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Impact of a motivational intervention (MI) on problem drug and alcohol use in adult mental health inpatient units

Submission date
17/04/2014

Recruitment status
No longer recruiting

Registration date
17/04/2014

Overall study status
Completed

Last Edited
05/10/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Substance misuse in people with severe mental health problems is common. It has been linked to people not taking part in their treatment and a lack of motivation to change their drug and alcohol misuse. People who misuse substances and have mental health problems are more likely to go into psychiatric hospitals. Often their substance use plays a big part. It is recommended that staff on psychiatric wards be trained to talk to patients about substance misuse and offer them treatment. However, this has not been addressed. Being admitted into a psychiatric hospital leads some people to spend time on the ward thinking about why they have been admitted. Some people may start to see that substance misuse made things worse for them and decide to stop using; however, after leaving hospital they may feel well and go back to misusing alcohol or drugs and refusing their mental health treatment. The time in hospital when people are thinking about what went wrong is an important and unique opportunity. If people who misuse substances are given a chance to receive therapy on the ward they could think about their use and be offered support for changes they want to make. This study will be the starting point for a larger study that will offer a motivational treatment that will link inpatient and community treatment. So, in the current study we want to see if we can train ward staff to offer a motivational treatment over 2 weeks to help inpatients get involved in substance misuse treatment and be more ready to change substance misuse. We will offer a booster session 1 month after discharge to help them transfer the skills and motivation gained during the treatment to the community. We also want to see how practical and suitable the treatment is for inpatients and staff as a part of care on the ward and carry out early work so that in the larger study we can see if this treatment reduces the costs/burden to health services and benefits patients.

Who can participate?
Adults with severe mental health problems, misusing alcohol and/or drugs.

What does the study involve?
Following initial assessments eligible participants will be randomly allocated to either the Brief Integrated Motivational Intervention along with treatment as usual, or treatment as usual alone.

Engagement in treatment and readiness to change substance misuse will be analysed. We will also check if this is cost-effective. Staff and participants will take part in interviews to find out if the intervention is acceptable.

What are the possible benefits and risks of participating?
Taking part in the study may help us to develop better ways of working with people receiving treatment in inpatient units for both their mental health and substance use. The study may involve discussing topics that are sensitive and/or distressing for you, but you can stop if you feel uncomfortable and you do not have to discuss anything that you find distressing.

Where is the study run from?
The study is run from Birmingham and Solihull Mental Health NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
The study started in April 2013 and will run until September 2014.

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

Who is the main contact?
Dr Hermine Graham
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13978

Study information

Scientific Title
A pilot study to assess the feasibility and impact of a motivational intervention (MI) on problem drug and alcohol use in adult mental health inpatient units

Study objectives
The primary hypothesis to be evaluated is whether engagement in treatment for substance misuse can be significantly improved by the MI provided in the context of treatment as usual (TAU). The secondary hypotheses are that those receiving the MI will show greater readiness to change substance use behaviour than those receiving treatment as usual and that the MI+TAU will be more cost effective than TAU.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committee West Midlands The Black Country; 11/01/2013; ref. 12/WM /0369

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

Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: Addictions; Disease: Addictions, Addictive Substances alcohol, Addictive Substances illegal drugs, Schizophrenia

Interventions
The trial uses concealed randomisation; blind, independent assessment of outcome at 3 months. Participants are randomised on a 1:1 basis to one of two experimental conditions: MI in the context of Treatment As Usual or Treatment As Usual.

The Intervention
The MI is offered in the context of TAU. The MI seeks to encourage participants to engage in

talking about their substance use and its impact on their mental health, the fundamental first step in the process of promoting a readiness and willingness to change problematic drug/alcohol use. The initial aim is two-fold; firstly to increase awareness of the advantages and the disdvantages of continued substance misuse, and secondly to build awareness of the impact of substance use on mental health. The next stage encourages participants to contemplate change and make a change plan, thereby making change feel possible. Participants are provided with individually tailored psychoeducational material about substances and between sessions are also encouraged to access websites offering information about alcohol (Down your Drink) and drugs (Talk to Frank). Participants are offered a Peer Mentor following the first week of the intervention. The Peer Mentor will aim to show empathy and understanding during a difficult time for the participants, share personal experiences, offer an alternative outlook on problematic substance use and provide some support and solidarity.

Treatment as Usual (TAU)
Treatment as usual will be documented. It is primarily provided by nursing and medical staff on the mental health admission units in line with inpatient trust policies which is regularly monitored by the UK Care Quality Commission. It will primarily consist of assessment and monitoring of mental state, provision of medication and stabilisation of mental state.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Engagement with substance misuse treatment; timepoint(s): baseline and 3-month follow-up

Secondary outcome measures
1. Cost-Effectiveness Analysis; timepoint(s): baseline and 3-month follow-up
2. Drug and alcohol use; timepoint(s): baseline and 3-month follow-up
3. Motivation to change alcohol and drug use; timepoint(s): baseline, 2-weeks post treatment and 3-month follow-up
4. Psychological functioning; timepoint(s): baseline, 2-week post treatment and 3-month follow-up

Overall study start date
15/04/2013

Completion date
30/09/2014

Eligibility

Key inclusion criteria
1. Adult (aged 18-65 years)
2. Service users of BSMHFT community mental health services
3. Admitted to BSMHFT mental health inpatient units
4. Assessed by the Responsible Clinical Officer as having capacity to consent
5. Have a Care Co-ordinator in BSMHFT Community Mental Health Teams
6. With severe mental health problems with one of the following diagnoses:

6.1. ICD-10 schizophrenia, schizoaffective or delusional disorders (F20,22,23,25,28,29)
6.2. Bipolar affective disorders (F31)
6.3. Recurrent depressive disorder without psychotic symptoms (F33.2) (32)
7. Misusing alcohol and/or drugs (abuse/dependent use based on DSM-IV diagnostic criteria for substance-related disorders) over the last 6 months, based on a minimum score of 3 on the Clinicians Alcohol/Drugs Use rating scale (33).

If participants are readmitted to the in-patient units they will be reallocated to the treatment they were assigned previously
Target Gender: Male & Female; Upper Age Limit 65 years; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 68; UK Sample Size: 68

Key exclusion criteria
1. Do not meet the inclusion criteria
2. Are unable to provide informed consent
3. Do not speak English sufficiently for them to be able to complete the questionnaires or engage in the motivational intervention

Date of first enrolment
15/04/2013

Date of final enrolment
30/09/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

School of Psychology
Birmingham
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Sponsor information

Organisation
Birmingham and Solihull Mental Health NHS Foundation Trust (UK)

Sponsor details
Research & Innovation
Radclyffe House
66-68 Hagley Road
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B16 8PF

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00cjeg736

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-1010-23138

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	01/08/2014		Yes	No
Results article	results	01/04/2016		Yes	No