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Childhood adversity and deliberate self-poisoning in Sri Lanka: a protocol for a hospital-based case-control study

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Manuscripts

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3 **Childhood adversity and deliberate self-poisoning in Sri Lanka: a protocol for a hospital-based case-**
4 **control study**
5

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ABSTRACT

Introduction:

Childhood adversity (CA) has been suggested as a key risk factor for suicidal behaviour, but evidence from low and middle-income countries (LMIC) is lacking. In Sri Lanka, CA, in the form of child maltreatment or as a consequence of maternal separation, has been highlighted in primarily qualitative or case-series work as a potentially important determinant of suicidal behaviour. To date, there have been no quantitative studies to investigate CA as a key exposure associated with suicidal behaviour in Sri Lanka. The aim of the research is to understand the association between CA and suicidal behaviour in Sri Lanka and to identify potentially modifiable factors to reduce any observed increased risk of suicidal behaviour associated with CA.

Methods and analysis:

This is a hospital-based case-control study. Cases (n=200) will be drawn from individuals admitted to the medical toxicology ward of the Teaching Hospital Peradeniya (THP), Sri Lanka for medical management of intentional self-poisoning. Sex and age frequency matched controls (n=200) will be recruited from either patients or accompanying visitors presenting at the outpatient department and clinic of the same hospital for conditions unrelated to the outcome of interest. Conditional logistic regression will be used to investigate the association between CA and deliberate self-poisoning and whether the association is altered by other key factors including socio-economic status, psychiatric morbidity, current experiences of domestic violence and social support.

Ethics and dissemination:

Ethics approval has been obtained from the Ethical Review Committee of the Faculty of Medicine, University of Peradeniya, Sri Lanka. Researchers have been trained in administering the questionnaire and a participant safety and distress protocol has been designed to guide researchers in ensuring participant safety and how to deal with a distressed participant. Results will be disseminated in local policy fora and peer-reviewed articles, local media, and national and international conferences.

ARTICLE SUMMARY

Strengths and limitations of this study

- This is the first quantitative study to determine the association of childhood adversity and intentional self-harm in Sri Lanka.
- This study will help identify potentially modifiable risk factors to inform the design of interventions and policies to reduce suicidal behaviour in the Sri Lankan context.
- Internationally validated instruments for the assessment of childhood adversity, depression, alcohol use and domestic violence and pretested forms for the assessment of other variables of interest are used.
- Hospital control outpatients may have a different exposure distribution compared to the base-population, introducing the potential for selection bias.
- The reported rate of abuse (childhood and current) may be underestimated due to cultural stigma and recall issues.

INTRODUCTION

Suicide is a significant cause of mortality resulting in approximately 800,000 deaths per year globally, 39% of which occur in the WHO region of South-East Asia.¹ WHO estimates suggest that cases of non-fatal self-harm occur at least 20 times more frequently than the number of suicides.² In the last few decades, Sri Lanka, a middle-income country in South Asia, has experienced significant variations in its suicide rate, reaching its peak in 1995 of 47.0 per 100,000.^{3,4} In response to the magnitude of this public health issue, a Presidential Task Force on Suicide Prevention was established in 1997, whose actions included decriminalising suicidal acts and restricting the availability of pesticides, the most common means of suicide in Sri Lanka.⁵ Although reported rates of suicide have declined over the past two decades, studies of trends in intentional self-harm suggest that incidence of non-fatal intentional self-harm is increasing, especially among young people.^{6,7} A better understanding of the risk factors for suicide and self-harm in these settings is essential for developing informed suicide prevention policies.

Childhood adversity (CA) has been suggested as a key risk factor for suicidal behaviour⁸, but evidence from low and middle-income countries (LMIC) is lacking. Adverse childhood experiences may comprise acts of physical, sexual, emotional abuse as well as emotional and physical neglect and witnessing domestic violence.^{9,10} It has been estimated that 30% of the risk of mental disorders in LMICs is attributable to CA,¹¹ and evidence from high income countries (HIC) reports that CA is a significant risk factor for suicidal behaviour.^{8,12} However, the challenges faced in LMICs are likely to be different, as parental mortality is much higher and the rise in temporary labour migration has resulted in millions of children growing up with one or both parents absent, disrupting parental ties and family structures.¹³ In Sri Lanka, CA, in the form of child maltreatment (e.g. domestic violence), or as a consequence of maternal separation, has been highlighted in primarily qualitative or case-series work as a significant contributor for suicidal behaviour.^{14,15} To date, there have been no quantitative studies to investigate CA as a key exposure associated with suicidal behaviour in Sri Lanka, nor how CA might be associated with suicidal behaviour in the presence of other established socio-demographic and psychiatric risk factors. Current epidemiological evidence is lacking and is urgently needed as Sri Lanka formulates its suicide prevention activities.

The aim of this research is to investigate the association between CA and suicidal behaviour in Sri Lanka, and to identify potentially modifiable factors to reduce any increased risk of suicidal behaviour associated with CA (see Figure 1 – Hypothesised conceptual model of self-harm). The results from this study will help inform the design of appropriate interventions to reduce the number of preventable suicide deaths in this country and thereby also reduce the number of individuals bereaved by suicide.

METHODS AND ANALYSIS

Study setting

The study will be carried out in the Teaching Hospital Peradeniya (THP), located in the Kandy District, Central Province of Sri Lanka. Kandy District has a total population of 1,375,382 and is 115 km east from Colombo, the capital of Sri Lanka.¹⁶ The THP is a tertiary referral hospital with a catchment area that includes the North Central, North Western and Sabaragamuwa Provinces.

