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Identifying Factors Associated with Overweight and Obesity among Intermediate School Students Aged 12-15 Years in School Settings: Mixed Methodology Protocol

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Abstract

Introduction

Childhood obesity is a public health concern globally. In Arab countries, the prevalence of overweight and obesity has increased significantly over the last three decades. The level of childhood overweight and obesity in the Kingdom of Saudi Arabia (KSA) is high and continues to increase. This study will explore factors associated with overweight and obesity among adolescents and identify barriers and enablers to the implementation of comprehensive schoolbased obesity prevention interventions.

Methods and Analysis

Socio-ecological Model will inform this mixed-methods study. The study will include three phases: (1) a scoping review of the literature; (2) the development of a student survey instrument; and (3) a mixed-method study comprising a cross-sectional survey targeting students aged 12-15 years with the collection of the students' height and weight measurements; one-on-one interviews with physical education teachers and school principals; and the administration of school climate audits using the Health Promoting School (HPS) framework. Reliability and validity of the survey instrument will be examined during survey development. Descriptive, inferential and thematic analysis will be employed using appropriate statistical software.

Ethics and Dissemination

Ethical approval has been granted from the Curtin University of Human Research Ethics Committee (HR2020-0337). Permission to conduct the study has been granted from the KSA Ministry of Education. School principals will provide permission to conduct the study in individual schools. Individual consent/assent will be obtained from students and their parents, and teachers. Study findings will be disseminated via peer-review publications, reports and conferences.

Strengths and limitations of this study

- The study will employ multiple methodologies to explore barriers and enablers within a school context to inform the development of interventions to reduce the prevalence of overweight and obesity among adolescents.
- An instrument will be developed and tested for reliability and validity with adolescents and validity with experts.

- A review of the published literature has indicated that this will be the first study to use Audit tools to assess the KSA school environment using the Health Promoting School (HPS) framework as a planning and evaluation tool and as a result, will inform the development of school-based interventions and policy focusing on reducing the prevalence of obesity.
- Participants will be recruited from intermediate level students from multiple schools; however, the study will be conducted only in one region of KSA, Jeddah.

For peer review only

Introduction

Obesity in general, and childhood obesity specifically, is a key public health issue in many high-income countries (HIC) and is a steadily rising public health problem in low- and middleincome countries (LMIC). Globally, the overall overweight and obesity prevalence has nearly tripled since the mid-1970s and it is the fifth most common cause of mortality globally, contributing to at least 2.8 million deaths per year (1,2). Obesity among children and adolescents is associated with a range of psychological health issues including depression (3,4), low self-esteem (5) and increased risk of infections (6). Childhood obesity is also a risk factor for several non-communicable chronic diseases in adulthood (7) such as diabetes (8), hypertension (9), musculoskeletal disorders (10) and heart disease (11). It also impacts academic outcomes of school students, overall quality of life (12) and has been linked to psychosocial factors such as weight-based teasing (13). Obesity is also responsible for deaths in later life as a complication of chronic diseases (14,15). There is a substantial direct and indirect economic burden attributed to childhood overweight and obesity (16). Studies have reported costs attributable to overweight and obesity are three times higher for men and nearly five times higher for women with a history of childhood obesity (17,18).

During the past three decades, the prevalence of overweight and obesity in Arabic speaking countries has steadily increased (19). A study among adults involving 52 countries found the Middle East region to score the highest mean body mass index after North America (20). The increasing prevalence of overweight and obesity among children and adolescents in Eastern Mediterranean countries has reached a critical level where the prevalence of overweight and obese adolescents is greater than adolescents classified as normal weight (21). In a review conducted among children under 12 years in the Gulf countries, there was a 5%-14% and 3%-18% prevalence of obesity among males and females respectively (22).

Similarly, the level of childhood overweight and obesity in the Kingdom of Saudi Arabia (KSA) is high and continues to increase (23,24). A study in 2012 in KSA among 19,317 children and adolescents (aged 5-18 years) found the prevalence of overweight, obesity and severe obesity to be 23%, 9% and 2%, respectively (25). Another recent study in 2015 in KSA among 7930 children aged 6-16 years reported 13% to be overweight and 18% to be obese (26). In recent decades, the population of KSA has undergone a nutritional transition where traditional food is being substituted by fast food which is usually energy-dense and nutrient-poor (27). The consumption of unhealthy foods and sugary carbonated drinks, especially

among children and adolescents is increasing at a rapid rate (28). In addition, Saudi people are more likely to adopt sedentary lifestyles when compared to other non-Arab cultures (29). The increased socio-economic status of KSA residents has also resulted in increased use of personal cars for transportation and an increase in indoor games and television viewing which has resulted in children and adolescents being less likely to walk to school and play outdoors than in the past (30).

Considering the increased prevalence along with the health and economic issues associated with childhood obesity, effective programs to encourage physical activity and improve healthy eating behaviours to prevent obesity are imperative (31). Schools have been identified as an ideal setting to promote health given the association between health and education along with the amount of time children and adolescents spend at school (32).

The Health-Promoting Schools (HPS) Framework is adopted by the World Health Organization and recommends a whole of school approach to promote healthy schools. (33,34). The HPS Framework focuses on the domains of Curriculum, Teaching and Learning; School Organisation, Ethos and Environment; and Partnerships and Services.

Published research in KSA has primarily focused on a single element in regards to the determinants of weight-related issues among adolescents including anthropometric measurement (35); dietary patterns such as eating in restaurants; and sedentary lifestyles with low levels of physical activity (23,36). There is no published research that focuses on broader socio-ecological influences of overweight and obesity among Saudi children and adolescents within the school setting (37). This study aims to address this gap by adopting a mixed methods approach to explore factors associated with overweight and obesity among Intermediate School students aged 12-15 years within the school setting in Jeddah, KSA

Methods

Objectives

The specific objectives of the study are: a) to identify self-reported physical activity and nutrition knowledge, attitudes, and behaviours; b) to determine the association between BMI, sociodemographic factors, and nutrition and physical activity related knowledge, attitudes, and behaviours; and c) to explore barriers and enablers to the implementation of comprehensive school-based obesity prevention interventions perceived by schoolteachers and school

principals; and d) undertake school audits to determine factors within the schools that may influence overweight and obesity.

Research design

This mixed methods study will be informed by the Social-Ecological Model (SEM) (38) which has been used in the context of obesity elsewhere (39,40). The Health Promoting Schools (HPS) Framework will also inform the study design (41). This study will be conducted in three phases: (1) a scoping review of the literature; (2) the development of a student survey instrument; and (3) a mixed methods study comprising a cross-sectional survey of students aged 12-15 years investigating their knowledge, attitudes, and behaviours with regard to physical activity and nutrition; the collection of student BMI measurements; one-on-one interviews with physical education teachers and school principals; and school climate audits.

Theoretical framework

Major tenets of the SEM acknowledge and situate adolescents within their environment and further recognize the position of ecology or contextual elements for children within their family and wider social context (42). The theory posits that the health and health behaviours of individuals are interconnected with their surroundings, and that environment needs to be understood in order to explain health (40,42,43). In essence, the socio-ecological perspective considers a more comprehensive view of the influences on childhood and adolescent overweight and obesity (44). The SEM recognizes influences at the student, interpersonal (family, peers and teachers), school environment, community and policy levels (45). The factors associated with childhood overweight and obesity are multifactorial and interconnected, hence the social-ecological framework (SEM) will be used to inform this study. Figure 1 describes the interrelationship between the SEM and the study design.

