A randomised controlled trial of two brief intervention strategies in male patients with alcohol related facial injury sustained as a result of interpersonal violence

Submission date	Recruitment status	Prospectively registered
02/04/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
22/06/2007	Completed	☐ Results
Last Edited	Condition category	Individual participant data
16/03/2016	Mental and Behavioural Disorders	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

A randomised controlled trial of two brief intervention strategies in male patients with alcohol related facial injury sustained as a result of interpersonal violence

Acronym

BMI vs SS-COVAID

Study objectives

The null hypotheses for the study are:

- 1. Neither Brief Motivational Intervention (BMI) for alcohol nor Single Session Control Of Violence for Angry Impulsive Drinkers (SS-COVAID) will have a significant effect in reducing alcohol consumption in male patients with alcohol related facial trauma
- 2. Neither BMI or SS-COVAID will have a significant effect in reducing proneness to alcohol related violence in male patients with alcohol related facial trauma
- 3. Neither BMI nor SS-COVAID will cause a reduction in the recurrence rate of alcohol related facial trauma in male patients with alcohol related facial injury

Ethics approval required

Old ethics approval format

Ethics approval(s)

Glasgow South and Clyde Ethics Review Committee COREC, 24/04/2007, ref: 07/S0710/47

Study design

Prospective randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Alcohol consumption

Interventions

BMI for alcohol versus SS-COVAID intervention for proneness to alcohol related violence.

Each intervention will last approximately 30 minutes. The first visit to the clinic will take longer as we are required to gather demographic information from the patients as well as basline information relating to the outcome measures. Both of the interventions are brief psychological interventions which will be delivered by research nurses in a motivational style. The patients will be randomised to one of two intervention groups by an automated telephone randomisation system. Nurses will have undergone standard training in intervention provision and will undergo refresher training throughtout the period of the trial.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Self reported drinking measures (change in drinking days in past 30 days, number of drinks per drinking day, number of heavy drinking days in past 30 days since intervention)
- 2. Self reported aggression or involvement in violence (change in incidence of involvement in violent or aggressive behaviour since intervention)
- 3. AUDIT score
- 4. Alcohol Related Aggression Questionnaire score (ARAQ)

All measured at six and 12 months post intervention.

Secondary outcome measures

- 1. Self reported recurrent facial or other traumatic injuries since intervention, measured at six and 12 months post intervention
- 2. Recurrent alcohol related facial or other traumatic injuries tracked via the Information and Statistics Division of the Scottish Executive since intervention; this will be carried out at six and 12 months but also for the two years prior to intervention and five years after intervention with the patient's consent

Overall study start date

14/05/2007

Completion date

14/05/2009

Eligibility

Key inclusion criteria

- 1. Male patients over 16 years of age with facial injuries sustained due to involvement in interpersonal violence while drinking
- 2. Alcohol Use Disorders Identification Test (AUDIT) score greater than or equal to eight
- 3. Within 28 days of injury
- 4. Able to give informed consent and willing to commit to follow up over 12 months

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

300

Key exclusion criteria

- 1. Female
- 2. Males under 16 years of age
- 3. Unable to give informed consent, e.g., adults with dementia, severe psychiatric problems, patients with learning difficulties who cannot consent for themselves
- 4. Inadequate grasp of English and unable to give informed consent for that reason
- 5. Injury more than 28 days old
- 6. AUDIT score less than eight

Date of first enrolment

14/05/2007

Date of final enrolment

14/05/2009

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre Department of Oral and Maxillofacial Surgery Glasgow United Kingdom G2 3JZ

Sponsor information

Organisation

Southern General Hospital (UK)

Sponsor details

c/o Sonia Whyte R&D Academic Co-ordinator Greater Glasgow and Clyde South Glasgow Division Research and Development Office Neurosurgery Building Glasgow Scotland United Kingdom G51 4TF

Sponsor type

Hospital/treatment centre

Website

http://www.nhsgg.org.uk/content/

ROR

https://ror.org/04wvkky61

Funder(s)

Funder type

Government

Funder Name

Violence Reduction Unit (UK) - £100,000

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