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Measuring the effects of adapting a digital alcohol intervention to individuals' motives for drinking and their readiness to change

Submission date 12/06/2024	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/06/2024	**Overall study status** Ongoing	
Last Edited 06/02/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Alcohol consumption continues to be a leading cause of disease in Sweden. More than 40% of the Swedish population drinks at levels that significantly increase the risk of negative consequences. Digital interventions could help people to reduce their drinking. This study explores if a digital intervention's effectiveness can be improved by adapting it to the individuals' motives for drinking and their readiness to change.

Who can participate?
People aged 18 years or older who have a Swedish mobile phone and who drink above Swedish guidelines

What does the study involve?
Some participants will be given access to a digital alcohol intervention which involves receiving text message prompts every Sunday to monitor drinking and receive feedback and advice. Other participants will receive referrals to national information sources. All participants will be asked to complete digital questionnaires on their mobile phones.

What are the potential benefits and risks of participating?
Support will be provided that may help participants to reduce their drinking. The interventions will not be effective for everyone, so participating in the study may lead to disappointment due to not changing behaviour.

Where is the study run from?
Linköping University (Sweden)

When is the study starting and how long is it expected to run for?
January 2023 to July 2027

Who is funding the study?
Swedish Research Council for Health, Working Life, and Welfare (Sweden)

Who is the main contact?
Dr Marcus Bendtsen, marcus.bendtsen@liu.se

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Marcus Bendtsen

ORCID ID
https://orcid.org/0000-0002-8678-1164

Contact details
Linköping University
Linköping
Sweden
581 83
+46 (0)13-28 10 00
marcus.bendtsen@liu.se

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1.0, 2022-00193

Study information

Scientific Title
The effects of a drinking motives and readiness to change adapted digital alcohol intervention among online help-seekers

Acronym
TOPHAT-5

Study objectives
The primary aim of the study is to estimate the effects of an individual personalised (adapted) digital alcohol intervention. The adapted intervention will be contrasted against two comparators: (1) an existing digital alcohol intervention which is not personalised (non-adapted), which has previously been found to be effective; and (2) referral to online resources that would typically be found when looking online. The secondary aims of the study include estimating the degree to which the effects of the interventions are mediated through mechanisms of behaviour

change and estimating individual-level effects. User evaluation and analyses of engagement in the intervention materials will also be part of the study.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/04/2024, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Uppsala, 750 02, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: 2024-01630-01

Study design
Three-arm (1:1:1) parallel-group randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Behaviour change support for individuals who want to reduce their alcohol consumption

Interventions
Current interventions as of 26/02/2025:

Block randomisation with random block sizes of 3 and 6 to three arms (1:1:1). All randomisation procedures will be computerised.

Non-adapted intervention:
The non-adapted intervention will be delivered to participants via their mobile phones as a toolbox with six modules to manipulate these critical health-determining factors. The content of these modules is anchored in state-of-the-art empirical evidence for which active ingredients are effective for supporting reduced alcohol consumption, including behaviour substitution, problem-solving, goal setting, review of behavioural goals, self-monitoring, normative feedback, and understanding the consequences of alcohol consumption. The core element of the intervention is a text message sent to participants each Sunday afternoon. The message includes a prompt to self-monitor one’s current alcohol consumption and a link to a web-based screening tool. The screening tool assesses the past week's consumption, and participants are subsequently given access to the toolbox with six modules. In brief, these modules consist of:
1. Normative feedback on the past week’s consumption based on age and sex.
2. Information about some of the risks of drinking alcohol, including the risk of disease, how it may affect children in proximity, injuries, and traffic accidents.
3. A goal-setting tool with feedback on previously set goals and a timeline showing consumption over time.
4. Tips and teaching of skills which participants can use in their everyday life to immediately reduce their drinking, including tasks designed to make participants reflect on their behaviour.
5. Text messages with tips, skills, and reflection tasks that can be turned on at participants' discretion, which are then sent to participants’ mobile phones throughout the week.
6. A planning tool which allows participants to write messages to themselves that are sent to them at regular intervals throughout the week.

Adapted intervention
The adapted intervention will follow the same logic as the non-adapted intervention. The key difference between the two is that after the weekly self-monitoring and feedback on current consumption, participants will be given tailored exercises and advice for behaviour change which have been selected based on the participant's drinking motives and readiness to change. Periodically, participants in the tailored intervention group will be asked to re-assess their readiness to change and motives, using the readiness to change questionnaire (treatment version) and the drinking motives questionnaire (short form). Matching will be based on the latest available data for participants concerning motives for drinking and readiness to change.

