SUPPLEMENTARY MATERIAL

Table S1 PubMed search strategy

Search ID	Search term
#1	"spinal cord"[tiab] OR spine[tiab] OR spinal[tiab] OR epidural[tiab] OR "dorsal column*"[tiab] OR invasive[tiab] OR implant*[tiab] OR "spinal nerve*"[tiab] OR "spinal gangli*"[tiab] OR "spinal root*"[tiab] OR "noot*"[tiab] OR "spinal nerve*"[tiab] OR "spinal gangli*"[tiab] OR "spinal nerve*"[tiab] OR "spinal gangli*"[tiab] OR "spinal noot*"[tiab] OR "noot*"[tiab] OR "noot*"[tiab] OR "spinal nerve*"[tiab] OR "spinal gangli*"[tiab] OR "spinal noot*"[tiab] OR "spinal nerve*"[tiab] OR "spinal noot*"[tiab] O
#2	stimulation[tiab] OR stimulator[tiab] OR neuromodulation[tiab] OR neurostimulator[tiab]
#3	#1 AND #2
#4	"spinal cord stimulation"[mesh] OR "electric stimulation therapy"[mesh] OR scs[tiab] OR drg[tiab]
#5	#3 OR #4
#6	"Diabetic Neuropathies"[mesh]
#7	diabet*[tiab] AND (neuropath*[tiab] OR amyotroph*[tiab] OR polyneuropath*[tiab] OR mononeuropath*[tiab] OR neuralg*[tiab] OR pain*[tiab])
#8	#6 OR #7
#9	neuropathy[tiab] OR neuropathies[tiab] OR polyneuropath*[tiab] OR mononeuropath*[tiab]
#10	#8 OR #9
#11	#5 AND #10

Table S2 Cochrane Risk of Bias Assessment (performed using the RoB 2.0 tool) for randomized controlled trials

Ref cada Rest and solution Rest and solutin Rest and solution Res	Uninus ID		Study ID	Determine at al (2021)	A	
Ref de de general de la control de la co	Unique ID		Study ID		Assessor	DE
Indeminy (inc) (inc	Ref or Label		Aim	effect)		
Odd/column Mark Mark Concord Image: Column Image: Column </td <td>Experimental</td> <td colspan="5">djunctive high-frequency 10 kHz SCS therapy Comparator Source Journal article(s)</td>	Experimental	djunctive high-frequency 10 kHz SCS therapy Comparator Source Journal article(s)				
Index decision decision (IIII) distribution decision decision (IIII) distribution decision decisi	Outcome					
Part of the second se	Domain	Signalling question			Response	Comments
Index Index Index Index A construction of part and part of the standing denome in the standing d		1.1 Was the allocation sequence random?			Y	Computer generated randomization.
Ideal Ideal <th< td=""><td></td><td>1.2 Was the allocation sequence concealed until p</td><td>participants were enrolled</td><td>and assigned to interventions?</td><td>Y</td><td>Randomization was concealed.</td></th<>		1.2 Was the allocation sequence concealed until p	participants were enrolled	and assigned to interventions?	Y	Randomization was concealed.
			groups suggest a probler	n with the randomization process?	N	Baseline characteristics appear to be well-balanced
Image: Section of the sectin of the section of the section		Risk of bias judgement			Low	
		2.1.Were participants aware of their assigned inter	rvention during the trial?		Y	Onen-Jahel study without blinding of participants or study personnel or sham control
point provide provide provide For Part Part Part Part Part Part Part Par		2.2.Were carers and people delivering the interver	ntions aware of participan	ts' assigned intervention during the trial?	Y	oportrador stady warrout bilinaing of participants of stady personnel, of sharn control
Term intervention 2.1 IV PV NI 0 2.4 Work these deviations from intervided intervention balanced between googs? NA 2.5 VI VV NI 0 2.4 Work these deviations from intervided intervention intervided intervention? NA An ITT appreads in reported in the explore the the automed these reported intervention? 2.6 VI VV NI 0 2.4 Work these deviations from intervided intervention? NA An ITT appreads in reported in the explore the the automed these reported intervention? 2.7 VI VV NI 0 2.4 Work these deviations from intervided intervention? NA Concern 3.1 View readsoft tilts outdome available of all or newly all purblediant reports and the explore data? NA The work of mining data wis not balanced between the arms. In addition, the mining patient and the explore data in addition. The mining patient and the explore data in addition. The mining patient and the explore data in addition. The mining patient and the explore data in addition. The mining patient and the explore data in addition. The mining patient and the explore data in addition. The mining patient and the explore data in addition. The mining patient approximation and the explore data in addition. The intervention is addition of the patient and the explore data in addition. The mining patient and the explore data in addition. The intervention is additin additin the explore data in addition. The intervention is addit			s from the intended interve	ention that arose because of the experimental	PN	No deviations were reported.
