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Developing and evaluating interventions for adolescents with alcohol use disorders who present through emergency departments: randomised feasibility study and exploratory randomised controlled trial

Submission date
05/06/2014

Recruitment status
No longer recruiting

Registration date
05/06/2014

Overall study status
Completed

Last Edited
13/06/2019

Condition category
Mental and Behavioural Disorders

✓ Prospectively registered
✓ Protocol added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
Background and study aims
Alcohol is a major global threat to public health. Although the main burden of long-term alcohol-related disease is in adults, its foundations often lie in adolescence. Alcohol consumption and related harm increase steeply from the age of 12 until 20 years. Several studies focusing upon young people have reported significant positive effects of brief interventions on alcohol consumption. A recent assessment of reviews also suggests that electronic brief interventions (eBIs) using internet and smartphone technologies may also markedly reduce alcohol consumption. Interventions that target non-drinking youth are known to delay the onset of drinking behaviours. Web based alcohol interventions for adolescents also demonstrate significantly greater reductions in consumption and harm among 'high-risk' drinkers; however changes in risk status at follow-up for non-drinkers or low-risk drinkers have not been assessed in controlled trials of brief alcohol interventions. This study is made up of two parts and aims to look at the effectiveness and cost-effectiveness. The first part focus on high-risk adolescent drinkers attending Emergency Departments (ED) and the other will focus on those identified as low-risk drinkers or those who don't drink but attending the same ED.

Who can participate?
Adolescents aged 14-18 who are high-risk drinkers attending an ED and low-risk or non-drinkers attending an ED.

What does the study involve?
After agreeing to take part, participants are asked to fill out a questionnaire using an iPad. The questionnaire asks about their diet, the exercise they take, whether they smoke and whether they drink alcohol. The questionnaire also asks about their health in general and how often they use health and social services. The questionnaire takes less than 15 minutes to complete, but for

most people it should take around 5 minutes. Participants can choose to skip past questions or decide not to complete the questionnaire once they have started. The questionnaire is confidential and their answers are not be passed on to their parents/carers or doctors. Participants can complete it on their own, or ask for support from a member of the research team if something is not clear to them. Participants receive a £5 gift voucher for their time after completing the questionnaire. After they complete the questionnaire, some people are also be given some information about alcohol. Sometimes a researcher gives them this information and other times they might also be given information on a smartphone app. The information is given on the same day whilst they are in the Emergency Department and it takes no more than 15 minutes. Participants are contacted again two weeks later to ask them how they found taking part in the project. A member of the research team also contacts them to ask similar questions in 6 and 12-month time. This is either by phone or in person, depending on their preference. They receive a £5 gift voucher for their time after completing each follow up.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
St Thomas' Hospital and nine other NHS hospitals in England (UK)

When is the study starting and how long is it expected to run for?
March 2014 to February 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Paolo Deluca
paolo.deluca@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Paolo Deluca

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
16780

Study information

Scientific Title
Developing and evaluating interventions for adolescents with alcohol use disorders who present through emergency departments: randomised feasibility study and exploratory randomised controlled trial

Acronym
SIPS jr RCT

Study hypothesis
The aim of this study is to:
1. Investigate the effectiveness and cost-effectiveness of alternative interventions in reducing alcohol consumption for high-risk alcohol using adolescents
2. Investigate the effectiveness and cost-effectiveness of alternative interventions in reducing the transition from low to high-risk alcohol consumption in low risk alcohol using adolescents

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Fulham, 06/08/2014, 14/LO/0721
Amendment approved: 25/08/2015

Study design
Randomised; Interventional; Design type: Treatment

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

Condition
Topic: Mental Health, Injuries and emergencies; Subtopic: Addictions, Injuries and Emergencies (all Subtopics); Disease: Addictions, Addictive Substances alcohol, Injuries and Emergencies