The third (control) arm will be referred to national websites with information about alcohol and health (https://www.1177.se and https://www.iq.se). Both intervention groups will also be referred to these sites.

The interventions last for 4 months and the final follow-up is at 8 months.

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Block randomisation with random block sizes of 3 and 6 to three arms (1:1:1). All randomisation procedures will be computerised.

Non-adapted intervention:
The non-adapted intervention will be delivered to participants via their mobile phones as a toolbox with six modules to manipulate these critical health-determining factors. The content of these modules is anchored in state-of-the-art empirical evidence for which active ingredients are effective for supporting reduced alcohol consumption, including behaviour substitution, problem-solving, goal setting, review of behavioural goals, self-monitoring, normative feedback, and understanding the consequences of alcohol consumption. The core element of the intervention is a text message sent to participants each Sunday afternoon. The message includes a prompt to self-monitor one's current alcohol consumption and a link to a web-based screening tool. The screening tool assesses the past week's consumption, and participants are subsequently given access to the toolbox with six modules. In brief, these modules consist of:
1. Normative feedback on the past week's consumption based on age and sex.
2. Information about some of the risks of drinking alcohol, including the risk of disease, how it may affect children in proximity, injuries, and traffic accidents.
3. A goal-setting tool with feedback on previously set goals and a timeline showing consumption over time.
4. Tips and teaching of skills which participants can use in their everyday life to immediately reduce their drinking, including tasks designed to make participants reflect on their behaviour.
5. Text messages with tips, skills, and reflection tasks that can be turned on at participants' discretion, which are then sent to participants' mobile phones throughout the week.
6. A planning tool which allows participants to write messages to themselves that are sent to them at regular intervals throughout the week.

Adapted intervention
The adapted intervention will follow the same logic as the non-adapted intervention. The key difference between the two is that after the weekly self-monitoring, participants will be given a personalised version of the toolbox, where the content has been selected based on the participant's drinking motives and readiness to change. Initially, this matching will be done based on how participants responded at baseline; however, every two weeks, participants in the

adapted group will be asked to re-assess their readiness to change to measure if they have advanced (or reversed) along the readiness to change states. Participants will also be asked to re-assess their motives. Matching will, therefore, be based on the latest available data for participants concerning motives for drinking and readiness to change. The additional supportive messages sent to participants throughout the week will also be matched based on motives and readiness to change.

The third (control) arm will be referred to a national website with information about alcohol and health (https://www.1177.se).

The interventions last for 4 months and the final follow-up is at 8 months.

Intervention Type
Behavioural

Primary outcome(s)
Measured at baseline, and at 2, 4 and 8 months post-randomisation:
1. Past week's alcohol consumption, measured by asking about the number of standard drinks consumed each day of the past week (which are then summed)
2. Frequency of heavy episodic drinking, measured by asking about the number of episodes of heavy drinking in the past month (four or more standard drinks)

Key secondary outcome(s))
Current secondary outcome measures as of 20/06/2025:

Measured at 8-month follow-up = T3:

Secondary outcome measures:
1. Frequency of drinking measured using the first item of the Alcohol Use Disorders Identification Test (AUDIT-C) (T3)
2. Typical number of drinks consumed on a drinking day, measured using the second item of the AUDIT-C (T3)
3. Frequency of drinking six or more drinks: measured using the third item of the AUDIT-C (T3)
4. Combined consumption measure: measured using the total score of AUDIT-C, with the primary outcome measure for frequency of heavy episodic drinking categorised into the response options of the third AUDIT-C item (T3)
5. Hazardous and risky drinking measured using the AUDIT-C scale (T3)
6. Alcohol-related consequences measured by asking the 15-item Short Inventory of Problems questionnaire (SIP) (T3)
7. Alcohol-related injury measured using a single item based on the SIP questionnaire concerning injuries inflicted while drinking or being intoxicated (T3)
8. Use of emergency health care services measured using a single item concerning the number of visits to emergency health care services, adapted from EconForm90 (T3)
9. Quality of life measured using the PROMIS Global Health 1.2 items, a 10-item questionnaire with higher scores indicating higher quality of life (T3)

Mediation outcomes measured using face-valid single-item scales:
Measured at baseline, and at 2, 4 and 8 months post-randomisation:
1. Confidence: in one’s ability to reduce drinking

