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Research Article

# The Impact of Skipping Breakfast on the Body Weight of Children and Young People in Saudi Arabia: A Systematic Review

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## Abstract

**Aim:** To review evidence of the impact of skipping breakfast on the body weight of children and young people of Saudi Arabia. **Method:** A systematic search of the Cochrane Library, EBSCO (AMED, MEDLINE, and CINAHL), Web of Science, SCOPUS, PubMed, and EMBASE was conducted in March 2018 to identify primary published research. Additional studies were identified by hand searching in other sources such as subject-specific journals and grey literature. Any observational study published in the English language in the last 20 years (1998–2018), involving healthy children and/or young people (5–24 years) in Saudi Arabia was included, and the effect of skipping breakfast on their body weight was evaluated. Pre-defined information was extracted from each study onto a data-extraction form for evaluation, following the Cochrane method for undertaking a systematic review. Study quality was evaluated using a Quality Assessment Tool for Quantitative Studies. **Results:** Eight studies met the inclusion criteria, of which seven graded weak in quality assessment, while one article scored moderate. Six studies show that regular breakfast consumption has a protective effect against overweight/obesity, of which three studies tested the correlation, while controlling for confounding variables. Two of the eight studies demonstrated no significant correlation. Breakfast intake was also found to have a positive association with student's academic performance, with two out of three trials demonstrating a significant relationship, but in linking regular breakfast habit with socioeconomic status, no effect was found. **Conclusion:** The findings suggest that skipping breakfast is associated with a higher risk of overweight and obesity in children and adolescents in Saudi Arabia and thus breakfast consumption is associated with a reduced risk of overweight and obesity. However, in view of the array of methods used to define breakfast skipping and overweight/obesity, as well as the less robust nature of observational studies, we cannot conclusively assume this relationship, suggesting further more controlled studies are required.

**Keywords:** obesity, overweight, breakfast, breakfast skipping, children, young people, Saudi Arabia

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## 1. Introduction

Globally, obesity rates have risen markedly from 1975 to 2014, increasing from 3.2% to 10.8% in males, and from 6.4% to 14.9% in the female population [24]. This constitutes a large financial and health burden on society ([34]; WHO, 2016). In Saudi Arabia, for example, the World Obesity Federation (2015) reported that the prevalence of obesity was 24.1% in males and 33.5% in females in 2013. A global epidemic level has been reached in childhood obesity as well. In 2012, there were 23.8% and 22.6% of boys and girls, respectively, who were overweight or obese in developed countries, while the percentages were 12.9% and 13.4%, respectively, in developing countries [51]. While in Saudi Arabia the 2010 estimated prevalence of overweight and obesity among school-aged children was 19.6% and 7.9%, respectively, higher rates were reported for adolescents, with 26.6% overweight and 10.6% obese [22]. Body weight status during early life – whether overweight or underweight – has a direct impact on the overall health of an individual by its consequences later throughout the life course [2].

Nutritionally, breakfast is deemed to be the most essential meal of the day [60]. Many studies have shown the proven positive impact of breakfast in appetite regulation [4] and in reducing the risk of type 2 diabetes [53]. Despite all these facts, breakfast is frequently skipped, especially among the young generation, with almost 74% of female students being found to be skipping or irregularly consuming breakfast in Saudi Arabia [48].

Many causes of skipping breakfast and changing eating patterns could be considered. For instance, Saudi cultural and economic shifts, such as a recent increase in the number of working mothers together with the increasing economic wealth of the population may have contributed to changing family habits and food choices [8, 9, 54]. This has been found to have had a negative impact on children's breakfast intake [59].

Appetite has been found to fluctuate across the course of a day, with its lowest point occurring in the early morning; thus, the relatively early school and work start time in Saudi Arabia may contribute to a reduced appetite [28, 33].

Research from other countries have indicated a correlation between skipping breakfast and obesity and overweight in children and adolescents, but the evidence are contradictory between studies. It was found to be significant only for boys in several studies [21, 61, 62, 67], while in others, significant only for girls [29, 36, 52, 66]. On the other hand, some studies take into consideration that apart from just skipping breakfast, there are other family behavior factors and breakfast locations that indirectly influence body weight changes, [43, 64], and some studies address nutrient intake

along with breakfast as predictors for overweight prevention [6, 66, 73]. However, surprisingly, Hopkins et al. (2017) demonstrated no significant effect of breakfast intake on body weight in adolescents of urban families living in the USA.

With all this uncertainty and a lack of adequate research examining the hypothesis of an association between breakfast skipping and body weight in Saudi children and young people, this systematic review aims to review the evidence on the impact of skipping breakfast on the body weight of children and young people of Saudi Arabia and the strength of that impact. The objectives of this review are:

- To evaluate the association between breakfast skipping of children and young people and their body weights.
- To establish a comprehensive picture of the phenomenon through different studies conducted in different regions of Saudi Arabia where the issue of skipping breakfast is common.

## 2. Methods

Many different approaches and frameworks have been developed as a guide for conducting systematic reviews [23, 39, 42]. These guidelines are similar in linking to the main concept of a systematic review but have minor differences. The Cochrane online framework includes an easy-to-access handbook, tools for review of studies, and provides an online short training course on the process of conducting a systematic review. Reviewers following the Cochrane method are also able to use tools from different sources according to the suitability [26, 39]. Therefore, the Cochrane approach was selected to be used for the current systematic review. Although the Cochrane handbook for systematic reviews of interventions is designed mainly for randomized trials, it can also be used for supporting reviews that include other observational studies [39]. Following Cochrane guidance, a protocol for this systematic review was registered on PROSPERO (2018) with the registration number CRD42018094084.

### 2.1. Inclusion and exclusion criteria for selection of studies

#### 2.1.1. Type of studies

All types of studies, including observational studies, were considered for this systematic review as no experimental studies were identified during a preliminary scan of the literature. Furthermore, the publication period extended over the past 20 years

to include studies published from 1998 to 2018 as the initial background search of 10 years yielded only a few studies.

### 2.1.2. Type of participants

Only children and young people living in Saudi Arabia were included. The subjects' age in primary studies ranged from 5 to 24 years, as they are all students (from primary school to undergraduate university). Children under 5 years were excluded as their breakfast habits may differ from older children, taking into account that they are at home generally and therefore having the access to food differently. Participants of both genders were included and no study with disease-specific participants was eligible.

### 2.1.3. Types of intervention and comparison

All studies that considered breakfast as an intervention were included, whether considered alone or evaluated with other lifestyle variables. Furthermore, the current review included studies that define breakfast skippers as people who consume breakfast a few times a week, as well as studies that define them as never or rarely consuming breakfast.

### 2.1.4. Types of outcome measures

Body weight was the main outcome measure identified in the present review, and this was measured in terms of Body Mass Index (BMI). Considering that age ranges varied, all different cut-off references were included with no specifications.

