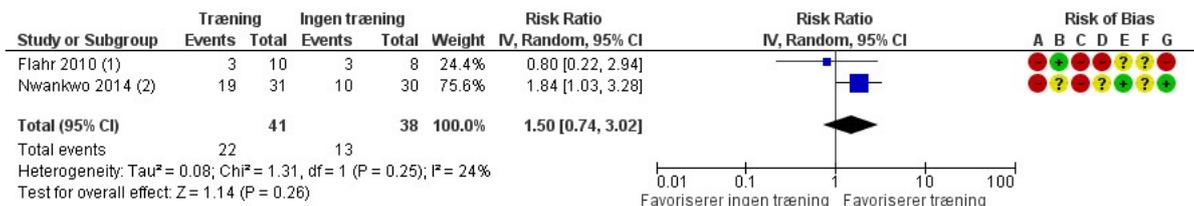


Risk of bias legend

- (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 Træning vs ingen træning, outcome: 1.1 Underkøstremittets amputationer, længste follow-up, risk difference.

Figure 2 (Analysis 1.2)



Footnotes

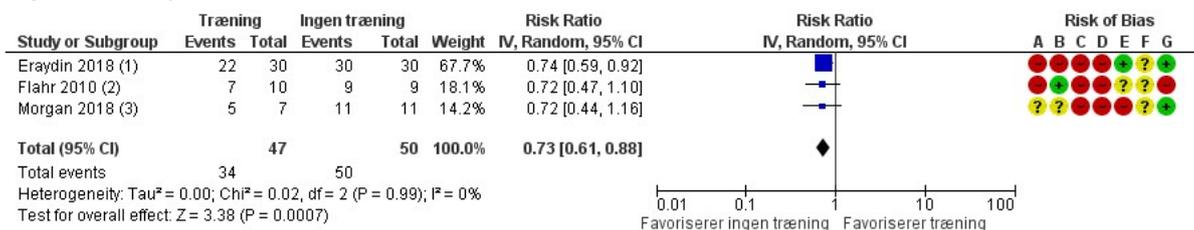
- (1) 12-ugers intervention.
- (2) 12-ugers intervention.

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 Træning vs ingen træning, outcome: 1.2 Sårheling (total sårlukning(ja/nej)), efter endt behandling.

Figure 3 (Analysis 1.3)



Footnotes

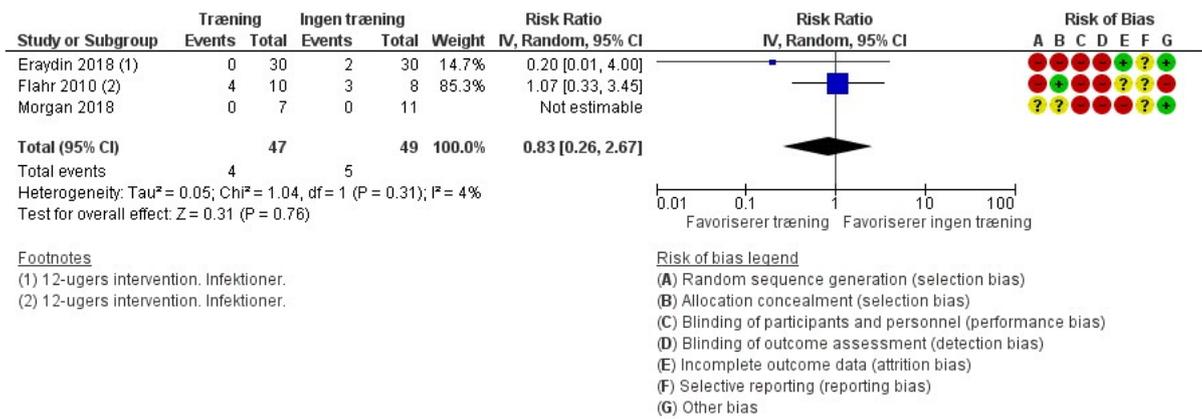
- (1) 12-ugers intervention. Selv-rapporteret træningsfrekvens. Ingen compliance = ingen...
- (2) 12-ugers intervention. Selv-rapporteret træningsfrekvens. <31 dage træning =...
- (3) Adherence treatment (e.g. attending exercise classes)

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

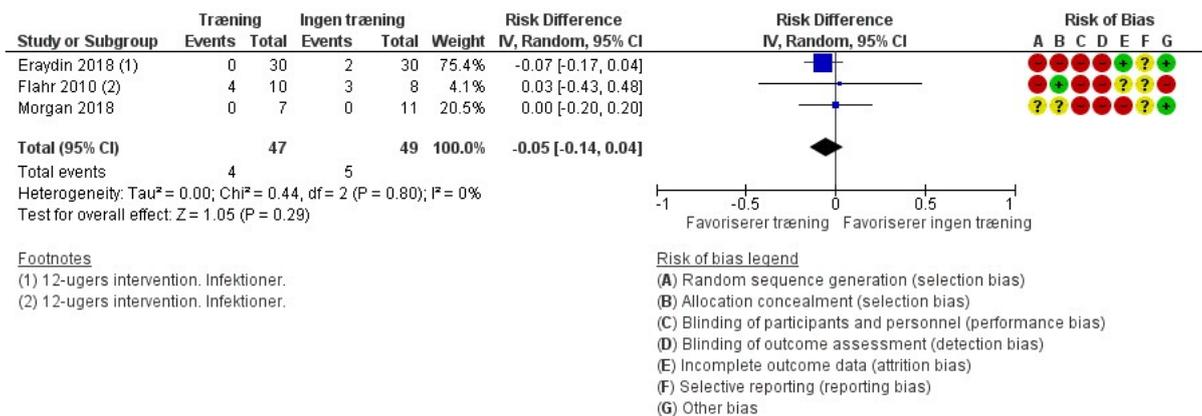
Forest plot of comparison: 1 Træning vs ingen træning, outcome: 1.3 Behandlings adherence/kompliance, i interventionsperioden.

Figure 4 (Analysis 1.4)



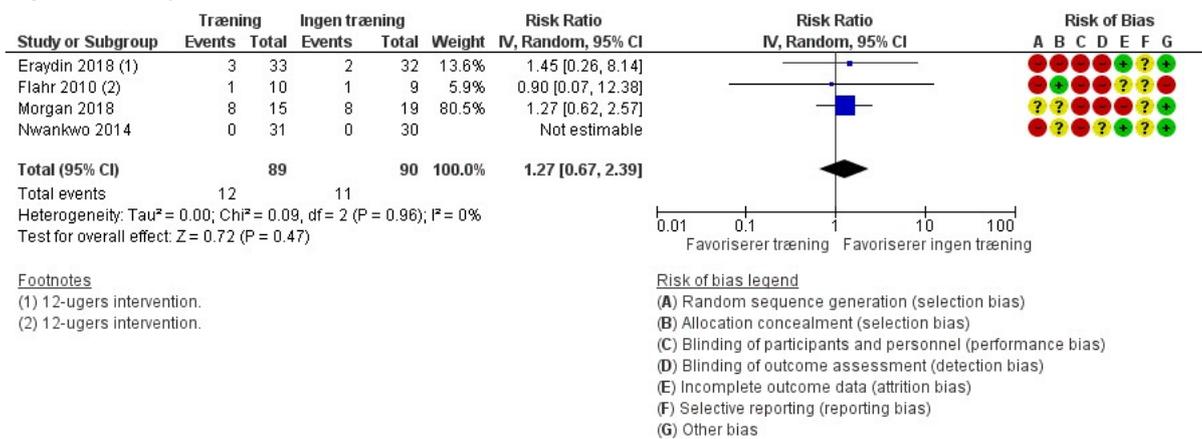
Forest plot of comparison: 1 Træning vs ingen træning, outcome: 1.4 Bivirkninger, i interventionsperioden, risk ratio.

Figure 5 (Analysis 1.5)



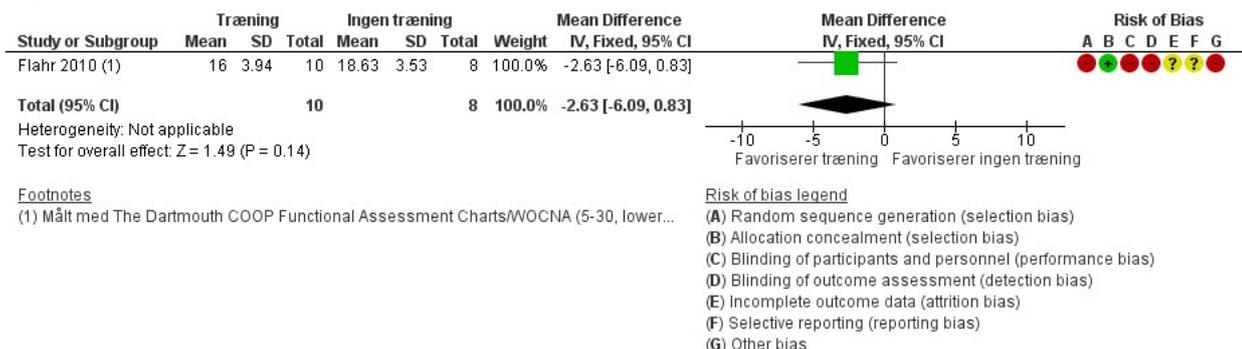
Forest plot of comparison: 1 Træning vs ingen træning, outcome: 1.5 Bivirkninger, i interventionsperioden, risk difference.

Figure 6 (Analysis 1.6)



Forest plot of comparison: 1 Træning vs ingen træning, outcome: 1.6 Frafald, alle årsager, efter endt behandling.

Figure 7 (Analysis 1.7)



	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Eraydin 2018	⊖	⊖	⊖	⊖	⊕	?	⊕
Flahr 2010	⊖	⊕	⊖	⊖	?	?	⊖
Morgan 2018	?	?	⊖	⊖	⊖	?	⊕
Nwankwo 2014	⊖	?	⊖	?	⊕	?	⊕

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