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Alcohol-related harm in rural and remote communities: protocol for a scoping review

Journal:	BMJ Open
Manuscript ID	bmjopen-2019-036753
Article Type:	Protocol
Date Submitted by the Author:	31-Dec-2019
Complete List of Authors:	Friesen, Erik; University of Toronto, Institute of Health Policy, Management & Evaluation Kurdyak, Paul; Centre for Addiction and Mental Health,
Keywords:	MENTAL HEALTH, PUBLIC HEALTH, Substance misuse < PSYCHIATRY

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Title: Alcohol-related harm in rural and remote communities: protocol for a scoping review

Authors: Erik Loewen Friesen, Paul Kurdyak

Author Information

Erik Loewen Friesen

Email: erik.friesen@mail.utoronto.ca

Affiliations:

- Institute of Health Policy Management & Evaluation, University of Toronto (Toronto, Canada)
- Faculty of Medicine, University of Toronto (Toronto, Canada)

Paul Kurdyak

Email: Paul.Kurdyak@camh.ca

Affiliations:

- Institute of Health Policy Management & Evaluation, University of Toronto (Toronto, Canada)
- Centre for Addiction & Mental Health (Toronto, Canada)

Corresponding Author

Erik Loewen Friesen

Institute of Health Policy, Management & Evaluation, University of Toronto (Toronto, Canada)

155 College St 4th Floor, Toronto, ON, Canada M5T 3M6

Email: erik.friesen@mail.utoronto.ca

Phone: 1-647-938-2413

Word Count (excluding title page, abstract, references, figures and tables): 2,387

Abstract

Introduction Alcohol-related harm is a major public health concern and appears to be particularly problematic in rural and remote communities. Evidence from several countries has shown that the prevalence of harmful alcohol use and alcohol-attributable hospitalizations and emergency department visits are higher in rural and remote communities than in urban centers. The extent of this rural-urban disparity in alcohol-related harm as well as the factors that mediate it are poorly understood. The objective of this scoping review is to synthesize the international research on the factors that influence the prevalence or risk of alcohol-related harm in rural and remote communities. This will help to clarify the conceptual landscape of rural and remote alcohol research and identify the gaps in knowledge that need to be addressed.

Methods and Analysis This scoping review will access published literature through search strategies developed for Medline, PsychINFO, Embase, CINAHL and Sociological Abstracts. Title-and-abstract, followed by full-text screening will be conducted by two independent reviewers to evaluate all identified articles against a set of pre-specified inclusion and exclusion criteria. Data from selected articles will be extracted and compiled into a final manuscript that adheres to the PRIMSA extension for Scoping Reviews (PRSMA-ScR) checklist guidelines.

Ethics and Dissemination The results of this review will be helpful in guiding future research on rural and remote alcohol use and alcohol-related harm, which will inform more effective, evidence-based public health strategies to reduce alcohol-related harm in rural and remote communities. The results will be disseminated via field-specific conference presentations and peer-reviewed publication.

Strengths and limitations of this study

- This novel scoping review employs a rigorous protocol that adheres to internationally accepted standards and guidelines
- The search strategy has no restrictions on study methodology, study population, date, country or language to capture all relevant published literature
- The international scope of this scoping review makes including a rigorous grey literature search unfeasible
- This study does not review research that has been done on public health strategies used to reduce alcohol-related harm in rural and remote communities

INTRODUCTION

Alcohol use is a leading cause of morbidity and mortality worldwide and is associated with harms that arise from both the short-term effects of acute intoxication and the long-term consequences of chronic overuse. 1, 2 Certain populations are particularly burdened by the harms associated with alcohol use and would benefit from tailored public health and treatment strategies that address the unique, population-specific factors contributing to the burden of harm. Individuals living in rural and remote communities are one such population. 3-5 Studies from several countries have indicated that the prevalence of binge drinking, alcohol use disorder, and alcohol-related hospitalizations is higher in select rural and remote regions than in urban centers. 3, 6-10 As a result, there has been a growing emphasis on improving public health strategies to reduce the harms associated with alcohol use in rural and remote communities. The development of these strategies requires identifying the factors that underly the increased risk of harmful alcohol consumption and alcohol-related harm in rural and remote communities and understanding how these factors can be appropriately addressed.

Some research has been done in this regard; however, there are several shortcomings within the existing literature. Namely, publications emanate from multiple countries with differing social, economic and cultural landscapes, employ heterogeneous definitions of rural, remote and urban, and often focus on specific subpopulations of individuals residing in rural and remote communities (e.g., adolescents, women, individuals presenting to hospital or ED, etc.).^{4, 11-14} There are also conflicting results within the existing body of literature. Indeed, some studies have found that rural communities have a lower, rather than higher, burden of alcohol-related harm than nearby urban populations. 11 As a result, the generalizability of each study is somewhat unclear and our knowledge of the factors that modify the risk alcohol-related harm in rural and remote communities is incomplete. Equally unclear is precisely how incomplete the available data is. In the past decade, only two reviews have been done on rural and remote alcohol research.^{4, 11} Both studies restrict their literature search to a single country (Australia and the United States, respectively) and only one includes a review protocol in the manuscript. As a result, the development of evidence-based public health strategies to reduce alcohol-related harm in rural and remote communities is limited, and, without a clear sense of what gaps in knowledge need to be addressed, the development of relevant research questions to improve our understanding of rural and remote alcohol use and alcohol-related harm is similarly constrained.

OBJECTIVES & RATIONALE

The objectives of this scoping review are to (1) synthesize the global literature pertaining to alcohol use and alcohol-related harm in rural and remote communities, (2) define the conceptual landscape and boundaries of international rural and remote alcohol research, and, in turn, (3) clarify the gaps in knowledge that currently exist in the field. The results from this review have the potential to guide the development of public health strategies to reduce alcohol-related harm in rural and remote communities. More importantly, however, identifying the current gaps in knowledge will help to inform the development of future research aimed at improving our understanding of alcohol use and alcohol-related harm in rural and remote communities. Of note, the objective of this review is not to identify or evaluate the efficacy of alcohol harm reduction strategies that have already been implemented.

MEHTODS & ANALYSIS

A scoping review approach was chosen because it is an effective method of systematically understanding the nature of a research field, including important concepts, themes and limitations that exist. ¹⁵ These features align with the objectives of this study. A systematic review would be inappropriate in this context because the highly specific nature of the research question would result in an inclusion of very few studies and likely fail to effectively identify larger-scale gaps in knowledge present in the field.

