Evidence tables for review question: B.1b What physical rehabilitation interventions are effective and acceptable for children and young people with complex rehabilitation needs after traumatic injury?

Table 10: Evidence tables

Study details	Participants	Interventions	Outcomes and Results	Comments
Full citation Cucuzzo, N. A., Ferrando, A., Herndon, D. N., The effects of exercise programming vs traditional outpatient therapy in the rehabilitation of severely burned children, The Journal of burn care & rehabilitation, 22, 214-20, 2001 **Ref Id** 1123218 **Country/ies where the study was carried out** USA **Study type** RCT **Aim of the study** To compare the effectiveness of a comprehensive exercise programme	**Sample size** N= 21 (randomised) • Inpatient exercise: 11 • Outpatient therapy: 10 N= 21 (analysed) • Inpatient exercise: 11 • Outpatient therapy: 10 **Characteristics** Age in years [Mean (SD)]: • Inpatient exercise = 11.9 (1.2) • Outpatient therapy = 9.2 (1.4) Gender (M/F): • Total (N) = 8/3 Time since injury in years: not reported Total burn surface area: • Inpatient exercise	**Interventions** • *Intervention group: Inpatient exercise* 12-week comprehensive rehabilitation and wellness programme conducted at hospital. If patients lived off-site, they were shuttled to and from facility. Exercise took the form of general conditioning exercise, focusing on moderate intensity, progressive resistance training as well as aerobic and general conditioning exercises. Sessions last 1 hour, took place 3 times per week, for 12 weeks (totalling 36 sessions). Sessions focused on strength training (isotonic, isometric and isokinetic exercises using free weights) with secondary exercises added for balanced general conditioning effects (using treadmill, stationary bike or walking). In the first week, participants performed 1-2 training sessions of 1-2 sets for each exercise, in order to introduce correct technique. The programme was divided into 2 phases. Phase 1 Maximum load for resistance training was set at 50% of the 3 rep maximum weight, 4-10	**Results** *Changes in mobility (Change in distance walked measured using 6MWT) [mean (SEM)]* Higher = better. At baseline (Original 6MWT score in metres, 6 months post-burn): • Inpatient exercise: 456 (30) • Outpatient therapy: 508 (32) • No significant difference (p value not reported) 3 months from baseline (at intervention completion, 9 months post-burn): • Inpatient exercise (N=11): 186 (29) • Outpatient therapy (N=10): 66 (21) • Significantly higher (better) in intervention group (p = 0.004, unpaired t-test)	**Limitations** **Quality assessment:** Risk of bias assessed using revised Cochrane risk of bias tool (RoB 2) Domain 1: Risk of bias arising from the randomization process 1.1 Was the allocation sequence random? NI - Simply states randomised. 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions? NI. 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process? PN - Paper mentions no statistically significant difference between groups for age, TBSA, height and weight. No further details reported. *Risk of bias judgement:* Some concerns Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention) 2.1. Were participants aware of their assigned intervention during the trial? NI. 2.2. Were carers and people

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with traditional outpatient therapy on function and trainability of muscle strength in severely burned children. **Study dates** Not reported. **Source of funding** This study received funding from the National Institute on Disease and Rehabilitation Research and Shriners Hospital.	(%) = 62.0 (4.6) • Outpatient therapy (%) = 57.1 (4.2) **Inclusion criteria** Patients had to: • Be provided rehabilitation services within the Shriners-University of Texas hospital systems • Have burns >40% TBSA • Be older than 6 years old • Be treated at a burn centre within 72 hours of injury • Have 95% wound healing • Be able to be followed up throughout the length of study (including follow-up data collection) **Exclusion criteria** • Anoxic brain injury • Psychological disorders • Quadriplegia • Severe behavioural disorder	repetitions performed. Phase 2 Maximum load for resistance training was set at 70-85% of 3 rep maximum, 8-15 repetitions. No strength training was allowed outside of these sessions. Participants also received occupational and physical therapy twice per day for 1 hour, school for 2-3 hours per day, with play therapy and psychological therapy as appropriate. Exercise sessions were taken by an exercise physiologist and were strictly limited to 1 hour each. Individual exercise programmes were reviewed each week, with resistance increasing along with a patient's strength and aerobic capacity by 10-20% of average weekly work volume. Aerobic exercise was designed to increase energy expenditure by 50-80% of heart rate reserve. • *Control group: Traditional outpatient therapy* Occupational and physical therapy department of Shriners Hospital referred to outpatient therapy centres near their home. Focused on the relief of scar contractures and wound care and did not include a quantifiable exercise prescription to increase musculoskeletal strength. The number of visits and duration of		delivering the interventions aware of participants' assigned intervention during the trial? NI. 2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? PY – Control group did not have a specific programme to follow, and it varied between rehabilitation centres. 2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups? N – Issue with control group only. 2.5 If No/PN/NI to 2.4: Were these deviations likely to have affected the outcome? Y. 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? Y - Intention to treat. 2.7 If No/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized? NA. *Risk-of-bias judgement:* High risk <u>Domain 3: Missing outcome data</u> 3.1 Were data for this outcome available for all, or nearly all, participants randomized? Y - Data available for all participants. 3.2 If No/PN/NI to 3.1: Is there evidence that the result was not