Study design

An individually matched hospital-based case-control design will be used in this study. Cases will be drawn from individuals admitted to the medical toxicology ward (ward 17) of the THP (Sri Lanka) for medical management of intentional self-poisoning. This case definition excludes self-harm due to other methods, for example cutting; however self-poisoning represents the most common method of self-harm cases presenting to hospital in Sri Lanka.¹⁷⁻¹⁹

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4 Sex and age frequency matched controls will be drawn from patients and accompanying visitors
5 presenting to the outpatient department of the THP. Outpatients typically present with conditions
6 such as cough, chest infection, hypertension, pregnancy and diabetes related complications,
7 conditions unrelated to the outcome of interest for this study.²⁰ Visitors and patients attending the
8 nearby outpatient clinic for specialist care treatment and management will also be recruited.
9

10 **Inclusion and exclusion criteria**

11 All patients aged 18 years and over, admitted to the study site (ward 17, THP) during the 6-month
12 study period, for medical management of intentional self-poisoning, will be considered for inclusion
13 in the study as a case. Patients and visitors attending the outpatient department and specialist clinics
14 of the THP will be considered for recruitment as controls. All participants will be provided with the
15 participant information sheet and will sign a consent form prior to being enrolled into the study.
16
17

18 Patients who are physically unable or too unwell to participate in the study interview prior to discharge
19 from hospital, and those already diagnosed with an intellectual disability or dementia, will be excluded
20 from the study. Those admitted for management of accidental poisoning will not be recruited.
21 Controls with a previous self-harm episode will not be excluded from the study but this information
22 will be recorded.
23
24

25 **Sample size**

26 The estimated monthly case admission for intentional self-poisoning within ward 17 is approximately
27 100 cases per month. With the aim of collecting 50% of cases per month, we plan to recruit 200 cases
28 in total and 200 age and sex frequency matched controls over a 6-month time period. Assuming 20%
29 of controls report a history of CA (odds=0.25), a 2-fold difference in risk will be detectable with 86%
30 power ($\alpha = 0.05$).^{21,22}
31
32

33 **DATA COLLECTION**

34 The study is expected to recruit participants over a 6-month period. Interviews will be conducted by
35 trained data collectors in the participant's preferred language (Sinhala, Tamil or English). Interviewers
36 are not blinded to the case or control status of the participant, and in order to limit any interviewer
37 bias the interviewers will be given a standard script which they were requested to follow regardless
38 of case status. The supervisor (PB) will regularly shadow interviewers to ensure that the interviewers
39 adhered to the script.
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42

43 Given the nature of the physical layout of the ward and outpatient department, and the sensitivity of
44 the questions, interviews will only be conducted with the participant if they are able to accompany
45 the data collector to a designated confidential space nearby, for interview. This ensures that the
46 interview can be conducted in private and in the absence of accompanying friends or family members.
47 Interviews will be conducted during non-visiting hours for patients in ward 17 to ensure responses will
48 not be influenced by another person and for patient safety.
49
50

51 **Questionnaires**

52 **Main exposure**

53 The main exposure of interest in this study is childhood adversity. Childhood adversity data will be
54 collected using the WHO Adverse Childhood Experiences International Questionnaire, a culturally
55 adapted screening tool for childhood adversity.²³ The questionnaire is designed for administration to
56 people over the age of 18. Questions cover family dysfunction; physical, sexual and emotional abuse
57 and neglect by parents or caregivers; peer violence; witnessing community violence, and exposure to
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collective violence. The English questionnaire has been translated, back-translated and previously piloted into the two local languages.

In addition to the questions included in the WHO questionnaire, participants will be asked pretested questions about their experiences of parental (mother/father) absence due to temporary foreign migration during the first 18 years of life.

Confounders and other study factors

Demographic data will be collected using a pretested questionnaire. Data on age, sex, ethnicity, religion, marital status, residential area, household composition, parenting status (i.e. presence and number of children and age of youngest child) will be collected. Employment status will also be ascertained, and a description of participant occupation will be defined based on the following categories, 'elementary occupation', 'armed forces', 'craft or related trades worker', 'skilled agricultural worker', 'service worker', 'technician', 'small business holder', 'big business holder', 'professional', 'manager/legislator/administration'.

For socioeconomic position, data will be collected on individual educational attainment, parental education and motorised vehicle ownership (a proxy measure of household socioeconomic position). For individual and parental educational attainment, participants will be asked to select the highest completed level of education from the following categories, 'no schooling', 'completed between grades 1-5', 'completed between grades 6-10', 'passed ordinary level', 'passed advanced level', 'completed university/postgraduate qualifications'. For motorised vehicle ownership, participants will be asked if they own a motorbike, three-wheeler vehicle, car/van, tractor, and/or a bus.

Information on the type of poison ingested for the current self-harm episode will be collected based on the following categories: 'medicinal overdose', 'pesticide ingestion', 'plant poison', 'petroleum-based products', 'rat poison', 'other household chemical', or 'other'. Where possible, participants will be asked to specify the name of the poison ingested.

Data on past self-harm behaviour, including if the participant has previously self-harmed or if they know of a close friend or family member who has self-harmed or died by suicide will also be collected. Past psychiatric morbidity (i.e. diagnosed with a mental disorder) and whether or not the participant experiences existing comorbidities, such as chronic illness and physical disabilities, will also be collected.

Data on current psychiatric morbidity will also be collected. Participants will be asked to complete the 9-item Patient Health Questionnaire (PHQ-9). The PHQ-9 is a brief, one-page self-administered questionnaire, that is internationally validated for assessing the severity of depression. The PHQ-9 has been translated and validated for use in the Sinhala-speaking Sri Lankan population.²⁴ The translated questionnaire has previously been used in the National Mental Health Survey of Sri Lanka for both Sinhala and Tamil populations.²⁵

Information on alcohol use disorders will be collected, based on the Alcohol Use Disorders Identification Test (AUDIT), which has been developed by the WHO and also been validated for the local population,²⁶ and has been previously used in Sri Lanka. The AUDIT comprises questions related to the frequency and quantity of alcohol consumption and the effect of alcohol consumption on behaviour.

Participants will also be asked if they have learned about sexual and reproductive health rights through school and if the information delivered was useful. In addition, data on current exposure to domestic violence will be collected using a translated, back-translated and piloted version of the 4-question

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3 HARK questionnaire.²⁷ The four short questions aim to capture different components of domestic
4 violence, relating to emotional abuse, psychological abuse, sexual, and physical violence.
5

6
7 Finally, participants will also be asked questions relating to their social capital, including their
8 emotional support networks and sense of belonging. The questions used in this survey are questions
9 that have been used as part of a large social capital community survey in the North Central Province
10 of Sri Lanka.²⁸ Questions are designed to capture whether participants are currently emotionally
11 supported at the household and community levels and if they feel a sense of belonging. Information
12 will also be collected on past social capital based on a sense of belonging at school, and interaction
13 with peers and teachers.^{29,30}
14

15 **Analysis plan**

16 Conditional logistic regression techniques will be used to examine the association between CA and
17 deliberate self-poisoning (outcome). In the primary analysis, CA will be quantified using the total score
18 of the WHO Adverse Childhood Experiences International Questionnaire, and unadjusted associations
19 with the outcome will be presented. Additionally, separate analyses will be conducted using questions
20 about parental absence (a proxy for CA) and including both the WHO questionnaire and the questions
21 about parental absence as separate covariates in the model to explore the partial association of each
22 with the outcome.
23

24
25 The study will investigate the potential confounding effects of parental education, ethnicity and
26 religion in a series of models. Potential confounders will be specified as covariates in models with
27 measures of CA and parental absence as the main exposures of interest, following investigation of
28 univariate associations between each potential confounder and self-harm. Additional key factors, such
29 as current socio-economic status, marital and parental status, psychiatric morbidity, current
30 experiences of domestic violence and social support, will also be incorporated to investigate potential
31 effect measure changes. The statistical software Stata version 15³¹ will be used for data analysis.
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33

34 **ETHICS**

35
36 Each participant will be given a verbal explanation of the study with a written information sheet and
37 their permission to participate will be sought via written informed consent. Participants will be
38 informed during their consent process that they have the right to withdraw at any time during or after
39 the interview.
40

41
42 The study includes questions related to self-harm, CA and current domestic violence which may result
43 in participant distress. A participant safety and distress protocol has been designed to guide
44 researchers in ensuring participant safety and how to deal with a distressed participant. With regards
45 to risk of self-harm, the protocol advises that if the participant reports experiencing suicidal thoughts
46 daily during the preceding two weeks, they will be referred to the Psychiatry Clinic, THP held every
47 Thursday for further management and follow up. Where project staff have reason to believe that the
48 participant is at an immediate risk to themselves or others, the psychiatric on-call doctor will be
49 notified. Participants are informed that they are eligible to withdraw from the study at any point, and
50 that this will have no adverse effect on their medical or psychiatric management or follow up. All
51 interviews will be conducted in a manner that ensures that the participants' usual medical treatment
52 or care does not get delayed or adversely impacted due to study participation.
53

54
55 If during the completion of this questionnaire the participant discloses a child safeguarding issue (i.e.
56 current sexual abuse of a child, under the age of 18), project staff will notify the principal investigator
57 (DWK) and the local principal investigator (TR) will inform the National Child Protection Authority
58 (NCPA), as appropriate. Participants will be informed during the consent process that such disclosures
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3 will result in notification. The circumstances under which confidentiality would be broken will be
4 explained to the participant during the informed consent process.
5

6 Participants will be asked questions about domestic abuse, and if these questions are asked in the
7 presence of the perpetrator of that abuse or other family members this may have adverse outcomes
8 for the participant. In recognition of this risk, the interview will only be conducted in private during
9 non-visiting hours and in a private location in the hospital. If current domestic abuse is disclosed, the
10 participant will be offered information about help available locally and if appropriate, the patient will
11 also be offered a referral to the psychiatry clinic.
12
13

14 **DISSEMINATION**

15
16 Findings from this research will be published academically in peer-reviewed articles and will also be
17 given publicity in the local media. Findings may also be disseminated at national and international
18 conferences, health symposia and local policy fora, for example, local government and non-
19 government agencies. Any participant who is interested can also receive a copy of the report of the
20 research and the outcomes from the investigators.
21
22

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33
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36 **Competing interests**

37 None declared.
38

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44

45 **Ethics approval**

46 Ethics approval was granted from the Ethical Review Committee of the Faculty of Medicine, University
47 of Peradeniya, Sri Lanka, on 14 June 2018.
48

