ISRCTN82405938 https://doi.org/10.1186/ISRCTN82405938

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

Protocol serial number
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).

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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)

Key secondary outcome(s)
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])

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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
United Kingdom

England

Russian Federation

Study participating centre
London School of Hygiene and Tropical Medicine
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

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

Results and Publications

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?
Results article	results	04/11/2011		Yes	No
Protocol article	protocol	31/03/2008		Yes	No