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	• Severe cognitive disorder	individual sessions varied from centre to centre. This group were not allowed to weight train during the study but were allowed to maintain daily activities, physical therapy sessions and recreational/sports activities.		biased by missing outcome data? NA. 3.3 If No/PN to 3.2: Could missingness in the outcome depend on its true value? NA. 3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value? NA. *Risk-of-bias judgement:* Low risk Domain 4: Risk of bias in measurement of the outcome 4.1 Was the method of measuring the outcome inappropriate? PN. 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups? PN. 4.3 If No/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants? NI. 4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received? N - Metres walked is an objective measurement. 4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received? NA. *Risk-of-bias judgement:* Low risk Domain 5: Risk of bias in selection of the reported result 5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan

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				that was finalized before unblinded outcome data were available for analysis? NI. Is the numerical result being assessed likely to have been selected, on the basis of the results, from... 5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain? PN. 5.3 ... multiple analyses of the data? PN. *Risk-of-bias judgement:* Some concerns Overall risk of bias *High risk* **Other information** None.
Full citation Ebid, Anwar Abdelgayed, El-Shamy, Shamekh Mohamed, Draz, Amira Hussin, Effect of isokinetic training on muscle strength, size and gait after healed pediatric burn: a randomized controlled study, Burns : journal of the International Society for Burn Injuries, 40, 97-105, 2014	**Sample size** N= 37 (randomised) • Home exercise + isokinetic training: 18 • Home exercise only: 19 N= 33 (analysed) • Home exercise + isokinetic training: 16 • Home exercise only: 17 **Characteristics**	**Interventions** • *All participants.* Same physical therapy program, consisting of positioning, range of motion, stretching exercise for lower limb muscles, daily walking, and exercise • *Intervention group: Isokinetic training + home exercise.* 12-week isokinetic training program on Biodex system, performed 3 times per week (36 sessions in total) and involving 5-min warm-up on treadmill (velocity = 4 km/h), then quadriceps stretching ("the	**Results** *Changes in mobility (Stride length measured in cm) [mean (SD)]* Higher = better At baseline: • Home exercise + isokinetic training (N=18): 88 (2.09) • Home exercise only (N=19): 88.11 (2.28) 12 weeks from baseline (intervention completion):	**Limitations** **Quality assessment:** Risk of bias assessed using revised Cochrane risk of bias tool (RoB 2) Domain 1: Risk of bias arising from the randomization process 1.1 Was the allocation sequence random? NI "random process that involved opening an opaque envelope prepared by an independent person with random number generation. The randomization process was carried out by a registration clerk who was not involved in any part of the study." (p. 99). No further