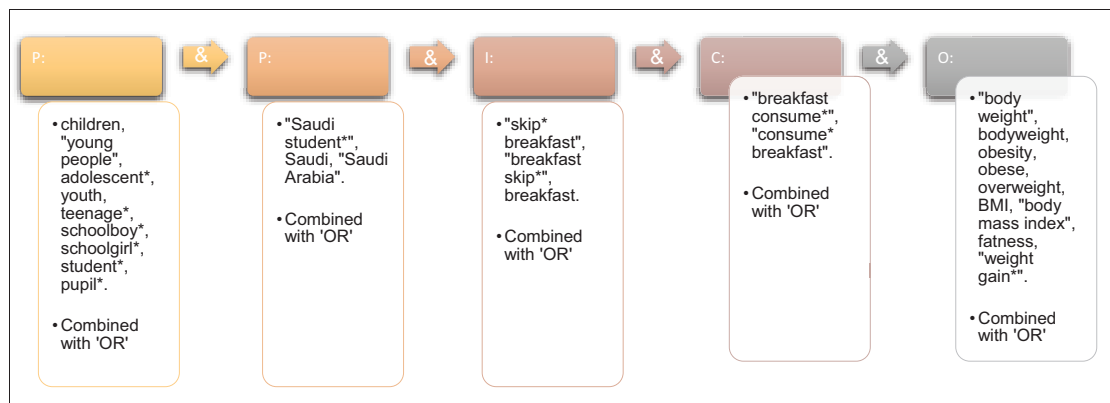
Moreover, two secondary outcome measures were included. First, students' academic achievements as measured and classified, if applicable, by the Saudi grading system into 'Excellent, Very good, Good, Pass, and Fail' [25]. Second, the socioeconomic status (SES) of participants and their families, using, if applicable, the classification of 'low, medium, and high' in terms of their income, educational level, and occupation.

## 2.2. Search strategy

One reviewer selected studies for inclusion in the review, following stages 1 to 5 of the Cochrane process. **Stage 1 (Bibliographic database search):** as guided by Cochrane [39]; the following bibliographic databases were located during March 2018:

- Cochrane Library
- EBSCO: AMED
- EBSCO: MEDLINE
- EBSCO: CINAHL
- Web of Science
- SCOPUS
- PubMed
- EMBASE

By using the following PICO question [37]: What is the impact of skipping breakfast on the body weight of children and young people in Saudi Arabia?, Figure 1 shows the retrieved key terms which were used for the systematic search. The 'OR' operator was used in each category below, then an 'AND' operator was used to combine those terms to identify relevant articles. An example of one electronic search strategy is provided in Appendix 1.



**Figure 1:** Literature search terms; P = population, I = intervention, C = comparison, and O = outcome.

## Stage 2 (Hand searching)

Referring to the Cochrane [39], subject-specific journals, such as *BMC Obesity*, *BMC Nutrition*, *Nutrition Journal*, and *Journal of Nutrition Science* were searched manually for articles that examine the habit of breakfast intake in Saudi Arabia and its effect on body weight. The searching panels in those journals were not of the same level of advance as in the bibliographic databases, therefore, the keywords used were limited to 'breakfast, skipping, and Saudi Arabia'.

### Stage 3 (Grey literature)

Sources such as Google Scholar, Openthesis, DOAJ, Ethos, and Open grey were searched for any PhD thesis or unpublished studies. The following stages of search (4 and 5) will be explained after the study selection section.

### 2.3. Study selection

Retrieved studies from stages 1 to 3 were screened in two ways for removing any duplication. Manually by looking at titles and then by the Mendeley<sup>®</sup> Software for reference management (2018). Afterward, both lists were checked and compared.

Following that, studies' titles and abstracts were screened against the inclusion criteria for the purpose of selecting the relevant and excluding any irrelevant articles. In case of being unsure, the full article was reviewed to make the final decision [39].

### Stage 4 – of searching – (Hand searching of the sources)

The reference list of all finally selected studies was screened in order to locate any potentially relevant studies.

### Stage 5 (Citation search)

In terms of forward citation search, Web of Science database was used to check if any included studies were cited by other articles that may be relevant for this review.

### 2.4. Data extraction and study quality assessment

Two independent reviewers performed the process of data extraction and study-quality assessment of the selected studies. For data extraction, it was recommended to design a form suitable for the review, as it can vary from topic to topic [39]. Thus, a specially designed form was used for that purpose (Appendix 2) that included the key items recommended by the Cochrane for data extraction [39].

The Effective Public Health Practice Project (EPHPP) quality assessment tool for quantitative studies (Appendices 3 and 4), established by Thomas and Ciliska in 1999 [45], was utilized for the current review, as it is suitable for all quantitative studies and covers the quality assessment domains. It is also simple, easy to use, and showed a

fair inter-rater agreement in terms of individual domains, and an excellent agreement of final decision [20].

Both data extraction and study-quality assessment steps were undertaken first in a pilot phase. It was completed independently by both reviewers using two studies, to check for any modification needed. It was planned that in case of any disagreement between both reviewers, this would be resolved by discussion, consulting a third reviewer, or if needed the author of the primary study will be contacted for any additional information required to aid in solving the disagreement.

## 2.5. Data synthesis

Once data was extracted and the quality of each study was assessed, a descriptive analysis of all included studies was undertaken. A narrative synthesis was also performed in combination with the analysis of risk of bias between studies. Moreover, due to the considerable heterogeneity between the included studies in terms of intervention and outcome definitions, a quantitative analysis of the results and meta-analysis was not appropriate.

### 2.5.1. Ethical consideration

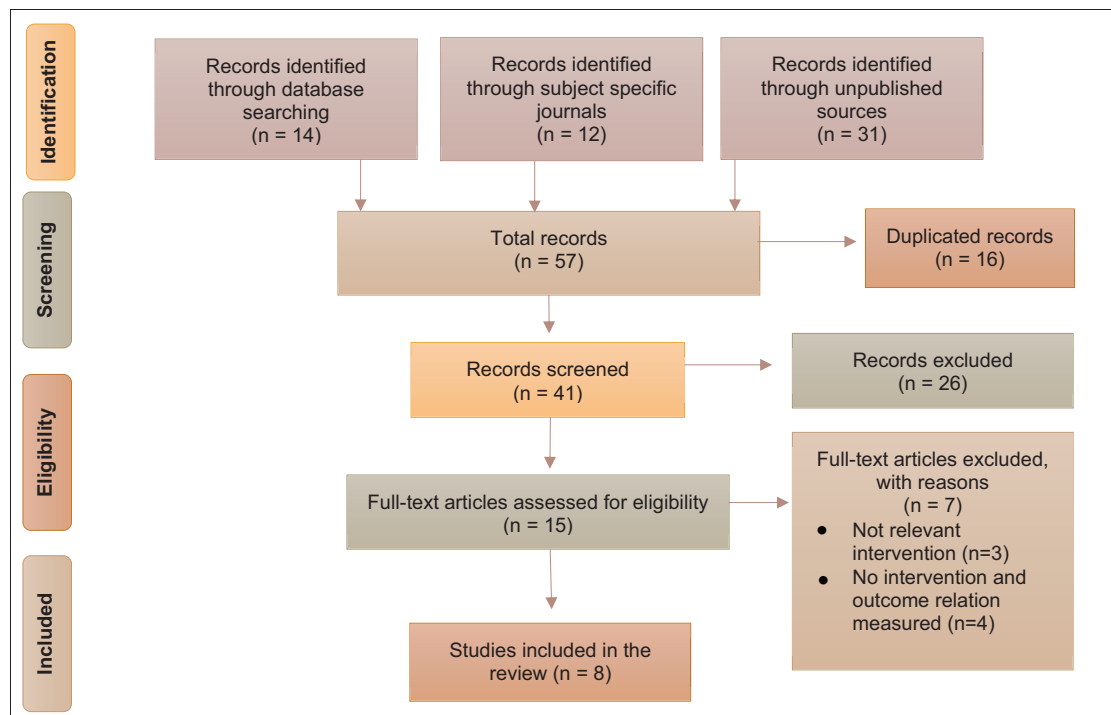
Conducting a systematic review does not require any ethical approval, however, ethical requirements were highly considered in the primary studies for evaluation and quality assessment.

