# Assertive community treatment for people with alcohol dependence: a pilot randomised controlled trial

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## Abstract

### Background

Alcohol dependence is a significant and costly problem yet engagement in conventional specialist treatment is often problematic. Assertive community treatment (ACT) has been identified as a potential model of care for people with moderate to severe alcohol dependence but no robust research has been undertaken to date.

### Aims

A pilot randomised controlled trial (RCT) to assess the feasibility and acceptability of an assertive community treatment model of care for people with alcohol dependence and a history of previous unsuccessful alcohol treatment.

### Methods

Single blind, pilot RCT of ACT plus care as usual (CAU) versus CAU alone in three NHS community drug and alcohol services in South London. Participants were adults (age 18+) with alcohol dependence and a history of previous unsuccessful alcohol treatment in the last 5 years. ACT aimed to assertively engage participants for 12 months with regular, minimum weekly contact and a focus on both health and social care needs. Stratification was by severity of alcohol dependence and site. CAU comprised access to the full range of services provided by the community teams including detoxification, and psychological and pharmacological interventions. Research follow up was conducted at 6 and 12 months post randomisation by researchers blinded to treatment allocation.

### Results

Recruitment and follow up was feasible. Of 126 individuals assessed 94 (74.6%) were randomised, 45 in ACT and 49 in CAU, and follow up was achieved with 100% of ACT and 86% of CAU participants at 6 months, and 98% and 88% respectively at 12 months. Those in ACT were in contact with addiction services for significantly longer, had more contacts, better treatment engagement, and were more often seen in their homes or local community than CAU participants. The ACT group had a higher percentage of days abstinent but lower quality of life at 6 months. At 12 months the ACT group had more problems related to drinking and lower quality of life than CAU but there were no differences in drinking measures. The ACT group had fewer days in hospital and hospital visits but more visits to their GP than CAU, however, there were no differences in unplanned NHS service use at 12 months.

### Conclusions

An RCT of ACT was feasible to implement in a typical treatment seeking alcohol dependent population and showed promising improvements in drinking and reduced unplanned health care use compared to CAU. A definitive RCT of ACT versus care as usual in alcohol dependence is now warranted.

## Introduction

Alcohol misuse places a considerable burden on society, and is the third leading cause of disability in Europe (Rehm et al., 2009). In England, approximately 4% of the adult population are alcohol dependent (McManus et al 2009) and the government has identified provision of effective treatment as a priority in reducing these costs (Department of Health 2012). Current specialist alcohol service provision in the UK focuses on discrete, time-limited episodes of intervention, typically up to 12 weeks duration and emphasises personal choice and motivation. However, amongst those referred there are high rates of non-attendance (Mitchell and Selmes 2007), less than 70% complete a treatment programme (Passetti et al 2008), and after successful completion approximately one third continue to drink heavily and have poor long term outcomes (Marshall et al 1994). For this group of patients, alcohol dependence is a chronic relapsing disorder and in typical practice, treatment often involves multiple episodes extending over many years. Best practice guidance for this population recommended the use of case management approaches for patients with moderate to severe alcohol dependence who are at risk, or have a previous history, of disengagement from treatment (National Institute for Health and Care Excellence, 2011).

Assertive community treatment (ACT) is a model of case management which has been shown to be effective in improving engagement and retaining those with serious mental illness and those with alcohol and drug use disorders comorbidities (Marshall 2011; Burns 1995). A number of studies have applied individual components of ACT to the treatment of alcohol dependence with positive outcomes (Gilbert 1998; Stout 1999; Hilton et al 2001). A non-randomised cohort study of assertive engagement methods resulted in a significantly greater number of patients completing treatment and entering aftercare (Passetti 2008). Also an assertive outreach approach for alcohol related frequent hospital attenders has been the subject of a recent cohort study (Hughes et al., 2013). However, the potential benefits of individual elements of ACT in patients with alcohol dependence without severe mental illness remain unclear and there have been no published randomised controlled trials investigating the impact of ACT in this population to date.

We conducted a pilot randomised controlled trial of ACT in people with alcohol dependence and a history of previous unsuccessful treatment to investigate (a) the feasibility of recruiting and retaining people seeking treatment for alcohol dependence in a clinical trial of ACT and (b) the potential efficacy of ACT on the drinking behaviours and quality of life of people with alcohol dependence and a history of disengagement from specialist alcohol treatment services.

## Method

This study was reviewed and approved by the National Research Ethics Service Committee London – Chelsea (REC number: 08/H0801/113) and the trial was registered with the International Standard Randomised Controlled Trial registry (ISRCTN22775534) prior to the commencement of data collection. Progress of the trial, adherence to protocol and participant safety were overseen by an independent trial steering committee. A detailed protocol for the study has already been published (Gilburt et al., 2012).

### Trial design

We undertook a single blind, pilot randomised controlled trial of ACT plus care as usual (CAU) compared with a CAU alone for people with alcohol dependence. The trial was conducted across two NHS trusts in South London: participants were recruited on accessing one of three specialist community drug and alcohol services. Participants were recruited between 23 March 2010 and 23 January 2012.

Randomisation was conducted using a secure independent service at the level of the individual and was stratified by alcohol dependence (< or = 30 and > 30) as measured by the Severity of Alcohol Dependence Questionnaire (Stockwell et al., 1979) and by site. Researchers were blind to the allocated treatment.

As a pilot study, the sample size was selected to determine feasibility, acceptability and to allow for an analysis of potential effect prior to designing a full scale definitive trial. In order to ascertain these parameters, we considered a clinically meaningful difference in alcohol consumption between the groups at 12 months to be of the order of 30% and estimated the numbers required with 80% power and an alpha of 0.2, appropriate for a pilot study, using two-sided test. In addition, we considered an acceptable rate of follow-up at 12 months to be not less than 75%. Our required sample size was estimated as 45 in each group at baseline, with the expectation that at least 34 would be followed-up at 12 months.

### Recruitment

All potential participants were in the first instance identified and approached by a member of the community drug and alcohol team who informed them about the trial and obtained verbal consent to being contacted by a researcher. A member of the research team met with the participant to explain the trial further and check eligibility for the trial. Participants who met all the criteria were invited to provide written consent for the trial.

### Inclusion and exclusion criteria

All participants met the following criteria: (a) age 18 years or over; (b) able to understand English sufficiently well to obtain informed consent and complete the assessment instruments; (c); attended an NHS community addiction service in either of the participating trusts for alcohol dependence on at least one previous occasion in the last five years; (d) an ICD-10 diagnosis of alcohol dependence as determined using the Composite International Diagnostic Interview (Robbins et a., 1988). We excluded patients who were: (a) unable to provide written informed consent; (b) street homeless; (c) diagnosed with a psychotic disorder; (d) in receipt of assertive outreach services or has community mental health team input once a month or more; (e) had severe cognitive impairment as determined by the Mini Mental State Examination score of ≤ 10 (Folstein et al., 1975); (f) who had a history of violence to staff or were registered under the UK Multi-Agency Public Protection Arrangement.

### Interventions

#### Assertive community treatment

The intervention was informed by the original ACT model used for people with psychosis and findings from research identifying effective elements of assertive outreach in UK studies. The ACT intervention comprised:

1. A maximum caseload of 15 ACT patients per ACT practitioner;
2. Input from a multidisciplinary team (including psychiatrists and substance misuse specialists);
3. Regular contact (minimum of once a week), with 50% of contacts occurring outside of the service settings either in the patients’ home or neighbourhood, and in which short frequent contacts rather than long complex contacts are encouraged;
4. Assertive engagement where there are persistent and repeated attempts to contact, and an emphasis on maintaining contact and building relationships;
5. A focus on both health and social care needs, including accommodation, leisure, occupation, and physical and mental health;
6. A flexible approach, focusing on the patients goals even when these are peripheral to the alcohol dependence;
7. Openness, practitioners are explicit about their role both in care planning and in visits
8. An ethos of ‘going out of your way’, where practitioners are encouraged to step outside of professional roles and ‘go the extra mile’ for patients;
9. Extended care provided for a prolonged period of 1 year.