This scoping review protocol adheres to the method developed by Arskey & O'Malley (2005)¹⁶ and built upon by Levac *et al.* (2010)¹⁷ and the Joanna Briggs Institute (2015).¹⁸ This method employs a six-stage approach involving: (1) identifying the research question, (2) identifying relevant studies, (3) selecting studies, (4) charting the data, (5) collating, summarizing and reporting the results, and (6) expert consultation. An additional section, (7) patient and public involvement, has also been included in accordance with the BMJ patient partnership strategy.

Identifying the Research Question

For the purposes of this scoping review, two separated but closely related outcomes of interest must be defined: (1) harmful alcohol use and (2) alcohol-related harm. 'Harmful alcohol use' refers to alcohol consumption patterns that are associated with an increased risk of alcohol-related harm, including, but not limited to, binge drinking, drinking above low risk drinking guidelines, and alcohol use disorder. Alcohol-related harm' refers to the harmful outcomes associated with alcohol use including, but not limited to, alcohol attributable hospitalizations, ED visits and mortality, diseases and disorders entirely attributable to alcohol, drunk driving, and alcohol-related interpersonal violence and self-harm. The research question that has been developed for this scoping review is:

What literature exists on the factors that modify the prevalence or risk of either harmful alcohol use or alcohol-related harm in communities defined as rural or remote?

Within this question, 'factors' refers to any exposure variable that has been associated with harmful alcohol use or alcohol-related harm in rural or remote communities, including 'rural' or 'remote' residence itself as an exposure. This captures two types of studies: (1) those that have evaluated how residing in areas defined as rural or remote influences the prevalence or risk of harmful alcohol use or alcohol-related harm *relative* to residing in areas not defined as rural or remote, and (2) those that have investigated how specific exposure variables (e.g., distance to nearest care, socioeconomic status, sex, etc.) influence the prevalence or risk of harmful alcohol use or alcohol-related harm *within* communities defined as rural or remote. 'Communities defined as rural or remote' specifies that this review will include studies with any definition of rural or remote.

Identifying relevant studies

In order to identify the published literature relevant to this research question, the following databases will be searched: MEDLINE, PsychINFO, Embase, CINAHL and Sociological Abstracts. Reference lists from included primary research articles and relevant reviews will also be hand searched for additional articles that may have been initially missed. The search strategy will be developed by the authors in MEDLINE and translated for use in the other databases. Relevant search terms will be developed by the authors with the assistance an experienced research librarian and will include a search of both keywords within

titles and abstracts and database specific subject headings (MeSH, EMTREE, CINAHL Headings, etc.). Our review will build upon the search terms for alcohol consumption that have been developed in previous systematic reviews in this topic area.^{20, 21} The search terms from the relevant subject domains, (1) 'rural or remote health' and (2) 'harmful alcohol use' or 'alcohol-related harm', will be combined in the final search strategy. The search strategies developed for this study are available in Supplementary File 1. No date, country or language restrictions were placed on the search.

Date and time stamps for each search will be recorded and included in the final publication. Articles will be uploaded to Covidence systematic review software for study selection.²²

Selecting Studies

Study selection will occur via title and abstract screening followed by full text review using Covidence. Study selection during the title and abstract screening phase will be guided by a set of inclusion and exclusion criteria that are outlined below and have been synthesized into a study eligibility form (Supplementary File 2). A team of five reviewers (EF, FF, SH, AE, JB) will be responsible for study selection. Using the study eligibility form, each title and abstract will be independently screened by two reviewers and will be moved forward to full text screening if either or both reviewers deem it worthy of inclusion. A preliminary test set of 100 articles will be initially screened to ensure the efficacy of the inclusion and exclusion criteria. Slight adjustments to inclusion and exclusion criteria will be made if necessary, and all changes will be clearly noted in the final manuscript. During full text screening, two reviewers will independently evaluate each full text using the study eligibility form. In the scenario of a disagreement, a third independent reviewer will be involved, and a discussion will take place until a consensus is reached. Inter-rater agreement will be calculated for both title and abstract and full text screening phases using Cohen's k statistic.

Studies will be included if they assess:

- 1. How rural or remote residence, relative to non-rural/remote residence, influences the prevalence or risk of harmful alcohol use or alcohol-related harm, or
- 2. How a specific exposure variable (e.g., socioeconomic status, age, sex, etc.) influences the prevalence or risk of harmful alcohol use or alcohol-related harm within rural or remote communities, or
- 3. Both

There will be no restriction on the type of study methodology used, i.e., quantitative observational studies using case-control, retrospective or prospective cohort, or cross-sectional methodological frameworks are all acceptable. Qualitative and mixed methods studies that focus on harmful alcohol use or alcohol-related harm in rural communities will also be included. Commentaries will be excluded. Review articles will also be excluded, but their reference lists will be hand searched for any potentially relevant articles. There will be no restriction on the type of study population (e.g., only adolescent, only male, entire population, etc.); however, studies will be excluded if they do not specify the definition of rural and/or remote that was used. Studies will also be excluded if they do not include an outcome that is either harmful alcohol use or alcohol-related harm or if the outcome is a composite outcome of an alcohol use or alcohol-related harm parameter combined with one or more parameter(s) that are not relevant to alcohol use or alcohol-related harm.

Charting the Data

After studies have been selected, two independent reviewers will extract data from each study into a pre-tested Microsoft Excel sheet. Variables to be extracted include, but are not limited to: year of publication, country of publication, journal name, author list, type of study (qualitative, mixed methods, cross-section, cohort, case-control, etc.), characteristics of study population (n, age, sex, ethnicity, any other recorded variables), definition of rural and/or remote, exposure variable and measurement, outcome variable (type of harmful alcohol use or alcohol-related harm) and measurement, measure of association (odds ratio, hazard ratio, relative risk, etc.) if applicable, and any identified gaps in the literature mentioned in the article. In order to capture all relevant information, additional fields will be added as necessary during the data extraction process. Any discrepancies in extracted data between the two reviewers will be resolved through discussion and mediation with a third independent reviewer.

Collating, summarizing and reporting the results

The results of the screening process will be presented using a PRISMA flow diagram and the final manuscript will adhere to the guidelines of the recently developed PRISMA Extension for Scoping Reviews (PRISMA-ScR) checklist.²³ The final excel sheet derived from the data extraction process will be included as a supplementary file in the final publication. Because this review will include a variety of different types of study design, the final manuscript will be narrative in nature, describing the themes arising in the studies chosen for inclusion. Many different definitions of rural, remote and urban are used in studies of rural alcohol use.^{4,11} Therefore, a focus will be put on describing and compiling the different definitions used within the selected studies with the intent of highlighting the most common definitions as well as the range of definitions that are used. The final manuscript will also present a summary of studies that have evaluated rural-urban differences in a quantitative harmful alcohol use or alcohol-related harm outcome and indicate whether the study found the prevalence or risk of the outcome to be higher, lower or equal in rural/remote communities relative to urban centers. Lastly, there will be a discussion of the gaps in knowledge that were identified either in (1) the discussion section of individual included studies or (2) during our evaluation of the conceptual landscape and limitations of all included studies. Consistent with the iterative nature of scoping reviews, other sections and discussions will be included as necessary based on the themes that arise during the review.

