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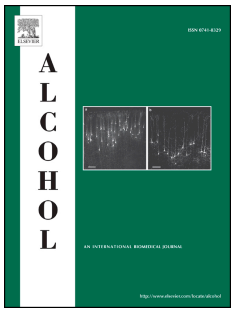

Home-detoxification and relapse prevention for alcohol dependence in low resource settings: an exploratory study from Goa, India.

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Home-detoxification and relapse prevention for alcohol dependence in low resource settings: an exploratory study from Goa, India.

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Abstract

Despite the increasing burden of alcohol dependence, treatment resources in low- and middle-income countries such as India, are concentrated in poorly accessible tertiary care facilities. The aim of our study was to examine the feasibility and acceptability of lay health worker delivered home-based packages of care for alcohol dependence. We conducted an uncontrolled treatment cohort with alcohol dependent adult males recruited in primary and secondary care. Lay health workers delivered home-detoxification and/or relapse prevention counselling. Process data was analysed using descriptive statistics. 11 men with alcohol dependence received home detoxification and relapse prevention counselling and 27 received only relapse prevention counselling. Of the 11 receiving home detoxification, one participant re-started drinking; all the rest safely completed the home detoxification. During detoxification, the pulse, blood pressure and temperature remained within the normal range and ataxia, dehydration, disorientation, sleep normalised over the course of the detoxification. Of the 38 who entered relapse prevention treatment, 15 (39.5%) completed treatment or had a planned discharge. The mean number of sessions was 2.4 (SD=1.3); those who had a planned discharge received on an average 3.7 (SD 0.5) sessions and those who dropped out received on an average 1.4 (SD 0.8) sessions. There was no significant change in daily alcohol consumption and percentage days of heavy drinking (PDHD) between baseline and follow-up in the whole cohort. The SIP score reduced significantly in the whole cohort (24.5 vs 15.0, p=0.002), and also when segregated by treatment settings, and type of treatment package received. With appropriate adaptations, our intervention warrants further research as it has the potential to bridge the significant treatment gap for alcohol dependence in low- and middle- income countries.

Key words

Home-detoxification, relapse prevention, alcohol dependence, India, non-specialist health worker

Introduction

Alcohol use is linked causally to several disease and injury categories, with more than 40 WHO International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) categories being fully attributable to alcohol (Rehm et al., 2017). Among all mental and substance disorders, alcohol use disorders (AUDs) are one of the leading causes of disability, and the largest contributor to premature mortality; and overall one of the five leading risk factors for adult chronic disease (Forouzanfar et al., 2016; Vos et al., 2017). In India, there are high rates of alcohol-attributable mortality and prevalence of AUDs, relative to the per capita volume of alcohol consumed (Benegal, 2005; Rehm et al., 2009).

Alcohol dependence, the most severe form of AUD, is a direct cause of premature death and disability, and a risk factor for other communicable (e.g. tuberculosis and HIV) and non-communicable (e.g. hypertension and stroke) diseases (Holst et al., 2017; Rehm et al., 2017; Schoepf & Heun, 2015; Wood et al., 2018). It also impacts multiple domains of the affected person's life, including reduced productivity, job loss or absenteeism, loss of relationships, problems with family roles, vandalism, social drift downwards and stigma. The official response in India to the growing public health problem of alcohol dependence remains focused primarily on funding tertiary care services. However, such services are scarce, resource-intensive, and often difficult to access because of financial or geographical factors (Dhawan et al., 2017; National Collaborating Centre for Mental Health, 2011), and certainly not indicated for less severely dependent patients (Day et al., 2015; National Collaborating Centre for Mental Health, 2011; Spithoff et al., 2015). For instance, many of the detoxification and 'counselling' centres that fall under the remit of the National Drug De-addiction Programme (Prasad, 2009) in India are defunct and the existing centres are not adequate to address the psychosocial needs of patients and their families (Dhawan et al., 2017; Mattoo et al., 2015; Prasad, 2009). Hence, the treatment of alcohol dependence in existing platforms of institutional care in India is both limited by its accessibility, and sub-optimal, because community-based care is rarely available despite it being recommended in most cases (National Collaborating Centre for Mental Health, 2011) as both a viable and efficient solution (Ibrahim and Gilvarry, 2005). As a result, a large proportion of people with AUD in India do not have access to help for

their alcohol related problems, leading to a high treatment gap of 86% (Gururaj et al., 2016).