An intervention manual was developed in collaboration with experts in the provision of ACT. The manual outlined the core components of the ACT intervention and the principles of delivery in line with components of the alcohol treatment pathway. This included hours of operation, caseload, target client group, source of referrals, assessment, interventions and care plan, and the use of interventions for alcohol dependence. Policies on training and development for ACT practitioners, home visiting, lone working and risk assessment and the withdrawal from treatment were also incorporated. Finally the manual provided an overview of the research processes involved in the trial.

#### Care as usual

Participants randomised to the intervention arm received CAU plus ACT, while those randomised to the control group received CAU alone. CAU included the allocation of a keyworker when available with contact as required and as per local team policies. Contact was primarily conducted within a service setting (community addictions service or general practice) via an appointment-based system. Participants received a full assessment of alcohol, social and physical health needs, and a risk assessment. The focus of treatment was primarily on alcohol dependence, promoting abstinence and relapse prevention. This included access to medical detoxification, psychological interventions focused on drinking behaviour and aftercare as required. CAU also included input from specialists in addiction psychiatry, clinical psychology and social work where available. When these services were not directly provided by the community drug and alcohol treatment service, participants were most often referred or signposted to other relevant agencies as required. The majority of participants were discharged to primary care from the specialist service within 12 weeks of being allocated a keyworker unless significant risks were identified. Failure to attend several appointments resulted in discharge from the service. These approaches are broadly in line with national service delivery at the time of the study. In addition we collected data on the actual care received in order to understand the content of CAU (see below).

### Training and support

A training programme for ACT staff was developed by the team in collaboration with experts in ACT and addictions treatment. The training comprised workshops providing information on ACT, its history, implementation in mental health and trial processes; a one day clinical placement with a mental health assertive outreach team shadowing a member of staff; and a final workshop day focused on the application of ACT in addictions services. A total of 7 practitioners from the trial sites attended the training (4 from one service, 3 from the second) including substance misuse, nursing and additions psychiatry professionals. Additional training was delivered on a one-to-one basis to a further three practitioners at a third service setting owing to its late incorporation into the trial, and in response to staff turnover.

In addition to existing team based clinical supervision, practitioners delivering ACT were encouraged to attend monthly ACT group supervision meetings throughout the course of the study. These meetings were facilitated by the Chief Investigator, an experienced addictions psychiatrist, and the trial manager. Meetings focused on enabling practitioners to share experience and practice in order to support delivery of ACT, address clinical issues arising as a result of the intervention, and reinforce fidelity of the ACT intervention.

### Intervention fidelity

Staff providing care to participants in both arms of the trial completed a contact log detailing the care they provided for each patient following each contact. The log, developed from a previous study of assertive outreach, included details about the mode of contact, (i.e. face to face, telephone), setting, focus of contact, and the member of staff involved (ref). To enhance accuracy, data was additionally collected from the electronic clinical records of each participating service following completion of the trial. Data highlighting additional contacts with a participant and information absent from contacts recorded in the log was used to supplement existing information.

### Outcome measures

Feasibility and acceptability of delivering assertive community treatment to people with alcohol dependence was measured by levels of recruitment into the trial and retention of participants in both arms of the study at 12 months follow-up.

The primary outcome measures was mean drinks per drinking day at 12 months measured using the Time Line Follow Back form 90I (TLFB; Miller, 1995). Secondary outcomes included total alcohol consumed, percent days abstinent, and other drug use measured using TLFB, alcohol related problems (Alcohol Problems Questionnaire; Drummond, 1990), severity of alcohol dependence (Severity of Alcohol Dependence Questionnaire; Stockwell et al., 1979), health utility (EQ-5D; EuroQol group, 1990), health related quality of life (SF-12; Ware et al., 1996), motivation to change (Readiness to Change Treatment version; Heather et al., 1999), social network involvement (Important People and Activities Inventory; Clifford & Longabaugh, 1991), health service utilisation (York Service Use Questionnaire; Drummond et al., 2009). All measured at baseline and then 6 and 12 months after randomisation.