Introduction Introduction 2 Provide 24. Work media window form introduction provide status Introduction 2 Provide 24. Work media window form introduction provide status Introduction provide status 2 Provide 24. Work media window form introduction provide status Introduction provide status 2 Provide 24. Work media window form introduction provide status Introduction provide status 3 Provide 24. Work media window form introduction provide status Introduction provide status 3 Provide 24. Work media window form introduction provide status Introduction provide status 3 Provide 24. Work media window form introduction provide status Introduction provide status 3 Provide 24. Work media window form introduction provide status Introduction provide status 3 Provide 24. Work media window form introduction provide status Introduction provide status 4 Provide 24. Work media window form introduction provide status Introduction provide status 4 Provide 24. Work media window form introduction provide status Introduction provide status 5 Provide 24. Work media window form introduction provide status Introduction provide status 6 Provide 24. Work media window form introduction provide status Introduction provide status 6 Provide status Introduction provide st		2.4 If Y/PY to 2.3: Were these deviations likely to I	have affected the outcom	9?	NA	
Intersection Intersection Intersection Intersection Intersection Bits in bits of this underent Intersection Interse		2.5. If Y/PY/NI to 2.4: Were these deviations from	intended intervention bala	anced between groups?	NA	
pick which we were individe? in Ma pick which we year individe? in Ma pick which we year individe? in Ma pick were pick which were individent in any individual stand member in a distance were individual to the stand in the maximum and the maximum a		2.6 Was an appropriate analysis used to estimate	the effect of assignment	o intervention?	Y	An ITT approach is reported, although there were 8 exclusions after exposure to the treatment during the screening trial.
Bits due to missing outcome available for all, or nearly all, participants randomized? N Low level of missing data at 8 months: 10 kHz SCS plus CMM: 15%, 17 of 113; CMM: 9%, 9 of 103. Bits due to missing outcome data? N The level of missing data was not balanced between the arms. In addition, the missing participants were excluded from the 6-month analysis. 3 if NPN to 3.2. Could missingness in the outcome depend on its true value? PN Considering the 10 kHz SCS proxp, there were 8 exclusions after exposure to the trastment during the screening trial. The published additiones of proximation that at 8 paints? 3 if NPN to 3.2. Could missingness in the outcome depend on its true value? NA Considering the 10 kHz SCS proxp, there were 8 exclusions after exposure to the trastment during the screening trial. The published additiones on protocol math the exclusions were not valued to the pain outcome. Networe, individual patient data (PD) continue data at 8 and 75% pain relief. This suggests that the exclusions were not valued to the pain outcome. Networe, individual patient data (PD) continue data at 8 and 75% pain relief. This suggests that the exclusions were not valued to the pain outcome. Networe, individual patient data (PD) continue data at 8 and 75% pain relief. This suggests that the exclusions were not valued to the pain outcome. Networe, individual patient data (PD) continue data at 8 and 75% pain relief. This suggests that the exclusions were not valued to the pain outcome. Networe, individual patient data (PD) continue data at 8 and 75% pain relief. This suggests that the exclusions were not valued to the pain outcome. Networe, individual patient data (PD) continue data at 8 and 75% pain relief. This suggests that the exclusions were not valued			ostantial impact (on the re	sult) of the failure to analyse participants in the	NA	