Expert Consultation

Experts in both alcohol epidemiology research and rural and remote health research at the Institute for Mental Health Policy Research at the Centre for Addiction and Mental Health (CAMH) and the Institute of Health Policy, Management & Evaluation (IHPME) at the University of Toronto will be contacted for input and interpretation of the results and final manuscript.

Patient and Public Involvement

Patient input will not be directly solicited for this scoping review. The population of interest is all individuals residing in rural or remote communities that have been impacted by harmful alcohol consumption or alcohol-related harm. This population is highly heterogeneous and contains many members with sub-clinical alcohol consumption patterns or outcomes that are only visible in survey data rather than in structured patient-physician settings. It would be difficult to solicit feedback from a sample of individuals that adequately represents this heterogeneous population. In order to mitigate

any bias that could arise due to the lack of direct patient input, our scoping review search strategy has been designed to be as inclusive as possible by not having any date, country, study population or language restrictions on our published literature search, and including a broad range of study methodologies including quantitative, qualitative and mixed methods research.

ETHICS & DISSEMINATION

This will be the first review to synthesize all internationally published literature on rural and remote alcohol use and alcohol-related harm. Since the review only makes use of published and publicly available data, no ethics approval is required. The results from this study will be disseminated via publication in a peer-reviewed journal and presentation at relevant rural health, addiction and psychiatry conferences. Our research team is actively investigating alcohol use and alcohol-related harm in rural and remote communities in Ontario, Canada, with the goal of improving public health strategies to reduce the burden of alcohol-related harm in these regions. Therefore, the results from this scoping review will be helpful in guiding our research program as well as other programs like ours.

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Authors' Contributions: ELF and PK conceptualized the manuscript and approved the final version. ELF wrote the manuscript.

Funding Statement: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing Interests Statement: None.

Supplementary File 1: Search Strategies

MEDLINE Search Strategy

- 1 Remote Consultation/
- 2 remote*.tw,kf.
- 3 Rural Population/
- 4 exp Rural Health Services/
- 5 Hospitals, Rural/
- 6 rural*.tw,kf.
- 7 Rural Health/
- 8 1 or 2 or 3 or 4 or 5 or 6 or 7
- 9 exp Alcohol Drinking/
- 10 exp Alcohol-Related Disorders/
- 11 Liver Cirrhosis, Alcoholic/
- 12 exp Liver Diseases, Alcoholic/
- 13 exp Fetal Alcohol Spectrum Disorders/
- 14 alcohol*.tw,kf.
- 15 (Wine* or Liquor* or spirits* or beer*).tw,kf. (drink* and (excess* or heavy or heavily or hazard* or binge or harmful or
- 16 problem*)).tw,kf.
- 17 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 1 Or 13 C.
- 18 8 and 17

Supplementary File 1: Search Strategies

PsychINFO (Ovid) Search Strategy

- 1 exp "alcohol use disorder"/
- 2 exp Alcohol Drinking Patterns/
- 3 Fetal Alcohol Syndrome/
- 4 (Wine* or Liquor* or spirits* or beer*).tw. (drink* and (excess* or heavy or heavily or hazard* or binge or harmful or
- 5 problem*)).tw.
- 6 alcohol*.tw.
- 7 alcohol drinking.mh.
- alcohol-related disorders.mh.
- 9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
- 10 Rural Environments/
- 11 remote*.tw.
- 12 rural*.tw.
- 13 remote consultation.mh.
- 14 rural population.mh.
- 15 rural health services.mh.
- 16 hospitals, rural.mh.
- 17 10 or 11 or 12 or 13 or 14 or 15 or 16 S Oi II
- 18 9 and 17

Embase Search Strategy

- 1 rural health care/
- rural population/
- rural area/
- rural health/
- rural*.tw,kw.
- remote*.tw,kw.
- exp alcohol abuse/
- alcohol consumption/
- alcohol intoxication/
- exp alcohol liver disease/
- "alcohol use disorders identification test"/
- exp alcohol withdrawal syndrome/
- fetal alcohol syndrome/
- exp alcohol psychosis/
- alcohol*.tw,kw.
- (Wine* or Liquor* or spirits* or beer*).tw,kw.
- (drink* and (excess* or heavy or heavily or hazard* or binge or harmful or problem*)).tw.
- 1 or 2 or 3 or 4 or 5 or 6
- 14 or 15 or ... 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
- 20 18 and 19

Supplementary File 1: Search Strategies

Sociological Abstracts Search Strategy

((MAINSUBJECT.EXACT("Drunkenness") OR

MAINSUBJECT.EXACT("Drinking Behavior") OR

MAINSUBJECT.EXACT.EXPLODE("Alcoholic Beverages") OR

MAINSUBJECT.EXACT.EXPLODE("Alcoholism") OR

MAINSUBJECT.EXACT.EXPLODE("Alcohol Abuse"))

OR ((TI(alcohol*) AND TI(drink*OR beverage* OR intoxicat*OR abus* OR misus* OR risk*OR consum* OR excess* OR problem*)) OR (AB(alcohol*)AND AB(drink* OR beverage*OR intoxicat* OR abus* OR misus* OR risk* OR consum*OR excess* OR problem*))) OR

OR ((TI(drink*) AND TI(excess* OR heavy OR heavily OR hazard*OR binge OR harmful OR problem*)) OR (AB(drink*)AND AB(excess* OR heavy OR heavily OR hazard* OR bingeOR harmful OR problem*)))

OR (TI(wine* OR liquor* OR beer*OR spirits*) OR AB(wine* OR liquor* OR beer* OR spirits*))

OR (TI alcohol* OR AB alcohol*))

AND

((MAINSUBJECT.EXACT.EXPLODE("Rural Population") OR

MAINSUBJECT.EXACT.EXPLODE("Rural Areas") OR

MAINSUBJECT.EXACT.EXPLODE("Rural Sociology") OR

MAINSUBJECT.EXACT.EXPLODE("Rural Urban Differences") OR

MAINSUBJECT.EXACT.EXPLODE("Rurality") OR

MAINSUBJECT.EXACT.EXPLODE("Rural Urban Continuum") OR

MAINSUBJECT.EXACT.EXPLODE("Rural Communities")) OR

OR (TI remote OR AB remote)

