

**Appendix 2**

**Data Collection Form**

<b>Review title</b> <b>Authors</b>	<b>Systematic Review of the Effects of Current Transtibial Prosthetic Socket Designs; Part 1: Qualitative Outcomes</b> <b>Safari M. R., Meier M. R.</b>
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**General Information**

Date form completed	
Name of the person extracting data	
Report title	
Report ID	
Reference details	
Report author contact details	
Study funding sources	
Possible conflicts of interest	
Note	

**Inclusion/Exclusion**

<b>Study characteristics</b>	<b>Eligibility criteria</b>	<b>Yes</b>	<b>No</b>	<b>Unclear</b>	<b>Location in text</b>
Type of study	Randomised	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Non Randomised	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Type of intervention		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Type of outcome measure		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Include</b> <input type="checkbox"/>		<b>Exclude</b> <input type="checkbox"/>			
<b>Reason for exclusion</b>					
Note					

**Population and setting**

	Description	Location in text
Population description		
Setting		
Inclusion criteria		
Exclusion criteria		
Method/s of recruitment of participants		
Informed consent obtained		
Note		

**Methods**

	Description	Location in text
Aim of study		
Design		
Unit of allocation		
Start date		
End date		
Total study population		
Ethical approval needed/ obtained for study		
Note		

**Risk of Bias assessment**

Sub-scales	Items	Description	Score	Location in text
Reporting	R1	Is the hypothesis/aim/objective of the study clearly described?		
	R2	Are the main outcomes to be measured clearly described in the Introduction or Methods section?		
	R3	Are the characteristics of the patients included in the study clearly described?		
	R4	Are the interventions of interest clearly described?		
	R5	Are the distributions of principal confounders in each group of subjects to be compared clearly described?		
	R6	Are the main findings of the study clearly described?		
	R7	Does the study provide estimates of the random variability in the data for the main outcomes?		
	R8	Have all important adverse events that may be a consequence of the intervention been reported?		
	R9	Have the characteristics of patients lost to follow-up been described?		
	R10	Have actual probability values been reported?		
		Sum Score		0

External validity	EV1	Were the subjects asked to participate in the study representative of the entire population from which they were recruited?		
	EV2	Were those subjects who were prepared to participate representative of the entire population from which they were recruited?		
	EV3	Were the staff, places and facilities where the patients were treated, representative of the treatment the majority of patients receive?		
	Sum Score			0
Internal validity-bias	IV1	Was an attempt made to blind study subjects to the intervention they have received?		
	IV2	Was an attempt made to blind those measuring the main outcomes of the intervention?		
	IV3	If any of the results of the study were based on "data dredging", was this made clear?		
	IV4	In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?		
	IV5	Were the statistical tests used to assess the main outcomes appropriate?		
	IV6	Was compliance with the intervention/s reliable?		
	IV7	Were the main outcome measures used accurate (valid and reliable)?		
Sum Score			0	
Internal validity - confounding (selection bias)	SB1	Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls		
	SB2	Were study subjects in different intervention groups (trials and cohort studies) or were the cases and		
	SB3	Were study subjects randomised to intervention groups?		
	SB4	Was the randomised intervention assignment concealed from both patients and healthcare staff until recruitment was complete and irrevocable?		
	SB5	Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?		
	SB6	Were losses of patients to follow-up taken into account?		
	Sum Score			0
Power	P1	Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?		
Total score			0	

**Participants**

	Description as stated in report/paper	Location in text
Total number		
Clusters		
Baseline imbalances		
Withdrawals and exclusions		
Age		
Sex		
Country		
Co-morbidities		
Other treatment received		
Stump characteristic		
Years since amputation		
Years wearing a definitive prosthesis		
Other relevant		
Note		

**Intervention group**

	Description as stated in report/paper	Location in text
Group name		
No. randomised to group		
Theoretical basis		
Description		
Duration of treatment period		
Timing		
Delivery		
Providers		
Co-interventions		
Economic variables		
Resource requirements to replicate intervention		
Note		

**Outcome 1**

	Description as stated in report/paper	Location in text
Outcome name		
Time points measured		
Time points reported		
Outcome definition		
Person measuring/reporting		
Unit of measurement		
Scales: upper and lower limits		
Is outcome/tool validated?		
Imputation of missing data		
Assumed risk estimate		
Power		
Note		

**Outcome 2**

	Description as stated in report/paper	Location in text
Outcome name		
Time points measured		
Time points reported		
Outcome definition		
Person measuring/reporting		
Unit of measurement		
Scales: upper and lower limits		
Is outcome/tool validated?		
Imputation of missing data		
Assumed risk estimate		
Power		
Note		

## Results

### Dichotomous outcome

	Description as stated in report/paper				Location in text
Comparison					
Outcome					
Subgroup					
Timepoint					
Results	Intervention		Comparison		
	No. Events	No. Participants	No. Events	No. Participants	
No. missing participants and reasons					
No. participants moved from other group and reasons					
Any other results reported					
Unit of analysis					
Statistical methods used and appropriateness of these methods					
Reanalysis required?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unclear <input type="checkbox"/>		
Reanalysis possible?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unclear <input type="checkbox"/>		
Reanalysed results					
Notes					

### Continuous outcome

	Description as stated in report/paper						Location in text
Comparison							
Outcome							
Subgroup							
Timepoint							
Results	Intervention			Comparison			
	Mean	SD	No. Participants	Mean	SD	No. Participants	
No. missing participants and reasons							
No. participants moved from other group and reasons							
Any other results reported							
Unit of analysis							
Statistical methods used and appropriateness of these methods							
Reanalysis required?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unclear <input type="checkbox"/>				
Reanalysis possible?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unclear <input type="checkbox"/>				
Reanalysed results							
Notes							

<b>Other Outcome</b>					
	<b>Description as stated in report/paper</b>				<b>Location in text</b>
Comparison					
Outcome					
Subgroup					
Timepoint					
Results	Intervention Result	SD	Control Result	SD	
	Overall results		SE (or other variants)		
No. Participants	Intervention		Control		
No. missing participants and reasons					
No. participants moved from other group and reasons					
Any other results reported					
Unit of analysis					
Statistical methods used and appropriateness of these methods					
Reanalysis required?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unclear <input type="checkbox"/>		
Reanalysis possible?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unclear <input type="checkbox"/>		
Reanalysed results					
Notes					

<b>Applicability</b>			
Have important populations been excluded from the study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unclear <input type="checkbox"/>
Is the intervention likely to be aimed at disadvantaged groups?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unclear <input type="checkbox"/>
Does the study directly address the review question?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unclear <input type="checkbox"/>
Notes			

**Other information**

	Description as stated in report/paper	Location in text
Key conclusions of study authors		
Comments from study authors		
References to other relevant studies		
Correspondence required for further study information		

Notes