Bits due to the residue that result was not biased by missing outcome data? N The level of missing data was not balanced between the arms. In addition, the missing participants were excluded from the 6-month analysis. Bits due to the section of the section of the restored data from the restored after exposure to the restored data from the restored after exposure to the restored data. Considering the 10 ktrs CS group, there were 8 exclusions after exposure to the restored data. The overeit of the section of the restored data from the restored after exposure to the restored data. The overeit of the section of the restored data from the restored after exposure to the restored data. The overeit of the section of the restored data from the restored data from the restored data. The overeit of the section of the restored data from the restored data. The overeit of the section of the restored data from the restored data from the restored data. The overeit of the section of the restored data from the restored data. The overeit of the section of the restored data from the restored data from the restored data. The overeit of the section of the section of the restored data from the restored data. The overeit of the section of the section of the section of the restored data. The overeit of the section of the		Risk of bias judgement			Low	
Bits due to missing 3.3 HVPN to 3.2. Could missingness in the outcome depend on its true value? PN Considering the 10 kHz SCS group, there were 8 exclusions after exposure to the treatment during the screening trial. The published article does not provid sufficient detail to confirm that the exclusions were not related to the pain outcome. However, individual patient data (PD) confirmed that all 8 patients sufficient detail to confirm that the exclusions were not related to the pain outcome. However, individual patient data (PD) confirmed that all 8 patients sufficient detail to confirm that the exclusions were probably not related to the pain outcome. Bits in measurement A1 WPS the method of measuring the outcome have differed between intervention groups? N VAS is a validated pain intensity scale A1 Were outcome assessors aware of the intervention received by study participants? Y VAS score was patient-reported outcome (subjective scale). Since the trial was open-label in design, the assessor (ie, the patient) was aware of the treatment assignment. 0 the outcome VAS score was patient-reported outcome (subjective scale). Since the trial was open-label in design, the assessor (ie, the patient) was aware of the treatment assignment. 0 the outcome have differed beauting the outcome have differed beauting the outcome have differed details of narrowice? Y VAS score was patient-reported outcome (subjective scale). Since the trial measign, the assessor (ie, the patient) was aware of the treatment assignment. VAS score was patient-reported outcome (subjective scale). Since the trial measign absent from 10 kHz SCS, or not perceiving CMM as a prope treatment ass		3.1 Were data for this outcome available for all, or	nearly all, participants ra	ndomized?	N	Low level of missing data at 6 months: 10 kHz SCS plus CMM: 15%, 17 of 113; CMM: 9%, 9 of 103.
outcome data Image: Control of the second of t		3.2 If N/PN/NI to 3.1: Is there evidence that result	was not biased by missin	g outcome data?	Ν	The level of missing data was not balanced between the arms. In addition, the missing participants were excluded from the 6-month analysis.
All MPP VN to 3.3 is it likely but missingness in the outcome depended on its two value? NA ompleted the trial, all were responders, and 6 had at least 75% pain relief, this suggests that the exclusions were probably not reliated to the pain outcome. Bis of bis judgement All VPP VN to 3.3 is it likely that missingness in the outcome inappropriate? All vass ment of the sustained of the outcome have differed between intervention groups? All VPP VN to 4.3 is it likely that assessment of the intervention received by study participants? All VPP VN to 4.3 is it likely that assessment of the outcome have been influenced by knowledge of intervention received? All VPP VN to 4.3 is it likely that assessment of the outcome have been influenced by knowledge of intervention received? All VPP VN to 4.3 is it likely that assessment of the outcome was influenced by knowledge of intervention received? All VPP VN to 4.3 is it likely that assessment of the outcome was influenced by knowledge of intervention received? All VPP VN to 4.3 is it likely that assessment of the outcome was influenced by knowledge of intervention received? All VPP VN to 4.3 is it likely that assessment of the outcome was influenced by knowledge of intervention received? All VPP VN to 4.3 is it likely that assessment of the outcome was influenced by knowledge of intervention received? All VPP VN to 4.3 is it likely that assessment of the outcome data were available for analysis? <t< td=""><td></td><td>3.3 If N/PN to 3.2: Could missingness in the outco</td><td>me depend on its true va</td><td>ue?</td><td>PN</td><td>Considering the 10 kHz SCS group, there were 8 exclusions after exposure to the treatment during the screening trial. The published article does not provide sufficient detail to confirm that the exclusions ware not related to the pain outcome. However, individual patient data (IPD) confirmed that all 8 patients</td></t<>		3.3 If N/PN to 3.2: Could missingness in the outco	me depend on its true va	ue?	PN	Considering the 10 kHz SCS group, there were 8 exclusions after exposure to the treatment during the screening trial. The published article does not provide sufficient detail to confirm that the exclusions ware not related to the pain outcome. However, individual patient data (IPD) confirmed that all 8 patients