Setting

The study will be conducted in Jeddah City, KSA in three boys' and three girls' Intermediate Schools. Schools will be randomly selected from 262 Intermediate Government Schools, recruiting approximately even numbers of males and females. Students (Grades 7 to 9; 12 - 15 years), teachers and principals will be invited to participate in the study. In KSA, all schools are single gender (46).

Phase One: Scoping Review

A scoping review will be initially conducted to understand school-based obesity prevention interventions in Arabic speaking countries. PICO format (47) will be used to guide the development of the review's question, generating relevant keywords for searching and developing in inclusion and exclusion criteria. This review will consider school-based interventions focusing on overweight and obesity prevention (including promotion of healthy eating and physical activity) within schools in predominantly Arabic speaking countries (n=22 countries) within the last 10 years. Finally, a systematic search and screening will be conducted and reported according to the PRISMA flowchart (48).

Search Strategy and Study Selection

Systematic searches of the following electronic databases will be undertaken through PubMed, Medline, Scopus, CINHAL, Cochrane, ERIC, EMBASE, ProQuest, EBSCO Host and Global Health and manual exploration of relevant publications will be conducted. School-based intervention studies will be included with keywords (Child or Adol*) and (Bahrain or Kuwait or Oman or Qatar or Saudi Arabia or United Arab Emirates or gulf countries or Gulf Cooperation Council or Algeria or Palestinian Territories or Comoros or Djibouti or Egypt or Iraq or Jordan or Lebanon or Libya or Mauritania or Morocco or Somalia or Sudan or Syria or Tunisia or Yemen) and school and (intervention or program or curriculum or health promotion or health education) and (physical activity or exercise or diet or nutrition or food choices or obesity or overweight or BMI or Body Mass Index or body weight). Inclusion criteria will be studies which focus on school-aged children from five to 18 years, interventions aiming to prevent overweight and obesity, school-based quantitative and/or qualitative intervention studies, peer-reviewed articles published in English or Arabic and articles for which full text is available. Systematic searching will be documented, and duplicates will be removed using reference management software (i.e. EndNote X9). The relevant data extracted from each article will be systematically summarized and tabulated and will be analysed for intervention characteristics, measurable outcomes, and the enablers and barriers of the interventional studies (34).

Phase Two: Survey Development:

A self-report survey will be developed to measure demographics and knowledge, attitudes, and behaviours (KAB) regarding physical activity and nutrition among Grade 7 to 9 students

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(Figure 2). The survey will be informed by the literature and where possible previously validated items will be used. The survey be tested for validity and reliability (49). Content validity testing of the survey will be conducted with experts (i.e. public health academics with clinical and education backgrounds from KSA; n = 6-8) initially in English and the final format in Arabic. The survey will be tested for reliability. A test-retest will be conducted in Jeddah KSA with seventh grade (aged 12) students (male, n= 60 and female= 60) from two schools (one male and one female) not involved in the main study. The survey will be administered by a research assistant in a classroom at a time convenient to the school in paper or online. The survey will be administered to the same 60 students two weeks after the initial survey administration. This pilot study will inform the researchers, the minimum and maximum time required to complete the survey.

Instrumentation

Demographics including age, gender, grade level and parent education level will be collected. Physical activity knowledge will be measured using five questions adapted from a Malaysian study involving 8-11 year old children (responses "True", "False" and "I don't know") (50). Attitudes toward physical activity will be measured using an eight question scale adapted from a university study in Gambia (Likert scale: strongly agree (1) to strongly disagree (5) (51). Physical activity behaviours will be measured using eight questions. The first question uses the SCREENS questionnaire which was originally developed for children aged 6 to 10 years in Denmark (SCREENS-Q). This question includes six-sub questions and focuses on time per day spent on different screen-related activities (52). The remaining five questions were adapted to the KSA intermediate school context from the Australian National Nutrition and Physical Activity Survey which collected data about 5-17-year olds. These questions focus on usual daily activity, level of activity and amount and type of sports activities provided at school (53).

Nutrition knowledge will be measured using eight items adapted from a validated nutritional survey developed for use among urban South African adolescents (responses: true, false, I don't know) (54,55). Eight 8 items adapted from an English survey for 11-12 year olds will measure nutrition attitudes (Likert scale: strongly agree (1) to strongly disagree (5) (55). Nutrition-related behaviours will be measured using nine questions adapted from an Australian school students survey. These questions focus on types and approximate quantities of food consumed

on a usual day. Questions focus of fruit, vegetable, bread and cereal, fast food, energy dense snacks, sugary drinks, milk and water consumption (56).

Phase Three: Mixed Methods Study

 Phase three will comprise the mixed methods study which includes a cross-sectional survey and BMI measurements with Grade 7 to 9 students. Individual interviews with physical education teachers and school principals and the administration of school environment audits will also be undertaken (Figure 2).

Study population and sample size (a) Cross-sectional and BMI measurements

Of the 262 Intermediate Schools in Jeddah, six schools will be randomly selected. A random sample of six Intermediate Schools will be generated from six different geographical regions in Jeddah using SPSS random generated sample selection method. Intermediate Schools include students from Grades 7 to 9. All students within participating classes from each school will be invited.

Principals will provide consent for the school to participate in the study. Parental consent and student assent will be required for individual student participation. Inclusion criteria will be children from Grades 7 to 9 who assent to participate and for whom parental consent is provided. Students who are unable to take the survey for any reason and/or are unable to stand up long enough to have their height and weight measured (i.e. students who are not cognitively or physically able to participate) will be excluded from the study.

In order to calculate sufficient sample size to ensure representativeness of the study population, the highest available prevalence of overweight and obesity (23.1%) reported among KSA children and adolescents in a study by El Mouzan et al., (25) was used. The following formula was used for sample size calculation: Sample size (n) = $Z1^2 - \alpha/2$ Pq /d² (57). Based on the formula, the required minimum sample size for Intermediate School (12-15 years old), is 273 participants. To factor in 10% non-response rate, a total of 300 students is required for this study. Since this study employed cluster sampling a design effect will be employed. A design effect usually ranges from 1 to 3 (58). Therefore, the design effect of two will be used to reach a sample size of 600. Since this study is targeting both male and female students, the total estimated sample size will be 1200 students (600 males and 600 females).

(b) Interview with school principals and sport teachers

We will aim to recruit six physical education teachers and six principals or deputy principals (one teacher and one principal/deputy from each school; n= 12). Due to cultural reasons, the male principal researcher will conduct face to face interviews with male participants and phone interviews with the female participants.

(c) School Climate Audit

The principal researcher (or the research assistant for female schools) will complete the school audit checklist with the school principal or deputy and one physical education teacher.

Data Collection

(a) Cross-sectional and BMI measurements

The validated self-administrated survey (developed in Phase 2) will collect demographic information and physical activity and nutrition knowledge, attitudes and behaviours. The self-report instrument will be administered via paper or online during class time by the principal researcher (or research assistant in the girls' schools) with the assistance of the classroom teachers in each school.

The height and weight of consenting students will also be measured. The researcher will follow the international standards for anthropometric assessment (59). The BMI for age will be calculated (59). The principal investigator will take the measurements of the male students and female research assistant will be employed to measure female students and both will be trained in correct anthropometric measurement techniques. A calibrated digital measuring scale will be used, and the scale will be reset before measurement. The use of such digital scales has been supported for good accuracy with evidence (60). Student height will be measured using a portable stadiometer set up on a hard, flat surface (61). Privacy will be given to each child so that their measurements are known only to the person taking the measurements. The height and weight data measurement will be written on the individual survey forms.

(b) Interview with school principals and sport teachers

Individual in-depth interviews will be conducted with physical education teachers and principals to explore their beliefs and perceptions of the barriers and enablers to the implementation of school-based interventions focusing on obesity prevention. This is expected to provide a richer understanding of the topic from the point of view of relevant school staff.

The questions will be informed by the results of the systematic review, the cross-sectional study and relevant literature (62–67), and a semi-structured interview guide will be developed. The interview guide will be piloted with two teachers uninvolved in the study to estimate the time the interview can be expected to take and to obtain feedback on the clarity of the interview questions.

The semi-structured one-on-one interviews will be audiotaped, transcribed verbatim, translated and will be reviewed by the researcher and supervisors to maintain dependability and determine credibility (68). The translation process will resume after transcription with an audio converter Arabic to Arabic then the researcher will review all the resulting transcriptions and adjust for accuracy. The principal investigator will translate for the closest intended meaning based on his knowledge of English and Arabic then will get this checked by an Accredited English-Arabic translator.

(c) School Climate Audit

A school climate audit tool will be developed from previous tools based on the Health Promoting Schools (HPS) Framework (33,69) and will be based on the three interrelated components of the HPS Framework: curriculum, teaching and learning; school organisation, ethos and environment; and partnerships and services. (70–72). The tool will be adapted from the items from four studies with acceptable psychometric levels: a tool developed for multiple countries with almost perfect reliability (κ =0.80–0.96) (70); an audit tool focusing on the walkability of school environments with average interrater reliability score from US (κ =0.839) (73); school audit tools used in the IDEA study in the US (74); and the Australian HPS school audit (72). The tool includes whole school strategies relevant to promoting good nutrition and physical activity.

Data Analysis

Phase Two: Survey Analysis:

Survey development (validity and reliability testing)

Validity and reliability during the survey development and the cross-sectional survey will be examined using different types of factor analysis as details are detailed below (Figure 2).

Explanatory factor Analysis

The initial construct validity of the instrument will be established through exploratory factor analysis (EFA), allowing the transformation of correlations among a set of observed variables into each of the six proposed subscales of overweight and obesity (75). EFA will be used to extract factors with eigenvalues > 1, which will then be rotated to identify subscales or factors that best fit the instrument (76) and decisions will be made if the items need to be excluded which is testing the initial construct validity of the instrument. The assumptions should be met where the number of participants is sufficient as literature states that three to 20 people per variable is sufficient to run this EFA analysis (77), the Kaiser-Mayer-Olkin (KMO) (>0.50) and Bartlett's test of sphericity (P<0.05). For the sample size of 120 students, the sufficient factor loading is above 0.50 (78).

Internal consistency

Once the factors are extracted using the EFA, internal consistency of each factor within the instrument and its items will be measured using Cronbach's alpha, an alpha greater than or equal to 0.7 will be considered adequate (79).

Test-retest reliability

The scores and mean scores obtained during the two surveys will be calculated with the Pearson product-moment correlation analysis. Spearman's rho, a measure of agreement between scores on different administrations of the instrument will be calculated and the correlation coefficient between 0.7 and 1.0 indicate that the instrument is reliable or shows consistency across time (80,81).

Phase Three: Mixed Methods Study

(a) Cross-sectional and BMI measurements

Confirmatory factor analysis

In this phase, the construct validity will be assessed using confirmatory factor analysis (CFA). For confirmatory content analysis and explanatory analysis more than 500 or 10 samples per item are sufficient (82). In our study, the sample size calculated is 1200 which is sufficient to undergo confirmatory factor analysis. This construct validity using CFA will indicate whether the subscales of overweight and obesity identified in phase two are valid and is achieved when the fitness indexes is achieved to the required level: Chi-square χ^2 (p-value >0,05), Chi-Square/

df < 3.0, Root Mean Square Error of Approximation (RMSEA) < 0.08), Goodness-of-Fit Index (GFI) > 0.90 comparative fit index (CFI) > 0.90 Normed Fit Index > 0.90 (83). The second stage of EFA analysis at this phase is to identify and estimate whether it fits the model and the degrees of freedom as well. The CFA will be analysed using a powerful structural equation modelling software IBM SPSS Amos. Finally, the model will be rearranged revised to improve the fit as indicated and Akaike Information Criterion (AIC) will be used to compare between model during the fitting process (84).

Descriptive data analysis

 During data entry, exploratory data analysis will be conducted to identify outliers, missing data, describe and check the assumption of normality and distribution of continuous data using histogram and Kolmogorov-Smirnov test and Shapiro-Wilk test (85). The central tendencies will be expressed in mean, median, standard deviations and interquartile range for continuous data while frequencies and percentages will be used to express data for categorical variables. Chi-square tests (χ 2) will assess the associations between each independent variable and overweight and obesity.

Inferential data analysis

Initially, all variables will be analysed univariately and those with p-value more than 0.25 will be included in the model to avoid the possibility of residual cofounders (57). Logistic regression will be employed to analyse the predictors of obesity and overweight (BMI measurements). The significance level will be set at P < 0.05 at 95% confidence interval (CI). Data analysis will be carried out using the Statistical Package for Social Sciences (SPSS) software version 26.0.

(b) Interview with school principals and sport teachers

Content analysis will explore perceptions and experiences, generating rich and in-depth information on the underlying studied phenomena (86). Themes will be identified, and responses coded to elicit shared meanings of perceptions across interviews and to guide the researchers in reporting the results. For this purpose, directed thematic analysis approach will be employed (87). Common themes and subthemes will be identified based on the interview responses (88). The qualitative data will be managed using software package NVivo 12. When

 the interview is transcribed, it will be sent back to a sample of consenting participants for verification.

(c) School Climate Audit

The school climate audit will be reviewed by health promotion and education experts from Australia and KSA to determine face and content validity. The tool will be tested with two teachers from the two Intermediate Schools in Jeddah conducting the student survey test-retest. The audit responses will be classified as "implemented", "partially implemented" and "not implemented" and will be tabulated and evaluated section by section.

Patient and public involvement

No patient or public involved.

Ethics and dissemination 🥒

Ethical approval has been granted through Curtin University's Human Research Ethics Committee (HRE2020-0337) and permission granted from the General Directorate of Education in Jeddah. Initially consent will be obtained from the principals of each school involved to allow their school to participate in the study. Individual consent will be sought from teachers, principal/deputy and parents and assent sought from students. Participant information sheets will be provided for the principal describing the school's involvement. All participants (teachers, principals/deputies, students) and parents will be provided individual participant information sheets describing the study and highlighting the voluntary nature of the study.

All information collected from participating schools, principals, teachers and students will be de-identified. Students completing the survey will be assigned an identification (ID) number/code stipulated in the survey prior to data collection so that their BMI can be linked to their survey responses. If surveys are conducted on paper they will be scanned, and originals stored securely until appropriately disposed. All electronic data will be stored on a secure password protected network which can only be accessed by the researchers. Data will be appropriately disposed of after a minimum of seven years after project completion or until the participant has reached 25 years of age (89). Results will be presented as aggregate and there will be no identification of individuals.

To facilitate knowledge, transfer the study findings will be disseminated in a number of ways. Findings will be published as a doctoral thesis, in peer review publications and at conferences. In addition, key findings will be shared with the KSA Ministry of Education, participating schools and to the broader school community through newsletters.

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Competing interests none declared

Ethics approval Ethics approval has been obtained from Curtin University (**HRE2020-0337**), and from the General Directorate of Education in Jeddah.

Patient consent for publication Not required.

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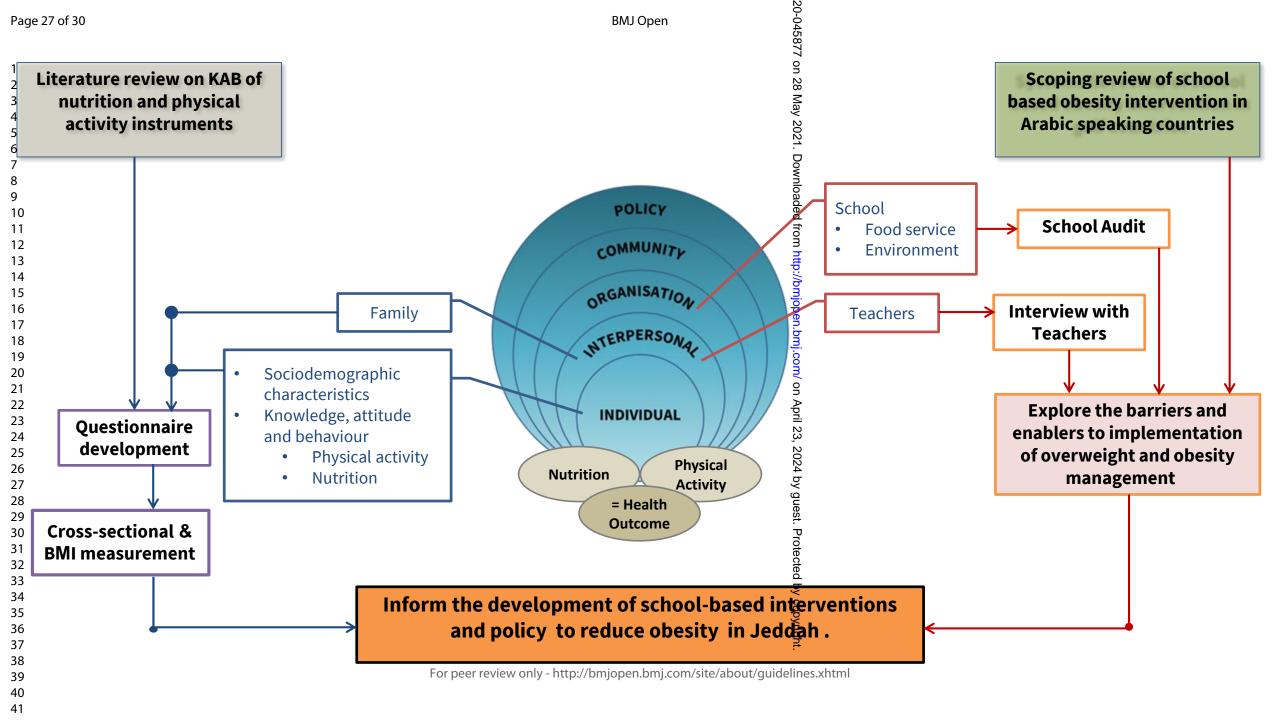
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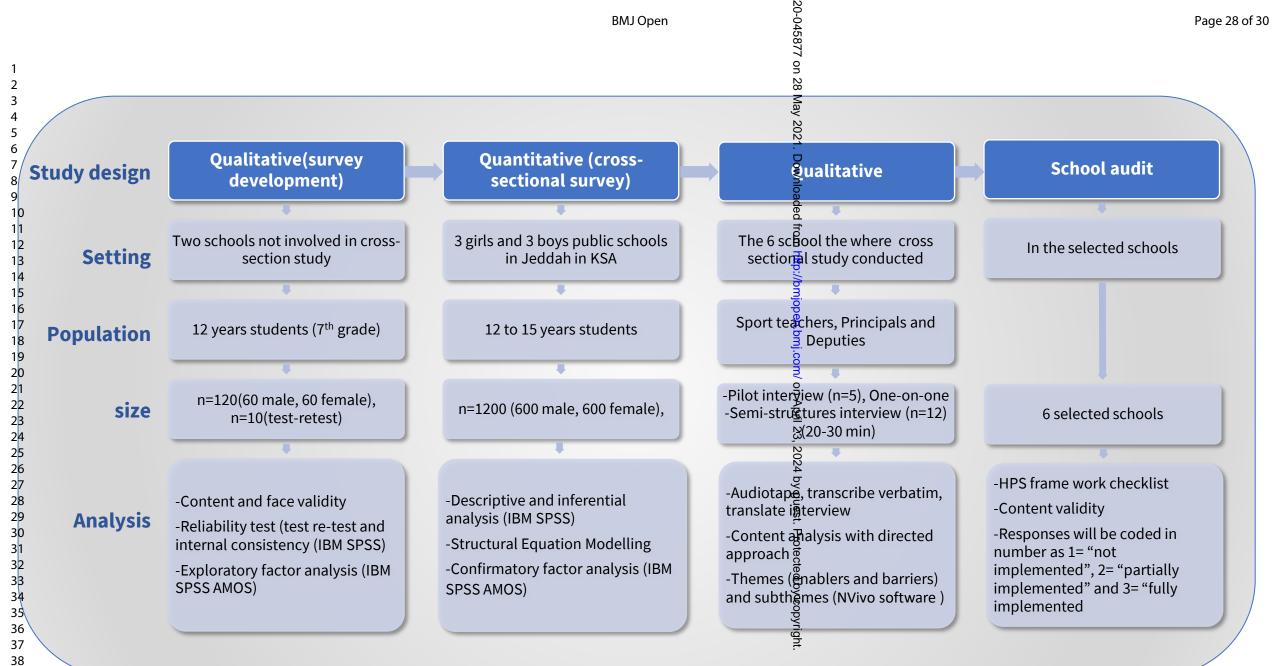
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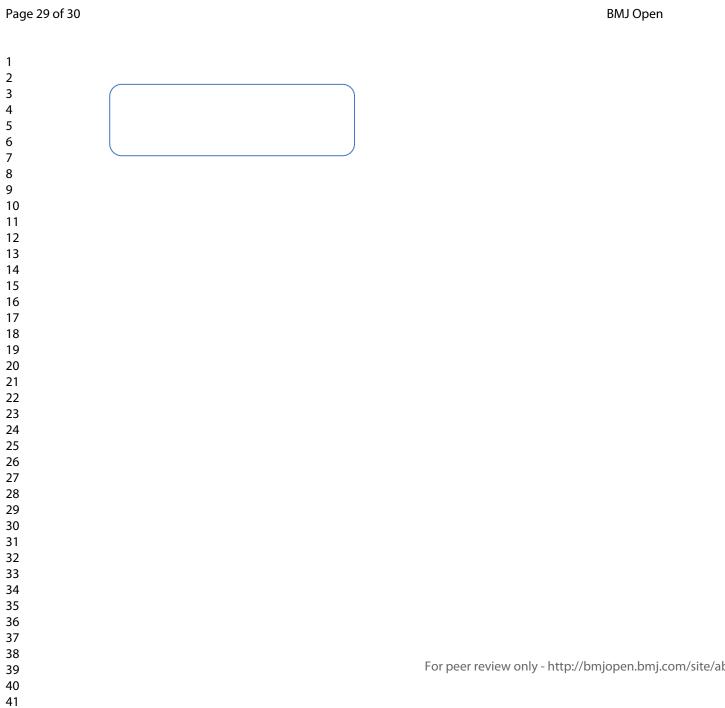
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	BMJ Open <u>B</u>		
	ST	ROBE 2007 (v4) Statement—Checklist of items that should be included in reports of <i>cross-sectional studies</i>	
Section/Topic	ltem #	Recommendation S	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction		021.	
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-4
Objectives	3	State specific objectives, including any prespecified hypotheses	
Methods	•		
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(<i>a</i>) Give the eligibility criteria, and the sources and methods of selection of participants	8-9
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9
Data sources/	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe	9-10
measurement		comparability of assessment methods if there is more than one group 호.	
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	8-9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which grougings were chosen and why	9
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	11-13
		(b) Describe any methods used to examine subgroups and interactions	
		© Explain how missing data were addressed	
		(d) If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	
Results		ב. קי	

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Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examine $\breve{\Xi}$ for eligibility,	8-9
		confirmed eligible, included in the study, completing follow-up, and analysed 했	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision deg, 95% confidence	
		interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of any lyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results 월	
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in controls in case-control studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine are http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Identifying Factors Associated with Overweight and Obesity among Intermediate School Students Aged 12-15 Years in School Settings: Mixed Methodology Protocol

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Identifying Factors Associated with Overweight and Obesity among Intermediate School Students Aged 12-15 Years in School Settings: Mixed Methodology Protocol

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Key words: Obesity, Children, Adolescents, Mixed-methodology, Kingdom of Saudi elez onz Arabia

Word count: 3987

Abstract Introduction

Childhood obesity is a public health concern globally. In Arab countries, the prevalence of overweight and obesity has increased significantly over the last three decades. The level of childhood overweight and obesity in the Kingdom of Saudi Arabia (KSA) is high and continues to increase. This study will explore factors associated with overweight and obesity among adolescents and identify barriers and enablers to the implementation of comprehensive schoolbased obesity prevention interventions.

Methods and Analysis

Socio-ecological Model will inform this mixed methods study. The study will include three phases: (1) a scoping review of the literature; (2) the development of a student survey instrument; and (3) a mixed-method study comprising a cross-sectional survey targeting students aged 12-15 years with the collection of the students' height and weight measurements; one-on-one interviews with physical education teachers and school principals; and the administration of school climate audits using the Health Promoting School (HPS) framework. Reliability and validity of the survey instrument will be examined during survey development. Descriptive, inferential and thematic analysis will be employed using appropriate statistical software.

Ethics and Dissemination

Ethical approval has been granted from the Curtin University of Human Research Ethics Committee (HR2020-0337) and from the KSA Ministry of Education (4181827686). School principals will provide permission to conduct the study in individual schools. Individual consent/assent will be obtained from students and their parents, and teachers. Study findings will be disseminated via peer-review publications, reports and conferences.

Strengths and limitations of this study

- The study will employ multiple methodologies to explore barriers and enablers within a school context to inform the development of interventions to reduce the prevalence of overweight and obesity among adolescents.
- The validated student survey and whole school Audit tools will be enhance schoolbased planning.

- A review of the published literature has indicated that this will be the first mixed methods study to collecting data from students and teachers to specifically inform the development of whole school interventions and policy focusing on obesity preventions. Findings will inform school-based interventions in KSA.
- Participants will be recruited from intermediate level students from multiple schools; however, the study will be conducted only in one region of KSA, Jeddah.

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Introduction

Obesity in general, and childhood obesity specifically, is a key public health issue in many high-income countries (HIC) and is a steadily rising public health problem in low- and middleincome countries (LMIC). Globally, the overall overweight and obesity prevalence has nearly tripled since the mid-1970s and it is the fifth most common cause of mortality globally, contributing to at least 2.8 million deaths per year (1,2). Obesity among children and adolescents is associated with a range of psychological health issues including depression (3,4), low self-esteem (5) and increased risk of infections (6). Childhood obesity is also a risk factor for several non-communicable chronic diseases in adulthood (7) such as diabetes (8), hypertension (9), musculoskeletal disorders (10) and heart disease (11). It also impacts academic outcomes of school students, overall quality of life (12) and has been linked to psychosocial factors such as weight-based teasing (13). Obesity is also responsible for deaths in later life as a complication of chronic diseases (14,15). There is a substantial direct and indirect economic burden attributed to childhood overweight and obesity (16). Studies have reported costs attributable to overweight and obesity are three times higher for men and nearly five times higher for women with a history of childhood obesity (17,18).

During the past three decades, the prevalence of overweight and obesity in Arabic speaking countries has steadily increased (19). A study among adults involving 52 countries found the Middle East region to score the highest mean body mass index after North America (20). The increasing prevalence of overweight and obesity among children and adolescents in Eastern Mediterranean countries has reached a critical level where the prevalence of overweight and obese adolescents is greater than adolescents classified as normal weight (21). In a review conducted among children under 12 years in the Gulf countries, there was a 5%-14% and 3%-18% prevalence of obesity among males and females respectively (22).

Similarly, the level of childhood overweight and obesity in the Kingdom of Saudi Arabia (KSA) is high and continues to increase (23,24). A study in 2012 in KSA among 19,317 children and adolescents (aged 5-18 years) found the prevalence of overweight, obesity and severe obesity to be 23%, 9% and 2%, respectively (25). Another recent study in 2015 in KSA among 7930 children aged 6-16 years reported 13% to be overweight and 18% to be obese (26). In recent decades, the population of KSA has undergone a nutritional transition where traditional food is being substituted by fast food which is usually energy-dense and nutrient-poor (27). The consumption of unhealthy foods and sugary carbonated drinks, especially

among children and adolescents is increasing at a rapid rate (28). In addition, Saudi people are more likely to adopt sedentary lifestyles when compared to other non-Arab cultures (29). The increased socio-economic status of KSA residents has also resulted in increased use of personal cars for transportation and an increase in indoor games and television viewing which has resulted in children and adolescents being less likely to walk to school and play outdoors than in the past (30).

Considering the increased prevalence along with the health and economic issues associated with childhood obesity, effective programs to encourage physical activity and improve healthy eating behaviours to prevent obesity are imperative (31). Schools have been identified as an ideal setting to promote health given the association between health and education along with the amount of time children and adolescents spend at school (32).

The Health-Promoting Schools (HPS) Framework is adopted by the World Health Organization and recommends a whole of school approach to promote healthy schools. (33,34). The HPS Framework focuses on the domains of Curriculum, Teaching and Learning; School Organisation, Ethos and Environment; and Partnerships and Services.

Published research in KSA has primarily focused on a single element in regards to the determinants of weight-related issues among adolescents including anthropometric measurement (35); dietary patterns such as eating in restaurants; and sedentary lifestyles with low levels of physical activity (23,36). There is no published research that focuses on broader socio-ecological influences of overweight and obesity among Saudi children and adolescents within the school setting (37). This study aims to address this gap by adopting a mixed methods approach to explore factors associated with overweight and obesity among Intermediate School students aged 12-15 years within the school setting in Jeddah, KSA

Methods

Objectives

The specific objectives of the study are: a) to identify self-reported physical activity and nutrition knowledge, attitudes, and behaviours; b) to determine the association between BMI, sociodemographic factors, and nutrition and physical activity related knowledge, attitudes, and behaviours; and c) to explore barriers and enablers to the implementation of comprehensive school-based obesity prevention interventions perceived by schoolteachers and school

principals; and d) undertake school audits to determine factors within the schools that may influence overweight and obesity.

Research design

This mixed methods study will be informed by the Social-Ecological Model (SEM) (38) which has been used in the context of obesity elsewhere (39,40). The Health Promoting Schools (HPS) Framework will also inform the study design (41). This study will be conducted in three phases: (1) a scoping review of the literature; (2) the development of a student survey instrument; and (3) a mixed methods study comprising a cross-sectional survey of students aged 12-15 years investigating their knowledge, attitudes, and behaviours with regard to physical activity and nutrition; the collection of student BMI measurements; one-on-one interviews with physical education teachers and school principals; and school climate audits.

