

BIBS Data Extraction and Assessment Form

Study details

Study ID:	Report ID :	Date form completed:
First author:	Year of study:	Data extractor:
Citation (including title):		
<i>REFIDs of possibility related studies (was there a pilot study?):</i>		

1. General Information

Publication type	Journal Article c Abstract c Other (specify e.g. book chapter) _____
Country/countries of study:	
Funding source of study:	Potential conflict of interest from funding? Y / N / unclear
Author(s)' disciplinary background(s):	Any other details of researcher(s):
Ethics	Study design (who involved, any pilot?)

2. Study Eligibility

Study Characteristics		Page/ Para/ Figure #
Type of study (Review authors to add/remove designs based on criteria specified in protocol)	c Randomised Controlled Trial (RCT) c Cluster Randomised Controlled Trial (cluster RCT)	c Non-randomised study
	c A process evaluation of an included study design	c Other design (specify):
	Description in text:	

3. Study details

Study intention	Descriptions as stated in the report/paper	Page/ Para/ Figure #
Epistemological perspective		
Aim of intervention	<i>What was the problem that this intervention was designed to address?</i>	
Aim of study (outcomes)	<i>What was the study designed to assess? Are these clearly stated?</i>	
Equity pointer: Social context of the study	<i>e.g. was study conducted in a particular setting that might target/exclude specific population s? See also Inclusion/exclusion criteria under Methods, below.</i>	
Start and end date of the study	<i>Identify which elements of planning of the intervention should be included</i>	
Total study duration		

Methods	Descriptions as stated in the report/paper	Page/ Para/ Figure #
Method/s of recruitment of participants <i>(How were potential participants approached and invited to participate? Where were participants recruited from? Does this differ from the intervention setting?)</i>		
Inclusion/exclusion criteria for participation in study		
Representativeness of sample: Are participants in the study likely to be representative of the target population?*		
Total number of groups		
Assumed risk estimate <i>(e.g. baseline or population risk noted in Background)</i>	<i>References:</i>	
Sample size calculation:** What assumptions were made? Were these assumptions appropriate?	<i>(Yes/No/Unclear)</i>	
What was the unit of analysis (e.g. cluster/patient)? Is this the same as the unit of randomisation? (Yes/No/Unclear)		
Statistical methods used and appropriateness of these methods**	<i>(Check with your statistician if unsure about appropriateness)</i>	

** - will be determined in separate quality assessment form for quantitative studies

Results

Participants <i>Include if relevant</i>	Include information for each group (i.e. intervention and controls) under study	Page/ Para/ Figure #
What percentage of selected individuals agreed to participate (were sampling criteria met)?		
Total number randomised (or total pop. at start of study for NRCTs)		
Number allocated to each intervention group (no. of individuals)		
For cluster trials, number of clusters, number of people per cluster		
Where there any significant baseline imbalances?*	Yes c No c Unclear c Details:	
Number and reason for (and sociodemographic differences of) withdrawals and exclusions for each intervention group)		
Were patients who entered the study adequately accounted for?*		
What percentage of patients completed the study?		
What percentage of participants received the allocated intervention or exposure of interest?		
Is the analysis performed by intervention allocation status (intention to treat) rather than the any attempts been made to impute actual intervention received? Have missing data?)		
Age (median, mean and range if possible)		
Sex		
Race/Ethnicity		
Relationship status		
Household behaviour (smoking in household)		
Principal behavior (incl. stage/type of pregnancy)		
Principal health condition (incl. details of smoking behavior)		
Diagnostic criteria (how behaviour is assessed)		
Co-morbidity		
Other sociodemographics (e.g. Educational level, literacy level, soci-economic status, first language, place of residence, occupation, religion, social capital. Also consider possible proxies for these e.g. low baseline nutritional status)		

intervention Groups

Group names:	<i>(State brief name for this intervention group.)</i>	<i>(State brief name for this intervention group.)</i>	<i>(State brief name for this intervention group.)</i>	<i>(State brief name for this intervention group.)</i>	Page/ Para/ Figure #
Details of intervention or control condition <i>(Include if relevant in sufficient detail for replication)</i>					
Where appropriate state how measured					
Setting e.g. multicentre, university teaching hospitals, rural, metropolitan, school, workplace, community, GP clinic, etc.					
Theoretical basis (include key references to literature and any					
Content (list the strategies intended and delivered, including					
Did the intervention include strategies to address diversity/disadvantage?	<i>Enter a description of any relevant strategies</i>				
Delivery (e.g. Stages (sequential or simultaneous), timing, frequency, duration, intensity, follow-up, fidelity – process indicators, communication)					
Providers (who, number, education/training in intervention delivery, ethnicity etc. if potentially relevant to acceptance and uptake by participants or because of possible bias in data collection)					
Co-interventions					
Was sustainability discussed by the authors? Was it a consideration in study development?					
Economic variables i.e. costs of the intervention, and changes in other (e.g. health care) costs as result of intervention *	Yes c List in Outcome section if appropriate No c Unclear c Details:				

Other economic information (from a societal, non-healthcare view – e.g. lost wages, time)	Yes c No c Details:	
Resource requirements to replicate intervention (e.g. staff numbers, hours of implementation, equipment?)		
What are the moderators/mediators		
Barriers/facilitators		
Intrinsic/extrinsic motivators		
Do the authors describe any political or organisational context?	<i>List relevant dot points</i>	
Were any partnerships referred to?	<i>List these as dot points</i>	
Were service users involved in the intervention design?		
Was a process evaluation conducted?	<i>What components were included in the process evaluation? (e.g.</i>	
Participants' perceptions of intervention (acceptability and feasibility)		
Any other method details/suggestions regarding the method?		

* Costs associated with the intervention can be linked with provider or participant outcomes in an economic evaluation (depends on the type of economic evaluation)

Outcomes

Question	General outcome details	Page/ Para/ Figure #
Is there an analytic framework applied (e.g. logic model, conceptual framework)?		
List of definitions for each outcome (with diagnostic criteria if relevant)		

List outcome types: Is each outcome a modifiable variable (Community level, neighbourhood level, individual level) or desired health outcome					
Is there adequate latency for the outcomes to be observed?*					
How are the outcomes reported? Self or study assessor					
Is this outcome/tool validated?					
...And has it been used as validated?*					
Is it a reliable outcome measure?*					
Is there adequate power for this outcome?*					
List any subgroups for which data are available for each arm.					
Specific outcome details	<i>(State brief name for this intervention group.)</i>	<i>(State brief name for this intervention group.)</i>	<i>(State brief name for this intervention group.)</i>	<i>(State brief name for this intervention group.)</i>	
Outcome 1: Observed at: Unit of measurement: Subgroup data Y/N (see					
Outcome 2: Observed at: Unit of measurement: Subgroup data Y/N (see					
Outcome 3: Observed at: Unit of measurement: Subgroup data Y/N (see					
Outcome 4: Observed at: Unit of measurement: Subgroup data Y/N (see					
Outcome 5: Observed at: Unit of measurement: Subgroup data Y/N (see					

Subgroup of: for outcome: Observed at: Unit of measurement:					
Subgroup of: for outcome: Observed at: Unit of measurement:					
Subgroup of: for outcome: Observed at: Unit of measurement:					
Adverse event (<i>brief description</i>):					
Adverse event (<i>brief description</i>):					
Adverse event (<i>brief description</i>):					
Adverse event (<i>brief description</i>):					
Adverse event (<i>brief description</i>):					
Withdrawals/exclusions:					
Withdrawals/exclusions:					
Withdrawals/exclusions:					
Additional details on outcomes reported:					

Other relevant information

Were outcomes relating to harms/unintended effects of the intervention described? ** Include any data for these in the outcomes tables above	
Potential for author conflict <i>i.e. evidence that author or data collectors would benefit if results favoured the intervention under study or the control</i>	
Key conclusions of the study authors	
Could the inclusion of this study potentially bias the generalisability of the review?*** Equity pointer: Remember to consider whether disadvantaged populations may have been excluded from the study.	

<p>Is there potential for differences in relative effects Between advantage and disadvantaged populations? (e.g. are children from lower income families less likely to wear bicycle helmets)</p>	
<p>Are interventions likely to be aimed at the disadvantaged? (e.g. school meals aimed at poor children).</p>	
<p>Issues affecting directness** (Note any aspects of population, intervention, etc. that affect this study's direct applicability to the review question)</p>	
<p>Strengths and limitations recognised by author(s)</p>	
<p>Strengths and limitations recognised by reviewer(s)</p>	
<p>Additional notes by review authors (any additional emergent themes not covered?)</p>	