A1. Was the method of measuring the outcome inappropriate? N VAS is a validated pain intensity scale Bias in measurement of the outcome assessors aware of the intervention received by study participants? N VAS score was patient-reported outcome (subjective scale). Since the trial was open-label in design, the assessor (ie, the patient) was aware of the reatment assignment. 4.1 W.Y.PY.NI to 4.3: Could assessment of the outcome have differed between influenced by knowledge of intervention received? Y Since the patient was aware of the intervention, they may have been influenced by expecting a benefit from 10 kHz SCS, or not perceiving CMM as a proper reatment. In addition, the patient was aware of being allowed to crossover at 6 months. Risk of Dias judgement High Bias in selection of the outcome measurements (e.g. scales, definitions, time points) within the outcome domain? PY A summary of the rail protocol was published by Mekhail et al (2020). A statistical analysis plan (SAP) is also publicly available. However, it is not confirmed that the final SAP preceded the availability of unblinded outcome data to the trait investigators. Bias in selection of the pelipble outcome measurements (e.g. scales, definitions, time points) within the outcome domain? PN No apparent indications of reporting selectivity at 6 months from examination of the protocol and SAP. Bias in selection of the bia judgement File of bias judgements PN No apparent indications of reporting selectivity at 6 months from examination of the protocol and SAP.		3.4 If Y/PY/NI to 3.3: Is it likely that missingness in	the outcome depended	on its true value?	NA	
Bits in measurement A control A control 4.2 Could measurement or ascertainment of the outcome have differed between intrivention groups? N 4.3 Were outcome assessors aware of the intervention received by study participants? Y VAS score was patient-reported outcome (subjective scale). Since the trial was open-label in design, the assessor (ie, the patient) was aware of the intervention, they may have been influenced by knowledge of intervention received? Y Since the patient was aware of the intervention, they may have been influenced by expecting a benefit from 10 kHz SCS, or not perceiving CMM as a propertent to a difficient. In addition, the patient was aware of being allowed to crossover at 6 months. 8 is of bias judgement High In addition, the patient was aware of the intervention, they may have been influenced by expecting a benefit from 10 kHz SCS, or not perceiving CMM as a propertent was aware of being allowed to crossover at 6 months. 8 is of bias judgement High In addition, the patient was aware of the intervention, they may have been influenced by expecting a benefit from 10 kHz SCS, or not perceiving CMM as a propertent was aware of the inal protocol was published by Mekhail et al (2020). A statistical analysis plan (SAP) is also publicly available. However, it is not confirmed the trial investigators. 8 is nelection of the protocol measurements (e.g. scales, definitions, time points) within the outcome domain? PN A summary of the trial protocol was published by Mekhail et al (2020). A statistical analysis plan (SAP) is also publicly available. However, it is not confirmed that the final SAP preceded the availab		Risk of bias judgement			Low	
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4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received? Y Since the patient was aware of the intervention, they may have been influenced by expecting a benefit from 10 kHz SCS, or not perceiving CMM as a propertertertert. In addition, the patient was aware of being allowed to crossover at 6 months. Rise of bais judgement PY Bias in selection of the reported result. PY Since the patient was aware of the intervention, they may have been influenced by expecting a benefit from 10 kHz SCS, or not perceiving CMM as a propertertertert. Bias in selection of the select a hat proposed this result analysed in accordance with a pre-specified analysis plan that was finalized ber on unbined outcome data were available for analysis? PY A summary of the trial protocol was published by Mekhail et al (2020). A statistical analysis plan (SAP) is also publicly available. However, it is not confirme that the final SAP preceded the availability of unbined outcome data to the trial investigators. Bias in selection of the protocol measurements (e.g. scales, definitions, time points) within the outcome domain? PN A summary of the trial protocol was published by Mekhail et al (2020). A statistical analysis plan (SAP) is also publicly available. However, it is not confirme that the protocol and SAP. reported result 5.2 multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain? PN No apparent indications of reporting selectivity at 6 months from examination of the protocol and SAP. Sinc the paint data prot		4.3 Were outcome assessors aware of the interve	ntion received by study pa	articipants?	Y	
4.5 If V/P/N1 to 4.4 is it likely that assessment of the outcome was influenced by knowledge of intervention received? PY Rist of bias judgement High 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? PY 6.1 were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized per on blinded outcome data were available for analysis? PY A summary of the trial produced the availability of unblinded outcome data to the trial investigators. 8 as means of the eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain? PN A summary of the trial control on specified the availability of unblinded outcome data to the trial investigators. 5.3 multiple eligible analyses of the data? PN No apparent indications of reporting selectivity at 6 months from examination of the protocol and SAP. 6.4 of bias judgement Low Low Low Low	o. and outcome	4.4 If Y/PY/NI to 4.3: Could assessment of the out	come have been influenc	ed by knowledge of intervention received?	Y	Since the patient was aware of the intervention, they may have been influenced by expecting a benefit from 10 kHz SCS, or not perceiving CMM as a proper treatment. In addition, the patient was aware of being allowed to crossover at 6 months.
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 produced the variability of unblinded outcome data were available for analysis? PY A summary of the trial protocol was published by Mekhail et al (2020). A statistical analysis plan (SAP) is also publicly available. However, it is not confirmed that the final SAP preceded the availability of unblinded outcome data to the trial investigators. Bias in selection of the protocol measurements (e.g. scales, definitions, time points) within the outcome domain? PN No apparent indications of reporting selectivity at 6 months from examination of the protocol and SAP. 5.3 multiple eligible analyses of the data? PN PN Image: Comparison of the protocol and SAP. Risk of bias judgement Low Low Empty for the trial protocol was published by Mekhail et al (2020). A statistical analysis plan (SAP) is also publicly available. However, it is not confirmed that the final SAP preceded the availability of unblinded outcome data to the trial investigators.			f the outcome was influen	ced by knowledge of intervention received?		
Bias in selection of the reported result before unblinded outcome data were available for analysis? Image: PY that the final SAP preceded the availability of unblinded outcome data to the trial investigators. Bias in selection of the reported result 52 multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain? PN No apparent indications of reporting selectivity at 6 months from examination of the protocol and SAP. 53 multiple eligible analyses of the data? PN PN Risk of bias judgement Low					High	
reported result Image: Comparison of the data? Image: Comparison of the data? 5.3 multiple eligible analyses of the data? PN Risk of bias judgement Low				re-specified analysis plan that was finalized	PY	A summary of the trial protocol was published by Mekhail et al (2020). A statistical analysis plan (SAP) is also publicly available. However, it is not confirmed that the final SAP preceded the availability of unblinded outcome data to the trial investigators.
Risk of bias judgement Low		5.2 multiple eligible outcome measurements (e.	g. scales, definitions, time	points) within the outcome domain?	PN	No apparent indications of reporting selectivity at 6 months from examination of the protocol and SAP.