Interventions
Screening and eBI: Following a simple feedback procedure participants will receive the eBI smartphone intervention. This is an offline-capable mobile web app which will work on a variety of platforms but will be optimised for recent iPhone and Android phones. It has been developed around the concept of a high street where users will be able to navigate/explore, learn facts and figures about alcohol and receive ongoing personalised feedback and support. Games components within the web app will include supporting a ; Screening and PFBA, Trained research assistants will be responsible for the delivery of the face-to-face brief advice that is tailored to high-risk alcohol users. The researcher will explain that the PFBA is designed specifically for young people who misuse alcohol and attend ED. Initially the research assistant will identify the young person as either a High or Low-risk alcohol user and discuss the risks associated with this or increasing levels of alcohol consumption (as indicated). The intervention will take 5 m; Screening only group (+TAU), To minimise possible intervention effects we will blind participants allocated to this study arm to the main aims of the trial. They will be told that the trial focuses on general health behaviours, including alcohol use. After agreeing to be followed up at 6 and 12 months patients will be then returned to the care of ED staff for usual care with no further interaction until the follow up stages.; Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary outcome measure as of 12/10/2016:
Total alcohol consumed over the past 3 months, in standard units (1 unit = 8g ethanol), is assessed using the Alcohol Use Disorders Identification Test – Consumption version (AUDIT-C) at baseline 6 and 12 months.

Original primary outcome:
The Timeline Follow Back 28 days (TLFB28) interview at 12 months

Secondary outcome measures
Secondary outcome measures as of 12/10/2016:
1. Percent days abstinent, drinks per drinking day and heavy episodic alcohol use will be measured using the AUDIT-C at baseline and then 6 and 12 months
2. High risk alcohol use will be measured using the Extended AUDIT-C questionnaire at baseline and then 6 and 12 months
3. Past year and lifetime alcohol use will be measured using question 19 from the ESPAD study at baseline and 12 months
4. The consequences associated with alcohol consumption will be measured using questions 21-22 from the ESPAD study at baseline and 12 months
5. General health and functioning will be measured using the Strengths and Difficulties Questionnaire measured at baseline and 12 months.
6. Health status will be measured using the EQ-5D-5L at baseline, 6 and 12 months

7. Service use including health and social services, school attendance and involvement in criminal justice will be measured using a bespoke version of the Client Service Receipt Inventory (CSRI) at baseline and then at 6 and 12 months

Original secondary outcome:
1. Economic outcome measures; Timepoint(s): Stage 2 will involve collecting data on the costs of the interventions together with data on use of
2. Process outcome measures; Timepoint(s): Expectancy will be measured using the ESPAD Question 21 (96), this will be assessed at baseline, pri;
3. Participants will also be asked questions about past year and lifetime alcohol use and the consequen

Overall study start date
01/03/2014

Overall study end date
28/02/2017

Eligibility

Participant inclusion criteria
1. Age 14 years or more and less than 18 years
2. Alert and orientated, able to speak English sufficiently well to complete the research assessment
3. Able and willing to provide informed consent to screening, intervention and follow-up
4. If under 16 Gillick competent or having a parent/guardian able and willing to provide informed consent
5. Owning a smartphone or alternatively having access to the internet at home

Participant type(s)
Patient

Age group
Child

Lower age limit
14 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 1500; UK Sample Size: 1500

Participant exclusion criteria
1. Severe injury
2. Suffering from serious mental health problem

3. Gross intoxication
4. Patient, parent or guardian unable or unwilling to provide informed consent (if under 16)
5. Specialist services involved because of social or psychological needs
6. Receiving, or having received in the past 6 months, treatment for an alcohol or substance use disorder
7. Current participation in other alcohol research

Recruitment start date
08/10/2014

Recruitment end date
31/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Croydon Hospital
530 London Road
Croydon
United Kingdom
CR7 7YE

Study participating centre

Ealing Hospital
Uxbridge Road
Southall
United Kingdom
UB1 3HW

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
Queen Elizabeth Hospital
Queen Elizabeth Avenue
Gateshead
United Kingdom
NE9 6SX

Study participating centre
North Tees Hospital
Holdforth Road
Hartlepool
United Kingdom
TS24 9AH

Study participating centre
South Tyneside District Hospital
Harton Lane
South Shields
United Kingdom
NE34 0PL

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Sponsor information

Organisation
King's College London

Sponsor details
National Nursing Research Unit
London
England
United Kingdom
SE5 8AF

Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal by September 2017. Final report to NIHR to be submitted by March 2017 and to be published on the NIHR Journal Series.

Intention to publish date
30/09/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/04/2015		Yes	No
Results article	qualitatve study results	12/06/2019	13/06/2019	Yes	No
HRA research summary			26/07/2023	No	No