## 3. Results

### 3.1. Identified studies

Details of the search process results are presented in the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) flow diagram (2015) in Figure 2. A total of 57 articles were screened to remove duplications ( $n = 16$ ). The remaining 41 studies were screened for their titles and abstracts, of which 26 did not meet the inclusion criteria. The final 15 articles needed a full-paper review in order to make the decision, which yields back only 8 eligible articles to be included, while 7 articles were excluded due to reasons listed in Figure 2. Forward and backward citation searches did





**Figure 2:** PRISMA flow chart of search result and selection process.

not result in any potentially relevant studies. Therefore, the final number of included studies was eight.

### 3.2. Descriptive analysis of included studies

The summary of studies characteristics and key findings are presented in Table 1. All included studies used the cross-sectional design in their method. The geographic location varied among those articles. Two studies have covered three major cities (Jeddah, Riyadh, and Alkhobar) in Saudi Arabia [13, 14], while one study covered a governorate in the eastern part of the country [19]. The remaining five studies [1, 12, 15, 17, 18] have surveyed one city each, resulting in covering different areas around the country. These cities and areas were: Arar 'northern', Riyadh -twice - 'central', Jeddah 'western', and Rass 'central', respectively.

### 3.3. Study participants

Both genders were involved in three studies [1, 13, 14]. Only one considered females alone [15], while Amin et al. (2008), Alsubaie (2010), Alenazi et al. (2014), and Alrethaa et al. (2010) have included only male participants in their surveys. As shown in

Table 1, the participant's age groups ranged from 5 to 24 years old, at different school levels.

### 3.4. Definition of intervention/comparison

There were variations in terms of defining 'breakfast skipping' among included articles (Table 1). Five studies have considered the frequency of breakfast intake/week as a method, either by categorizing them into 3-4 groups as in Alsubaie (2010), Aloboudi, (2010), Alhazzaa et al. (2012), and Alrethaiaa et al. (2010); or numerical data of breakfast intake frequency without categorization as found in Alhazzaa et al. (2011). Two studies defined skipping as irregular breakfast intake compared to regular intake Alenazi et al. (2014), and Abalkhail and Shawky (2002). While Amin et al. (2008) have combined two methods of identification. In other words, using 'yes, no' question for asking if breakfast was taken at home on the same day of the interview, as well as the frequency of breakfast intake/previous week. Moreover, most studies have used a self-reported questionnaire for defining the intervention, while only two depended on an interview using a structured questionnaire (Table 1).

### 3.5. Definition of the main outcome

Body weight outcome definitions also varied across the included studies (Table 1). Overweight/obesity was defined by height and weight measurements to determine BMI, but the cut-off values were referenced differently among the studies. However, that was not clearly defined in two papers Alenazi et al. (2014) and Aloboudi (2010). The cut-off references in the remaining six studies were the IOTF by Cole et al. (2000), the adult reference [70], the National Institutes for Health [50], and the National Health and Nutrition Examination Survey (NHANES) by Must et al. (1991).

BMI was not the only indicator, Alrethaiaa et al. (2010) and Alhazzaa et al. (2012) have considered combining BMI with % of body fat (%BF), and visceral fat (VF); as well as waist/height ratio (WHtR), respectively, in terms of defining abdominal obesity.

### 3.6. Studies quality assessment

Both reviewer's feedbacks were similar in terms of assessing the risk of bias, except for two papers, where there was a disagreement in the final scoring and resolved

TABLE 1: Descriptive analysis of included studies, part 1 of 2.

Study	Settings	Participants	Definition of breakfast skipping	Method for ascertainment	Definition of overweight/obesity	Method of collecting
<b>Abalkhail and Shawkly (2002) (Cross-sectional)</b>	Private and governmental schools in Jeddah city	800, 376 males and 424 females (9-21 years)	Regular versus irregular	In-person interview using a structured questionnaire	BMI calculated, NHANES cut-off reference was used	Height and weight measured by the researchers and clearly explained
<b>Alenazi et al. (2014) (Cross-sectional)</b>	Primary schools in Arar city	Confusing numbers (559 or 359) males (5-9 year)	Regular versus irregular	Self-reported questionnaire	BMI, calculated but no cut-off reference stated	Height and weight measured by the researchers and clearly explained
<b>Alhazzaa et al. (2011) (Cross-sectional)</b>	Private and governmental secondary schools in Riyadh, Jeddah and Al-Khobar	2908, 1401 males and 1507 females (14-19 years).	Numerical frequency/week (0-7 days/week).	Self-reported questionnaire	BMI calculated, Cole et al.'s cut-off reference was used for adolescents (14-17 years), and WHO cut-offs for older participants (> 18 years)	Height and weight measured by the researchers and clearly explained
<b>Alhazzaa et al. (2012) (Cross-sectional)</b>	Private and governmental secondary schools in Riyadh, Jeddah and Al-Khobar	2906, 1400 males and 1506 females (14-19 years)	Frequency/week ≥ 5, 3-4 and < 3 days	Self-reported questionnaire	BMI calculated, Cole et al.'s cut-off reference was used for adolescents (14-17 years), and adult cut-offs for older participants (> 18 years)	Height and weight measured by the researchers and clearly explained. Waist to height ratio was also measured for abdominal obesity
<b>Alouboudi (2010) (Cross-sectional)</b>	Governmental primary schools in Riyadh city	120 females (9-13.9 years)	Frequency/week: usual/always (5-7), often (2-4) and rare/never (0-1)	Self-reported questionnaire	BMI, calculated but no cut-off reference stated	Height and weight measured by the researchers but not clearly explained
<b>Alrethaiiaa et al. (2010) (Cross-sectional)</b>	College of Health Sciences in Rass city	357 males (18-24 years)	Frequency/week: (daily, 3-4, 1-2, rarely)	Self-reported questionnaire	BMI calculated, NIH cut-off reference was used	Height and weight measured by the researchers but not clearly explained. % of body fat and visceral fat was also measured for abdominal obesity

Study	Settings	Participants	Definition of breakfast skipping	Method for ascertainment	Definition of overweight/obesity	Method of collecting
<b>Alsubaie (2010) (Cross-sectional)</b>	Private and governmental secondary schools in Riyadh city	1501 males (15-20 years)	Frequency/week, (skippers are less than 5 times/week)	Self-reported questionnaire	BMI calculated, Cole et al.'s cut-off reference was used for adolescents (15-17 years), and adults cut-offs for older participants (> 18 years)	Height and weight measured by the researcher and clearly explained
<b>Amin et al. (2008) (Cross-sectional)</b>	5th and 6th grades of governmental primary schools in Al-Hassa Governorate	1139 males (10-14 years)	Frequency/last week: (Daily, 3-6, less than 2), and at the same day of interview (yes or no)	FFQ by personal interview	BMI calculated, Cole et al.'s cut-off reference was used	Height and weight measured by the researchers and clearly explained

TABLE 1: Continued, part 2 of 2.