Overall bias Risk of bias judgement High		· · ·			-	
	Overall bias	Risk of blas judgement			High	1

Unique ID	Slangen et al (2014)	Study ID	Slangen et al (2014)	Assessor	DE			
	Slangen et al (2014)	Aim	assignment to intervention (the 'intention-to-treat'					
	Best medical therapy with adjunctive LF-SCS		effect) Best medical therapy (BMT) alone		l suural adid (4). Naa aanaanid kiel aadida (aa of CinicalTride anu aanad)			
	therapy 6 months: Pain intensity; Responder rate (at	Comparator		Source	Journal article(s); Non-commercial trial registry record (e.g. ClinicalTrials.gov record)			
Outcome	least 50% pain reduction) Results			Weight	1			
Domain	Signalling question			Response	Comments			
	1.1 Was the allocation sequence random?			Y	Computer generated randomization.			
Bias arising from the	1.2 Was the allocation sequence concealed until	participants were enrolled	and assigned to interventions?	NI	No information is provided regarding concealment; however, it is likely that the allocation was concealed since computer randomization was used.			
randomization process	1.3 Did baseline differences between intervention	n groups suggest a probler	n with the randomization process?	N	Baseline characteristics appear to be well-balanced.			
	Risk of bias judgement			Low				
	2.1.Were participants aware of their assigned inte	ervention during the trial?		Y				
	2.2.Were carers and people delivering the interve	entions aware of participan	ts' assigned intervention during the trial?	Y	Open-label study without blinding of participants or study personnel.			
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviation context?	ns from the intended interve	ention that arose because of the experimental	PN	No deviations were reported.			
	2.4 If Y/PY to 2.3: Were these deviations likely to	have affected the outcom	e?	NA				
from intended interventions	2.5. If Y/PY/NI to 2.4: Were these deviations from	n intended intervention bala	anced between groups?	NA				
Ī	2.6 Was an appropriate analysis used to estimate	e the effect of assignment	to intervention?	Y	ITT analysis was performed			
	2.7 If N/PN/NI to 2.6: Was there potential for a su group to which they were randomized?	ıbstantial impact (on the re	sult) of the failure to analyse participants in the	NA				
ĺ	Risk of bias judgement			Low				
	3.1 Were data for this outcome available for all, o	or nearly all, participants ra	ndomized?	Y	Low level of missing data from each arm, but not balanced between the arms: LF-SCS 14% (3 of 22); CMM 7% (1 of 14). However, missing participants were treated as nonresponders.			
	3.2 If N/PN/NI to 3.1: Is there evidence that result	t was not biased by missin	g outcome data?	NA				
Bias due to missing outcome data	3.3 If N/PN to 3.2: Could missingness in the outco	ome depend on its true va	lue?	NA				
	3.4 If Y/PY/NI to 3.3: Is it likely that missingness i	in the outcome depended	on its true value?	NA				
	Risk of bias judgement			Low				
	4.1 Was the method of measuring the outcome ir	nappropriate?		Ν	NRS is a validated pain intensity scale			
	4.2 Could measurement or ascertainment of the o	outcome have differed bet	ween intervention groups?	N				
Bias in measurement	4.3 Were outcome assessors aware of the interve	ention received by study pa	articipants?	Y	NRS score was patient-reported outcome (subjective scale). Since the trial was open-label in design, the assessor (ie, the patient) was aware of the treatment assignment.			
of the outcome	4.4 If Y/PY/NI to 4.3: Could assessment of the out	utcome have been influenc	ed by knowledge of intervention received?	Y	Since the patient was aware of the intervention, they may have been influenced by expecting a benefit from LF-SCS, or not perceiving BMT as a proper treatment.			
	4.5 If Y/PY/NI to 4.4: Is it likely that assessment of	of the outcome was influen	ced by knowledge of intervention received?	PY				
ſ	Risk of bias judgement			High				
	5.1 Were the data that produced this result analy before unblinded outcome data were available for		pre-specified analysis plan that was finalized	NI	Analysis intentions are not available, ie, no published protocol or statistical analysis plan			
Bias in selection of the	5.2 multiple eligible outcome measurements (e	e.g. scales, definitions, time	e points) within the outcome domain?	PN	No apparent indications of reporting selectivity. The use of dichotomous responder status is standard in the SCS field (ie, not selective reporting). The analysis used the standard definition of treatment response (at least 50% pain reduction).			
