

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

<b>Submission date</b> 22/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/08/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Anna Williams

**Contact details**  
Institute of Psychiatry, King's College London  
Addictions Department  
Addiction Sciences Building  
First Floor B12  
4 Windsor Walk  
Denmark Hill  
London  
United Kingdom  
SE5 8AF  
+44 (0)20 7848 0027  
anna.v.williams@kcl.ac.uk

## Additional identifiers

## 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

### **Study type(s)**

Treatment

### **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(s)**

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

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**Institute of Psychiatry, King's College London**

London

United Kingdom

SE5 8AF

## Sponsor information

**Organisation**

Institute of Psychiatry, Kings College London (UK)

**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

## 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?
<a href="#">Results article</a>	results	01/02/2014	07/08/2020	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes