Data extraction form - SECOND ROUND

EPIDEMIOLOGY OF AT-RISK ALCOHOL USE AND ASSOCIATED COMORBIDITIES AMONG HOME-DWELLING OLDER ADULTS

General Information – Study ID: ……..

Date form completed *(dd/mm/yyyy):*	Name person extracting data:
Publication title :***(title of paper/ abstract/ reports that data is extracted from):*** …… ……	

Eligibility (exclude if one of the follow reference is unclear)

Study Characteristics	**Inclusion Criteria**	**Yes/No/ Unclear**	**Location in text** *(pg & ¶/fig/table)*
Type of study	Randomised trial		
	Cluster randomised controlled trial (CRCT)		
	Non-randomised trial – Quasi experimental study		
	Retrospective or prospective **epidemiological** study		
	Cohort study		
	Controlled before-and-after study • Contemporaneous data collection • At least 2 intervention and 2 control clusters		
	Interrupted time series OR repeated measures study • At least 3 time-points before and 3 after the intervention • Clearly defined intervention point		
	Case-control study		
Language	French, German, English, Spanish and Chinese		
Participants	• Home-dwelling adults a minimum mean age of 60 age (age minimum age 55 age) • At least 1 alcoholic drink per day without acception (glas, onz ….		
Types of intervention	Epidemiology (incidence – prevalence – occurrence) Measurement of at-risk drinking / alcoholism/alcohol abuse/alcohol		
Types of outcome measures	**Primary outcome :** • **Epidemiology of at-risk alcohol consumption,** • **Age of onset** • **Severity of alcohol use (amount).** **Secondary outcome measures:** • Psychiatric and somatic comorbidities frequently occurring in home-dwelling older adults with at-risk alcohol consumption; • Documentation of tools and the measurement of comorbidities associated with at-risk drinking; • Presence of epidemiological data on very old adults' drinking habits; • Associations between drinking volume and alcohol-related harm		
Decision:	❍ Excluded ❍ Included		
Reason for exclusion			
Notes:			

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

Definitions

Assumed risk estimate	An estimate of the risk of an event or average score without the intervention, used in Cochrane 'Summary of findings tables'. If a study provides useful estimates of the risk or average score of different subgroups of the population, or an estimate based on a representative observational study, you may wish to collect this information.
Bias	A systematic error or deviation in results or inferences from the truth. In studies of the effects of health care, the main types of bias arise from systematic differences in the groups that are compared (selection bias), the care that is provided, exposure to other factors apart from the intervention of interest (performance bias), withdrawals or exclusions of people entered into a study (attrition bias) or how outcomes are assessed (detection bias). Reviews of studies may also be particularly affected by reporting bias, where a biased subset of all the relevant data is available.
Change from baseline	A measure for a continuous outcome calculated as the difference between the baseline score and the post-intervention score.
Clusters	A group of participants who have been allocated to the same intervention arm together, as in a cluster-randomised trial, e.g. a whole family, town, school or patients in a clinic may be allocated to the same intervention rather than separately allocating each individual to different arms.
Co-morbidities	The presence of one or more diseases or conditions other than those of primary interest. In a study looking at treatment for one disease or condition, some of the individuals may have other diseases or conditions that could affect their outcomes.
Compliance	Participant behaviour that abides by the recommendations of a doctor, other health care provider or study investigator (also called adherence or concordance).
Contemporaneous data collection	When data are collected at the same point(s) in time or covering the same time period for each intervention arm in a study (that is, historical data are not used as a comparison).
Controlled Before and After Study (CBA)	A non-randomised study design where a control population of similar characteristics and performance as the intervention group is identified. Data are collected before and after the intervention in both the control and intervention groups
Exclusions	Participants who were excluded from the study or the analysis by the investigators.
Imputation	Assuming a value for a measure where the true value is not available (e.g. assuming last observation carried forward for missing participants).
Integrity of delivery	The degree to which the specified procedures or components of an intervention are delivered as originally planned.
Interrupted Time Series (ITS)	A research design that collects observations at multiple time points before and after an intervention (interruption). The design attempts to detect whether the intervention has had an effect significantly greater than the underlying trend.
Post-intervention	The value of an outcome measured at some time point following the beginning of the intervention (may be during or after the intervention period).
Power	In clinical trials, power is the probability that a trial will obtain a statistically significant result when the true intervention effect is a specified size. For a given size of effect, studies with more participants have greater power. Note that power should not be considered in the risk of bias assessment.
Providers	The person or people responsible for delivering an intervention and related care, who may or may not require specific qualifications (e.g. doctors, physiotherapists) or training.
Quasi-randomised controlled trial	A study in which the method of allocating people to intervention arms was not random, but was intended to produce similar groups when used to allocate participants. Quasi-random methods include: allocation by the person's date of birth, by the day of the week or month of the year, by a person's medical record number, or just allocating every alternate person.
Reanalysis	Additional analysis of a study's results by a review author (e.g. to introduce adjustment for correlation that was not done by the study authors).