reported result	5.3 multiple eligible analyses of the data?			PN				
	Risk of bias judgement			Some concerns				
Overall bias	Risk of bias judgement			High				

Unique ID	de Vos et al (2014)	Study ID	de Vos et al (2014)	Assessor	DE		
Ref or Label	de Vos et al (2014)	Aim	assignment to intervention (the 'intention-to-treat' effect)				
	Best medical therapy with adjunctive LF-SCS therapy	Comparator	Best medical therapy (BMT) alone	Source	Journal article(s); Non-commercial trial registry record (e.g. ClinicalTrials.gov record)		
	6 months: Pain intensity; Responder rate (at least 50% pain reduction)	Results		Weight	1		
Domain	Signalling question			Response	Comments		
	1.1 Was the allocation sequence random?			Y	Block stratified randomization is likely to be computer based.		
Bias arising from the	1.2 Was the allocation sequence concealed until	participants were enrolled	and assigned to interventions?	NI	No information is provided regarding concealment; however, it is likely that the allocation was concealed if computer randomization was used.		
randomization process	1.3 Did baseline differences between interventior	n groups suggest a problem	n with the randomization process?	N	Baseline characteristics appear to be well-balanced (no statistically significant differences between the groups).		
	Risk of bias judgement			Low			
	2.1.Were participants aware of their assigned inte	ervention during the trial?		Y			
	2.2.Were carers and people delivering the interve	entions aware of participan	ts' assigned intervention during the trial?	Y	Open-label study without blinding of participants or study personnel.		
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviation context?	ns from the intended interve	ention that arose because of the experimental	PN	No deviations were reported.		
Bias due to deviations	2.4 If Y/PY to 2.3: Were these deviations likely to	have affected the outcom	e?	NA			
from intended interventions	2.5. If Y/PY/NI to 2.4: Were these deviations from	n intended intervention bala	anced between groups?	NA			
	2.6 Was an appropriate analysis used to estimate	e the effect of assignment t	o intervention?	Y	ITT analysis was performed		
	2.7 If N/PN/NI to 2.6: Was there potential for a su group to which they were randomized?	ibstantial impact (on the re	sult) of the failure to analyse participants in the	NA			
	Risk of bias judgement			Low			
	3.1 Were data for this outcome available for all, c	or nearly all, participants ra	ndomized?	Y	Low and balanced level of missing data in each arm: LF-SCS 10%, 4 of 40; BMT 10%, 2 of 20. The authors presented an ITT analysis.		
	3.2 If N/PN/NI to 3.1: Is there evidence that resul	t was not biased by missin	g outcome data?	NA			
Bias due to missing outcome data	3.3 If N/PN to 3.2: Could missingness in the outc	ome depend on its true val	ue?	NA			
	3.4 If Y/PY/NI to 3.3: Is it likely that missingness i	in the outcome depended of	on its true value?	NA			
	Risk of bias judgement			Low			
	4.1 Was the method of measuring the outcome ir	nappropriate?		N	VAS is a validated pain intensity scale		
	4.2 Could measurement or ascertainment of the	outcome have differed bet	veen intervention groups?	N			
Bias in measurement	4.3 Were outcome assessors aware of the interve	ention received by study pa	articipants?	Y	VAS score was patient-reported outcome (subjective scale). Since the trial was open-label in design, the assessor (ie, the patient) was aware of the treatment assignment.		
of the outcome	4.4 If Y/PY/NI to 4.3: Could assessment of the out	utcome have been influenc	ed by knowledge of intervention received?	Y	Since the patient was aware of the intervention, they may have been influenced by expecting a benefit from LF-SCS, or not perceiving BMT as a proper		
	4.5 If Y/PY/NI to 4.4: Is it likely that assessment of	of the outcome was influen	ced by knowledge of intervention received?	PY	treatment. In addition, the patient was aware of being allowed to crossover at 6 months.		
