Supervised exercise and bandages versus bandages for Chronic edema

Review information

Authors

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[1][Empty affiliation]

Citation example: S. Supervised exercise and bandages versus bandages for Chronic edema. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Characteristics of studies

Characteristics of included studies

Jull 2009

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Age mean (sd)*: 54.6 (19.9) ● *Number of females*: 16 ● *Number of males*: 5 ● *Mean weight*: ● *Mean BMI*: ● *Main reason for chronic oedema*: not reported ● *Mobile*: 18 ● *Immobile*: Control ● *Age mean (sd)*: 53.3(19.9) ● *Number of females*: 11 ● *Number of males*: 8 ● *Mean weight*: ● *Mean BMI*: ● *Main reason for chronic oedema*: not reported ● *Mobile*: 16 ● *Immobile*: Overall ● *Age mean (sd)*: ● *Number of females*: 27 ● *Number of males*: 13 ● *Mean weight*: ● *Mean BMI*: ● *Main reason for chronic oedema*: ● *Mobile*: ● *Immobile*: **Included criteria:** Patients were Included If they were aged 18 years or older, were able to give informed consent, met the case definition, tolerated compression and were able to perform hel ralses.The case definition for venous ulceration was: any break in the skin on the lower leg that had been present for six weeks or more; no other causative aetiology being present; the ulcer appearing clinically venous, and an ancle brachial Index of more or at 0.8. **Excluded criteria:** rheumatold arthritis ar If their general practitioner considered the intervention was contraindicated. **Pretreatment:** Excercise Group: 21 people. 5 male and 16 females. Control: 19 people. 8 male and 11 female.
Interventions	**Intervention Characteristics** Intervention ● *Time interval*: 12 weeks ● *Description of treatment*: The intervention was an individually tallored 12-weekprogressive resistance exeriseprogramme in addition to compression. instructlon from the research nurse on the safe performance at heel raises: they were to support themselves with one arm or two arms against a wall,and slowly ralse themselves onto their tiptoes. Thechoiceofcompressionsystemwasattheparticipant’sand/orcilnidan’sdiscetlon Control ● *Time interval*: 12 weeks

	● *Description of treatment*: Parucipantsinthecontrol(usualcare)grouprecelvedcompresslononly
Outcomes	*Smerter (Pain) grundet fysisk aktivitet (bivirkning) End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Ødem End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Ankelbevægelighed End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Drop out End of treatment, max 6 mdr.* ● **Outcome type**: DichotomousOutcome *Funktionsniveau End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Kondition (evt. 6 min gangtest, trappetest) End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Livskvalitet End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Sårheling (prioriteret rækkefølge: total sårheling, sårstørrelse) End of treatment, max 6 mdr.* ● **Outcome type**: DichotomousOutcome *Tyngdefornemmelse (tunge ben) End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Sårheling (sårstørrelse) End of treatment, max 6 mdr.* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** The study was funded byt he Health Research Council of NewZealand.ARANZ Medical provided access to a Silhouette Mobile device **Country:** New Zealand **Setting:** Participants from an existing leg ulcer service. The study intervention could be reproduced at home. **Comments:** **Authors name:** A Jull, RN,PhD, **Institution:** School of nursing and department of General practice and primary care, University of Auckland New Zealand **Email:** a.jull@auckland.ac.nz **Address:** ?
Notes	*Stina Kjær* on 28/02/2017 21:21 **Select** Jeg er meget i tvivl om dette studie. De måler ikke på ødem, men til gengæld handler det om bensår hvorfor jeg synes det skal med.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Committee (WrYIO6/101092) approved the study. Participants were approached through an existing leg ulcer service, and atter consent underwent a baseline assessment, following which the>' were ran domi>' allocated to the sttdy using sequentialiy numbered opaque sealed envelopes. Block randomisatlon was used, stratified by the Margolis Index (a prognostic index at ulcer heahng based on ulcer size and durat1on),' with random numbers generated in Spius. Study treatments The study intervention"
Allocation concealment (selection bias)	Low risk	Judgement Comment: opaque Sealed envelopes
Blinding of participants and personnel (performance bias)	High risk	Quote: "themselves onto thelr Uptoes. At baseline, three, slx and nine weeks, the research nurse assessed the maximum number of hed raises, and prescrlbed a regimen of three set5 of repeUUons at 80% at the parilcipant's maximum." Judgement Comment: It seems like they are not blinded. It could be unclear instead.
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: This is not commented in the article
Incomplete outcome data (attrition bias)	Low risk	Quote: "Ali data analyses were carried mit on an inten tion-to-treat basis." Judgement Comment: There are also reported why two participants where excluded.

Selective reporting (reporting bias)	High risk	Quote: "Northem Regional Ethics Committee (WrYIO6/101092) approved the study." Judgement Comment: There must be a protocol when the study has been approved.There is no primary outcome, which is due to this being a pilot study. A bit strange!Ulcer healing is said to be outcome only reported in the text. Not possible to do meta-analysis.
Other bias	Low risk	Judgement Comment: Not enough power to do the analysis. Risk of type 2 error.

Meagher 2012

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Age mean (sd)*: 66 (32-84) ● *Number of females*: 12 ● *Number of males*: 6 ● *Mean weight*: ● *Mean BMI*: ● *Main reason for chronic oedema*: ● *Mobile*: 17 ● *Immobile*: 1 Control ● *Age mean (sd)*: 78 (55-91) ● *Number of females*: 13 ● *Number of males*: 4 ● *Mean weight*: ● *Mean BMI*: ● *Main reason for chronic oedema*: ● *Mobile*: 14 ● *Immobile*: 3 Overall ● *Age mean (sd)*: ● *Number of females*: ● *Number of males*: ● *Mean weight*: ● *Mean BMI*: ● *Main reason for chronic oedema*: ● *Mobile*: ● *Immobile*: **Included criteria:** Newly diagnosed with VLU. Never had treatment with compression. Older than 18 years. ABPI 0.8-1.3. Ulcer teween ancle and knee. **Excluded criteria:** Diabetes. Pregnant women. And people WHO were unable to give informed consent. **Pretreatment:** Age, Ulcer size,
Interventions	**Intervention Characteristics** Intervention ● *Time interval*: 12 weeks ● *Description of treatment*: The target for the exercise Group was 10000 steps per day. Supportive interventions with regular phonecalls, the researcher available to answer questions. Bandages med multilayerbandages. Intervention ikke yderligere beskrevet. Control ● *Time interval*: 12 weeks ● *Description of treatment*: Information om projektet men blev ikke bedt om at ændre noget. Bandagering med multilayerbandages.
Outcomes	*Smerter (Pain) grundet fysisk aktivitet (bivirkning) End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Ødem End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Ankelbevægelighed End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Drop out End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Funktionsniveau End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome

	Kondition (evt. 6 min gangtest, trappetest) End of treatment, max 6 mdr. ● **Outcome type**: ContinuousOutcome *Livskvalitet End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Sårheling (prioriteret rækkefølge: total sårheling, sårstørrelse) End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Tyngdefornemmelse (tunge ben) End of treatment, max 6 mdr.* ● **Outcome type**: ContinuousOutcome *Sårheling rækkefølge: total sårheling End of treatment, max 6 mdr.* ● **Outcome type**: DichotomousOutcome ● **Direction**: Higher is better
Identification	**Sponsorship source:** No external sources of funding **Country:** Ireland **Setting:** University Hospital Limerisk. Participants recruited from two community leg ulcer clinics and three vascular outpatient clinics. **Comments:** **Authors name:** Helen Meagher **Institution:** Department of Nursing University Hospital Limerick, Ireland. **Email:** helen.meagher@hse.ie **Address:** Bioeletronic engineering, national university of Ireland, Galway, Ireland
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement Comment: Sealed envelopes, but no further desribtion
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Not described,but they have excluded 5 patients after enrollement without desribing how. The patient did not adhere to compression.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Participants not blinded.Unclear when it comes to personnel. But since the participants are doing the intervention at home, there are no personnel besides the ones WHO gives the first information.
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: Not desribed
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: Two participant failed to record their steps on week 12. What did they do with the data?
Selective reporting (reporting bias)	High risk	Judgement Comment: The independent variable measured in this study was the number of steps taken by each participants. But they want to conclude is excersice can better ulcer healing? Ulcer healing reported as numbers in the text. Not suiteble for meta-analysis.
Other bias	High risk	Judgement Comment: The participants did not reach the number of steps as they should. So they can´t really concluded since the participants didn't do the intervention.Baseline imbalance according to age.

Footnotes

References to studies

Included studies

Jull 2009

Jull, A.; Parag, V.; Walker, N.; Maddison, R.; Kerse, N.; Johns, T.. The prepare pilot RCT of home-based progressive resistance exercises for venous leg ulcers. Journal of wound care 2009;18(12):497-503. [DOI:]

Meagher 2012

Meagher, H.; Ryan, D.; Clarke-Moloney, M.; O'Laighin, G.; Grace, P. A.. An experimental study of prescribed walking in the management of venous leg ulcers. Journal of wound care 2012;21(9):421-430. [DOI:]