Theoretical framework

Major tenets of the SEM acknowledge and situate adolescents within their environment and further recognize the position of ecology or contextual elements for children within their family and wider social context (42). The theory posits that the health and health behaviours of individuals are interconnected with their surroundings, and that environment needs to be understood in order to explain health (40,42,43). In essence, the socio-ecological perspective considers a more comprehensive view of the influences on childhood and adolescent overweight and obesity (44). The SEM recognizes influences at the student, interpersonal (family, peers and teachers), school environment, community and policy levels (45). The factors associated with childhood overweight and obesity are multifactorial and interconnected, hence the social-ecological framework (SEM) will be used to inform this study. Figure 1 describes the interrelationship between the SEM and the study design.

Setting

The study will be conducted in Jeddah City, KSA in three boys' and three girls' Intermediate Schools. Schools will be randomly selected from 262 Intermediate Government Schools, recruiting approximately even numbers of males and females. Students (Grades 7 to 9; 12 - 15 years), teachers and principals will be invited to participate in the study. In KSA, all schools are single gender (46).

Phase One: Scoping Review

A scoping review will be initially conducted to understand school-based obesity prevention interventions in Arabic speaking countries. PICO format (47) will be used to guide the development of the review's question, generating relevant keywords for searching and developing in inclusion and exclusion criteria. This review will consider school-based interventions focusing on overweight and obesity prevention (including promotion of healthy eating and physical activity) within schools in predominantly Arabic speaking countries (n=22 countries) within the last 10 years. Finally, a systematic search and screening will be conducted and reported according to the PRISMA flowchart (48).

Search Strategy and Study Selection

Systematic searches of the following electronic databases will be undertaken through PubMed, Medline, Scopus, CINHAL, Cochrane, ERIC, EMBASE, ProQuest, EBSCO Host and Global Health and manual exploration of relevant publications will be conducted. School-based intervention studies will be included with keywords (Child or Adol*) and (Bahrain or Kuwait or Oman or Qatar or Saudi Arabia or United Arab Emirates or gulf countries or Gulf Cooperation Council or Algeria or Palestinian Territories or Comoros or Djibouti or Egypt or Iraq or Jordan or Lebanon or Libya or Mauritania or Morocco or Somalia or Sudan or Syria or Tunisia or Yemen) and school and (intervention or program or curriculum or health promotion or health education) and (physical activity or exercise or diet or nutrition or food choices or obesity or overweight or BMI or Body Mass Index or body weight). Inclusion criteria will be studies which focus on school-aged children from five to 18 years, interventions aiming to prevent overweight and obesity, school-based quantitative and/or qualitative intervention studies, peer-reviewed articles published in English or Arabic and articles for which full text is available. Systematic searching will be documented, and duplicates will be removed using reference management software (i.e. EndNote X9). The relevant data extracted from each article will be systematically summarized and tabulated and will be analysed for intervention characteristics, measurable outcomes, and the enablers and barriers of the interventional studies (34).

Phase Two: Survey Development:

A self-report survey will be developed to measure demographics and knowledge, attitudes, and behaviours (KAB) regarding physical activity and nutrition among Grade 7 to 9 students

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(Figure 2). The survey will be informed by the literature and where possible previously validated items will be used. The survey be tested for validity and reliability (49). Content validity testing of the survey will be conducted with experts (i.e. public health academics with clinical and education backgrounds from KSA; n = 6-8) initially in English and the final format in Arabic. The survey will be tested for reliability. A test-retest will be conducted in Jeddah KSA with seventh grade (aged 12) students (male, n= 60 and female= 60) from two schools (one male and one female) not involved in the main study. The survey will be administered by a research assistant in a classroom at a time convenient to the school in paper or online. The survey will be administered to the same 60 students two weeks after the initial survey administration. This pilot study will inform the researchers, the minimum and maximum time required to complete the survey.

Instrumentation

Demographics including age, gender, grade level and parent education level will be collected. Physical activity knowledge will be measured using five questions adapted from a Malaysian study involving 8-11 year old children (responses "True", "False" and "I don't know") (50). Attitudes toward physical activity will be measured using an eight question scale adapted from a university study in Gambia (Likert scale: strongly agree (1) to strongly disagree (5) (51). Physical activity behaviours will be measured using eight questions. The first question uses the SCREENS questionnaire which was originally developed for children aged 6 to 10 years in Denmark (SCREENS-Q). This question includes six-sub questions and focuses on time per day spent on different screen-related activities (52). The remaining five questions were adapted to the KSA intermediate school context from the Australian National Nutrition and Physical Activity Survey which collected data about 5-17-year olds. These questions focus on usual daily activity, level of activity and amount and type of sports activities provided at school (53).

Nutrition knowledge will be measured using eight items adapted from a validated nutritional survey developed for use among urban South African adolescents (responses: true, false, I don't know) (54,55). Eight 8 items adapted from an English survey for 11-12 year olds will measure nutrition attitudes (Likert scale: strongly agree (1) to strongly disagree (5) (55). Nutrition-related behaviours will be measured using nine questions adapted from an Australian school students survey. These questions focus on types and approximate quantities of food consumed

on a usual day. Questions focus of fruit, vegetable, bread and cereal, fast food, energy dense snacks, sugary drinks, milk and water consumption (56).

Phase Three: Mixed Methods Study

 Phase three will comprise the mixed methods study which includes a cross-sectional survey and BMI measurements with Grade 7 to 9 students. Individual interviews with physical education teachers and school principals and the administration of school environment audits will also be undertaken (Figure 2).

Study population and sample size (a) Cross-sectional and BMI measurements

Of the 262 Intermediate Schools in Jeddah, six schools will be randomly selected. A random sample of six Intermediate Schools will be generated from six different geographical regions in Jeddah using SPSS random generated sample selection method. Intermediate Schools include students from Grades 7 to 9. All students within participating classes from each school will be invited.

Principals will provide consent for the school to participate in the study. Parental consent and student assent will be required for individual student participation. Inclusion criteria will be children from Grades 7 to 9 who assent to participate and for whom parental consent is provided. Students who are unable to take the survey for any reason and/or are unable to stand up long enough to have their height and weight measured (i.e. students who are not cognitively or physically able to participate) will be excluded from the study.

In order to calculate sufficient sample size to ensure representativeness of the study population, the highest available prevalence of overweight and obesity (23.1%) reported among KSA children and adolescents in a study by El Mouzan et al., (25) was used. The following formula was used for sample size calculation: Sample size (n) = $Z1^2 - \alpha/2$ Pq /d² (57). Based on the formula, the required minimum sample size for Intermediate School (12-15 years old), is 273 participants. To factor in 10% non-response rate, a total of 300 students is required for this study. Since this study employed cluster sampling a design effect will be employed. A design effect usually ranges from 1 to 3 (58). Therefore, the design effect of two will be used to reach a sample size of 600. Since this study is targeting both male and female students, the total estimated sample size will be 1200 students (600 males and 600 females).

(b) Interview with school principals and sport teachers

We will aim to recruit six physical education teachers and six principals or deputy principals (one teacher and one principal/deputy from each school; n= 12). Due to cultural reasons, the male principal researcher will conduct face to face interviews with male participants and phone interviews with the female participants.

(c) School Climate Audit

The principal researcher (or the research assistant for female schools) will complete the school audit checklist with the school principal or deputy and one physical education teacher.

Data Collection

(a) Cross-sectional and BMI measurements

The validated self-administrated survey (developed in Phase 2) will collect demographic information and physical activity and nutrition knowledge, attitudes and behaviours. The self-report instrument will be administered via paper or online during class time by the principal researcher (or research assistant in the girls' schools) with the assistance of the classroom teachers in each school.