49 **Author contributions**

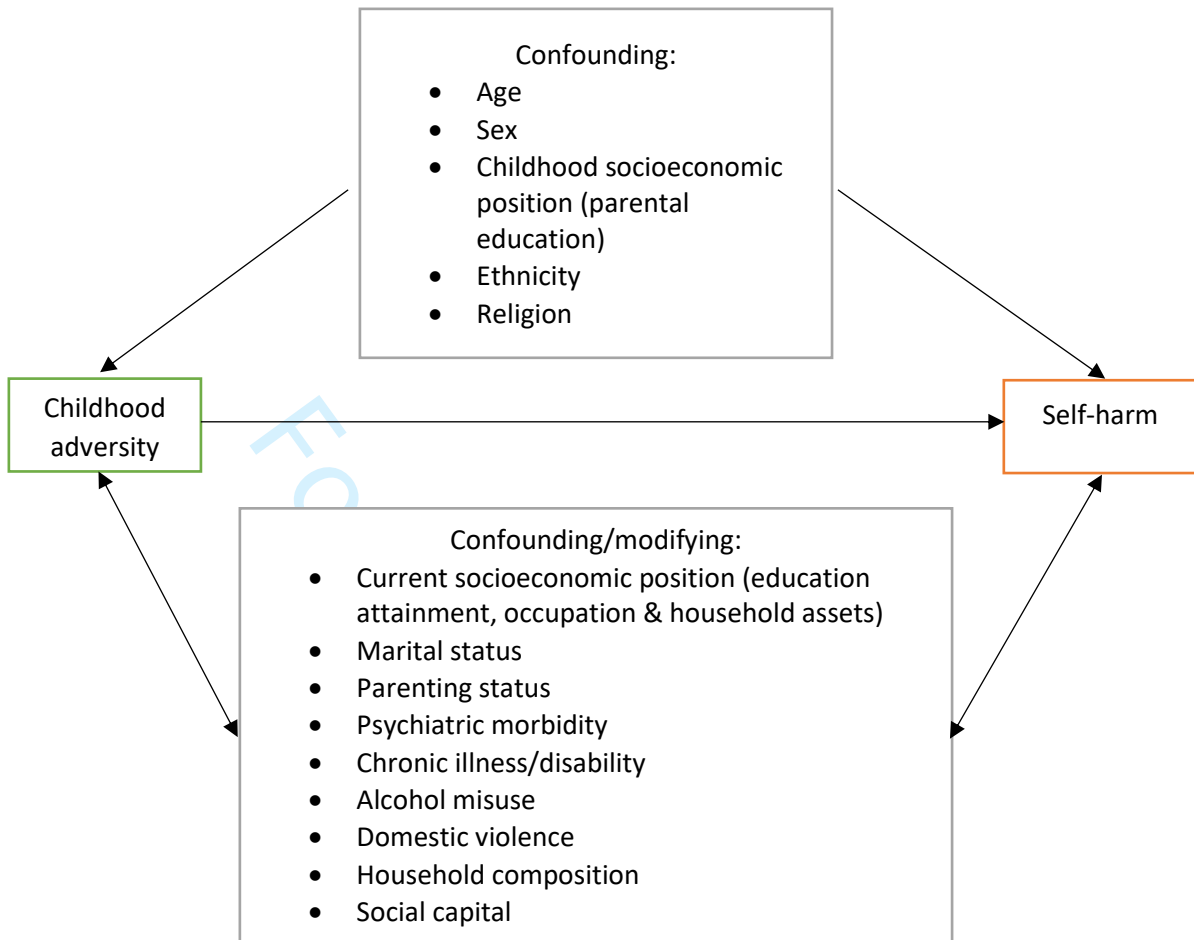
50 DWK, LS, JK, JLL and TR were responsible for study concept, design and funding acquisition. DWK and
51 TR wrote the protocol. PB drafted the manuscript and coordinated manuscript preparation and
52 revision. DWK, TR and PB were responsible for piloting the survey, and PB is responsible for supervising
53 data collection. All authors provided critical evaluation and revision of the manuscript and have given
54 final approval of the manuscript accepting responsibility for all aspects.
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Figure 1 – Hypothesised conceptual model of self-harm



STROBE Statement—Checklist of items that should be included in reports of *case-control studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3, 4
Participants	6	(a) Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	4
		(b) For matched studies, give matching criteria and the number of controls per case	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4,5
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	4,5
Bias	9	Describe any efforts to address potential sources of bias	4
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	N/A
		(d) If applicable, explain how matching of cases and controls was addressed	6
		(e) Describe any sensitivity analyses	6
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N/A
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers in each exposure category, or summary measures of exposure	N/A

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3	Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
4			N/A
5			
6			
7			(b) Report category boundaries when continuous variables were categorized
8			N/A
9			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
10			N/A
11	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
12			N/A
13			
14			
15	Discussion		
16	Key results	18	Summarise key results with reference to study objectives
17			N/A
18	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
19			N/A
20	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
21			N/A
22	Generalisability	21	Discuss the generalisability (external validity) of the study results
23			N/A
24	Other information		
25	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
26			7
27			
28			

*Give information separately for cases and controls.

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.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.

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Childhood adversity and deliberate self-poisoning in Sri Lanka: a protocol for a hospital-based case-control study

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3 **Childhood adversity and deliberate self-poisoning in Sri Lanka: a protocol for a hospital-based case-**
4 **control study**
5

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ABSTRACT

Introduction:

Childhood adversity (CA) has been suggested as a key risk factor for suicidal behaviour, but evidence from low and middle-income countries (LMIC) is lacking. In Sri Lanka, CA, in the form of child maltreatment or as a consequence of maternal separation, has been highlighted in primarily qualitative or case-series work as a potentially important determinant of suicidal behaviour. To date, there have been no quantitative studies to investigate CA as a key exposure associated with suicidal behaviour in Sri Lanka. The aim of the research is to understand the association between CA and suicidal behaviour in Sri Lanka and to identify potentially modifiable factors to reduce any observed increased risk of suicidal behaviour associated with CA.

Methods and analysis:

This is a hospital-based case-control study. Cases (n=200) will be drawn from individuals admitted to the medical toxicology ward of the Teaching Hospital Peradeniya (THP), Sri Lanka for medical management of intentional self-poisoning. Sex and age frequency matched controls (n=200) will be recruited from either patients or accompanying visitors presenting at the outpatient department and clinic of the same hospital for conditions unrelated to the outcome of interest. Conditional logistic regression will be used to investigate the association between CA and deliberate self-poisoning and whether the association is altered by other key factors including socio-economic status, psychiatric morbidity, current experiences of domestic violence and social support.