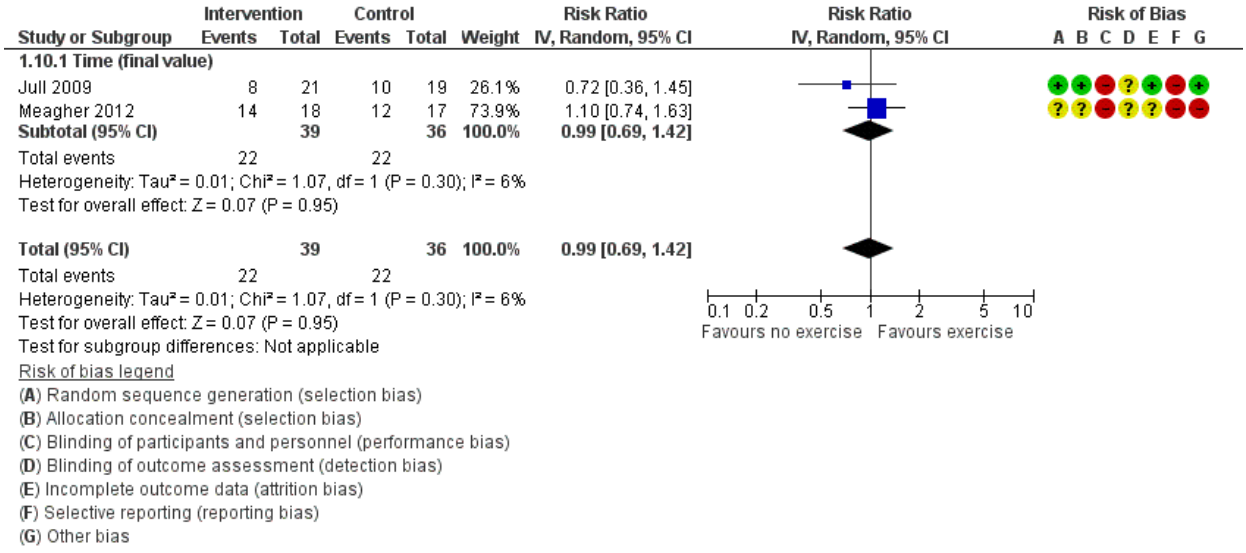
Data and analyses

1 Intervention vs Control

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Smerter (Pain) grundet fysisk aktivitet (bivirkning) End of treatment, max 6 mdr.	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.2 Ødem End of treatment, max 6 mdr.	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.3 Ankelbevægelighed End of treatment, max 6 mdr.	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.4 Drop out End of treatment, max 6 mdr.	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.5 Funktionsniveau End of treatment, max 6 mdr.	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.6 Kondition (evt. 6 min gangtest, trappetest) End of treatment, max 6 mdr.	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.7 Livskvalitet End of treatment, max 6 mdr.	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.9 Tyngdefornemmelse (tunge ben) End of treatment, max 6 mdr.	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.10 Total sårheling End of treatment	2	75	Risk Ratio (IV, Random, 95% CI)	0.99 [0.69, 1.42]
1.10.1 Time (final value)	2	75	Risk Ratio (IV, Random, 95% CI)	0.99 [0.69, 1.42]
1.11 Drop out End of treatment, max 6 mdr.	1	40	Risk Ratio (IV, Fixed, 95% CI)	2.73 [0.12, 63.19]
1.11.1 Time (final value)	1	40	Risk Ratio (IV, Fixed, 95% CI)	2.73 [0.12, 63.19]

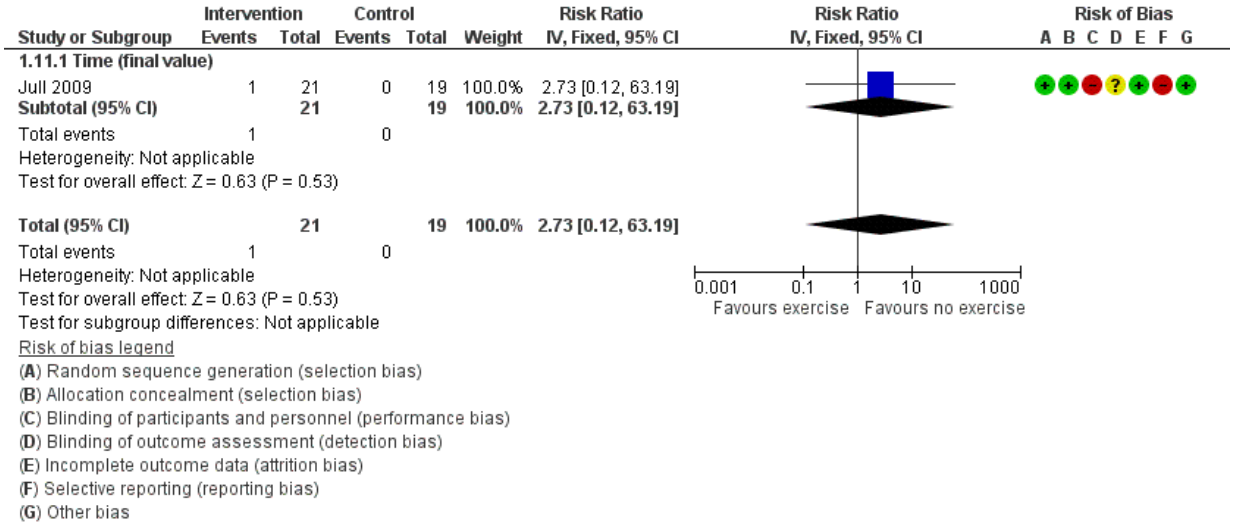
Figures

Figure 1 (Analysis 1.10)



Forest plot of comparison: 1 Intervention vs Control, outcome: 1.10 Total sårheling End of treatment.

Figure 2 (Analysis 1.11)



Forest plot of comparison: 1 Intervention vs Control, outcome: 1.11 Drop out End of treatment, max 6 mdr..