ISRCTN22775534 https://doi.org/10.1186/ISRCTN22775534

# Pilot study of Assertive Community Treatment in Alcohol Dependence

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 21/01/2009 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 27/03/2009 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 19/12/2017 | Mental and Behavioural Disorders | |

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

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
MRC ref: G0701818

# Study information

## Scientific Title
Assertive Community Treatment in Alcohol Dependence: a pilot randomised controlled trial

## Acronym
ACTAD

## Study objectives
As of 15/03/2010, this record has been substantially amended to include changes to the protocol; all changes can be found in the relevant field with the above update date. At this time, the target number of participants was increased from 88 to 132.

Assertive community treatment for chronic relapsing alcohol dependence results in better clinical outcomes than standard treatment and is more cost effective.

More details can be found at: http://www.iop.kcl.ac.uk/departments/?locator=1070

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Joint South London and Maudsley and the Institute of Psychiatry NHS Research Ethics Committee, approved on 15/09/2008 (ref: 08/H0801/113)

Added 15/03/2010:
A substantial amendment was approved by the above ethics board on the 29th January 2010.

## Study design
Pilot randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
Can be found at: http://www.iop.kcl.ac.uk/iopweb/blob/downloads/locator/l_1070_C2_PIS_08_H0801_113_SLAM_V2.doc

## Health condition(s) or problem(s) studied
Alcohol dependency/ community alcohol services

## Interventions

Current interventions as of 15/03/2010:
Participants will be individually randomised to the following two arms (randomisation ration 2:1).

Arm 1: Control condition, standard treatment comprising:
1. An assigned keyworker (caseload greater than 25)
2. Care plan
3. Psychological interventions as necessary
4. Pharmacotherapies
5. Inpatient treatment
6. Referral to, and liaison with, other agencies)
7. Duration of care less than or equal to 3 months

Arm 2: Assertive Community Treatment, including standard treatment plus:
1. Rapid access to services
2. Staff with a small caseload (less than or equal to 15)
3. A high ratio of in vivo to office-based appointments
4. Assertive engagement
5. Focus of care extended beyond alcohol dependence
6. A shared care approach
7. Care coordinators working within a multidisciplinary team that meets frequently
8. Extended contact with patients over 12 months

Initial information at time of registration:
Participants will be individually randomised to the following two arms (randomisation ratio 1:1):

Control condition, standard treatment comprising:
a. An assigned keyworker (caseload >25)
b. Care plan
c. Psychological interventions as necessary
d. Pharmacotherapies
e. Inpatient treatment
f. Referral to, and liaison with, other agencies

Assertive Community Treatment, including standard treatment plus:
a. Rapid access to services
b. A small caseload (<=15)
c. A high ratio of 'in vivo' to office based appointments
d. Extensive motivational interviewing
e. Assertive coordinators working within a multidisciplinary team that meets frequently
f. Extended contact with patients over 12 months

The interventions will be running for 26 months of the trial. The length of the interventions for each patient will be 12 months.

## Intervention Type

Other

## Phase

Not Applicable

### Primary outcome measure
Alcohol consumption assessed using the Time Follow Back Interview (Form 90) to provide a measure of mean drinks per drinking day and percent days abstinent. This will be assessed at baseline (receipt of referral by community alcohol team), at 6 months and 12 months follow up.

### Secondary outcome measures
1. Severity of Alcohol Dependence Questionnaire, assessed at baseline (receipt of referral by community alcohol team), 6 months and 12 months follow up
2. Alcohol Problems Questionnaire, assessed at baseline (receipt of referral by community alcohol team), 6 months and 12 months follow up
3. Motivation, assessed by the Readiness to Change Questionnaire, assessed at baseline (receipt of referral by community alcohol team), 6 months and 12 months follow up
4. Social Network Involvement, assessed by the Important People and Activities Inventory, assessed at baseline (receipt of referral by community alcohol team), 6 months and 12 months follow up
5. Psychiatric symptoms, assessed by the SF-12® Health Survey, assessed at baseline (receipt of referral by community alcohol team), 6 months and 12 months follow up
6. Quality of Life, assessed by Euroqol EQ-5D, assessed at baseline (receipt of referral by community alcohol team), 6 months and 12 months follow up
7. Therapeutic relationships, assessed by the Scale To Assess Relationships in community mental health care (STAR), assessed during the 6 month and 12 month follow up interviews
8. Service User Questionnaire, assessed at baseline (receipt of referral by community alcohol team), 6 months and 12 months follow up
9. Treatment engagement, including completion of assessment, detoxification and aftercare, assessed during the 6 month and 12 month follow up interviews

### Overall study start date
12/01/2009

### Completion date
11/01/2012

## Eligibility

### Key inclusion criteria
Current inclusion criteria as of 15/03/2010:
1. Both males and females, adult patients (greater than or equal to 18 years)
2. One or more previous episodes of treatment for alcohol dependence in the last 5 years in community drug and alcohol services
3. Alcohol dependent (as determined by Composite International Diagnostic Interview- Short Form [CIDI-SF])

Initial information at time of registration:
1. Both males and females, adult patients (greater than or equal to 18 years)
2. Severe alcohol dependence (Diagnostic and Statistical Manual of Mental Disorders, fourth edition [DSM-IV] and Severity of Alcohol Dependence Questionnaire Score greater than or equal to 30)
3. History of premature disengagement from alcohol services (one or more previous episodes of non-completion of treatment)
4. Patients with potentially more complex needs (e.g., lack of social support, unstable housing, physical illness, depression, legal problems)

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
88

### Key exclusion criteria
Current exclusion criteria as of 15/03/2010:
1. Attended a professional service for alcohol dependence in the last 6 months
2. Street homeless
3. Diagnosed with a psychotic disorder
4. Is in receipt of assertive outreach services, or has Community Mental Health Team (CMHT) input greater than or equal to once a month
5. Has a severe cognitive impairment
6. Has a history of violence to treatment staff and/or Multi-Agency Public Protection Arrangements (MAPPA) registered

Initial information at time of registration:
1. Patients with concurrent severe mental illness
2. Patients with severe cognitive impairment
3. Patients already in receipt of assertive treatment services

### Date of first enrolment
12/01/2009

### Date of final enrolment
11/01/2012

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre

**Section of Alcohol Research**
London
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SE5 8BB

# Sponsor information

**Organisation**
King's College London (UK)

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c/o Prof John Strang
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**Sponsor type**
University/education

**Website**
http://www.kcl.ac.uk/

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

# Funder(s)

**Funder type**
Government

**Funder Name**
Medical Research Council (UK) (ref: G0701818)

**Alternative Name(s)**
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## 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 | 20/02/2012 | | Yes | No |
| Results article | results | 09/03/2017 | | Yes | No |