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The effect of question order on the outcomes in the core outcome set for brief alcohol interventions among online help-seekers

Submission date
26/07/2020

Recruitment status
No longer recruiting

Registration date
05/08/2020

Overall study status
Completed

Last Edited
17/09/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Alcohol Brief Interventions (ABI) have been researched and disseminated in a variety of contexts over the past 60 years, in both face-to-face and digital settings. Defined by the World Health Organization (WHO) as “practices that aim to identify a real or potential alcohol problem and motivate an individual to do something about it”, ABI encompass a broad range of actions which aim to help individuals change their drinking behaviour. At their core, ABI assess and provide feedback on alcohol use, and can be used once or over time.

However, the variety of outcome measures used in trials to evaluate ABIs effectiveness and efficacy is a limiting factor in providing evidence about these interventions. Comparisons across trials is sometimes impossible despite interventions being similar. The Outcome Measures in Brief Intervention Trials: Alcohol (ORBITAL) project quantified this problem when they identified 2641 different outcomes, measured in approximately 1560 different ways, in 405 trials of ABIs. Through a systematic review of all trials of brief interventions and two e-Delphi rounds, the ORBITAL project established a consensus on a core outcome set (COS) for ABIs. The COS outcomes are:
1. Frequency of drinking
2. Typical number of drinks consumed on a drinking day
3. Frequency of heavy episodic drinking
4. Combined consumption measure
5. Hazardous or harmful drinking
6. Standard drinks consumed in the past week
7. Alcohol related problems or consequences
8. Alcohol related injury
9. Use of emergency healthcare services
10. Quality of life

The current study aims to assess if there is a concern for question order bias among the outcomes of the COS. Question order bias occurs when an individual’s response to a question is affected by previously asked questions, and is a well-known phenomenon which has been

studied, and perhaps abused, in marketing and political science for some time. Recently, it was discovered that question order bias may affect measures of alcohol consumption, as individuals who were asked to first report weekly alcohol consumption were then less likely to be screened as risky drinkers, in comparison to individuals who were first screened and then asked about weekly alcohol consumption.

This trial aims to estimate order effects among the questions within the COS for ABIs, and to investigate patterns of abandonment of the questionnaire. In particular, the trial findings will apply in the context of self-completion of the COS using digital questionnaires among online help-seeking individuals.

Who can participate?
Anyone can participate who is 18 years or older.

What does the study involve?
Responding to a questionnaire about alcohol consumption which is estimated to take 10 minutes.

What are the possible benefits and risks of participating?
There are no anticipated risks from participating. Responding to questions about one's alcohol consumption has been found to help some decide to reduce their consumption. There will also be links to further help available at the end of the questionnaire.

Where is the study run from?
Linköping University (Sweden) but is accessed by participants via the internet in all countries where Google is accessible.

When is the study starting and how long is it expected to run for?
October 2019 to October 2022

Who is funding the study?
The study is funded investigator initiated and funded.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Dnr 2020-01799

Study information

Scientific Title
The effect of question order on the outcomes in the core outcome set for brief alcohol interventions among online help-seekers: a double-blind randomized factorial design trial

Acronym
QOBCOS-1

Study objectives
1. The order in which the questions of the core outcome set for alcohol brief interventions is asked effects the way individuals respond
2. There are patterns with respect to both particular questions, and the order of the questions, which are associated with abandonment of the questionnaire

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/07/2020, the Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: Dnr 2020-01799

Study design
A double-blind randomized factorial design trial to investigate question order bias among the outcomes of the core outcome set for brief alcohol interventions

Primary study design
Interventional

Secondary study design
Factorial design

Study setting(s)
Internet/virtual

Study type(s)
Prevention

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Prevention of harmful and hazardous alcohol consumption

Interventions
The ten COS outcomes will be divided into four clusters of questions:
1. Cluster 1: frequency of drinking, the typical number of drinks consumed on a drinking day, frequency of heavy episodic drinking, combined summary consumption measure, hazardous or harmful drinking
2. Cluster 2: standard drinks consumed in the past week
3. Cluster 3: alcohol-related problems or consequences, alcohol-related injury, and use of emergency healthcare services
3. Cluster 4: quality of life

The order of these clusters will be permuted to create 24 order combinations. Block randomization (random block sizes of 24 and 48) will be used to achieve equal allocation among arms. The randomization sequence and allocation will be fully automated and computerized. Since no identifiers are collected for individuals, we will use web browser cookies and HTML5 storage to store allocation information on the participants' web-browsers. Participants who have not completed the questionnaire and return to the trial website will be presented with the cluster order according to their assignment. Participants who have completed the questionnaire and return to the trial website will be thanked for their participation, but not offered an opportunity to answer the questions again.

Participants will be aware that they are taking part in a research study, however, the true nature of the study will not be revealed to them, since this would interfere with the effect being studied. Therefore, participants will not be aware of which arm they are in, and hence will be blinded to allocation. Research personnel will also be blind to participant allocation.

Intervention Type
Behavioural

Primary outcome measure
1. The ten outcomes of the COS as follows:
1.1. Frequency of drinking
1.2. Typical number of drinks consumed on a drinking day
1.3. Frequency of heavy episodic drinking
1.4. Combined consumption measure
1.5. Hazardous or harmful drinking
1.6. Standard drinks consumed in the past week
1.7. Alcohol-related problems or consequences
1.8. Alcohol-related injury
1.9. Use of emergency healthcare services

1.10. Quality of life
Where 1.1 to 1.5 are measured using the WHO's Alcohol Use Disorders Identification Test – Consumption (AUDIT-C) tool; 1.6 is measured by asking how many standard drinks were consumed each day of the last week; 1.7 is measured using the Short Inventory of Problems (SIP) using the last 3 months as the time frame; 1.8 is measured by asking a single question about injuries inflicted while drinking or being intoxicated; 1.9 is measured by a single question about the number of visits to an emergency room or urgent care treatment facility; and 1.10. is measured using PROMIS Global Health.
2. Proportion abandoning the questionnaire, measured using data collected by the survey platform

Secondary outcome measures
1. Proportion visiting provided links at the end of the questionnaire, measured using data collected by the survey platform
2. Time spent on the questionnaire among completers and among abandoners, measured by a timer that starts when the survey is opened and ends when it is completed or abandoned

Overall study start date
01/10/2019

Completion date
01/10/2022

Eligibility

Key inclusion criteria
Aged ≥18 years

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A Bayesian group sequential design will be used, thus no fixed target exists. We do not expect recruiting more than 5,000 participants, but there are target posterior probabilities that will dictate this.

Total final enrolment
7334

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/10/2020

Date of final enrolment
01/10/2022

Locations

Countries of recruitment
Australia

Canada

India

New Zealand

South Africa

Sweden

United Kingdom

United States of America

Study participating centre
Linköping University
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Sponsor information

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University/education

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https://ror.org/05ynxx418

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Protocols and standard operating procedures will be developed to promote replication including modes other than online which will all be hosted on the Open Science Framework. The findings from this study are expected to be disseminated in peer-reviewed journals and presented at relevant international conferences during 2021-2022, after which all data will be made available on the Open Science Framework.

Intention to publish date
01/10/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/11/2020	27/11/2020	Yes	No
Results article		12/02/2023	20/02/2023	Yes	No
Participant information sheet	Informed consent materials		17/09/2024	No	Yes