Study details	Participants	Interventions	Outcomes and Results	Comments
Ref Id 1127734 **Country/ies where the study was carried out** Saudi Arabia **Study type** RCT **Aim of the study** "to investigate the effects of isokinetic training program on muscle strength, muscle size and gait parameters after healed paediatric burn." (p. 97) **Study dates** Not reported **Source of funding** Not reported	Age in years [Mean (SD)]: • Home exercise + isokinetic training = 13.46 (1.18) • Home exercise only = 13.6 (1.12) Gender (M/F): • Home exercise + isokinetic training (N) = 10/6 • Home exercise only (N) = 11.6 Time since injury in days [Mean (SD)]: • Home exercise + isokinetic training: 44.35 (3.95) • Home exercise only: 42.25 (3.49) Injury cause: • Home exercise + isokinetic training = all traumatic • Home exercise only = all traumatic Total burn surface area [mean (SD)]: • Home exercise + isokinetic training (%) = 42.06 (3.08)	participants stretched the quadriceps muscles of both limbs. Each muscle group was stretched 5 times for 30 s alternately for 5 min" p. 99). "Fifty percentages of average peak torque were selected as the initial dose of isokinetic exercise, and an increasing dose program was used in the first to fifth sessions (one set to five sets), and a dose of six sets was applied from the sixth to the 24th session and, finally, a dose of 10 sets was applied from the 25th to the 36th sessions. Each set consists of 10 repetitions concentric contraction at an angular velocity of 150°/s and patients were allowed 3 min of rest between sets" (p. 100). Patients were also given verbal encouragement and visual feedback from the equipment. + home-based physical therapy program involving range of motion exercise, splinting, stretching exercise for lower limb muscles, daily walking, functional training for ambulation and activities of daily living) to be performed 3 times per week; intensity, type and duration of exercises also prescribed to patients, but not further specified by authors. • *Control group: Home exercise*	• Home exercise + isokinetic training (N=16): 135.5 (2.82) • Home exercise only (N=17): 94 (2.69) *Changes in mobility (Step length measured in cm) [mean (SD)]* At baseline: • Home exercise + isokinetic training: 38.62 (1.14) • Home exercise only: 38 (1.83) 12 weeks from baseline (intervention completion): • Home exercise + isokinetic training: 63.25 (2.97) • Home exercise only: 43.76 (1.34) *Changes in mobility (Velocity measured in cm/s) [mean (SD)]* At baseline: • Home exercise + isokinetic training: 74.93 (1.38) • Home exercise only: 74.7 (1.53) 12 weeks from baseline (intervention completion): • Home exercise + isokinetic training: 135.94 (1.65) • Home exercise only: 81.11 (1.91)	information reported. 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions? PY (See 1.1) 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process? N *Risk-of-bias judgement:* Some concerns <u>Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)</u> 2.1. Were participants aware of their assigned intervention during the trial? Y 2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial? Y 2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? PN 2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups? NA 2.5 If No/PN/NI to 2.4: Were these deviations likely to have affected the outcome? NA 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? Y –

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	• Home exercise only (%) = 42.4 (3.13) The groups did not differ statistically significantly in age, weight, height, gender distribution, body mass index, length of hospitalization, lower extremity total body surface area or length of time between injury and initial evaluation. **Inclusion criteria** Participants had to: • Have healed burns with TBSA 36-45% • Be ambulatory without assistive devices • Not be athletes • "The burned children were categorized as having a circumferential lower limb deep second to third degree thermal injury extends from the lower trunk to the foot." (p. 98) • Patients described as recruited by therapists working in	*only.* The same home-based program as the intervention group.	*Changes in mobility (Cadence measured in step/min) [mean(SD)]* At baseline: • Home exercise + isokinetic training: 82.43 (1.54) • Home exercise only: 82.88 (1.53) 12 weeks from baseline (intervention completion): • Home exercise + isokinetic training: 137.63 (1.36) • Home exercise only: 90.35 (1.32)	Intention to treat. 2.7 If No/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized? NA *Risk-of-bias judgement:* Low risk <u>Domain 3: Missing outcome data</u> 3.1 Were data for this outcome available for all, or nearly all, participants randomized? PY 3.2 If No/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data? NA 3.3 If No/PN to 3.2: Could missingness in the outcome depend on its true value? NA 3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value? NA *Risk-of-bias judgement:* Low risk <u>Domain 4: Risk of bias in measurement of the outcome</u> 4.1 Was the method of measuring the outcome inappropriate? N 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups? N 4.3 If No/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants? N, they were blinded to group assignment

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	outpatient clinic **Exclusion criteria** • Children with diabetes • Neuropathy • Neurological disorders • Severe behaviour or cognitive disorders • Leg amputation, previous brain injury • Any disease affecting balance, vestibular or visual disorders • Lower limb deformity • History of epilepsy • Children who had participated in any rehabilitation program prior to the study • Children taking any medication that could affect strength adaptations, adversely affecting the results of the study			4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received? PN, automatic computer measurements used. 4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received? N *Risk-of-bias judgement:* Low risk Domain 5: Risk of bias in selection of the reported result 5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis? NI Is the numerical result being assessed likely to have been selected, on the basis of the results, from... 5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain? PN 5.3 ... multiple analyses of the data? NI *Risk-of-bias judgement:* Some concerns Overall risk of bias *Some concerns* **Other information** None.

Study details	Participants	Interventions	Outcomes and Results	Comments
Full citation Ebid, Anwar Abdelgayed, El-Shamy, Shamekh Mohamed, Amer, Maysa Abbas, Effect of vitamin D supplementation and isokinetic training on muscle strength, explosive strength, lean body mass and gait in severely burned children: A randomized controlled trial, Burns : journal of the International Society for Burn Injuries, 43, 357-365, 2017 **Ref Id** 1129564 **Country/ies where the study was carried out** Saudi Arabia **Study type** RCT **Aim of the study** To investigate the effectiveness of	**Sample size** N = 48 (randomised) • Isokinetic training + vitamin D: 15 • Isokinetic training + placebo: 17 • Standard care: 16 (not reported in data extraction after this) N = 48 (analysed) • Isokinetic training + vitamin D: 15 • Isokinetic training + placebo: 17 • Standard care: 16 (not reported in data extraction after this) **Characteristics** Age in years [Mean (SD)]: • Vitamin D = 13.80 (1.47) • Isokinetic training = 13.11 (1.45) Gender (M/F) • Vitamin D (N) = 10/7 • Isokinetic training (N) = 11/6 Time since injury: not reported	**Interventions** *Intervention group Standard care+ isokinetic training + vitamin D*. Standard care as described in control group + 12-week Isokinetic training programme using Biodex system as described in control group + Vitamin D (1000 IU Vitamin D3 [Cholecalciferol] taken orally once per day with food). No further details reported. *Control group Standard care + isokinetic training + placebo.* Routine physical therapy programme including range of motion exercises, lower limb stretching exercises, splinting, daily walking and training for activities of daily living. Also carried out a12 week Isokinetic training programme using Biodex system. 3 x training sessions per week consisting of 5 minute warm up on a treadmill at 4 km/hour and 5 sets (10 repetitions of concentric contraction at 150°/sec) of knee extensor stretching with 3-minute rest between. Initially, intensity was set at 50% of every peak torque. For the 1st 5 sessions, sets were increased from 1 to 5 sets. From session 6-24, 6 sets were performed, progressing to 10 sets for session 25-30. Placebo pills given in place of Vitamin D3.	**Results** *Changes in mobility (Stride length measured in cm) [mean (SD)]* Higher = better At baseline: • Vitamin D group + isokinetic training (N=15): 87.00 (2.08) • Isokinetic training (N=17): 88.00 (2.09) At 12 weeks (after intervention completion): • Vitamin D group + isokinetic training (N=15): 139.56 (2.57) • Isokinetic training (N=17): 110.60 (2.87) • Significant difference between groups at 12 weeks (p value < 0.0001, repeated-measured ANOVA with post hoc comparison) *Changes in mobility (Step length measured in cm) [mean (SD)]* Higher = better At baseline: • Vitamin D group + isokinetic training (N=15): 39.00 (1.83)	**Limitations** **Quality assessment:** Risk of bias assessed using revised Cochrane risk of bias tool (RoB 2) <u>Domain 1: Risk of bias arising from the randomization process</u> 1.1 Was the allocation sequence random? NI - Paper simply states that participants were randomised. 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions? Y - Opaque enveloped with random number which were opened by participants. 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process? N - No significant difference between groups at baseline. *Risk-of-bias judgement:* Low risk <u>Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)</u> 2.1. Were participants aware of their assigned intervention during the trial? N - Participants were blinded to group assignment. 2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial? N -

