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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
02/04/2007

Recruitment status
No longer recruiting

Registration date
22/06/2007

Overall study status
Completed

Last Edited
16/03/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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

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
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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