### Statistical analysis

The main hypothesis, stated as a null hypothesis, is that CAU augmented with ACT is no more effective than CAU in reducing alcohol consumption 12 months after randomisation. The primary outcome measure was mean drinks per drinking day and percent days abstinent at 12 months follow up. Our primary analysis was by intention-to-treat in which participants are analysed as part of their allocated group irrespective of the treatment received. This provides the most rigorous estimate of effectiveness. The primary outcome measure was analysed using an analysis of covariance approach adjusting for known confounding variables such as baseline mean drinks per drinking day, age and gender. If the assumptions underlying ANCOVA were not met transformations were undertaken and if transformations were not viable alternative non-parametric approaches were used. Continuous secondary measures were analysed in a similar manner. Categorical variables were analysed using chi-squared statistics and binary outcomes analysed using logistic regression controlling for known confounding variables. Estimates and the 80% confidence intervals are presented.

## Results

### Feasibility of recruitment

Feasibility outcomes for this study were assessed by recruitment and retention rates in both arms of the study. Participant flow is indicated in the Consort diagram (Figure 1). Of 126 individuals assessed for eligibility, 4 could not be contacted after referral by the team, 2 declined to participate, 2 were assessed as too intoxicated to participate and one needed to be seen immediately by the clinical team so could not be seen by a researcher. The majority of those not randomised, did not meet the inclusion criteria (n=22; 7 had been seen for treatment in the last 3 months, 5 had been diagnosed with a psychotic disorder, 3 had no history of treatment with the service, 2 had not been seen by the service within the last 5 years, 2 were not alcohol dependent, and one had a history of violence).

A total of 117 (93.0%) patients were eligible to take part and 94 (80.2%) provided consent and were randomised. Forty-five participants were randomised to ACT plus CAU arm (47.9%) and 49 participants were randomised to the CAU arm (52.1%). The follow-up rates at 6 months were 100% (n=45) in the ACT plus CAU arm and 86% (n=42) in the CAU arm. The follow-up rates at 12 months were 98% (n=44) in the ACT plus CAU arm and 88% (n=43) in the CAU arm.

### Baseline characteristics

The baseline demographics of the sample are shown in Table 1. The majority of the sample was male (61%), white (87%), not currently in a marital relationship (68%), and living in rented or temporary accommodation (76%), were parents (68%), and had either no or a basic level of educational qualifications. The mean age was 43 years.

[insert table 1]

At baseline no differences were observed between the groups in terms of study outcomes. All participants met the criteria for alcohol dependence with lower than population average mental and physical health-related quality of life. The majority were in the pre-contemplative stage of change and had high levels of alcohol dependence.

[insert table 2]

### Intervention delivery

Delivery of the intervention and care as usual are shown in Table 3. Compared with participants randomised to the CAU arm of the trial, participants receiving ACT + CAU were in contact with services for a significantly longer period of time, (U=99, p<0.001), received a greater mean number of contacts during treatment [stats?], and received a significantly greater proportion of contacts outside of the addictions service (X2=8.59, p<0.05, df=2).

While the contact data demonstrates differences in the content and delivery of CAU between sites, it also highlights differences in the implementation of the ACT+CAU intervention. Significant differences the ACT + CAU arm were found in the period of contact with the service ACT + CAU: (X2=9.54, p=0.008, df=2), and the mean number of contacts with participants. In each case, participants in site 3 received reduced contact with practitioners in comparison with sites 1 and 2 suggesting that implementation of ACT + CAU was suboptimal. Of the three sites originally identified, one site was withdrawn from the trial after their alcohol treatment services were decommissioned. Training and recruitment commenced in the first two sites and a further (site 3) was incorporated at a later stage. Although the training programme was delivered, this was done on an individual basis. Site 3 additionally experienced a change of ACT practitioner owing to retirement. Attendance of monthly group supervision by these practitioners was also limited.

### Primary outcomes

Tables 4 and 5 contain outcomes at 6 and 12 months. Data presented has been adjusted by baseline covariates; baseline value, age and gender. There were large reductions in drinks per drinking day in both groups at 12 and 6 months compared to baseline but the difference between allocated groups was small and not statistically significant.

[insert tables 4 and 5]

### Secondary outcomes

There were reductions in the total alcohol consumed and increases in the percent days abstinent and number of participants abstinent at 6 and 12 months. Significant differences were observed between the groups at 6 months with the ACT plus CAU group having a higher percentage of days abstinent. No other significant differences were observed at either time-point for the alcohol consumption outcomes.

At 6 months the CAU group had significantly fewer alcohol-related problems and health utility, measured using the EQ5D was significantly better for the CAU group at 6 and 12 months.

### Service use

The use of services used in the previous 6 months at 6 and 12 month follow-up are presented in table 6. At 6 and 12 months the ACT+CAU group used significantly more alcohol day care services than the CAU group and significantly more alcohol outpatient services at 12 months. At 6 months the ACT+CAU group had significantly fewer inpatient days, outpatient visits and significantly more GP visits. No significant differences were observed between the groups at 12 months.

[insert table 6]

## Discussion

This study demonstrates the feasibility of recruitment and retention of participants in a randomised controlled trial of ACT+CAU versus CAU. Of the 126 patients referred to the research team, 93.0% were eligible to participate and 80.2% of this group provided consent and were randomised. This compares favourably with previous RCTs in similar clinical populations where eligibility and consent rates were generally lower (e.g. UKATT Research Team, 2005). Further, the follow up rates were higher than in many previous RCTs with similar alcohol dependent clinical populations. We achieved a 92.6% follow up rate at 6 months and 92.6% at 12 months, exceeding our minimum target follow up rate of 75% at both follow up points, and may reflect the use of state-of-the-art methods to maximise follow-up (Woolard et al., 2004; Robinson et al., 2007; Zweben et al., 2009). The follow up rate was lower in the CAU group compared to the ACT+CAU group, which may have been related to the more intensive nature of the ACT intervention arm, and potentially a degree of disappointment in those randomised to CAU (Woolard et al., 2004). However the difference in follow up rate was within acceptable limits and greater than the planned minimum follow up rate in both groups.

The baseline characteristics of the sample were typical of patients attending UK specialist NHS alcohol services and were well balanced between the randomised groups.

In terms of implementation of the ACT intervention, we found that the clinical teams were able to engage participants for a significantly longer period of time than in CAU, and close to the intended 365 days. The ACT group also received significantly greater number of contacts with specialist staff, and contacts were more often in participants’ homes or local communities, than in the CAU only group. There were however significant differences between one of the clinical sites and the other two sites in terms of length of contact and number of contacts. This site experienced greater turnover of staff during the course of the trial, and the ACT staff were less engaged with the research and clinical supervision process than in the other two sites. This underlines the importance of monitoring and supporting teams to achieve fidelity to the ACT model of care. The number of participants in this trial does not allow meaningful comparisons of outcomes between sites and hence the impact of fidelity on treatment outcome, but this will be an important factor to study in a larger clinical trial.

This pilot study was not designed to be statistically powered to provide a definitive test of the effectiveness of ACT+CAU versus CAU alone. Nevertheless there were some differences in outcome between the two groups principally at 6 months follow up, with the ACT+CAU reporting fewer drinking days but lower quality of life and greater alcohol related problems than CAU. The ACT+CAU group also had greater engagement with alcohol services at both 6 and 12 months and significantly fewer unplanned inpatient care and outpatient hospital visits than the CAU group. The ACT+CAU group also had significantly more GP visits at 6 months. These differences may reflect improved facilitated access to planned health interventions supported by the ACT staff and a beneficial reduction in unplanned care. A larger trial is needed to establish the significance of this and its impact on health care costs and benefits of ACT.

Overall this pilot RCT demonstrated the feasibility of conducting a trial of ACT+CAU verus CAU. A definitive trial is now warranted.

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