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vitamin D supplementation and exercise on muscle strength, explosive strength, mobility and vitamin D levels in children with severe burns. **Study dates** Not reported. **Source of funding** No specific funding received from any funding agency, commercial enterprise or non-profit organisation.	Injury cause: not reported TBSA [mean(SD)]: • Vitamin D (%) = 24 (3.1) • Isokinetic training (%) = 26 (2.8) **Inclusion criteria** Participants had to: • Have TBSA between 40-55% • Be able to walk without assistance • Not be an athlete **Exclusion criteria** • Metabolic disorders • Neuropathy • Visual and vestibular disorders • Limb amputation • Lower limb deformity • Taking part in another study • History of adverse medical reactions • History of epilepsy History of imbalance		• Isokinetic training (N=17): 38.62 (1.32) At 12 weeks (after intervention completion): • Vitamin D group + isokinetic training (N=15): 67.26 (2.45) • Isokinetic training (N=17): 55.25 (2.49) • Significant difference between groups at 12 weeks (p value < 0.0001, repeated-measured ANOVA with post hoc comparison) *Changes in mobility (Velocity measured in cm/s) [mean (SD)]* Higher = better At baseline: Vitamin D group + isokinetic training (N=15): 73.34 (1.48) Isokinetic training (N=17): 73.93 (1.38) At 12 weeks (after intervention completion): • Vitamin D group + isokinetic training (N=15): 133.94 (1.65) • Isokinetic training (N=17): 99.94(1.65) • Significant difference between groups at 12 weeks (p value < 0.0001, repeated-measured	Therapists were blinded to group assignment. 2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? NA. 2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups? NA. 2.5 If No/PN/NI to 2.4: Were these deviations likely to have affected the outcome? NA. 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? Y - Intention to treat. 2.7 If No/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized? NA. *Risk-of-bias judgement:* Low risk <u>Domain 3: Missing outcome data</u> 3.1 Were data for this outcome available for all, or nearly all, participants randomized? Y - Data available for all participants. 3.2 If No/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data? NA. 3.3 If No/PN to 3.2: Could missingness in the outcome depend on its true value? NA. 3.4 If Y/PY/NI to 3.3: Is it likely

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			ANOVA with post hoc comparison) *Changes in mobility (Cadence measured in step/min) [mean (SD)]* Higher = better At baseline: • Vitamin D group + isokinetic training (N=15): 83.43 (1.65) • Isokinetic training (N=17): 83.50 (1.55) At 12 weeks (after intervention completion): • Vitamin D group + isokinetic training (N=15): 140.63 (1.36) • Isokinetic training (N=17): 132.63 (1.36) • Significant difference between groups at 12 weeks (p value < 0.0001, repeated-measured ANOVA with post hoc comparison)	that missingness in the outcome depended on its true value? NA. *Risk-of-bias judgement:* Low risk <u>Domain 4: Risk of bias in measurement of the outcome</u> 4.1 Was the method of measuring the outcome inappropriate? PN. 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups? N - Data collection occurred at baseline and 12 weeks. 4.3 If No/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants? NI. 4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received? N - All outcomes objectively measured. 4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received? NA. *Risk-of-bias judgement:* Low risk <u>Domain 5: Risk of bias in selection of the reported result</u> 5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis? NI Is the numerical result being assessed likely to have been selected, on the basis of the

Study details	Participants	Interventions	Outcomes and Results	Comments
				results, from... 5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain? PN 5.3 ... multiple analyses of the data? PN *Risk-of-bias judgement* Some concerns Overall risk of bias *Some concerns* **Other information** The results of isokinetic training +home exercise are reported separately in another paper (Ebid 2014). Only vitamin D+ isokinetic training and isokinetic training only will be extracted from this paper.

6MWT: 6 minute walk test; ANOVA: Analysis of variance statistical test; cm: centimetres; F: Female; IU: International units; M: Male; N: Number [or No if part of quality assessment]; NA: Not applicable; NI: No information; PN: Probably not; PY: Probably yes; RCT: Randomised controlled trial; SD: Standard deviation: SEM: standard error of mean; TBSA: Total burn surface area: Y: Yes