Ethics and dissemination:

Ethics approval has been obtained from the Ethical Review Committee of the Faculty of Medicine, University of Peradeniya, Sri Lanka. Researchers have been trained in administering the questionnaire and a participant safety and distress protocol has been designed to guide researchers in ensuring participant safety and how to deal with a distressed participant. Results will be disseminated in local policy fora and peer-reviewed articles, local media, and national and international conferences.

ARTICLE SUMMARY

Strengths and limitations of this study

- This is the first quantitative study to determine the association of childhood adversity and deliberate self-harm in Sri Lanka.
- This study will help identify potentially modifiable risk factors to inform the design of interventions and policies to reduce suicidal behaviour in the Sri Lankan context.
- Internationally validated instruments for the assessment of childhood adversity, depression, alcohol use and domestic violence and pretested forms for the assessment of other variables of interest are used.
- Hospital control outpatients may have a different exposure distribution compared to the base-population – for example they may have higher rates of mood disorders and suicidal ideation, introducing the potential for selection bias.
- The reported rate of abuse (childhood and current) may be underestimated due to cultural stigma and recall issues.

INTRODUCTION

Suicide is a significant cause of mortality resulting in approximately 800,000 deaths per year globally, 39% of which occur in the WHO region of South-East Asia.¹ WHO estimates suggest that cases of non-fatal self-harm occur at least 20 times more frequently than the number of suicides.² In the last few decades, Sri Lanka, a middle-income country in South Asia, has experienced significant variations in its suicide rate, reaching its peak in 1995 of 47.0 per 100,000.^{3 4} In response to the magnitude of this public health issue, a Presidential Task Force on Suicide Prevention was established in 1997, whose actions included decriminalising suicidal acts and restricting the availability of pesticides, the most common means of suicide in Sri Lanka.⁵ Although reported rates of suicide have declined over the past two decades, studies of trends in intentional self-harm suggest that incidence of non-fatal intentional self-harm is increasing, especially among young people.^{6 7} A better understanding of the risk factors for suicide and self-harm in these settings is essential for developing informed suicide prevention policies.

Childhood adversity (CA) has been suggested as a key risk factor for suicidal behaviour⁸, but evidence from low and middle-income countries (LMIC) is lacking. Adverse childhood experiences may comprise acts of physical, sexual, emotional abuse as well as emotional and physical neglect and witnessing domestic violence.^{9 10} It has been estimated that 30% of the risk of mental disorders in LMICs is attributable to CA,¹¹ and evidence from high income countries (HIC) reports that CA is a significant risk factor for suicidal behaviour.^{8 12} However, the challenges faced in LMICs are likely to be different, as parental mortality is much higher and the rise in temporary labour migration has resulted in millions of children growing up with one or both parents absent, disrupting parental ties and family structures.¹³ In Sri Lanka, CA, in the form of child maltreatment (e.g. domestic violence), or as a consequence of maternal separation, has been highlighted in primarily qualitative or case-series work as a significant contributor for suicidal behaviour.^{14 15} To date, there have been no quantitative studies to investigate CA as a key exposure associated with suicidal behaviour in Sri Lanka, nor how CA might be associated with suicidal behaviour in the presence of other established socio-demographic and psychiatric risk factors. Current epidemiological evidence is lacking and is urgently needed as Sri Lanka formulates its suicide prevention activities.

The aim of this research is to investigate the association between CA and suicidal behaviour in Sri Lanka, and to identify potentially modifiable factors to reduce any increased risk of suicidal behaviour associated with CA (see Figure 1 – Hypothesised conceptual model of self-harm). The results from this study will help inform the design of appropriate interventions to reduce the number of preventable suicide deaths in this country and thereby also reduce the number of individuals bereaved by suicide.

METHODS AND ANALYSIS

Study setting

The study will be carried out in the Teaching Hospital Peradeniya (THP), located in the Kandy District, Central Province of Sri Lanka. Kandy District has a total population of 1,375,382 and is 115 km east from Colombo, the capital of Sri Lanka.¹⁶ The THP is a tertiary referral hospital with a catchment area that includes the North Central, North Western and Sabaragamuwa Provinces.

Patient and Public Involvement

Priority of the research question, choice of outcome measures and questionnaire design were informed by discussions with community members. At the end of a previous study exploring the association between socioeconomic position and suicidal behaviour in Sri Lanka,¹⁷ ten community workshops were conducted in a rural area with a high risk of suicide. The workshops were conducted with community members aged 18 years and over, representing both sexes. A wide range of

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3 stakeholders were engaged including: teachers, social workers, Grama Niladhari (village officers),
4 community leaders/members, national government officials (Ministry of Health, Education, Social and
5 Welfare), non-governmental agencies, researchers and charities.¹⁸ During the workshops community
6 members engaged in discussions on the possible pathways to suicidal behaviour. In all ten workshops,
7 child abuse, maltreatment and neglect were highlighted as important risk factors on the causal
8 pathway and in the intergenerational cycle of poverty and heightened suicide risk. These discussions
9 informed the design of the questionnaire and planned analysis in terms of factors considered as
10 exposures and confounders. The questionnaire used in this study was also piloted with patients in the
11 toxicology unit and outpatient department of the THP and revised as a result.
12
13

14 **Study design**

15 An individually matched hospital-based case-control design will be used in this study. Cases will be
16 drawn from individuals admitted to the medical toxicology ward (ward 17) of the THP (Sri Lanka) for
17 medical management of deliberate self-poisoning. All persons presenting to the THP due to poisoning
18 (accidental or deliberate) for emergency care are admitted to the toxicology unit (ward 17) for
19 observation and treatment as needed. This case definition excludes self-harm due to other methods,
20 for example cutting; however self-poisoning represents the most common method of self-harm cases
21 presenting to hospital in Sri Lanka.¹⁹⁻²¹
22
23