Study	Adjusted confounders	Key results	Socioeconomic status	Academic performance
<b>Abalkhail and Shawky (2002)</b>	None	There was no difference in regular daily breakfast intake by gender or BMI	No difference in regular daily breakfast intake by social class was found	Students with poor school results reported significantly less breakfast intake than those with excellent results (statistical data is missing)
<b>Alenazi et al. (2014)</b>	None	Irregular breakfast consuming children were more likely to have an 'abnormal' BMI (overweight/underweight) ( $p < 0.001$ , OR 0.02)	Not included	Not included
<b>Alhazzaa et al. (2011)</b>	Age	Statistically but not clinically significant relationship was found between breakfast eating and BMI in females ( $r = -0.09$ , $p < 0.001$ ) and males ( $r = -0.13$ , $p < 0.001$ ), ( $r$ was very low)	Not included	Not included
<b>Alhazzaa et al. (2012)</b>	Age	In controlling of age, consuming breakfast on < 3 days per week was significantly associated with overweight and obesity (aOR 1.44, 95% CI 1.20-1.71, $p = 0.000$ )	Not clearly measured but assuming that private school pupils have higher SES. And being in a private school was associated with being obese or overweight (aOR 1.50, 95% CI 1.26-1.78, $p = 0.000$ )	Not included

Study	Adjusted confounders	Key results	Socioeconomic status	Academic performance
<b>Aloboudi (2010)</b>	None	Significantly, breakfast consumers were more likely to be in normal weight and skippers in overweight or underweight ( $p = 0.046$ )	Not included	A difference of mean grades rates of three subjects was found in participants for the benefit of breakfast consumers but not significant ( $p = 0.132, 0.401, \text{ and } 0.264$ )
<b>Alrethaiiaa et al. (2010)</b>	None	No significant relationship was found between breakfast habit and BMI status ( $p = 0.075$ )	Not included	Not included
<b>Alsubaie (2010)</b>	Age, parent's education, and type of school	In controlling of confounders, BMI has significant negative association with eating breakfast regularly among students; $p < 0.001$	No relationship was found between SES with both breakfast intake and BMI status	Good academic performance was positively associated with eating breakfast regularly, $p \leq 0.001$
<b>Amin et al. (2008)</b>	None	Significantly more obese versus non-obese children were likely to have breakfast only 3–6 times/week ( $OR\ 2.6, p < 0.001$ ) or < 2 times/week ( $OR\ 1.6, p < 0.001$ ), taking breakfast at home had an inverse relationship with obesity and overweight ( $OR\ 0.54, p = 0.018$ )	Obesity and overweight were significantly associated with an urban residence ( $OR\ 1.85, p = 0.011$ ), low maternal education ( $OR\ 1.87, p = 0.020$ ), working mothers ( $OR\ 1.85, p = 0.014$ ), and small family size ( $OR\ 1.95, p = 0.004$ )	Not included

Note: BMI = Body Mass Index; IOTF = International Obesity Task Force; FFQ = Food Frequency Questionnaire; NIH = National Institute for Health; NHANES = The first National Health and Nutrition Examination Survey; SES = Socioeconomic Status; OR = Odds Ratio; aOR = Adjusted Odds Ratio; r = Pearson Correlation Coefficient; CI = Confidence Intervals.

TABLE 2: Analysis of study quality for included articles.

Study	Reviewer	Selection bias	Study design	Confounders	Blinding	Data collection	Withdrawals	Overall score
Abalkhail and Shawky (2002)	1	S	W	W	W	M	N	W
	2	S	W	W	W	W	M	W
Alenazi <i>et al.</i> (2014)	1	W	W	W	W	W	N	W
	2	M	W	W	W	W	N	W
Alhazzaa <i>et al.</i> (2011)	1	M	W	S	M	S	N	M
	2	M	W	M	M	S	M	M
Alhazzaa <i>et al.</i> (2012)	1	M	W	W	W	M	N	W
	2	M	W	M	W	W	N	W
Aloboudi (2010)	1	M	W	W	W	W	N	W
	2	W	W	W	W	W	N	W
Alrethaiaa <i>et al.</i> (2010)	1	S	W	M	W	S	N	W
	2	S	W	S	W	S	N	W
Alsubaie (2010)	1	S	W	W	W	M	N	W
	2	M	W	W	W	W	N	W
Amin <i>et al.</i> (2008)	1	W	W	W	M	S	N	W
	2	M	W	W	W	S	S	W

S = Strong, 
 M = Moderate, 
 W = Weak, 
 N = N/A.

via discussing and reviewing the dictionary attached to the quality assessment tool (Appendix 4). Although both reviewer's scorings in the final stage were the same in terms of the overall rate of each study, there were some minor differences in the scoring rate of each section of the tool (Table 2). The majority of studies scored weak in the current review except for one study Alhazzaa *et al.* (2011) which had a moderate risk of bias.

### 3.7. Synthesis of key findings

#### 3.7.1. Skipping breakfast and body weight

An association between skipping breakfast and BMI status of participants was found in six papers. Alsubaie (2010) found an independent and positive association between regular breakfast intake and having low BMI with a p value of  $\leq 0.001$  when controlling for confounding factors such as students' age, type of school, and parent's education.

The same was found by Alhazzaa et al. (2012) when controlling for the effect of age only, the survey indicates that consuming breakfast on < 3 days per week was significantly associated with overweight and obesity (aOR 1.44, 95% CI 1.20–1.71,  $p = 0.000$ ), it was also associated significantly with abdominal obesity (aOR 1.47, 95% CI 1.22–1.76,  $p = 0.000$ ). While Alhazzaa et al. (2012) controlled for age concluding that there was a statistically significant relationship between breakfast eating and BMI in both females ( $r = -0.09$ ,  $p < 0.001$ ) and males ( $r = -0.13$ ,  $p < 0.001$ ); however, it was noticed that it was statistically significant but not clinically significant as the  $r$  value, as shown, is very low.

