

Health for Izhevsk Men

Submission date 28/01/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 29/01/2008	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 13/03/2013	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 (zapo) 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 (zapo) 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
United Kingdom
WC1E 7HT

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