The height and weight of consenting students will also be measured. The researcher will follow the international standards for anthropometric assessment (59). The BMI for age will be calculated (59). The principal investigator will take the measurements of the male students and female research assistant will be employed to measure female students and both will be trained in correct anthropometric measurement techniques. A calibrated digital measuring scale will be used, and the scale will be reset before measurement. The use of such digital scales has been supported for good accuracy with evidence (60). Student height will be measured using a portable stadiometer set up on a hard, flat surface (61). Privacy will be given to each child so that their measurements are known only to the person taking the measurements. The height and weight data measurement will be written on the individual survey forms.

(b) Interview with school principals and sport teachers

Individual in-depth interviews will be conducted with physical education teachers and principals to explore their beliefs and perceptions of the barriers and enablers to the implementation of school-based interventions focusing on obesity prevention. This is expected to provide a richer understanding of the topic from the point of view of relevant school staff.

The questions will be informed by the results of the systematic review, the cross-sectional study and relevant literature (62–67), and a semi-structured interview guide will be developed. The interview guide will be piloted with two teachers uninvolved in the study to estimate the time the interview can be expected to take and to obtain feedback on the clarity of the interview questions.

The semi-structured one-on-one interviews will be audiotaped, transcribed verbatim, translated and will be reviewed by the researcher and supervisors to maintain dependability and determine credibility (68). The translation process will resume after transcription with an audio converter Arabic to Arabic then the researcher will review all the resulting transcriptions and adjust for accuracy. The principal investigator will translate for the closest intended meaning based on his knowledge of English and Arabic then will get this checked by an Accredited English-Arabic translator.

(c) School Climate Audit

A school climate audit tool will be developed from previous tools based on the Health Promoting Schools (HPS) Framework (33,69) and will be based on the three interrelated components of the HPS Framework: curriculum, teaching and learning; school organisation, ethos and environment; and partnerships and services. (70–72). The tool will be adapted from the items from four studies with acceptable psychometric levels: a tool developed for multiple countries with almost perfect reliability (κ =0.80–0.96) (70); an audit tool focusing on the walkability of school environments with average interrater reliability score from US (κ =0.839) (73); school audit tools used in the IDEA study in the US (74); and the Australian HPS school audit (72). The tool includes whole school strategies relevant to promoting good nutrition and physical activity.

Data Analysis

Phase Two: Survey Analysis:

Survey development (validity and reliability testing)

Validity and reliability during the survey development and the cross-sectional survey will be examined using different types of factor analysis as details are detailed below (Figure 2).

Explanatory factor Analysis

The initial construct validity of the instrument will be established through exploratory factor analysis (EFA), allowing the transformation of correlations among a set of observed variables into each of the six proposed subscales of overweight and obesity (75). EFA will be used to extract factors with eigenvalues > 1, which will then be rotated to identify subscales or factors that best fit the instrument (76) and decisions will be made if the items need to be excluded which is testing the initial construct validity of the instrument. The assumptions should be met where the number of participants is sufficient as literature states that three to 20 people per variable is sufficient to run this EFA analysis (77), the Kaiser-Mayer-Olkin (KMO) (>0.50) and Bartlett's test of sphericity (P<0.05). For the sample size of 120 students, the sufficient factor loading is above 0.50 (78).

Internal consistency

Once the factors are extracted using the EFA, internal consistency of each factor within the instrument and its items will be measured using Cronbach's alpha, an alpha greater than or equal to 0.7 will be considered adequate (79).

Test-retest reliability

The scores and mean scores obtained during the two surveys will be calculated with the Pearson product-moment correlation analysis. Spearman's rho, a measure of agreement between scores on different administrations of the instrument will be calculated and the correlation coefficient between 0.7 and 1.0 indicate that the instrument is reliable or shows consistency across time (80,81).

Phase Three: Mixed Methods Study

(a) Cross-sectional and BMI measurements

Confirmatory factor analysis

In this phase, the construct validity will be assessed using confirmatory factor analysis (CFA). For confirmatory content analysis and explanatory analysis more than 500 or 10 samples per item are sufficient (82). In our study, the sample size calculated is 1200 which is sufficient to undergo confirmatory factor analysis. This construct validity using CFA will indicate whether the subscales of overweight and obesity identified in phase two are valid and is achieved when the fitness indexes is achieved to the required level: Chi-square χ^2 (p-value >0,05), Chi-Square/

df < 3.0, Root Mean Square Error of Approximation (RMSEA) < 0.08), Goodness-of-Fit Index (GFI) > 0.90 comparative fit index (CFI) > 0.90 Normed Fit Index > 0.90 (83). The second stage of EFA analysis at this phase is to identify and estimate whether it fits the model and the degrees of freedom as well. The CFA will be analysed using a powerful structural equation modelling software IBM SPSS Amos. Finally, the model will be rearranged revised to improve the fit as indicated and Akaike Information Criterion (AIC) will be used to compare between model during the fitting process (84).

Descriptive data analysis

 During data entry, exploratory data analysis will be conducted to identify outliers, missing data, describe and check the assumption of normality and distribution of continuous data using histogram and Kolmogorov-Smirnov test and Shapiro-Wilk test (85). The central tendencies will be expressed in mean, median, standard deviations and interquartile range for continuous data while frequencies and percentages will be used to express data for categorical variables. Chi-square tests (χ 2) will assess the associations between each independent variable and overweight and obesity.

Inferential data analysis

Initially, all variables will be analysed univariately and those with p-value more than 0.25 will be included in the model to avoid the possibility of residual cofounders (57). Logistic regression will be employed to analyse the predictors of obesity and overweight (BMI measurements). The significance level will be set at P < 0.05 at 95% confidence interval (CI). Data analysis will be carried out using the Statistical Package for Social Sciences (SPSS) software version 26.0.

(b) Interview with school principals and sport teachers

Content analysis will explore perceptions and experiences, generating rich and in-depth information on the underlying studied phenomena (86). Themes will be identified, and responses coded to elicit shared meanings of perceptions across interviews and to guide the researchers in reporting the results. For this purpose, directed thematic analysis approach will be employed (87). Common themes and subthemes will be identified based on the interview responses (88). The qualitative data will be managed using software package NVivo 12. When

the interview is transcribed, it will be sent back to a sample of consenting participants for verification.

(c) School Climate Audit

The school climate audit will be reviewed by health promotion and education experts from Australia and KSA to determine face and content validity. The tool will be tested with two teachers from the two Intermediate Schools in Jeddah conducting the student survey test-retest. The audit responses will be classified as "implemented", "partially implemented" and "not implemented" and will be tabulated and evaluated section by section.

Patient and public involvement

No patient or public involved.

Ethics and dissemination 🥒

Ethical approval has been granted through Curtin University's Human Research Ethics Committee (HRE2020-0337) and from the KSA Ministry of Education (4181827686). Initially consent will be obtained from the principals of each school involved to allow their school to participate in the study. Individual consent will be sought from teachers, principal/deputy and parents and assent sought from students. Participant information sheets will be provided for the principal describing the school's involvement. All participants (teachers, principals/deputies, students) and parents will be provided individual participant information sheets describing the study and highlighting the voluntary nature of the study.

All information collected from participating schools, principals, teachers and students will be de-identified. Students completing the survey will be assigned an identification (ID) number/code stipulated in the survey prior to data collection so that their BMI can be linked to their survey responses. If surveys are conducted on paper they will be scanned, and originals stored securely until appropriately disposed. All electronic data will be stored on a secure password protected network which can only be accessed by the researchers. Data will be appropriately disposed of after a minimum of seven years after project completion or until the participant has reached 25 years of age (89). Results will be presented as aggregate and there will be no identification of individuals.