OR (TI rural* OR AB rural*))

CINAHL Search Strategy

- (MH "Rural Health Personnel") OR (MH "Rural Health Centers") OR (MH "Hospitals, Rural") OR S1 (MH "Rural Population") OR (MH "Rural Health Services") OR (MH "Australian Rural Nurses and Midwives") OR (MH "Rural Health Nursing") OR (MH "Rural Areas") OR (MH "Association for Australian Rural Nurses") OR (MH "Services for Australian Rural and Remote Allied Health") OR (MH "Rural Health")
- S2 (MH "Remote Consultation")
- S3 TI rural* OR AB rural*
- **S4** TI remote OR AB remote
- S5 S1 OR S2 OR S3 OR S4
- **S6** (MH "Alcoholic Neuropathy") OR (MH "Alcohol Withdrawal Seizures") OR (MH "Alcohol Withdrawal Delirium") OR (MH "Alcohol Withdrawal Syndrome+") OR (MH "Alcohol-Induced Disorders, Nervous System+") OR (MH "Alcoholism") OR (MH "Alcohol-Related Disorders+") OR (MH "Alcohol Drinking+") OR (MH "Alcoholic Intoxication+") OR (MH "Alcohol Abuse+")
- **S7** TI alcohol* OR AB alcohol*
- S8 TI(wine* OR liquor* OR beer* OR spirits*) OR AB(wine* OR liquor* OR beer* OR spirits*)
- **S9** (TI(drink*) AND TI(excess* or heavy or heavily or hazard* or binge or harmful or problem*)) OR (AB(drink*) AND AB(excess* or heavy or heavily or hazard* or binge or harmful or problem*))
- S10 **S6 OR S7 OR S8 OR S9**
- S11 **S5 AND S10**

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YES

YES

YES

YES

YES

NO

NO

NO

NO

NO

Supplementary File 2: Study Eligibility Form

Alcohol-related harm in rural and remote communities: a scoping review **Study Eligibility Form**

December 5th, 2019

Paper: Any language or publication year acceptable

Population:

- Entire population defined as rural or remote OR
- Portion of the population defined as rural or remote*

Predictor:

- IF entire population defined as rural or remote: any predictor of harmful alcohol use or alcohol-related harm
- OTHERWISE: Rural or remote residence included as a predictor of harmful alcohol use or alcohol-related harm

Analysis: All forms of statistical analysis acceptable

Outcomes reported:

- Harmful alcohol use (defined below) OR
- Alcohol-related harm (defined below)

Type of article:

- Cohort study (retrospective or prospective) OR
- Case-control OR
- Cross-sectional OR
- Meta-analysis OR
- Qualitative OR
- Mixed methods

Duplicated population:

- If duplicated, does this study provide new information?
- If duplicated, is study more recent?

Study inclusion:		
 All the answers are YES 	INCLUDE	
Any answer is NO	EXCLUDE	
 If you are unsure of the answer, include for full text screening 	INCLUDE	

^{*} this can include a rural/remote to urban comparison within the study

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Outcome Definitions

Harmful Alcohol Consumption: studies word this in a variety of ways, use clinical judgement

- Examples:
 - Heavy drinking
 - Drinking above recommended limit (regional)
 - Alcoholism
 - Alcohol use disorder (DSM-V)
 - Alcohol dependence (DSM-IV)
 - Alcohol abuse (DSM-IV)

Alcohol-Related Harm Includes:

- Harmful alcohol-related behavior:
 - Alcohol-Related Violence
 - Interpersonal
 - Self-harm
 - Drunk Driving
- Hospitalizations entirely caused by alcohol (Canadian Institute of Health Information (CIHI) code descriptors)
 - Alcohol-induced pseudo-Cushing's syndrome
 - Mental and behavioural disorders due to use of alcohol
 - Degeneration of nervous system due to alcohol
 - Alcoholic polyneuropathy
 - Alcoholic myopathy
 - Alcoholic cardiomyopathy
 - Alcoholic gastritis
 - Alcoholic liver disease
 - Alcohol-induced acute pancreatitis
 - Alcohol-induced chronic pancreatitis
 - Maternal care for (suspected) damage to fetus from alcohol
 - Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium
 - Fetal alcohol syndrome (dysmorphic)
 - Finding of alcohol in blood
 - Toxic effects of alcohol
 - Accidental poisoning by and exposure to alcohol
 - Intentional self-poisoning by and exposure to alcohol
 - Poisoning by and exposure to alcohol, undetermined intent
 - Alcohol intoxication delirium or withdrawal delirium
 - Alcohol persisting amnestic disorder

Supplementary File 2: Study Eligibility Form

- Alcohol persisting dementia
- Alcohol-induced psychotic disorder, with hallucinations
- o Alcohol-induced psychotic disorder, with delusions
- Alcohol withdrawal
- o Alcohol-induced sleep disorder
- Alcohol-induced anxiety disorder, mood disorder or sexual dysfunction
- Alcohol-related disorder not otherwise specified
- Alcohol intoxication
- Alcohol dependence
- Alcohol abuse
- Alcohol intoxication delirium or withdrawal delirium
- Alcohol-induced major neurocognitive disorder, amnestic confabulatory type
- Alcohol-induced major neurocognitive disorder, nonamnestic confabulatory type
- Alcohol-induced anxiety disorder, bipolar and related disorder, depressive disorder, mild neurocognitive disorder or sexual dysfunction
- Alcohol-induced psychotic disorder or unspecified alcohol-related disorder
- Alcohol use disorder, moderate/severe
- Alcohol use disorder, mild
- Emergency department visits entirely caused by alcohol
 - Same definitions as hospitalizations
- Alcohol-attributable mortality

BMJ Open

Alcohol use and alcohol-related harm in rural and remote communities: protocol for a scoping review

Journal:	BMJ Open
Manuscript ID	bmjopen-2019-036753.R1
Article Type:	Protocol
Date Submitted by the Author:	03-May-2020
Complete List of Authors:	Friesen, Erik; University of Toronto, Institute of Health Policy, Management & Evaluation Kurdyak, Paul; Centre for Addiction and Mental Health,
Primary Subject Heading :	Addiction
Secondary Subject Heading:	Epidemiology, Mental health, Public health
Keywords:	MENTAL HEALTH, PUBLIC HEALTH, Substance misuse < PSYCHIATRY

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Title: Alcohol use and alcohol-related harm in rural and remote communities: protocol for a scoping review

Authors: Erik Loewen Friesen, Paul Kurdyak

Author Information

Erik Loewen Friesen

Email: erik.friesen@mail.utoronto.ca

Affiliations:

- Institute of Health Policy Management & Evaluation, University of Toronto (Toronto, Canada)
- Faculty of Medicine, University of Toronto (Toronto, Canada)

Paul Kurdyak

Email: Paul.Kurdyak@camh.ca

Affiliations:

- Institute of Health Policy Management & Evaluation, University of Toronto (Toronto, Canada)
- Centre for Addiction & Mental Health (Toronto, Canada)

Corresponding Author

Erik Loewen Friesen

Institute of Health Policy, Management & Evaluation, University of Toronto (Toronto, Canada)

155 College St 4th Floor, Toronto, ON, Canada M5T 3M6

Email: erik.friesen@mail.utoronto.ca

Phone: 1-647-938-2413

Word Count (excluding title page, abstract, references, figures and tables): 2,617

Abstract

Introduction Alcohol-related harm is a major public health concern and appears to be particularly problematic in rural and remote communities. Evidence from several countries has shown that the prevalence of harmful alcohol use and alcohol-attributable hospitalizations and emergency department visits are higher in rural and remote communities than in urban centers. The extent of this rural-urban disparity in alcohol-related harm as well as the factors that mediate it are poorly understood. The objective of this scoping review is to synthesize the international research on the factors that influence the prevalence or risk of alcohol-related harm in rural and remote communities. This will help to clarify the conceptual landscape of rural and remote alcohol research and identify the gaps in knowledge that need to be addressed.

Methods and Analysis This scoping review will access published literature through search strategies developed for Medline, PsychINFO, Embase, CINAHL and Sociological Abstracts. There will be no date, country or language restrictions placed on the search. Title-and-abstract, followed by full-text screening will be conducted by two independent reviewers to evaluate all identified articles against a set of prespecified inclusion and exclusion criteria. Data from selected articles will be extracted and compiled into a final manuscript that adheres to the PRIMSA extension for Scoping Reviews (PRSMA-ScR) checklist guidelines.

Ethics and Dissemination The results of this review will be helpful in guiding future research on rural and remote alcohol use and alcohol-related harm, which will inform more effective, evidence-based public health strategies to reduce alcohol-related harm in rural and remote communities. The results will be disseminated via field-specific conference presentations and peer-reviewed publication.

Strengths and limitations of this study

- This novel scoping review employs a rigorous protocol that adheres to internationally accepted standards and guidelines
- The search strategy has no restrictions on study methodology, study population, date, country or language to capture all relevant published literature
- The international scope of this scoping review makes including a rigorous grey literature search unfeasible
- This study does not review research that has been done on public health strategies used to reduce alcohol-related harm in rural and remote communities

INTRODUCTION

Alcohol use is a leading cause of morbidity and mortality worldwide and is associated with harms that arise from both the short-term effects of acute intoxication and the long-term consequences of chronic overuse. ¹² Certain populations are particularly burdened by the harms associated with alcohol use and would benefit from tailored public health and treatment strategies that address the unique, population-specific factors contributing to the burden of harm. Individuals living in rural and remote communities are one such population. ³⁻⁵ Studies from several countries have indicated that the prevalence of binge drinking, alcohol use disorder, and alcohol-related hospitalizations is higher in select rural and remote regions than in urban centers. ^{3 6-10} As a result, there has been a growing emphasis on improving public health strategies to reduce the harms associated with alcohol use in rural and remote communities. The development of these strategies requires identifying the factors that underly the increased risk of harmful alcohol consumption and alcohol-related harm in rural and remote communities and understanding how these factors can be appropriately addressed.

Some research has been done in this regard; however, there are several shortcomings within the existing literature. Namely, publications emanate from multiple countries with differing social, economic and cultural landscapes, employ heterogeneous definitions of rural, remote and urban, and often focus on specific subpopulations of individuals residing in rural and remote communities (e.g., adolescents, women, individuals presenting to hospital or ED, etc.). 411-14 There are also conflicting results within the existing body of literature. Indeed, some studies have found that rural communities have a lower, rather than higher, burden of alcohol-related harm than nearby urban populations. 11 As a result, the generalizability of each study is somewhat unclear and our knowledge of the factors that modify the risk alcohol-related harm in rural and remote communities is incomplete. Equally unclear is precisely how incomplete the available data is. In the past decade, only two reviews have been done on rural and remote alcohol research.^{4 11} Both studies restrict their literature search to a single country (Australia and the United States, respectively) and only one includes a review protocol in the manuscript. As a result, the development of evidence-based public health strategies to reduce alcohol-related harm in rural and remote communities is limited, and, without a clear sense of what gaps in knowledge need to be addressed, the development of relevant research questions to improve our understanding of rural and remote alcohol use and alcohol-related harm is similarly constrained.

OBJECTIVES & RATIONALE

The objectives of this scoping review are to (1) synthesize the global literature pertaining to alcohol use and alcohol-related harm in rural and remote communities, (2) define the conceptual landscape and boundaries of international rural and remote alcohol research, and, in turn, (3) clarify the gaps in knowledge that currently exist in the field. The results from this review have the potential to guide the development of public health strategies to reduce alcohol-related harm in rural and remote communities. More importantly, however, identifying the current gaps in knowledge will help to inform the development of future research aimed at improving our understanding of alcohol use and alcohol-related harm in rural and remote communities. Of note, the objective of this review is not to identify or evaluate the efficacy of alcohol harm reduction strategies that have already been implemented.

METHODS & ANALYSIS

A scoping review approach was chosen because it is an effective method of systematically understanding the nature of a research field, including important concepts, themes and limitations that exist. ¹⁵ These features align with the objectives of this study. A systematic review would be inappropriate in this context because the highly specific nature of the research question would result in an inclusion of very few studies and likely fail to effectively identify larger-scale gaps in knowledge present in the field.

This scoping review protocol adheres to the method developed by Arskey & O'Malley (2005)¹⁶ and built upon by Levac *et al.* (2010)¹⁷ and the Joanna Briggs Institute (2015).¹⁸ This method employs a six-stage approach involving: (1) identifying the research question, (2) identifying relevant studies, (3) selecting studies, (4) charting the data, (5) collating, summarizing and reporting the results, and (6) expert consultation. An additional section, (7) patient and public involvement, has also been included in accordance with the BMJ patient partnership strategy.

Identifying the Research Question

For the purposes of this scoping review, two separated but closely related outcomes of interest must be defined: (1) harmful alcohol use and (2) alcohol-related harm. 'Harmful alcohol use' refers to alcohol consumption patterns that are associated with an increased risk of alcohol-related harm, including, but not limited to, binge drinking, drinking above low risk drinking guidelines, and alcohol use disorder. 'Alcohol-related harm' refers to the harmful outcomes associated with alcohol use including, but not limited to, alcohol attributable hospitalizations, ED visits and mortality, diseases and disorders entirely attributable to alcohol, drunk driving, and alcohol-related interpersonal violence and self-harm. The research question that has been developed for this scoping review is:

What literature exists on the factors that modify the prevalence or risk of either harmful alcohol use or alcohol-related harm in communities defined as rural or remote?