24 Sex and age frequency matched controls will be drawn from patients and accompanying visitors
25 presenting to the outpatient department of the THP. Outpatients typically present with conditions
26 such as cough, chest infection, hypertension, pregnancy and diabetes related complications,
27 conditions unrelated to the outcome of interest for this study.²² Visitors and patients attending the
28 nearby outpatient clinic for specialist care treatment and management will also be recruited.
29
30

31 **Inclusion and exclusion criteria**

32 All patients aged 18 years and over, admitted to the study site (ward 17, THP) during the 6-month
33 study period, for medical management of deliberate self-poisoning, will be considered for inclusion in
34 the study as a case. Patients and visitors attending the outpatient department and specialist clinics of
35 the THP will be considered for recruitment as controls. All participants will be provided with the
36 participant information sheet and will sign a consent form prior to being enrolled into the study.
37
38

39 Patients who are physically unable or too unwell to participate in the study interview prior to discharge
40 from hospital, and those already diagnosed with an intellectual disability or dementia, will be excluded
41 from the study. Those admitted for management of accidental poisoning will not be recruited.
42 Accidental poisoning will be initially ascertained from the patient admission record and verbally
43 reconfirmed by the patient through self-report.
44
45

46 As the focus of this study is on current suicidal behaviour, controls with a previous self-harm episode
47 will not be excluded from the study but this information will be recorded. For every control with a
48 previous self-harm episode, another control matched by sex and age with no previous self-harm will
49 be recruited; and cases with a previous history of self-harm can be excluded in sensitivity analyses.
50
51

52 **Sample size**

53 The estimated monthly case admission for intentional self-poisoning within ward 17 is approximately
54 100 cases per month. With the aim of collecting 50% of cases per month, we plan to recruit 200 cases
55 in total and 200 age and sex frequency matched controls over a 6-month time period. Assuming 20%
56 of controls report a history of CA (odd=0.25), a 2-fold difference in risk will be detectable with 86%
57 power ($\alpha = 0.05$).^{11 23}
58
59

60 **DATA COLLECTION**

1
2
3 The study is expected to recruit participants over a 6-month period, from 18 July 2018 to 10 January
4 2019. Interviews will be conducted by trained data collectors in the participant's preferred language
5 (Sinhala, Tamil or English). Interviewers are not blinded to the case or control status of the participant
6 and the same interviewers who recruit cases will also recruit controls. In order to minimise interviewer
7 bias the interviewers will be given a standard script which they are requested to follow regardless of
8 case status. The supervisor (PB) will regularly shadow interviewers to ensure that the interviewers
9 adhered to the script.
10

11
12 Given the nature of the physical layout of the ward and outpatient department, and the sensitivity of
13 the questions, interviews will only be conducted with the participant if they are able to accompany
14 the data collector to a designated confidential space nearby, for interview. This ensures that the
15 interview can be conducted in private and in the absence of accompanying friends or family members.
16 Interviews will be conducted during non-visiting hours for patients in ward 17 to ensure responses will
17 not be influenced by another person and for patient safety.
18

19 20 **Questionnaires**

21 **Main exposure**

22 The main exposure of interest in this study is childhood adversity. Childhood adversity data will be
23 collected using the WHO Adverse Childhood Experiences International Questionnaire, a culturally
24 adapted screening tool for childhood adversity.²⁴ The questionnaire is designed for administration to
25 people over the age of 18. Questions cover family dysfunction; physical, sexual and emotional abuse
26 and neglect by parents or caregivers; peer violence; witnessing community violence, and exposure to
27 collective violence. The English questionnaire has been translated, back-translated and previously
28 piloted into the two local languages.
29

30
31 In addition to the questions included in the WHO questionnaire, participants will be asked pretested
32 questions about their experiences of parental (mother/father) absence due to temporary foreign
33 migration during the first 18 years of life.
34

35 **Confounders and other study factors**

36 Demographic data will be collected using a pretested questionnaire. Data on age, sex, ethnicity,
37 religion, marital status, residential area, household composition, parenting status (i.e. presence and
38 number of children and age of youngest child) will be collected. Employment status will also be
39 ascertained, and a description of participant occupation will be defined based on the following
40 categories, 'elementary occupation', 'armed forces', 'craft or related trades worker', 'skilled
41 agricultural worker', 'service worker', 'technician', 'small business holder', 'big business holder',
42 'professional', 'manager/legislator/administration'.
43

44
45 For socioeconomic position, data will be collected on individual educational attainment, parental
46 education and motorised vehicle ownership (a proxy measure of household socioeconomic position).
47 For individual and parental educational attainment, participants will be asked to select the highest
48 completed level of education from the following categories, 'no schooling', 'completed between
49 grades 1-5', 'completed between grades 6-10', 'passed ordinary level', 'passed advanced level',
50 'completed university/postgraduate qualifications'. For motorised vehicle ownership, participants will
51 be asked if they own a motorbike, three-wheeler vehicle, car/van, tractor, and/or a bus.
52

53
54 Information on the type of poison ingested for the current self-harm episode will be collected based
55 on the following categories: 'medicinal overdose', 'pesticide ingestion', 'plant poison', 'petroleum-
56 based products', 'rat poison', 'other household chemical', or 'other'. Where possible, participants will
57 be asked to specify the name of the poison ingested.
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3 Data on past self-harm behaviour will be collected via self-report. Participants will be asked if they
4 have ever previously self-harmed. This will be recorded regardless of whether or not the episode
5 resulted in hospital presentation. Participants will also be asked if they know of a close friend or family
6 member who has self-harmed or died by suicide during the past year. Past psychiatric morbidity (i.e.
7 diagnosed with a mental disorder) and whether or not the participant experiences existing
8 comorbidities, such as chronic illness and physical disabilities, will also be collected.
9