Sociodemographics	Social and demographic information about a study or its participants, including economic and cultural information, location, age, gender, ethnicity, etc.
Theoretical basis	The use of a particular theory (such as theories of human behaviour change) to design the components and implementation of an intervention
Unit of allocation	The unit allocated to an intervention arm. In most studies individual participants will be allocated, but in others it may be individual body parts (e.g. different teeth or joints may be allocated separately) or clusters of multiple people.
Unit of analysis	The unit used to calculate N in an analysis, and for which the result is reported. This may be the number of individual people, or the number of body parts or clusters of people in the study.
Unit of measurement	The unit in which an outcome is measured, e.g. height may be measured in cm or inches; depression may be measured using points on a particular scale.
Validation	A process to test and establish that a particular measurement tool or scale is a good measure of that outcome.
Withdrawals	Participants who voluntarily withdrew from participation in a study before the completion of outcome measurement.

Methods

	Descriptions as stated in report/paper	**Location in text** *(pg & ¶/fig/table)*
1. **Aim of study**		
2. **Design** *(e.g. parallel, crossover, non-RCT)*		
3. **Unit of allocation** *(by individuals, cluster/ groups or body parts)*		
4. **Start date**		
5. **End date**		
6. **Duration of participation** *(from recruitment to last follow-up)*		
7. **Notes:**		

Population and setting – epidemiological data

	Description *Include comparative information for each group (i.e. intervention and controls) if available*	**Location in text** *(pg &¶/fig/table)*
8. **Population description** *(from which study participants are drawn)*		
9. **Baseline characteristics** Sex Age SD / IQR Range Min-Max	 Male:……Female: …….. Average:……..Median: …… …….. ……	
10. **Race / ethnicity**		

	Description *Include comparative information for each group (i.e. intervention and controls) if available*	**Location in text** *(pg &¶/fig/table)*
11. **Setting** *(including location and social context)*		
12. **Inclusion criteria**		
13. **Exclusion criteria**		
14. **Recruitment of participants**		
15. **Length of follow-up**		
16. **Follow-up characteristics**		
17. **Target population and final number of subjects studied for outcome**		

Participants

	Description as stated in report/paper	**Location in text** (pg & /fig/table)
18. **Total number randomised** *(or total pop. at start of study for NRCTs)*		
19. **Clusters** *(if applicable, no., type, no. people per cluster)*		
20. **Baseline imbalances *(if applicable)***		
21. **Withdrawals and exclusions** *(if not provided below by the outcome)*		
22. **Severity of illness**		
23. **Comorbidities**		
24. **Other treatments received** *(additional to study intervention)*		
25. **Other relevant socio-demographics**		
26. **Subgroups measured**		
27. **Subgroups reported**		
28. **Notes:**		

Intervention groups

	Description as stated in report/paper	**Location in text** *(pg & ¶/fig/table)*
29. **Group name**		

	Description as stated in report/paper	Location in text *(pg & ¶/fig/table)*
30. **No. randomised to group** *(specify whether no. people or clusters)*		
31. **Description** *(include sufficient detail for replication, e.g. content, dose, components; if it is a natural experiment, describe the pre-intervention)*		
32. **Duration of treatment period**		
33. **Timing** *(e.g. frequency, duration of each episode)*		
34. **Delivery** *(e.g. mechanism, medium, intensity, fidelity)*		
35. **Providers** *(e.g. no., profession, training, ethnicity, etc. if relevant)*		
36. **Co-interventions**		
37. **Economic variables** *(i.e. intervention cost changes in other costs as result of intervention)*		
38. **Resource requirements to replicate intervention** *(e.g. staff numbers, cold chain, equipment)*		
39. **Notes:**		

Control Group

	Description as stated in report/paper	Location in text *(pg & /fig/table)*
40. **Group name**		
41. **No. randomised to group** *(specify whether no. people or clusters)*		
42. **Description** *(include sufficient detail for replication, e.g. content, dose, components; if it is a natural experiment, describe the pre-intervention)*		
43. **Duration of treatment period**		
44. **Timing** *(e.g. frequency, duration of each episode)*		
45. **Delivery** *(e.g. mechanism, medium, intensity, fidelity)*		
46. **Providers** *(e.g. no., profession, training, ethnicity, etc. if relevant)*		
47. **Co-interventions**		

	Description as stated in report/paper	Location in text *(pg & /fig/table)*
48. **Economic variables** *(i.e. intervention cost, changes in other costs as result of intervention)*		
49. **Resource requirements to replicate intervention** *(e.g. staff numbers, cold chain, equipment)*		
50. **Notes:**		

Outcomes

	Description as stated in report/paper		Location in text *(pg & ¶/fig/table)*
51. **Outcome name**			
52. **Time-points measured** *(specify whether from start or end of intervention)*			
53. **Time-points reported**			
54. **Outcome definition** *(with diagnostic criteria if relevant and note whether the outcome is desirable or undesirable if this is not obvious)*			
55. **Person measuring/ reporting**			
56. **Unit of measurement** *(if relevant)*			
57. **Scales: upper and lower limits** *(indicate whether high or low score is good)*			
58. **Is outcome/tool validated?**	*Yes/No/Unclear*		
59. **Imputation of missing data** *(e.g. assumptions made for Intention To Treat analysis)*			
60. **Assumed risk estimate** *(e.g. baseline or population risk noted in Background)*			
61. **Notes:**			

Results

For randomised or non-randomised trial with <u>dichotomous outcomes</u>

	Description as stated in report/paper				Location in text *(pg & /fig/table)*
62. **Comparison**					
63. **Outcome**					
64. **Subgroup**					
65. **Time point** *(specify whether from start or end of intervention)*					
66. **Results** *Note whether:*	**Intervention**		**Comparison**		
	No. events	No. participants	No. events	No. participants	

	Description as stated in report/paper				Location in text *(pg & /fig/table)*
... *post-intervention OR* **...** *change from baseline And whether* **...** *Adjusted OR* **...***Unadjusted*					
67. **Baseline data**	**Intervention**		**Comparison**		
	No. events	No. participants	No. events	No. participants	
68. **No. missing participants and reasons**					
69. **No. participants moved from other groups and reasons**					
70. **Any other results reported**					
71. **Unit of analysis** *(e.g. by individuals, health professionals, practice, hospital, community)*					
72. **Statistical methods used and appropriateness of these methods** *(e.g. adjustment for correlation)*					
73. **Reanalysis required?** *(if yes, specify why, e.g. correlation adjustment)*	... *Yes/No/Unclear*				
74. **Reanalysis possible?**	... *Yes/No/Unclear*				
75. **Reanalysed results**					
76. **Notes:**					

For randomised or non-randomised trials with <u>continuous outcomes</u>

	Description as stated in report/paper						Location in text *(pg & /fig/table)*
77. **Comparison**							
78. **Outcome**							
79. **Subgroup**							
80. **Time point** *(specify whether from start or end of intervention)*							
81. **Post-intervention or change from the baseline?**							
82. **Results** *Note whether:* **...** *post-intervention OR* **...** *change from baseline And whether* **...** *Adjusted OR* **...***Unadjusted*	**Intervention**			**Comparison**			
	Mean	SD (or other variance)	No. participants	Mean	SD (or other variance)	No. participants	
83. **Baseline data**	**Intervention**			**Comparison**			

	Description as stated in report/paper						Location in text *(pg & /fig/table)*
	Mean	SD (or other variance)	No. participants	Mean	SD (or other variance)	No. participants	
84. **No. missing participants and reasons**							
85. **No. participants moved from other groups and reasons**							
86. **Any other results reported**							
87. **Unit of analysis** *(e.g. by individuals, health professionals, practice, hospital, community)*							
88. **Statistical methods used and appropriateness of these methods** *(e.g. adjustment for correlation)*							
89. **Reanalysis required?** *(if yes, specify why)*	... *Yes/No/Unclear*						
90. **Reanalysis possible?**	... *Yes/No/Unclear*						
91. **Reanalysed results**							
92. **Notes:**							

For randomised or non-randomised trial with <u>other outcomes</u>

	Description as stated in report/paper				Location in text *(pg & ¶/fig/table)*
93. **Comparison**					
94. **Outcome**					
95. **Subgroup**					
96. **Time point** *(specify whether from start or end of intervention)*					
97. **Type of outcome**					
98. **Results**	Intervention result	SD (or other variance)	Control result	SD (or other variance)	
	Overall results		SE (or other variance)		
99. **No. participants**	Intervention		Control		
100. **No. missing participants and reasons**					
101. **No. participants moved from other groups and reasons**					
102. **Any other results reported**					

	Description as stated in report/paper		Location in text *(pg & ¶/fig/table)*
103. **Unit of analysis** *(e.g. by individuals, health professionals, practice, hospital, community)*			
104. **Statistical methods used and appropriateness of these methods**			
105. **Reanalysis required?** *(if yes, specify why)*			
106. **Reanalysis possible?**			
107. **Reanalysed results**			
108. **Notes:**			

For controlled before–after studies

	Description as stated in report/paper				Location in text *(pg & ¶/fig/table)*
109. **Comparison**					
110. **Outcome**					
111. **Subgroup**					
112. **Time point** *(specify whether from start or end of intervention)*					
113. **Post-intervention or change from the baseline?**					
114. **Results**	Intervention result	SD (or other variance)	Control result	SD (or other variance)	
	Overall results		SE (or other variance)		
115. **No. participants**	Intervention		Control		
116. **No. missing participants and reasons**					
117. **No. participants moved from other groups and reasons**					
118. **Any other results reported**					
119. **Unit of analysis** *(e.g. by individuals, cluster/ groups or body parts)*					
120. **Statistical methods used and appropriateness of these methods**					
121. **Reanalysis required?** *(specify)*	... *Yes/No/Unclear*				
122. **Reanalysis possible?**	... *Yes/No/Unclear*				
123. **Reanalysed results**					

	Description as stated in report/paper	Location in text *(pg & ¶/fig/table)*
124. **Notes:**		

For interrupted time series or repeated measures study

	Description as stated in report/paper				Location in text *(pg & /fig/table)*
125. **Comparison**					
126. **Outcome**					
127. **Subgroup**					
128. **Length of time-points measured** *(e.g. days, months)*					
Total period measured					
129. **No. participants measured**					
130. **No. missing participants and reasons**					
131. **No. time-points measured**	132. **Pre-intervention**		133. **Post-intervention**		
134. **Mean value** *(with variance measure)*					
135. **Difference in means (post–pre)**					
136. **Percentage of relative change**					
137. **Result reported by authors** *(with variance measure)*					
138. **Unit of analysis** *(e.g. by individuals or cluster/ groups)*					
139. **Statistical methods used and appropriateness of these methods**					
140. **Reanalysis required?** *(specify)*	... *Yes/No/Unclear*				
141. **Reanalysis possible?**	... *Yes/No/Unclear*				
142. **Individual time-point results**					
143. **Read from figures?**	... ***Yes/No/Unclear***				
144. **Reanalysed results**	**Change in level**	**SE**	**Change in slope**	**SE**	
145. **Notes:**					

Applicability

146. **Have important populations been excluded from the study?** *(consider disadvantaged populations and possible differences in the intervention effect)*	... *Yes/No/Unclear*	

147. **Is the intervention likely to be aimed at disadvantaged groups?** *(e.g. lower socioeconomic groups)*	... *Yes/No/Unclear*	
148. **Does the study directly address the review question?** *(any issues of partial or indirect applicability)*	... *Yes/No/Unclear*	
149. **Notes:**		

Other information

	Description as stated in report/paper	**Location in text** *(pg & ¶/fig/table)*
150. **Key conclusions by study authors**		
151. **References to other relevant studies**		
152. **Correspondence required for further study information** *(what and from whom)*		
153. **Further study information requested** *(from whom, what and when)*		
154. **Correspondence received** *(from whom, what and when)*		
155. **Note:**		

Risk of Bias assessment for RCTs

Domain	**Risk of bias** *Low/ High/Unclear*	**Support for judgment**	**Location in text** *(pg & ¶/fig/table)*
156. **Random sequence generation** *(selection bias)*			
157. **Allocation concealment** *(selection bias)*			
158. **Blinding of participants and personnel** *(performance bias)*		**Outcome group: All/**	
(if required)		**Outcome group:**	
159. **Blinding of outcome assessment** *(detection bias)*		**Outcome group: All/**	
(if required)		**Outcome group:**	
160. **Incomplete outcome data** *(attrition bias)*			
161. **Selective outcome reporting?** *(reporting bias)*			
162. **Other bias**			
163. **Notes:**			