Within this question, 'factors' refers to any exposure variable that has been associated with harmful alcohol use or alcohol-related harm in rural or remote communities, including 'rural' or 'remote' residence itself as an exposure. This captures two types of studies: (1) those that have evaluated how residing in areas defined as rural or remote influences the prevalence or risk of harmful alcohol use or alcohol-related harm *relative* to residing in areas not defined as rural or remote, and (2) those that have investigated how specific exposure variables (e.g., distance to nearest care, socioeconomic status, sex, etc.) influence the prevalence or risk of harmful alcohol use or alcohol-related harm *within* communities defined as rural or remote. 'Communities defined as rural or remote' specifies that this review will include studies with any definition of rural or remote.

Identifying relevant studies

In order to identify the published literature relevant to this research question, the following databases will be searched: MEDLINE, PsychINFO, Embase, CINAHL and Sociological Abstracts. Reference lists from included primary research articles and relevant reviews will also be hand searched for additional articles that may have been initially missed. The search strategy will be developed by the authors in MEDLINE and translated for use in the other databases. Relevant search terms will be developed by the authors with the assistance an experienced research librarian and will include a search of both keywords within

titles and abstracts and database specific subject headings (MeSH, EMTREE, CINAHL Headings, etc.). Our review will build upon the search terms for alcohol consumption that have been developed in previous systematic reviews in this topic area.²⁰ ²¹ The search terms from the relevant subject domains, (1) 'rural or remote health' and (2) 'harmful alcohol use' or 'alcohol-related harm', will be combined in the final search strategy. The search strategies developed for this study are available in Supplementary File 1. No date, country or language restrictions were placed on the search.

Date and time stamps for each search will be recorded and included in the final publication. Articles will be uploaded to Covidence systematic review software for study selection.²²

Selecting Studies

Study selection will occur via title and abstract screening followed by full text review using Covidence. Study selection during the title and abstract screening phase will be guided by a set of inclusion and exclusion criteria that are outlined below and have been synthesized into a study eligibility form (Supplementary File 2). Using the study eligibility form, each title and abstract will be independently screened by two reviewers and will be moved forward to full text screening if either or both reviewers deem it worthy of inclusion. The study eligibility form was created collaboratively by the research team in consultation with the research librarian and was deemed to appropriately describe the inclusion and exclusion criteria of this review, as outlined below. Nonetheless, a preliminary test set of 100 articles will be initially screened to ensure the efficacy of the inclusion and exclusion criteria, a process that has been suggested to reduce error and completion time of the screening process.²³ Slight adjustments to inclusion and exclusion criteria will be made if necessary, and all changes will be clearly noted in the final manuscript. During full text screening, two reviewers will independently evaluate each full text using the study eligibility form. In the scenario of a disagreement, a third independent reviewer will be involved, and a discussion will take place until a consensus is reached. Inter-rater agreement will be calculated for both title and abstract and full text screening phases using Cohen's k statistic.

Studies will be included if they assess:

- 1. How rural or remote residence, relative to non-rural/remote residence, influences the prevalence or risk of harmful alcohol use or alcohol-related harm, or
- 2. How a specific exposure variable (e.g., age, sex, socioeconomic status, ethnicity, etc.) influences the prevalence or risk of harmful alcohol use or alcohol-related harm within rural or remote communities, or
- 3. Both

There will be no restriction on the type of study methodology used, i.e., quantitative observational studies using case-control, retrospective or prospective cohort, or cross-sectional methodological frameworks are all acceptable. Qualitative and mixed methods studies that focus on harmful alcohol use or alcohol-related harm in rural communities will also be included. There will be no restriction on the date, language, or country of origin of the study. Articles in a language other than English will be translated and interpreted using the language skill available within our research group. If this is insufficient to meet the translation need, translators external to our research group will be sought. Articles that have been translated to English from another language will be clearly identified in the final manuscript. There will be no restriction on the type of study population, i.e., study populations that only include specific demographic subgroups such as adolescents, men, etc. will be eligible for inclusion.

Finally, in the context of articles that assess how specific exposure(s) influence the prevalence or risk of harmful alcohol use or alcohol-related harm in rural or remote communities, no restriction will be placed on the type or nature of exposure variable(s) included in the study.

Commentaries will be excluded. Review articles will also be excluded, but their reference lists will be hand searched for any potentially relevant articles. Similarly, the reference lists of all included primary studies will be hand searched for any relevant articles that were missed during the initial search. Studies that compare rural/remote populations to urban populations will be excluded if they do not specify the definition of rural and/or remote that was used. However, if the study population is exclusively rural or remote and no rural-urban comparison is made, a definition or rural or remote will not be required. Studies will also be excluded if they do not include an outcome that is either harmful alcohol use or alcohol-related harm or if the outcome is a composite outcome of an alcohol use or alcohol-related harm.

Charting the Data

After studies have been selected, two independent reviewers will extract data from each study into a pre-tested Microsoft Excel sheet. Variables to be extracted include, but are not limited to: year of publication, country of publication, journal name, author list, type of study (qualitative, mixed methods, cross-section, cohort, case-control, etc.), characteristics of study population (n, age, sex, ethnicity, any other recorded variables), definition of rural and/or remote, exposure variable and measurement, outcome variable (type of harmful alcohol use or alcohol-related harm) and measurement, measure of association (odds ratio, hazard ratio, relative risk, etc.) including confidence intervals and p-values if applicable, and any identified gaps in the literature mentioned in the article. In order to capture all relevant information, additional fields will be added as necessary during the data extraction process. Any discrepancies in extracted data between the two reviewers will be resolved through discussion and mediation with a third independent reviewer.

Collating, summarizing and reporting the results

The results of the screening process will be presented using a PRISMA flow diagram and the final manuscript will adhere to the guidelines of the recently developed PRISMA Extension for Scoping Reviews (PRISMA-ScR) checklist.²⁴ The final excel sheet derived from the data extraction process will be included as a supplementary file in the final publication. Because this review will include a variety of different types of study design, the final manuscript will be narrative in nature, describing the themes arising in the studies chosen for inclusion. Many different definitions of rural, remote and urban are used in studies of rural alcohol use. 411 Therefore, a focus will be put on describing and compiling the different definitions used within the selected studies with the intent of highlighting the most common definitions as well as the range of definitions that are used. The final manuscript will also present a summary of studies that have evaluated rural-urban differences in a quantitative harmful alcohol use or alcohol-related harm outcome and indicate whether the study found the prevalence or risk of the outcome to be higher, lower or equal in rural/remote communities relative to urban centers. Within this analysis, similarities and differences between geographic regions (e.g., states, provinces, countries, etc.) will be highlighted and discussed. Lastly, there will be a discussion of the gaps in knowledge that were identified either in (1) the discussion section of individual included studies or (2) during our evaluation of the conceptual landscape and limitations of all included studies. Consistent with the iterative nature

of scoping reviews, other sections and discussions will be included as necessary based on the themes that arise during the review.

Expert Consultation

Throughout the review process, experts in both alcohol epidemiology research and rural and remote health research will be contacted for input and interpretation of the methods, results, and final manuscript. The guidance received from these expert consults will be highlighted in the acknowledgements section of the final manuscript.

Patient and Public Involvement

Patient input will not be directly solicited for this scoping review. The population of interest is all individuals residing in rural or remote communities that have been impacted by harmful alcohol consumption or alcohol-related harm. This population is highly heterogeneous and contains many members with sub-clinical alcohol consumption patterns or outcomes that are only visible in survey data rather than in structured patient-physician settings. It would be difficult to solicit feedback from a sample of individuals that adequately represents this heterogeneous population. In order to mitigate any bias that could arise due to the lack of direct patient input, our scoping review search strategy has been designed to be as inclusive as possible by not having any date, country, study population or language restrictions on our published literature search, and including a broad range of study methodologies including quantitative, qualitative and mixed methods research.

ETHICS & DISSEMINATION

This will be the first review to synthesize all internationally published literature on rural and remote alcohol use and alcohol-related harm. Since the review only makes use of published and publicly available data, no ethics approval is required. The results from this study will be disseminated via publication in a peer-reviewed journal and presentation at relevant rural health, addiction and psychiatry conferences. Our research team is actively investigating alcohol use and alcohol-related harm in rural and remote communities with the goal of improving public health strategies to reduce the burden of alcohol-related harm in these regions. Therefore, the results from this scoping review will be helpful in guiding our research program as well as other programs like ours.

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Authors' Contributions: ELF and PK conceptualized the manuscript and approved the final version. ELF wrote the manuscript.

Funding Statement: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing Interests Statement: None.

Acknowledgements: The authors thank research librarian Kaitlin Fuller for her insight and guidance on the methodological design of the study.

MEDLINE Search Strategy

Supplementary File 1: Search Strategies

- 1 Remote Consultation/
- 2 remote*.tw,kf.
- 3 Rural Population/
- 4 exp Rural Health Services/
- 5 Hospitals, Rural/
- 6 rural*.tw,kf.
- 7 Rural Health/
- 8 1 or 2 or 3 or 4 or 5 or 6 or 7
- 9 exp Alcohol Drinking/
- 10 exp Alcohol-Related Disorders/
- 11 Liver Cirrhosis, Alcoholic/
- 12 exp Liver Diseases, Alcoholic/
- 13 exp Fetal Alcohol Spectrum Disorders/
- 14 alcohol*.tw,kf.
- 15 (Wine* or Liquor* or spirits* or beer*).tw,kf. (drink* and (excess* or heavy or heavily or hazard* or binge or harmful or
- 16 problem*)).tw,kf.
- 17 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 Of 15 or =
- 18 8 and 17

PsychINFO (Ovid) Search Strategy

- 1 exp "alcohol use disorder"/
- 2 exp Alcohol Drinking Patterns/
- 3 Fetal Alcohol Syndrome/
- 4 (Wine* or Liquor* or spirits* or beer*).tw. (drink* and (excess* or heavy or heavily or hazard* or binge or harmful or
- 5 problem*)).tw.
- 6 alcohol*.tw.
- 7 alcohol drinking.mh.
- alcohol-related disorders.mh.
- 9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
- 10 Rural Environments/
- 11 remote*.tw.
- 12 rural*.tw.
- 13 remote consultation.mh.
- 14 rural population.mh.
- 15 rural health services.mh.
- 16 hospitals, rural.mh.
- 17 10 or 11 or 12 or 13 or 14 or 15 or 16
- 18 9 and 17

Embase Search Strategy

rural health care/

Supplementary File 1: Search Strategies

- rural population/
- rural area/
- rural health/
- rural*.tw,kw.
- remote*.tw,kw.
- exp alcohol abuse/
- alcohol consumption/
- alcohol intoxication/
- exp alcohol liver disease/
- "alcohol use disorders identification test"/
- exp alcohol withdrawal syndrome/
- fetal alcohol syndrome/
- exp alcohol psychosis/
- alcohol*.tw,kw.
- 16 (Wine* or Liquor* or spirits* or beer*).tw,kw.
- (drink* and (excess* or heavy or heavily or hazard* or binge or harmful or problem*)).tw.
- 1 or 2 or 3 or 4 or 5 or 6
- 24 or 15 or 12 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
- 20 18 and 19

Sociological Abstracts Search Strategy

((MAINSUBJECT.EXACT("Drunkenness") OR

MAINSUBJECT.EXACT("Drinking Behavior") OR

MAINSUBJECT.EXACT.EXPLODE("Alcoholic Beverages") OR

MAINSUBJECT.EXACT.EXPLODE("Alcoholism") OR

MAINSUBJECT.EXACT.EXPLODE("Alcohol Abuse"))

OR ((TI(alcohol*) AND TI(drink*OR beverage* OR intoxicat*OR abus* OR misus* OR risk*OR consum* OR excess* OR problem*)) OR (AB(alcohol*)AND AB(drink* OR beverage*OR intoxicat* OR abus* OR misus* OR risk* OR consum*OR excess* OR problem*))) OR

OR ((TI(drink*) AND TI(excess* OR heavy OR heavily OR hazard*OR binge OR harmful OR problem*)) OR (AB(drink*)AND AB(excess* OR heavy OR heavily OR hazard* OR bingeOR harmful OR problem*)))

OR (TI(wine* OR liquor* OR beer*OR spirits*) OR AB(wine* OR liquor* OR beer* OR spirits*))

OR (TI alcohol* OR AB alcohol*))

AND

((MAINSUBJECT.EXACT.EXPLODE("Rural Population") OR

MAINSUBJECT.EXACT.EXPLODE("Rural Areas") OR

MAINSUBJECT.EXACT.EXPLODE("Rural Sociology") OR

MAINSUBJECT.EXACT.EXPLODE("Rural Urban Differences") OR

MAINSUBJECT.EXACT.EXPLODE("Rurality") OR

MAINSUBJECT.EXACT.EXPLODE("Rural Urban Continuum") OR

MAINSUBJECT.EXACT.EXPLODE("Rural Communities")) OR

OR (TI remote OR AB remote)

OR (TI rural* OR AB rural*))

CINAHL Search Strategy

- (MH "Rural Health Personnel") OR (MH "Rural Health Centers") OR (MH "Hospitals, Rural") OR S1 (MH "Rural Population") OR (MH "Rural Health Services") OR (MH "Australian Rural Nurses and Midwives") OR (MH "Rural Health Nursing") OR (MH "Rural Areas") OR (MH "Association for Australian Rural Nurses") OR (MH "Services for Australian Rural and Remote Allied Health") OR (MH "Rural Health")
- S2 (MH "Remote Consultation")
- S3 TI rural* OR AB rural*
- **S4** TI remote OR AB remote
- **S5** S1 OR S2 OR S3 OR S4
- **S6** (MH "Alcoholic Neuropathy") OR (MH "Alcohol Withdrawal Seizures") OR (MH "Alcohol Withdrawal Delirium") OR (MH "Alcohol Withdrawal Syndrome+") OR (MH "Alcohol-Induced Disorders, Nervous System+") OR (MH "Alcoholism") OR (MH "Alcohol-Related Disorders+") OR (MH "Alcohol Drinking+") OR (MH "Alcoholic Intoxication+") OR (MH "Alcohol Abuse+")
- **S7** TI alcohol* OR AB alcohol*
- S8 TI(wine* OR liquor* OR beer* OR spirits*) OR AB(wine* OR liquor* OR beer* OR spirits*)
- S9 (TI(drink*) AND TI(excess* or heavy or heavily or hazard* or binge or harmful or problem*)) OR (AB(drink*) AND AB(excess* or heavy or heavily or hazard* or binge or harmful or problem*))
- S10 S6 OR S7 OR S8 OR S9
- S11 **S5 AND S10**

Supplementary File 2: Study Eligibility Form

Alcohol-related harm in rural and remote communities: a scoping review Study Eligibility Form

February 12th, 2019

Paper: Any language or publication year acceptable

Population:

- Entire population defined as rural or remote OR
- Portion of the population defined as rural or remote*

Predictor:

- IF entire population defined as rural or remote: any predictor of harmful alcohol use or alcohol-related harm
- OTHERWISE: Rural or remote residence included as a predictor of harmful alcohol use or alcohol-related harm

Analysis: All forms of statistical analysis acceptable

Outcomes reported:

- Alcohol consumption OR
- Alcohol-related harm (defined below)

Type of article:

- Cohort study (retrospective or prospective) OR
- Case-control OR
- Cross-sectional OR
- Meta-analysis OR
- Qualitative OR
- Mixed methods

Duplicated population:

- If duplicated, does this study provide new information?

YES

YES

YES

YES

NO

NO

NO

NO

• If duplicated, is study more recent?

Study inclusion:		
All the answers are YES	INCLUDE	
Any answer is NO	EXCLUDE	
 If you are unsure of the answer, include for full text screening 	INCLUDE	

^{*} this can include a rural/remote to urban comparison within the study

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Supplementary File 2: Study Eligibility Form

Outcome Definitions

Alcohol-Related Harm Includes:

- Harmful alcohol-related behavior:
 - Alcohol-Related Violence
 - Interpersonal
 - Self-harm
 - Drunk Driving
- Hospitalizations entirely caused by alcohol (Canadian Institute of Health Information (CIHI) code descriptors)
 - Alcohol-induced pseudo-Cushing's syndrome
 - Mental and behavioural disorders due to use of alcohol
 - Degeneration of nervous system due to alcohol
 - Alcoholic polyneuropathy
 - Alcoholic myopathy
 - Alcoholic cardiomyopathy
 - Alcoholic gastritis
 - Alcoholic liver disease
 - Alcohol-induced acute pancreatitis
 - Alcohol-induced chronic pancreatitis
 - Maternal care for (suspected) damage to fetus from alcohol
 - Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium
 - Fetal alcohol syndrome (dysmorphic)
 - Finding of alcohol in blood
 - Toxic effects of alcohol
 - Accidental poisoning by and exposure to alcohol
 - Intentional self-poisoning by and exposure to alcohol
 - Poisoning by and exposure to alcohol, undetermined intent
 - Alcohol intoxication delirium or withdrawal delirium
 - Alcohol persisting amnestic disorder
 - Alcohol persisting dementia
 - Alcohol-induced psychotic disorder, with hallucinations
 - Alcohol-induced psychotic disorder, with delusions
 - Alcohol withdrawal
 - Alcohol-induced sleep disorder
 - o Alcohol-induced anxiety disorder, mood disorder or sexual dysfunction
 - Alcohol-related disorder not otherwise specified
 - Alcohol intoxication
 - Alcohol dependence

Supplementary File 2: Study Eligibility Form

Alcohol abuse

- Alcohol intoxication delirium or withdrawal delirium
- o Alcohol-induced major neurocognitive disorder, amnestic confabulatory type
- o Alcohol-induced major neurocognitive disorder, nonamnestic confabulatory type
- o Alcohol-induced anxiety disorder, bipolar and related disorder, depressive disorder, mild neurocognitive disorder or sexual dysfunction
- Alcohol-induced psychotic disorder or unspecified alcohol-related disorder
- Alcohol use disorder, moderate/severe
- Alcohol use disorder, mild
- Emergency department visits entirely caused by alcohol
 - Same definitions as hospitalizations en..
 Itable mortant,
- Alcohol-attributable mortality

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol* address in a systematic review protocol*

Section and topic	Item No	Checklist item 6	Page
ADMINISTRATIVI	E INFO		
Title:		Identify the report of a protectal of a replacement of the second of the	
Identification	1a	Identity the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	N/A
Authors:		ad ee	
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	1/9
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:		$\frac{\partial}{\partial x}$	
Sources	5a	Indicate sources of financial or other support for the review	9
Sponsor	5b	Provide name for the review funder and/or sponsor	9
Role of sponsor or funder	5c	Indicate sources of financial or other support for the review Provide name for the review funder and/or sponsor Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	9
INTRODUCTION		1 Арг	
Rationale	6	Describe the rationale for the review in the context of what is already known	3
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4
METHODS		by g	·
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	4-6
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, tradit registers or other grey literature sources) with planned dates of coverage	4-5
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits such that it could be repeated	s1
Study records:		9 9	
		оругі́g	

		19-03	
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	5
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	5-6
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently in duplicate), any processes for obtaining and confirming data from investigators	6
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	N/A
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	N/A
1	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I², Kendall's)	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	6-7
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A

^{*} It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration cities when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.