10
11 Data on current psychiatric morbidity will also be collected. Participants will be asked to complete the
12 9-item Patient Health Questionnaire (PHQ-9). The PHQ-9 is a brief, one-page self-administered
13 questionnaire, that is internationally validated for assessing the severity of depression. The PHQ-9 has
14 been translated and validated for use in the Sinhala-speaking Sri Lankan population.²⁵ The translated
15 questionnaire has previously been used in the National Mental Health Survey of Sri Lanka for both
16 Sinhala and Tamil populations.²⁶
17

18
19 Information on alcohol use disorders will be collected, based on the Alcohol Use Disorders
20 Identification Test (AUDIT), which has been developed by the WHO and also been validated for the
21 local population,²⁷ and has been previously used in Sri Lanka. The AUDIT comprises questions related
22 to the frequency and quantity of alcohol consumption and the effect of alcohol consumption on
23 behaviour. Suicidal intention and lethality of the attempt will not be assessed due to constraints on
24 the length of the questionnaire.
25

26 Participants will also be asked if they have learned about sexual and reproductive health rights through
27 school and if the information delivered was useful. In addition, data on current exposure to domestic
28 violence will be collected using a translated, back-translated and piloted version of the 4-question
29 HARK questionnaire.²⁸ The four short questions aim to capture different components of domestic
30 violence, relating to emotional abuse, psychological abuse, sexual, and physical violence.
31

32 Finally, participants will also be asked questions relating to their social capital, including their
33 emotional support networks and sense of belonging. The questions used in this survey are questions
34 that have been used as part of a large social capital community survey in the North Central Province
35 of Sri Lanka.²⁹ Questions are designed to capture whether participants are currently emotionally
36 supported at the household and community levels and if they feel a sense of belonging. Information
37 will also be collected on past social capital based on a sense of belonging at school, and interaction
38 with peers and teachers.^{30 31}
39

40 41 **Analysis plan** 42

43
44 To ensure that questionnaires are as complete as possible, the supervisor (PB) will review data
45 missingness on a regular basis to ensure that data collectors are not consistently missing information.
46 Once the data collection has been finalised, the level of missingness will be assessed. It is anticipated
47 that any missingness will not be missing at random (a requirement for imputation) and therefore
48 missing data will not be imputed in the main analyses. Instead, it is anticipated that our main analyses
49 will be based on complete cases only, excluding case-control pairs that contain missing data. A full
50 case analysis (regardless of missing) will be conducted to explore whether excluding case-control pairs
51 with missing data might have introduced bias in the results.
52

53
54 Conditional logistic regression techniques will be used to examine the association between CA and
55 deliberate self-poisoning (outcome). In the primary analysis, CA will be quantified using the total score
56 of the WHO Adverse Childhood Experiences International Questionnaire, and unadjusted associations
57 with the outcome will be presented. Additionally, separate analyses will be conducted using questions
58 about parental absence (a proxy for CA) and including both the WHO questionnaire and the questions
59
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1
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3 about parental absence as separate covariates in the model to explore the partial association of each
4 with the outcome.
5

6
7 The study will investigate the potential confounding effects of parental education, ethnicity and
8 religion in a series of models. Potential confounders will be specified as covariates in models with
9 measures of CA and parental absence as the main exposures of interest, following investigation of
10 univariate associations between each potential confounder and self-harm. Additional key factors, such
11 as current socio-economic status, marital and parental status, psychiatric morbidity, current
12 experiences of domestic violence and social support, will also be incorporated to investigate potential
13 effect measure changes. The statistical software Stata version 15³² will be used for data analysis.
14

15 **ETHICS**

16
17 Each participant will be given a verbal explanation of the study with a written information sheet (in
18 their native language) and they will be given time to read it. Permission to recruit will be sought via
19 written informed consent. Participants will be informed during their consent process that the
20 interview is voluntary and that they have the right to withdraw at any time during or after the
21 interview. Participants will also be informed about the purpose of the study, the members of the
22 research team, the reason they have been chosen for the study, consequences of participation
23 (potential benefits and disadvantages), confidentiality, potential outcomes of the research, and
24 contact details of the Principal Investigator for further information. If the researcher suspects that the
25 participant does not have the cognitive functioning to give informed consent, the individual will not
26 be recruited for the study.
27
28
29

30 The study includes questions related to self-harm, CA and current domestic violence which may result
31 in participant distress. A participant safety and distress protocol has been designed to guide
32 researchers in ensuring participant safety and how to deal with a distressed participant. With regards
33 to risk of self-harm, the protocol advises that if the participant reports experiencing suicidal thoughts
34 daily during the preceding two weeks, they will be referred to the Psychiatry Clinic, THP held every
35 Thursday for further management and follow up. Where project staff have reason to believe that the
36 participant is at an immediate risk to themselves or others, the psychiatric on-call doctor will be
37 notified. Participants are informed that they are eligible to withdraw from the study at any point, and
38 that this will have no adverse effect on their medical or psychiatric management or follow up. All
39 interviews will be conducted in a manner that ensures that the participants' usual medical treatment
40 or care does not get delayed or adversely impacted due to study participation.
41
42
43

44 If during the completion of this questionnaire the participant discloses a child safeguarding issue (i.e.
45 current sexual abuse of a child, under the age of 18), project staff will notify the principal investigator
46 (DWK) and the local principal investigator (TR) will inform the National Child Protection Authority
47 (NCPA), as appropriate. Participants will be informed during the consent process that such disclosures
48 will result in notification. The circumstances under which confidentiality would be broken will be
49 explained to the participant during the informed consent process.
50
51

52 Participants will be asked questions about domestic abuse, and if these questions are asked in the
53 presence of the perpetrator of that abuse or other family members this may have adverse outcomes
54 for the participant. In recognition of this risk, the interview will only be conducted in private during
55 non-visiting hours and in a private location in the hospital. If current domestic abuse is disclosed, the
56 participant will be offered information about help available locally and if appropriate, the patient will
57 also be offered a referral to the psychiatry clinic.
58
59
60

DISSEMINATION

Findings from this research will be published academically in peer-reviewed articles and will also be given publicity in the local media. Findings may also be disseminated at national and international conferences, health symposia and local policy fora, for example, local government and non-government agencies. Any participant who is interested can also receive a copy of the report of the research and the outcomes from the investigators.

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Competing interests

None declared.

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Ethics approval

Ethics approval was granted from the Ethical Review Committee of the Faculty of Medicine, University of Peradeniya, Sri Lanka, on 14 June 2018.

Author contributions

DWK, LS, JK, JLL and TR were responsible for study concept, design and funding acquisition. DWK and TR wrote the protocol. PB drafted the manuscript and coordinated manuscript preparation and revision. DWK, TR and PB were responsible for piloting the survey, and PB is responsible for supervising data collection. All authors provided critical evaluation and revision of the manuscript and have given final approval of the manuscript accepting responsibility for all aspects.

Figure 1 – Hypothesised conceptual model of self-harm

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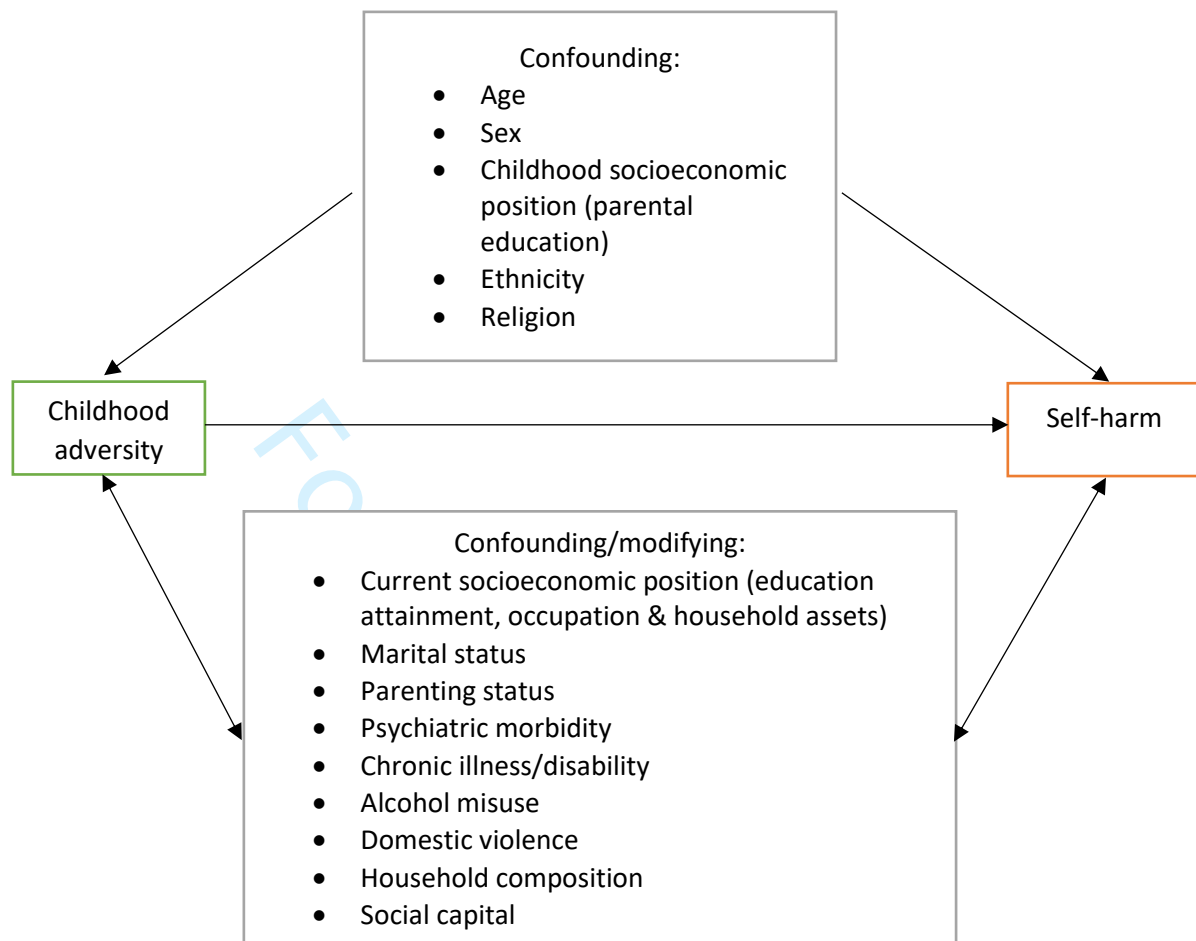
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Figure 1 – Hypothesised conceptual model of self-harm



STROBE Statement—Checklist of items that should be included in reports of *case-control studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3, 4
Participants	6	(a) Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	4
		(b) For matched studies, give matching criteria and the number of controls per case	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4,5
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	4,5
Bias	9	Describe any efforts to address potential sources of bias	4
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	N/A
		(d) If applicable, explain how matching of cases and controls was addressed	6
		(e) Describe any sensitivity analyses	6
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N/A
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers in each exposure category, or summary measures of exposure	N/A

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3	Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
4			N/A
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7			(b) Report category boundaries when continuous variables were categorized
8			N/A
9			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
10			N/A
11	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
12			N/A
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15	Discussion		
16	Key results	18	Summarise key results with reference to study objectives
17			N/A
18	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
19			N/A
20	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
21			N/A
22	Generalisability	21	Discuss the generalisability (external validity) of the study results
23			N/A
24	Other information		
25	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
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*Give information separately for cases and controls.

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.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.