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Training family members and carers of opiate users in overdose management and naloxone administration

Submission date
22/04/2010

Recruitment status
No longer recruiting

Registration date
05/05/2010

Overall study status
Completed

Last Edited
07/08/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.iop.kcl.ac.uk/departments/?locator=1111

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Training family members and carers of opiate users in overdose management naloxone administration: a randomised trial

Study objectives
To evaluate the short-term effects of a group-based intervention to train family members and carers of opioid users in overdose management and naloxone administration and compare with control information-only intervention.

Alternative hypotheses under investigation:
1. The group-based training is effective in increasing family members' knowledge and positive attitudes towards managing an overdose when compared to the controlled intervention
2. The group-based training is effective in increasing family members' positive attitudes in overdose management overdose when compared to the controlled intervention
3. Changes promoted by the interventions are robust after 3 months

Secondary objectives:
1. To verify if family members succeed in having a naloxone supply prescribed to their opiate user relative after training
2. To verify if family members have witnessed and managed an overdose 3, 6 and 12 months after the interventions
3. To assess qualitative aspects of training through trainers' and trainees' feedback on the group-based intervention
4. To determine the acceptability of possible alternative routes and devices of naloxone administration among family members and carers

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Joint South London and Maudsley and Institute of Psychiatry NHS Research Ethics Committee, 27/02/2009, ref: 08/H0807/90

Study design
Randomised interventional multicentre non-blinded controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Opioid overdose

Interventions
Intervention group:
The short-term objective of the training session is to produce an increase in knowledge, skills and positive attitudes towards managing an overdose. A group-based intervention previously used to train drug-using service users and clinicians in other studies conducted by the National Addiction Centre has been adapted for delivery among family members for the present study. The intervention should take approximately 2 hours. There will be two coordinators and 4 to 8 family members in each group. Sessions will be structured but informal to allow participants to interact.

The training session will be formed of two stages:
1. First there will be an oral presentation and all important aspects of managing an opiate overdose will be covered. The interactive session will include the following topics: how to recognise and manage an opioid overdose; an explanation of how naloxone reverses an opiate overdose; actions that should be taken and how naloxone should be administered. There will also opportunity for discussions and to clarify doubts and concerns on the topic.
2. The second stage will be a practice session. Trainers will demonstrate and participants will practice the skills which are going to be taught: how to manage an overdose and administer naloxone.

Each trained subject will receive copies of the presentation including guidelines on naloxone provision and links to useful websites. Information will be given on how to request a take-home emergency supply of naloxone through Addiction Services and GPs; this will be facilitated by the project.

Feedback form will be administered by the end of the session to assess quality and participants' satisfaction with training.

Control group:
At the moment in the Addiction Services across the UK family members are not offered training on overdose management. The current practice just includes the offer of information in the format of leaflets. For this reason the experimental intervention will be compared to the current practice of offering information only.

The control group will receive an information pack which will include:
1. Overdose booklet: produced by © Harm Reduction Works 'Overdose: everything you need to know'. The booklet contains comprehensive information about causes and signs of overdose, myths and actions to be taken.

Reading time for the information pack will be approximately 15 minutes. Participants from the control group will be given the pack and asked to immediately read it. This pack will also be distributed to the experimental group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Measured at 6 and 12 months:
1. Scores on the Overdose Knowledge Scale (OD-KS): risk, signs, action and naloxone domains and totals score
2. Scores on the Overdose Attitudes Scale (OD-AS): competence, concerns and readiness domains and total score

Secondary outcome measures
Measured at 6 and 12 months:
1. Characteristics of the sample
2. Number of family members who requested and successfully obtained a naloxone supply after interventions
3. Number of family members who witnessed, experienced and managed an overdose at 3, 6 and 12 months after the intervention
4. Preferable route and device of naloxone administration stated by family members
5. Trainers' and trainees' feedback on the group-based training
6. Scores in the Symptom Rating Test

Overall study start date
09/10/2009

Completion date
09/10/2011

Eligibility

Key inclusion criteria
1. Aged 18 years or older, either sex
2. To have at least one family member (e.g., parent, partner, sibling, carer) who uses opioids
3. Opioid being the main drug type taken by their relative
4. To have sufficient knowledge of English to understand the study protocol, intervention and the research instruments

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
A total sample size of 128 participants

Total final enrolment
187

Key exclusion criteria
1. Not having close contact with the opioid user (e.g., if they do not live in same house or frequently visiting)
2. Already trained in overdose management and naloxone administration in the past 3 years
3. Not interested in taking part in the study
4. Not willing to accept randomisation

Date of first enrolment
09/10/2009

Date of final enrolment
09/10/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry, King's College London
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Sponsor information

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Sponsor type
University/education

Website
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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
Institute of Psychiatry, Kings College London (UK)

Funder Name
Institute of Social Psychiatry (UK)

Funder Name
University of London (UK) - Central Research Funds

Funder Name
Alban Programme (UK)

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?
Results article	results	01/02/2014	07/08/2020	Yes	No