Aloboudi (2010), and Alenazi et al. (2014) found that frequent breakfast skippers were more likely to have an abnormal weight (overweight/underweight) with a statistical significance of ( $p = 0.046$ ) and ( $p < 0.001$ , OR 0.02), respectively. While Amin et al. (2008) showed that significantly more obese versus none obese children were likely to have breakfast only 3–6 times/week (OR 2.6, 95% CI 1.9–3.6,  $p < 0.001$ ) or < 2 times/week (OR 1.6, 95% CI 1.2–2.2,  $p < 0.001$ ). Also, taking breakfast at home had an inverse relationship with the development of obesity and overweight (OR 0.54, 95% CI 0.33–0.89,  $p = 0.018$ ).

On the other hand, the remaining two studies have indicated no significant relationship between breakfast intake and BMI status [1, 17] (Table 1). However, the latter did not provide sufficient statistical data to support the findings, as no  $p$  value was mentioned.

### 3.7.2. Secondary outcomes

Half of the studies did not include the measurement of socioeconomic status (SES) as illustrated in Table 1. Abalkhail and Shawky (2002) and Alsubaie (2010) have evaluated the association of socioeconomic status with breakfast intake status and found no difference in regular breakfast intake by SES. While Alsubaie (2010) and Amin et al., (2008) examined the relationship of SES with BMI status, Alsubaie (2010) found no association, but Amin et al. (2008) stated that living in urban areas (OR 1.85,  $p = 0.011$ ), low maternal education (OR 1.87,  $p = 0.020$ ), maternal occupation status (OR 1.85,  $p = 0.014$ ), and being in small family (OR 1.95,  $p = 0.004$ ) have significantly positive association with being overweight or obese. The same was indicated by Alhazzaa et al. (2012), but the SES was not clearly measured or classified. It was based on an assumption that children in private schools have higher SES and vice versa. The

survey indicated that being in private school was significantly associated with being overweight or obese (aOR 1.50, 95% CI 1.26–1.78,  $p = 0.000$ ).

The breakfast intake and academic performance association was measured only in three studies [1], [15], and [18]. Alsubaie (2010) found a negative association between low academic performance and eating breakfast regularly with a  $p$ -value of  $\leq 0.001$ . Abalkhail and Shawky's (2002) findings indicated that regular breakfast intake has an influence on school performance, 95% CI reporting 62.9–83.1 for fail/pass, 77.7–90.3 for good, 82.5–89.9 for very good, and 83.8–91.8 for excellent in regular breakfast consumers. While Aloboudi (2010) found insignificant association.

### 3.7.3. Summary

In terms of the main outcome, the evidence generally indicates that breakfast skipping has a negative effect on student's body weight. Therefore, students who skip breakfast are more likely to have a higher BMI than those who take breakfast regularly. Gender and age effects are demonstrated as strong confounders, showing that females and older subjects are more likely to skip breakfast. The overall weakness of study quality has limited the strength of evidence, largely a consequence of poor study design and a poor description of the study design in published papers, with uncontrolled confounding factors.

## 4. Discussion

This systematic review indicates that regular breakfast intake reduces the risk of overweight and obesity in children and young people in Saudi Arabia. They are more likely to have a normal BMI levels when compared to their peers who skip breakfast. Similar findings have been reported in the literature outside Saudi Arabia [6, 21, 29, 36, 43, 52, 61, 62, 64, 66, 67, 73]. Similarly, a systematic review and meta-analysis involving 19 observational studies conducted in Asian countries suggested the protective effect of breakfast consumption against developing overweight and obesity [41]. Also, in the USA children who skipped their breakfast are reported as having elevated levels of BMI when compared to consumers of breakfast [30].

However, in this present systematic review the relationship between breakfast and BMI was not statistically significant in two small studies by Alrethaiia et al. (2010) with  $n = 357$  subjects and Abalkhail and Shawky (2002) with  $n = 800$  subjects. Both are in agreement with the recently published cross-sectional survey on 239 US adolescents



by Hopkins et al.'s (2017), where the effect was also not significant ( $p < 0.10$ ). However, their focus group was only low-income urban families, and mostly African Americans, which cannot be generalized to the whole population [31].

#### 4.1. Intervention and outcome definitions

This present systematic review has identified considerable variation in the method of defining overweight/obesity and measuring breakfast intake in this research field. Van Lippevelde et al. (2013), Tin et al. (2012), Tee et al. (2018), and Hopkins et al. (2017) used the same definition of breakfast as 'any food' consumed after wake up in the morning, while Utter et al. (2007) was focusing on 'at home breakfast' and defines it as 'anything' eaten 'at home' before going to school. A question could be raised here, whether eating 'anything' could be considered as enough to reflect breakfast? Only Arora et al. (2012) defined breakfast as the first 'meal' consumed in the morning. Adolphus, Lawton, and Dye (2013) suggest including breakfast frequency and composition in the evaluation, as well as distinguishing between weekends and weekdays. Unfortunately, no specification was indicated among included studies.

Moreover, the four different cut-off references found in the included studies have also created confusion. In the USA three reference values were compared on children and adolescents [35]. They reported similar estimates among three reference values, but they were not identical, especially when observing different age groups and genders. Inconsistency in comparison findings were found [35] and similar observations were presented by Wang and Wang (2000). Surprisingly, found significant differences between overweight and obesity prevalence – in percentages – in their sample of French children when comparing between four BMI cut-off values. The findings revealed 16.3%, 18.1%, 20.6%, and 23.9% of overweight and obesity using French, Cole et al.'s, CDC, and Must et al.'s values, respectively [58].

Abrantes, Lamounier and Colosimo (2003) and Flegal et al. (2001) have recommended the use of Cole et al.'s cut-off values for international level comparisons.

#### 4.2. Considering other factors

This systematic review has found the same level of effect in both genders, which supports the findings of Nurul-Fadhilah et al., (2013) and Croezen et al. (2009). An age difference effect was also observed, as younger children are more likely to regularly consume their breakfast, as previously reported in earlier studies [6, 21, 62, 64, 66].

It is well-known that observational studies do not reflect the cause and effect relationship [38]. However, several lifestyle and dietary factors that underlie the association between skipping breakfast and weight status were found both in the literature and reviewed papers. For instance, regular breakfast intake was strongly associated with less consumption of high-fat food, and soft drinks; and more consumption of milk and dairy [13, 18]. BMI levels were also associated with physical activity, consumption of sugar-sweetened beverages, and snacking habits [14, 17, 18]. Moreover, eating with family negatively [17] and eating away from home was positively [19] associated with obesity and overweight.

### **4.3. Secondary outcomes**

#### **4.3.1. Socioeconomic status (SES)**

Among all indicators of SES measurement, the income level was missing. Also, Abalkhail and Shawky (2002) have considered only mother's education and employment status. In Uganda, mother's educational status was the stronger predictor for children's health and nutrition status when compared to other SES indicators [68], the same finding was reported in Cambodia [47], and China [72] but that was only for rural areas. Al-agma et al. (2017) have explained that generally as children's eating patterns are mainly influenced by their mothers, therefore mother's education and occupation have a strong impact on their health and nutritional status. However, recent Spanish cohort demonstrated a significant direct impact of both parent's SES on the health of their children, in fact, they also found that the effect was more from father's than mother's SES [55]. Fortunately, Alomar, Parslow and Law (2018) have recently formulated two new indices that cover the SES diversities over all geographical regions in Saudi Arabia, as well as a SES classes, established from common perceptions of the population. It is anticipated that these suggested indices will contribute to a significant improvement in research in this field if a unified tool for SES is available in Saudi Arabia.

