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# Health for Izhevsk Men

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 28/01/2008 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 29/01/2008 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 13/03/2013 | Mental and Behavioural Disorders | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
078557

## Study information

**Scientific Title**

Randomised controlled trial of motivational interviewing to reduce hazardous drinking among Russian working-age men

## Acronym
HIM

## Study objectives
The study is a trial to explore the efficacy and acceptability of a brief intervention aimed at reducing the prevalence of hazardous drinking in working age men in a typical Russian city (Izhevsk).

Hypothesis:
A brief adaptation of motivational interviewing will be effective in reducing self-reported hazardous drinking at 3 months.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval received from the London School of Hygiene and Tropical Medicine Ethics Committee on the 16th January 2008 (ref: 5230).

## Study design
The study will be an individually randomised, two-armed parallel group, single centre exploratory trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Hazardous drinking

## Interventions
An adaptation of Motivational Interviewing (MI) has been developed for the Russian context, and includes topics such as surrogate drinking and binge drinking (zapoi). MI involves empathic questioning and listening, with a view to the development of discrepancy between alcohol use

and other goals and values and the eliciting of personalised statements about change. The full intervention comprises up to four sessions. These will be delivered at home or in a clinic by specially trained practitioners.

The control group will not receive any intervention other than having a health check as part of the longitudinal study and being invited for 3 and 12 months follow-up.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
SELF report of hazardous drinking 3 months post-randomisation defined as one or more occurrences of:
1. Binge drinking (zapoi) in the past month
2. Surrogates in the past month
3. Hangover and/or excessive drunkenness and/or going to sleep clothed due to being drunk twice or more per week on average over the past month
4. 250 mls or more of ethanol from beverages in the past week from beverages (i.e., 25+ UK alcohol units)

### Secondary outcome measures
SELF and PROXY report of hazardous drinking 12 months post-randomisation defined as one or more occurrences of:
1. Binge drinking (zapoi) in the past month
2. Surrogates in the past month
3. Hangover and/or excessive drunkenness and/or going to sleep clothed due to being drunk twice or more per week on average over the past month
4. 250 mls or more of ethanol from beverages in the past week from beverages (i.e., 25+ UK alcohol units)

SELF completed:
5. AUDIT questionnaire (World Health Organization [WHO] developed global screening assessment of hazardous drinking
6. Leeds Dependency questionnaire
7. Short Index of Problems (SIP) questionnaire

Biomarkers of:
9. Liver damage (gamma-glutamyl transferase [GGT], alanine aminotransferase [ALT], aspartate aminotransferase [AST])
10. Recent heavy drinking (carbohydrate-deficient transferrin [CDT])

### Overall study start date
01/02/2008

### Completion date
31/07/2010

## Eligibility

### Key inclusion criteria
The men recruited into the trial will be drawn from a longitudinal observational study that is part of the Izhevsk Family Study II (aged 27 - 54 years).

PROXY reports (or self reports for men living alone) of hazardous drinking defined as one or more occurrences of:
1. Binge drinking in the past year
2. Surrogates in the past year
3. Hangover and/or excessive drunkenness and/or going to sleep clothed due to being drunk twice or more per week on average over the past year
4. Weekly average of 250 mls or more of ethanol from beverages over the past year (i.e., 25+ UK alcohol units/week)

### Participant type(s)
Patient

### Age group
Adult

### Sex
Male

### Target number of participants
250 participants

### Key exclusion criteria
1. Refusal to have a baseline health check
2. Refusal to be followed up at 3 and 12 months

Either of these criteria will result in exclusion from the trial.

### Date of first enrolment
01/02/2008

### Date of final enrolment
31/07/2010

## Locations

### Countries of recruitment
England

Russian Federation

United Kingdom

### Study participating centre

**London School of Hygiene and Tropical Medicine**
London
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# Sponsor information

**Organisation**
London School of Hygiene and Tropical Medicine (UK)

**Sponsor details**
Keppel Street
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**Sponsor type**
University/education

**Website**
http://www.lshtm.ac.uk/

**ROR**
https://ror.org/00a0jsq62

# Funder(s)

**Funder type**
Charity

**Funder Name**
The Wellcome Trust (UK) (grant ref: 078557)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 31/03/2008 | | Yes | No |
| Results article | results | 04/11/2011 | | Yes | No |