2. Knowledge: of how to reduce one's drinking
3. Injunctive norms: peer's approval of drinking
4. Descriptive norms: perceptions about other's drinking

Previous secondary outcome measures as of 26/02/2025:

Measured at 8-month follow-up = T3:

Secondary outcome measures:
1. Frequency of drinking measured using the first item of the Alcohol Use Disorders Identification Test (AUDIT-C) (T3)
2. Typical number of drinks consumed on a drinking day, measured using the second item of the AUDIT-C (T3)
3. Combined consumption measure: measured using the total score of AUDIT-C with the primary outcome measure for frequency of heavy episodic drinking categorised into the response options of the third AUDIT-C item (T3)
4. Hazardous and risky drinking measured using the AUDIT-C scale (T3)
5. Alcohol-related consequences measured by asking the 15-item Short Inventory of Problems questionnaire (SIP) (T3)
6. Alcohol-related injury measured using a single item based on the SIP questionnaire concerning injuries inflicted while drinking or being intoxicated (T3)
7. Use of emergency health care services measured using a single item concerning the number of visits to emergency health care services adapted from EconForm90 (T3)
8. Quality of life measured using the PROMIS Global Health 1.2 items, a 10-item questionnaire with higher scores indicating higher quality of life (T3)

Mediation outcomes measured using face-valid single-item scales:
Measured at baseline, and at 2, 4 and 8 months post-randomisation:
1. Confidence: in one's ability to reduce drinking
2. Knowledge: of how to reduce one's drinking
3. Injunctive norms: peer's approval of drinking
4. Descriptive norms: perceptions about other's drinking

Previous secondary outcome measures:

Measured at 4-month follow-up = T2 and 8-month follow-up = T3:

Secondary outcome measures:
1. Frequency of drinking measured using the first item of the Alcohol Use Disorders Identification Test (AUDIT-C) (T2, T3)
2. Typical number of drinks consumed on a drinking day, measured using the second item of the AUDIT-C (T2, T3)
3. Combined consumption measure: measured using the total score of AUDIT-C with the primary outcome measure for frequency of heavy episodic drinking categorised into the response options of the third AUDIT-C item (T2, T3)
4. Hazardous and risky drinking measured using the AUDIT-C scale (T2, T3)
5. Alcohol-related consequences measured by asking the 15-item Short Inventory of Problems questionnaire (SIP) (T2, T3)

6. Alcohol-related injury measured using a single item based on the SIP questionnaire concerning injuries inflicted while drinking or being intoxicated (T2, T3)
7. Use of emergency health care services measured using a single item concerning the number of visits to emergency health care services adapted from EconForm90 (T2, T3)
8. Quality of life measured using the PROMIS Global Health 1.2 items, a 10-item questionnaire with higher scores indicating higher quality of life (T3)

Mediation outcomes measured using face-valid single-item scales:
1. Confidence: in one's ability to reduce drinking (T2)
2. Knowledge: of how to reduce one's drinking (T2)
3. Injunctive norms: peer's approval of drinking (T2)
4. Descriptive norms: perceptions about other's drinking (T2)

Completion date
01/07/2027

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Have access to a mobile phone
3. Classified as drinking at risky levels according to current Swedish guidelines

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/02/2025

Date of final enrolment
31/10/2026

Locations

Countries of recruitment
Sweden

Study participating centre
Linköping University
Linköping
Sweden
581 83

Sponsor information

Organisation
Linköping University

ROR
https://ror.org/05ynxx418

Funder(s)

Funder type
Government

Funder Name
Forskningsrådet om Hälsa, Arbetsliv och Välfärd

Alternative Name(s)
Swedish Research Council for Health, Working Life and Welfare, Forskningsrådet om Hälsa, Arbetsliv och Välfärd, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan

Current individual participant data (IPD) sharing plan as of 25/06/2025:
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Marcus Bendtsen, marcus.bendtsen@liu.se or info@liu.se
• The type of data that will be shared: Baseline and outcome measures (primary and secondary) at the individual level (anonymized).
• Timing for availability: Anticipated 01/01/2028
• Whether consent from participants was required and obtained: Yes, consent was required and obtained.
• Comments on data anonymization: Data will be anonymized.
• Any ethical or legal restrictions: Ethical approval is required before data is shared.

Previous IPD sharing plan:
The datasets generated during and/or analysed during the current study are not expected to be made available due to GDPR limiting data sharing.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/07/2025	14/07/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes