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Addressing Drinking Among Patients: comparing Two Approaches

Submission date
27/10/2011

Recruitment status
No longer recruiting

Registration date
08/12/2011

Overall study status
Completed

Last Edited
19/11/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Alcohol misuse is a major cause of premature death and ill-health. Europe has the highest number of alcohol related illnesses in the world and alcohol accounts for approximately 1.8 million deaths. Although a high number of people are admitted to hospital with an illness linked to drinking alcohol, many are unaware that they have an alcohol problem. This means that they often do not directly seek treatment for their drinking. Providing specialist treatment for such problem drinkers can reduce use of the NHS as well as improving the health and social benefits for the individuals. A person's overall health lifestyle can often be linked to the amount of alcohol they drink and problem drinkers are likely to have a range of lifestyle problems (for example, smoking and obesity). It has been suggested that having a healthy or balanced lifestyle could possibly help reduce or stop alcohol use, and prevent relapse.
This initial study aims to look at whether a treatment focused on healthy living is better at reducing someone's alcohol intake than a treatment focused on alcohol alone.

Who can participate?
To take part you need to:
1. Be aged 18 years and older
2. Have been admitted to hospital with an illness linked to drinking alcohol
3. Score 16 or more on the modified Alcohol Use Disorders Identification Test

What does the study involve?
You will be randomly allocated to one of the following treatments:
1. An alcohol focused treatment: this is a social network based treatment for helping people to resolve their drinking problems, by reducing the amount they drink or becoming abstinent. You would be encouraged to seek the help of concerned and supportive others and to plan alternative activities to drinking and make relapse prevention plans.
2. A healthy living treatment: this would involve choosing three healthy living subject areas from a choice of seven. If you appear to have particular problems in an area, you would be encouraged to feel positive about addressing them. Treatment would begin with one session on each chosen area with a review at the beginning of the next session and a review of the success of the programme as the fourth session. You would be encouraged to invite a friend to participate in the behaviour change plans you draw up for each subject.

You will receive four sessions of your allocated treatment, each lasting 30 to 45 minutes, over a maximum period of eight weeks. You will also be asked to complete some questionnaires during your time on the study (at the start, after 6 months and after 12 months). We are also interested in talking to people about how they feel about being told their alcohol drinking could be a problem and how they felt being approached about this study. This will provide an opportunity for you to discuss your feelings and thoughts about being told that your diagnosis may be related to drinking alcohol. Even if you choose not to be allocated to a treatment, you can still talk to a researcher about your experiences if you would like to.

What are the possible benefits and risks of participating?
You will receive advice on reducing your drinking although we cannot promise the study will definitely help you. The information we get from this study will help to answer the question as to whether one of these treatments is better than the other. There are no known risks to participants.

Where is the study run from?
This study is being organised by Leeds Addiction Unit and the University of York. Patients will be recruited from Leeds General Infirmary and St James's Hospital in Leeds.

When is the study starting and how long is it expected to run for?
Patients will be recruited from approximately March 2012 until October 2012.

Who is funding the study?
National Institute of Health Research Collaborations for Leadership in Applied Health Research and Care (CLAHRC) programme.

Who is the main contact?
Dr Judith Watson
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Contact information

Type(s)
Scientific

Contact name
Dr Duncan Raistrick

Contact details
Leeds Addiction Unit
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United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.0

Study information

Scientific Title
A randomised controlled trial of an alcohol focused intervention versus a healthy living intervention for problem drinkers identified in a general hospital setting: a pilot study

Acronym
ADAPTA

Study objectives
A healthy living intervention with its broader focus on up to three lifestyle domains out of a choice of diet, exercise, smoking, drinking, personal care, drug use and medication concordance will have greater acceptability, and therefore be more effective, than a more specific focus on drinking alcohol behaviour change in a non help seeking population of problem drinkers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pragmatic qualitative randomised controlled open pilot study

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
Generic Health Relevance, alcohol consumption, problem drinkers

Interventions

1. An alcohol focused intervention - a manually driven, social network based, cognitive behavioural intervention using motivational dialogue with a strong evidence base in UK clinical trials and is increasingly commonly taught and practised in the UK addiction field
2. A healthy living intervention - a manually driven intervention which targets a possible seven domains (maximum of three) which contribute to overall health: diet, exercise, drinking, smoking and medication concordance, drug use and personal care

Both groups will receive four sessions (30-45 minutes each) delivered one to two weeks apart, over a maximum period of eight weeks.

Intervention Type
Behavioural

Primary outcome measure
AUDIT score at six months post randomisation

Secondary outcome measures
1. Qualitative research: The acceptability of the assessment process and interventions will be explored in order to inform future practice by means of semi-structured interviews. These interviews will add to the quantitative measures detailed below, in addressing the acceptability of these interventions and the possible mechanism of their impacts.
2. Dependence: Dependence will be measured at baseline, six and 12 months using the Leeds Dependence Questionnaire (LDQ)
3. Social Satisfaction: Social satisfaction will be measured at baseline, six and 12 months using the Social Satisfaction Questionnaire (SSQ).
4. Clinical Outcomes in Routine Evaluation (CORE-10): Subjective well-being, psychological problems and functioning using the Clinical Outcomes in Routine Evaluation (CORE-10) will be assessed at baseline, six and 12 months post randomisation
5. Health-related quality of life (HRQoL): HRQoL will be assessed at baseline, six and 12 months post randomisation using the European Quality of Life - 5 Dimensions (EQ-5D)
6. Costs: Costs of delivering a healthy living intervention and those of the alcohol focused intervention will be measured by recording the resources utilised in the identification and delivery of both interventions. Participant use of health services, other alcohol services outside the study, public services and criminal justice services will be assessed using a service use questionnaire at baseline, six and 12 months post randomisation

Overall study start date
01/02/2012

Completion date
31/10/2013

Eligibility

Key inclusion criteria
1. Men and women aged 18 years and over
2. Admitted to St James's Hospital and/or Leeds General Infirmary
3. Diagnosis likely to be responsive to addiction interventions, scoring equal to or more than 16 on the modified Alcohol Use Disorders Identification Test (AUDIT)

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
222

Key exclusion criteria
1. Aged less than 18 years of age at the time of screening
2. Have received specialist treatment with a primary focus on alcohol in the past 6 weeks
3. No-fixed abode (i.e. not available for follow-up)
4. Currently serving a sentence in prison or outstanding legal issues likely to lead to imprisonment (i.e. not available for follow-up)
5. Mental or physical illness likely to preclude active participation in treatment or follow up (e.g. not stable through current medication/treatment)
6. Unwilling to give written informed consent
7. Unable to give written informed consent
8. Unable to take part in either intervention using spoken English
9. Unable to self-complete the English language outcome measure tools

Date of first enrolment
01/03/2012

Date of final enrolment
01/10/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Addiction Unit
Leeds
United Kingdom
LS2 9NG

Sponsor information

Organisation
Leeds Partnerships NHS Foundation Trust (UK)

Sponsor details
c/o Dr James Hughes
Research and Development
North Wing St Mary's House
St Mary's Road
Leeds
England
United Kingdom
LS7 3LA

Sponsor type
Hospital/treatment centre

Website
http://www.leedspft.nhs.uk/professionals

ROR
https://ror.org/00n635c12

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - Collaborations for Leadership in Applied Health Research and Care (CLAHRC) programme

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	30/04/2013		Yes	No
Results article	results	01/09/2015		Yes	No