This study provides a unique opportunity to inform school-based interventions in KSA. Recommendations will be made to the KSA Ministry of Education regarding the implementation of whole school interventions. Findings will be used to advocate for schoolbased curriculum and policy change at a National level. The tools developed, and the learnings from the study will be made available to individual schools to support school-based planning. Findings will be published as a doctoral thesis, in peer review publications and at conferences. In addition, key findings will be shared with the KSA Ministry of Education, participating schools and to the broader school community through newsletters.

Contributors All authors contributed significantly to the conceptualisation, design and drafting of this protocol. NA, conceived the study which was developed with guidance and support from SB and LP. NA drafted the paper which was critically reviewed and edited by SB and LP. All authors approved the final version of the manuscript.

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Competing interests none declared

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59 60 *Figure 1. Conceptual framework using Socio-ecological Model to inform the study design* Setting

Figure 2: Processes and analysis of survey development and mixed methodology

Instrumentation

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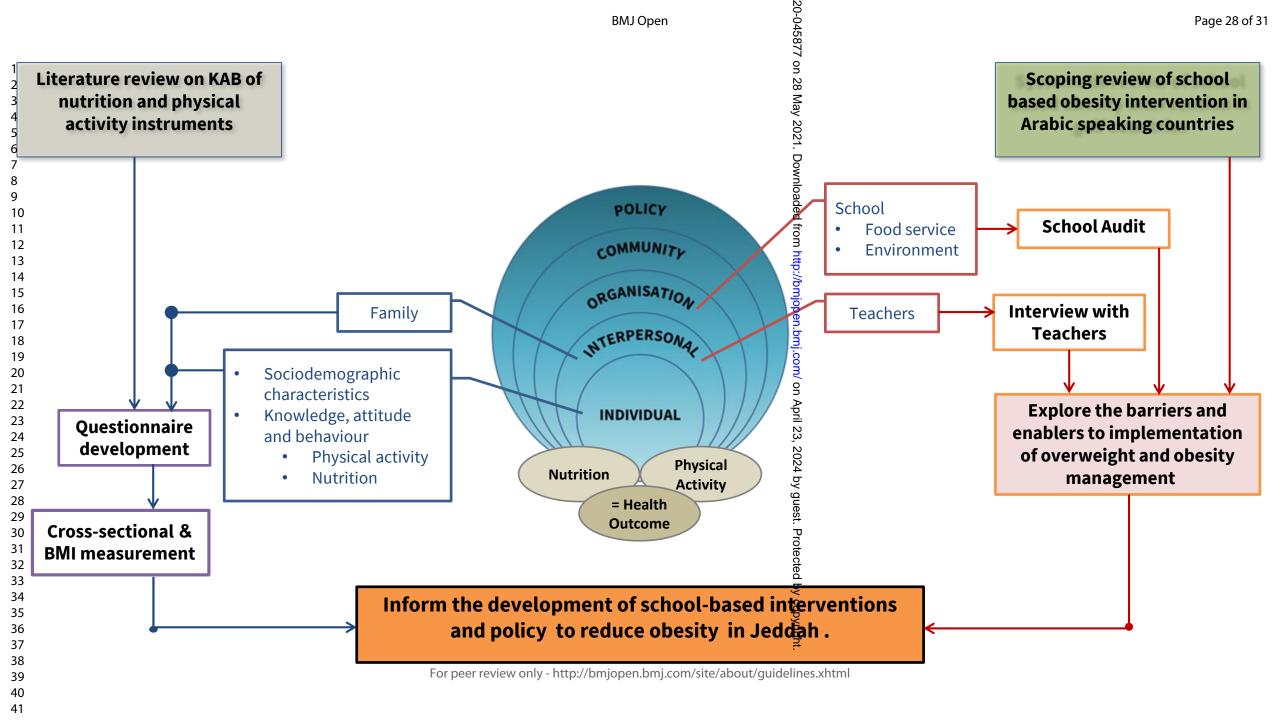
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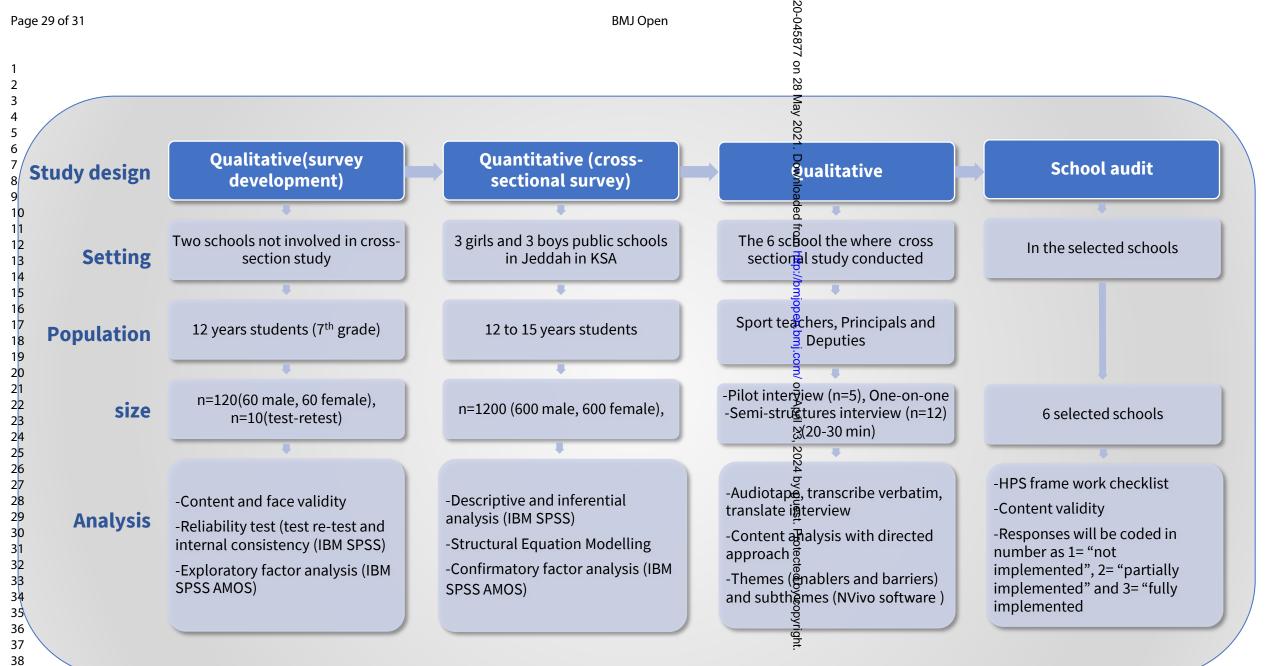
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	STI	ROBE 2007 (v4) Statement—Checklist of items that should be included in reports of <i>cross-sectional studies</i>	
Section/Topic	ltem #	Recommendation 9	Reported on page
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract a_{α}	1-2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction		021.	
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-4
Objectives	3	State specific objectives, including any prespecified hypotheses	
Methods	·		
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	8-9
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9-10
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	8-9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	11-13
		(b) Describe any methods used to examine subgroups and interactions ਰੋ ਰੋ	
		© Explain how missing data were addressed	
		(d) If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses Solution	
Results			

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Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examine of or eligibility,	8-9
rarticipants	15	confirmed eligible, included in the study, completing follow-up, and analysed	8-9
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision deg. 95% confidence	
		interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and	
		magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of any lyses, results from	
		similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	14
		which the present article is based	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in controls in case-control studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine are http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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