	Risk of bias judgement			High			
	5.1 Were the data that produced this result analy before unblinded outcome data were available fo		re-specified analysis plan that was finalized	NI	Analysis intentions are not available, ie, no published protocol or statistical analysis plan		
Bias in selection of the	5.2 multiple eligible outcome measurements (e	e.g. scales, definitions, time	e points) within the outcome domain?	PN	No apparent indications of reporting selectivity. The use of dichotomous responder status is standard in the SCS field (ie, not selective reporting). The analysis used the standard definition of treatment response (at least 50% pain reduction).		
reported result	5.3 multiple eligible analyses of the data?			PN			
	Risk of bias judgement			Some concerns			
Overall bias	Risk of bias judgement			High			



PRISMA 2020 Checklist

Section and Topic	ltem #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Title
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Section 1 Introduction, final paragraph
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Section 1 Introduction, final paragraph
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Section 2.1 Eligibility
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Section 2.2 Search Strategy
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Supplementary Material Table S1
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Section 2.3 Selection Process
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Section 2.4 Data Extraction and Outcomes
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Section 2.4 Data Extraction and Outcomes
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	N/A
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Section 2.5. Study Risk of Bias Assessment
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Section 2.6. Summary Measures
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	N/A (no meta-analysis performed)
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Section 2.7. Data synthesis
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Section 2.7. Data synthesis
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	N/A (no meta-analysis performed)
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta- regression).	N/A (no meta-analysis performed)



PRISMA 2020 Checklist

Section and Topic	ltem #	Checklist item	Location where item is reported
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A (no meta-analysis performed)
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N/A (no meta-analysis performed)
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A (no meta-analysis performed)
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Section 3.1. Study Selection, Figure 1
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	N/A
Study characteristics	17	Cite each included study and present its characteristics.	Section 3.2. Characteristics of Included Studies, Table 1
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Section 3.3. Risk of Bias in Studies
			(Performed for RCTs)
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Section 3.4. Outcomes in Painful Diabetic Neuropathy; Section 3.5. Outcomes in Other Painful Peripheral Neuropathies and Mixed Etiology Populations; Table 2; Table 3.
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	N/A (no meta-analysis performed)
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N/A (no meta-analysis performed)
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A (no meta-analysis performed)
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A (no meta-analysis performed)
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A (no meta-analysis performed)
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A (no meta-analysis performed)
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Section 4.1. Interpretation of Results
	23b	Discuss any limitations of the evidence included in the review.	Section 4.2. Strengths and Limitations of the Review
	23c	Discuss any limitations of the review processes used.	Section 4.2. Strengths and Limitations of the Review



Section and Topic	ltem #	Checklist item	Location where item is reported
	23d	Discuss implications of the results for practice, policy, and future research.	Section 4.3. Implications for Practice, Policy, and Future Research
OTHER INFORMA	TION		
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Figure 1
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Figure 1, DOI
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	See Funding and Author Contributions
Competing interests	26	Declare any competing interests of review authors.	See Conflicts of Interest
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	N/A

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71 For more information, visit: <u>http://www.prisma-statement.org/</u>



Section and Topic	ltem #	Checklist item	Reported (Yes/No)
TITLE	-		
Title	1	Identify the report as a systematic review.	Yes
BACKGROUND	-		
Objectives	2	Provide an explicit statement of the main objective(s) or question(s) the review addresses.	Yes
METHODS	-		
Eligibility criteria	3	Specify the inclusion and exclusion criteria for the review.	Yes
Information sources	4	Specify the information sources (e.g. databases, registers) used to identify studies and the date when each was last searched.	Yes
Risk of bias	5	Specify the methods used to assess risk of bias in the included studies.	Yes
Synthesis of results	6	Specify the methods used to present and synthesise results.	Yes
RESULTS	<u>.</u>		
Included studies	7	Give the total number of included studies and participants and summarise relevant characteristics of studies.	Yes
Synthesis of results	8	Present results for main outcomes, preferably indicating the number of included studies and participants for each. If meta-analysis was done, report the summary estimate and confidence/credible interval. If comparing groups, indicate the direction of the effect (i.e. which group is favoured).	Yes
DISCUSSION	<u>.</u>		
Limitations of evidence	9	Provide a brief summary of the limitations of the evidence included in the review (e.g. study risk of bias, inconsistency and imprecision).	No (see manuscript)
Interpretation	10	Provide a general interpretation of the results and important implications.	Yes
OTHER			
Funding	11	Specify the primary source of funding for the review.	No (see manuscript)
Registration	12	Provide the register name and registration number.	No (see manuscript)

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71