#### **4.3.2. Academic performance**

The analysis of Abalkhail and Shawky (2002), and Alsubaie (2010) were concerned with overall academic performances. However, it could be argued that self-reported academic performances in both papers may have resulted in inaccurate reporting, especially when it comes to a sensitive area for students [65].

Aloboudi (2010) focused on three subjects to evaluate the academic performance (Math, Science, and Reading). Arguably, there could be a chance of subject grades variability, children may achieve differently in different subjects as found by Ma (2001). It could also be anticipated that for that reason the result showed an association but failed to reach the significant level.

#### 4.4. Ethical considerations

All included studies state that research approvals was obtained from different governmental authorities. In Saudi Arabia, the main ethics committee is The National Committee of Medical and Bioethics (NCBE) [32]. However, the primary studies of this current systematic review did not state clearly the inclusion of that registered committee.

In addition, children are categorized as a 'vulnerable' group, and additional precautions should be taken into account when conducting research involving this category [10]. The Research Ethic Guidebook (2018) clearly emphasizes the importance of children and parents consents and this is also found at the top of almost all ethic guidelines of Arabian countries [11]. However, 5 out of 8 papers in the present systematic review did not state whether any participants or parents informed consent was obtained. One study stated that in Saudi Arabia parent's consents are not considered necessary especially when there is an approval from the Ministry of education [18].

#### 4.5. Strength and limitation

This systematic review has successfully reached its aim of identifying studies evaluating the nutritional habits of children in many different cities around Saudi Arabia, both from published and unpublished sources, to reduce the chance of publication bias. This is the first study, to the best of the author's knowledge, to investigate the correlation between breakfast habit and children's body weight for that particular country. The review has also succeeded in correlating the relationship. However, several unavoidable limitations were observed and should be acknowledged.

A limited number of relevant studies were obtained, most of which failed to focus on breakfast as the main element of investigation. With a shortcoming caused by the study design. Moreover, failure to undertake meta-analysis was due to the clinical heterogeneity of interventions and outcomes [39]. Lack of standardized definitions of

breakfast intake/skip, overweight/obesity, and the secondary outcomes were significant among the included studies. Which may contribute to incomparable variations in evidence.

## 5. Conclusion and Recommendations

Overall, this systematic review suggests that breakfast consumption is associated with reducing the risk of overweight and obesity in children and young people living in Saudi Arabia, by having a direct impact on their BMI. However, the overall quality of included studies was not strong enough to support that evidence. Therefore, ascertainment and causality should not be assumed based on findings of this review, strongly suggesting a need for further large research studies in this field, to answer the question of the mechanism of that impact.

In addition, our findings suggest adopting awareness programs for children and their families, with more focus on adolescents. Such programs should target schools, universities, community centers, and media in highlighting the impact of breakfast intake in the prevention of overweight/obesity. Additionally, when children are not consuming breakfast at home, it could be highly beneficial to have healthy breakfast meal sessions at school before starting their academic lessons, where children are able either to bring their packed breakfast or have a balanced meal from the school, organized by dietitians.

In research, there is a need for a unified definition of breakfast and how to measure its frequency, a unified cut-off values of BMI suitable for the Saudi population, as well as a well-known index of measuring SES. This will all ensure a higher level of evidence reported in Saudi studies.

## Conflicts of Interest

This research was conducted as a part of the MSc Advanced Professional Practice program with the University of Plymouth, UK, and the authors declare no conflict of interest or funding for this project.

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## Appendices

### Appendix 1: Electronic search strategy

8/17/2018

Print Search History: EBSCOhost



Friday, August 17, 2018 3:58:57 AM

#	Query	Limiters/Expanders	Last Run Via	Results
S7	TX ( children OR "young people" OR adolescent* OR youth OR schoolboy* OR schoolgirl* OR student* OR pupil* OR teenage* ) AND TX ( "body weight" OR bodyweight OR obesity OR obese OR overweight OR BMI OR "body mass index" OR fitness OR "weight gain*" ) AND TX ( "Saudi student*" OR Saudi OR "Saudi Arabia" ) AND TX ( "skip* breakfast" OR "breakfast skip*" OR breakfast ) AND TX ( "breakfast consume*" OR "consume* breakfast" )	Limiters - Published Date: 19980101-20181231 Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	2
S6	S1 AND S2 AND S3 AND S4 AND S5	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	Display
S5	"breakfast consume*" OR "consume* breakfast"	Limiters - Published Date: 19980101-20181231 Search modes - Find any of my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	Display
S4	"skip* breakfast" OR "breakfast skip*" OR breakfast	Limiters - Published Date: 19980101-20181231 Search modes - Find any of my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	Display

<http://web.a.ebscohost.com/ehost/searchhistory/PrintSearchHistory?vid=8&sid=13fbd044-bfb9-4425-ba7e-ba99b00f9a1%40sessionmgr4008&theSea...> 1/2

8/17/2018

Print Search History: EBSCOhost

S3	"Saudi student*" OR Saudi OR "Saudi Arabia"	Limiters - Published Date: 19980101-20181231 Search modes - Find any of my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	Display
S2	"body weight" OR bodyweight OR obesity OR obese OR overweight OR BMI OR "body mass index" OR fatness OR "weight gain"	Limiters - Published Date: 19980101-20181231 Search modes - Find any of my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	Display
S1	children OR "young people" OR adolescent* OR youth OR schoolboy* OR schoolgirl* OR student* OR pupil* OR teenage*	Limiters - Published Date: 19980101-20181231 Search modes - Find any of my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	Display

<http://web.a.ebscohost.com/ehost/searchhistory/PrintSearchHistory?vid=8&sid=13fbd044-bfb9-4425-ba7e-ba99b00f9a1%40sessionmgr4008&theSea...> 2/2

## Appendix 2: Data extraction form

Data extraction date:	
Reviewer name or ID:	
<b>General Information</b>	<b>Code</b>
	Title
	Author
	Date
	Study author contact details
	Publication type
	Source of funding
<b>Study characteristics</b>	<b>Design</b>
	Aim
	Settings
	Ethical Approval needed/ obtained for study
	Sample size
	City
<b>Participant characteristics</b>	<b>Age (range and/or mean with SD if applicable)</b>
	Gender (male/female or both)
	If both number of each with (% and/or mean with SD if applicable)
	Unit of allocation (cluster, group, individual,...)
	If cluster: (no., type, no. of people per cluster)
	Number of excluded/withdrawals
	Informed consent obtained (yes, no, unclear)
<b>Intervention (breakfast skipping) VS (consumption)</b>	<b>Definition (frequency, regular VS irregular)</b>
	Measure
	Method for ascertainment of breakfast intake or skipping (questionnaire/interview)
	Notes

Main outcome		
Bodyweight change	Method of obtaining (self-reported/measured)	
	Definition (BMI, weight change, international classification, other: specify)	
Secondary outcomes: if available		
Socioeconomic status	Definition	
	Unit of measurement	
Academic performance	Definition	
	Unit of measurement	
Confounding factors	Dietary factors	
	Non-dietary factors	
	Mention the adjusted factors in results	
Results		
Crud (correlation between intervention and..)	Main outcome	
	Statistical technique used	
	Notes	
	Socioeconomic status	
	Statistical technique used	
	Notes	
	Academic performance	
	Statistical technique used	
	Notes	
Adjusted (correlation after adjusting some factors)	Correlation between intervention and main outcome	
	Statistical technique used	
	Notes	
Key conclusion		
Notes		

## Appendix 3: EPHPP quality assessment tool for quantitative studies

### QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES



#### COMPONENT RATINGS

##### A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

- 1 Very likely
- 2 Somewhat likely
- 3 Not likely
- 4 Can't tell

(Q2) What percentage of selected individuals agreed to participate?

- 1 80 - 100% agreement
- 2 60 - 79% agreement
- 3 less than 60% agreement
- 4 Not applicable
- 5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

##### B) STUDY DESIGN

Indicate the study design

- 1 Randomized controlled trial
- 2 Controlled clinical trial
- 3 Cohort analytic (two group pre + post)
- 4 Case-control
- 5 Cohort (one group pre + post (before and after))
- 6 Interrupted time series
- 7 Other specify \_\_\_\_\_
- 8 Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3



**C) CONFOUNDERS**

**(Q1) Were there important differences between groups prior to the intervention?**

- 1 Yes
- 2 No
- 3 Can't tell

**The following are examples of confounders:**

- 1 Race
- 2 Sex
- 3 Marital status/family
- 4 Age
- 5 SES (income or class)
- 6 Education
- 7 Health status
- 8 Pre-intervention score on outcome measure

**(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?**

- 1 80 – 100% (most)
- 2 60 – 79% (some)
- 3 Less than 60% (few or none)
- 4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

**D) BLINDING**

**(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?**

- 1 Yes
- 2 No
- 3 Can't tell

**(Q2) Were the study participants aware of the research question?**

- 1 Yes
- 2 No
- 3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

**E) DATA COLLECTION METHODS**

**(Q1) Were data collection tools shown to be valid?**

- 1 Yes
- 2 No
- 3 Can't tell

**(Q2) Were data collection tools shown to be reliable?**

- 1 Yes
- 2 No
- 3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

**F) WITHDRAWALS AND DROP-OUTS****(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?**

- 1 Yes
- 2 No
- 3 Can't tell
- 4 Not Applicable (i.e. one time surveys or interviews)

**(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).**

- 1 80 -100%
- 2 60 - 79%
- 3 less than 60%
- 4 Can't tell
- 5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

**G) INTERVENTION INTEGRITY****(Q1) What percentage of participants received the allocated intervention or exposure of interest?**

- 1 80 -100%
- 2 60 - 79%
- 3 less than 60%
- 4 Can't tell

**(Q2) Was the consistency of the intervention measured?**

- 1 Yes
- 2 No
- 3 Can't tell

**(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?**

- 4 Yes
- 5 No
- 6 Can't tell

**H) ANALYSES****(Q1) Indicate the unit of allocation (circle one)**

community   organization/institution   practice/office   individual

**(Q2) Indicate the unit of analysis (circle one)**

community   organization/institution   practice/office   individual

**(Q3) Are the statistical methods appropriate for the study design?**

- 1 Yes
- 2 No
- 3 Can't tell

**(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?**

- 1 Yes
- 2 No
- 3 Can't tell

**GLOBAL RATING****COMPONENT RATINGS**

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

<b>A</b>	<b>SELECTION BIAS</b>	<b>STRONG</b>	<b>MODERATE</b>	<b>WEAK</b>
		1	2	3
<b>B</b>	<b>STUDY DESIGN</b>	<b>STRONG</b>	<b>MODERATE</b>	<b>WEAK</b>
		1	2	3
<b>C</b>	<b>CONFOUNDERS</b>	<b>STRONG</b>	<b>MODERATE</b>	<b>WEAK</b>
		1	2	3
<b>D</b>	<b>BLINDING</b>	<b>STRONG</b>	<b>MODERATE</b>	<b>WEAK</b>
		1	2	3
<b>E</b>	<b>DATA COLLECTION METHOD</b>	<b>STRONG</b>	<b>MODERATE</b>	<b>WEAK</b>
		1	2	3
<b>F</b>	<b>WITHDRAWALS AND DROPOUTS</b>	<b>STRONG</b>	<b>MODERATE</b>	<b>WEAK</b>
		1	2	3
				Not Applicable

**GLOBAL RATING FOR THIS PAPER (circle one):**

- |   |          |                            |
|---|----------|----------------------------|
| 1 | STRONG   | (no WEAK ratings)          |
| 2 | MODERATE | (one WEAK rating)          |
| 3 | WEAK     | (two or more WEAK ratings) |

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No      Yes

If yes, indicate the reason for the discrepancy

- |   |   |
|---|---|
| 1 | Oversight                                 |
| 2 | Differences in interpretation of criteria |
| 3 | Differences in interpretation of study    |

**Final decision of both reviewers (circle one):**

<b>1</b>	<b>STRONG</b>
<b>2</b>	<b>MODERATE</b>
<b>3</b>	<b>WEAK</b>

## Appendix 4: The dictionary of EPHPP quality assessment tool

### Quality Assessment Tool for Quantitative Studies Dictionary



The purpose of this dictionary is to describe items in the tool thereby assisting raters to score study quality. Due to under-reporting or lack of clarity in the primary study, raters will need to make judgements about the extent that bias may be present. When making judgements about each component, raters should form their opinion based upon information contained in the study rather than making inferences about what the authors intended. Mixed methods studies can be quality assessed using this tool with the quantitative component of the study.

#### A) SELECTION BIAS

**(Q1)** Participants are more likely to be representative of the target population if they are randomly selected from a comprehensive list of individuals in the target population (score very likely). They may not be representative if they are referred from a source (e.g. clinic) in a systematic manner (score somewhat likely) or self-referred (score not likely).

**(Q2)** Refers to the % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.

#### B) STUDY DESIGN

In this section, raters assess the likelihood of bias due to the allocation process in an experimental study. For observational studies, raters assess the extent that assessments of exposure and outcome are likely to be independent. Generally, the type of design is a good indicator of the extent of bias. In stronger designs, an equivalent control group is present and the allocation process is such that the investigators are unable to predict the sequence.

##### Randomized Controlled Trial (RCT)

An experimental design where investigators randomly allocate eligible people to an intervention or control group. A rater should describe a study as an RCT if the randomization sequence allows each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. If the investigators do not describe the allocation process and only use the words 'random' or 'randomly', the study is described as a controlled clinical trial.

See below for more details.

##### *Was the study described as randomized?*

Score YES, if the authors used words such as random allocation, randomly assigned, and random assignment.

Score NO, if no mention of randomization is made.

##### *Was the method of randomization described?*

Score YES, if the authors describe any method used to generate a random allocation sequence.

Score NO, if the authors do not describe the allocation method or describe methods of allocation such as alternation, case record numbers, dates of birth, day of the week, and any allocation procedure that is entirely transparent before assignment, such as an open list of random numbers of assignments.

If NO is scored, then the study is a controlled clinical trial.

*Was the method appropriate?*

Score YES, if the randomization sequence allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, sealed, opaque envelopes.

Score NO, if the randomization sequence is open to the individuals responsible for recruiting and allocating participants or providing the intervention, since those individuals can influence the allocation process, either knowingly or unknowingly.

If NO is scored, then the study is a controlled clinical trial.

**Controlled Clinical Trial (CCT)**

An experimental study design where the method of allocating study subjects to intervention or control groups is open to individuals responsible for recruiting subjects or providing the intervention. The method of allocation is transparent before assignment, e.g. an open list of random numbers or allocation by date of birth, etc.

**Cohort analytic (two group pre and post)**

An observational study design where groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention is not under the control of the investigators. Study groups might be non-equivalent or not comparable on some feature that affects outcome.

**Case control study**

A retrospective study design where the investigators gather 'cases' of people who already have the outcome of interest and 'controls' who do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest.

**Cohort (one group pre + post (before and after))**

The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pretest, act as their own control group.

**Interrupted time series**

A study that uses observations at multiple time points before and after an intervention (the 'interruption'). The design attempts to detect whether the intervention has had an effect significantly greater than any underlying trend over time. Exclusion: Studies that do not have a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention

**Other:**

One time surveys or interviews

**C) CONFOUNDERS**

By definition, a confounder is a variable that is associated with the intervention or exposure and causally related to the outcome of interest. Even in a robust study design, groups may not be balanced with respect to important variables prior to the intervention. The authors should indicate if confounders were controlled in the design (by stratification or matching) or in the analysis. If the allocation to intervention and control groups is randomized, the authors must report that the groups were balanced at baseline with respect to confounders (either in the text or a table).

**D) BLINDING**

(Q1) Assessors should be described as blinded to which participants were in the control and intervention groups. The purpose of blinding the outcome assessors (who might also be the care providers) is to protect against detection bias.

(Q2) Study participants should not be aware of (i.e. blinded to) the research question. The purpose of blinding the participants is to protect against reporting bias.

**E) DATA COLLECTION METHODS**

Tools for primary outcome measures must be described as reliable and valid. If 'face' validity or 'content' validity has been demonstrated, this is acceptable. Some sources from which data may be collected are described below.

Self reported data includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

Assessment/Screening includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

Medical Records/Vital Statistics refers to the types of formal records used for the extraction of the data.

**Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.**

**F) WITHDRAWALS AND DROP-OUTS**

Score **YES** if the authors describe BOTH the numbers and reasons for withdrawals and drop-outs.

Score **NO** if either the numbers or reasons for withdrawals and drop-outs are not reported.

Score **NOT APPLICABLE** if the study was a one-time interview or survey where there was no follow-up data reported.

The percentage of participants completing the study refers to the % of subjects remaining in the study at the final data collection period in all groups (i.e. control and intervention groups).

**G) INTERVENTION INTEGRITY**

The number of participants receiving the intended intervention should be noted (consider both frequency and intensity). For example, the authors may have reported that at least 80 percent of the participants received the complete intervention. The authors should describe a method of measuring if the intervention was provided to all participants the same way. As well, the authors should indicate if subjects received an unintended intervention that may have influenced the outcomes. For example, co-intervention occurs when the study group receives an additional intervention (other than that intended). In this case, it is possible that the effect of the intervention may be over-estimated. Contamination refers to situations where the control group accidentally receives the study intervention. This could result in an under-estimation of the impact of the intervention.

**H) ANALYSIS APPROPRIATE TO QUESTION**

Was the quantitative analysis appropriate to the research question being asked?

An intention-to-treat analysis is one in which all the participants in a trial are analyzed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis.

**Component Ratings of Study:**

For each of the six components A – F, use the following descriptions as a roadmap.

**A) SELECTION BIAS**

**Good:** The selected individuals are very likely to be representative of the target population (Q1 is 1) **and** there is greater than 80% participation (Q2 is 1).

**Fair:** The selected individuals are at least somewhat likely to be representative of the target population (Q1 is 1 or 2); **and** there is 60 - 79% participation (Q2 is 2). 'Moderate' may also be assigned if Q1 is 1 or 2 and Q2 is 5 (can't tell).

**Poor:** The selected individuals are not likely to be representative of the target population (Q1 is 3); **or** there is less than 60% participation (Q2 is 3) **or** selection is not described (Q1 is 4); **and** the level of participation is not described (Q2 is 5).

**B) DESIGN**

**Good:** will be assigned to those articles that described RCTs and CCTs.

**Fair:** will be assigned to those that described a cohort analytic study, a case control study, a cohort design, or an interrupted time series.

**Weak:** will be assigned to those that used any other method or did not state the method used.

**C) CONFOUNDERS**

**Good:** will be assigned to those articles that controlled for at least 80% of relevant confounders (Q1 is 2); **or** (Q2 is 1).

**Fair:** will be given to those studies that controlled for 60 – 79% of relevant confounders (Q1 is 1) **and** (Q2 is 2).

**Poor:** will be assigned when less than 60% of relevant confounders were controlled (Q1 is 1) **and** (Q2 is 3) **or** control of confounders was not described (Q1 is 3) **and** (Q2 is 4).

**D) BLINDING**

**Good:** The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **and** the study participants are not aware of the research question (Q2 is 2).

**Fair:** The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **or** the study participants are not aware of the research question (Q2 is 2).

**Poor:** The outcome assessor is aware of the intervention status of participants (Q1 is 1); **and** the study participants are aware of the research question (Q2 is 1); **or** blinding is not described (Q1 is 3 and Q2 is 3).

**E) DATA COLLECTION METHODS**

**Good:** The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have been shown to be reliable (Q2 is 1).

**Fair:** The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have not been shown to be reliable (Q2 is 2) **or** reliability is not described (Q2 is 3).

**Poor:** The data collection tools have not been shown to be valid (Q1 is 2) **or** both reliability and validity are not described (Q1 is 3 and Q2 is 3).

**F) WITHDRAWALS AND DROP-OUTS - a rating of:**

**Good:** will be assigned when the follow-up rate is 80% or greater (Q1 is 1 and Q2 is 1).

**Fair:** will be assigned when the follow-up rate is 60 – 79% (Q2 is 2) **OR** Q1 is 4 or Q2 is 5.

**Poor:** will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q1 is No or Q2 is 4).

**Not Applicable:** if Q1 is 4 or Q2 is 5.