Efficient utilisation of limited resources for treatment of mild to moderate dependence involves community-based treatment through home-based assisted withdrawal programs involving fixed dose medication regimens whenever indicated, a carer overseeing the process with daily monitoring by trained staff, and psychosocial support (National Collaborating Centre for Mental Health, 2011). Such a program, based on the principle of collaborative care, overcomes challenges related to accessibility and acceptability of treatment, that are often found in low resource settings (Nadkarni & Bhatia, 2019; Wright et al., 2018). However, there is no robust evidence about the acceptability, feasibility and effectiveness of community-based detoxification in low- and middle-income countries (LMICs) (Nadkarni et al., 2017a).

The aim of CONTAD (Community Orientated Non-specialist Treatment of Alcohol Dependence), a community program for alcohol dependence, was to systematically develop a lay health worker (LHW)-delivered home-based package of care for alcohol dependence which addresses the acute care needs related to alcohol detoxification and the longer term goals of relapse prevention. Home-based detoxification has several potential benefits for low resource settings-continued routine life and social ties, detoxification within a familiar setting, with family support, continuation of work, support to family members, and less stigma (Fleeman, 1997). Finally, there is evidence from HICs that community detoxification as outlined above (fixed dose medication regimens, a carer overseeing the process, daily monitoring by trained staff, and psychosocial support) can be delivered by well-trained non-specialist health workers (Nadkarni et al., 2017a), and that well-trained non-specialist health workers can be recruited and utilised effectively within LMICs to undertake a range of health- and psychosocial-related tasks (Nadkarni et al., 2017b; van Ginneken et al., 2013).

This paper describes the case series, one of the phases of the intervention development process, which aimed to demonstrate the acceptability, feasibility, and safety of the CONTAD package of care for alcohol dependence. The package of care was developed through a rigorous process developed in the study setting (Nadkarni et al., 2014) and included a) a systematic review to identify evidence-based components for the home-

detoxification intervention (Nadkarni et al., 2017a), b) utilisation of a systematic review conducted in a different study which developed an intervention for harmful drinkers in the same setting (Nadkarni et al., 2015), c) qualitative interviews with patients with alcohol dependence, their family members, and clinicians, and d) intervention development workshops at two de-addiction centres of excellence in India.

Materials and Methods

Setting and target population

Goa is a state on the west coast of India with a population of just over 1.4 million people (Government of India, 2011). The prevalence of current drinking among men attending primary care is 59% and the prevalence of hazardous drinking is 15% (D'Costa et al., 2007).

This study was conducted in two settings: a) primary care clinics (5 in the public and 3 in the private sector), and b) de-addiction centre in a secondary care district hospital. We only recruited males, because of the very low prevalence of AUD in women in India (Murthy et al., 2010).

Study design

Treatment cohort with before-and-after design.

Sample

As this was a proof of concept study we recruited a convenience sample of participants identified in four ways a) self-referral, b) referral by primary care physicians/GPs, c) universal screening in primary care, and d) referral from secondary care de-addiction centre. All patients, except those referred from de-addiction centre, were administered the Alcohol Use Disorders Identification Test (AUDIT), a 10-item screening questionnaire developed by the World Health Organization for the detection of probable AUD (Saunders et al., 1993). It has been validated and used in India (Pal et al., 2004), and a vernacular version has been used extensively in the study settings (Nadkarni et al., 2017b). Adult (≥18 years) male participants were eligible for inclusion in the study if they scored ≥20 on AUDIT indicating possible alcohol dependence. Participants who scored 16 to 19 (possible harmful drinkers) on the AUDIT were asked

follow-up questions to identify those with symptoms of alcohol withdrawal (Appendix 1). Anyone screening positive on these follow-up questions was also included in the case series. Finally, any patient admitted to the secondary care de-addiction centre for inpatient detoxification was eligible for participation in the relapse prevention component after completion of the detoxification. Exclusion criteria included the following: age <18 years, difficulty with hearing or speaking which made interviewing difficult, inability to speak the local vernacular or English, or if the patient was in a critical condition and not able to answer assessment questions.

Sampling and sample sizes

As CONTAD aimed at treatment development, assessment of acceptability and feasibility of the intervention package and generation of preliminary estimates of impact, no formal sample size estimations were carried out. Sample size for the treatment cohort was based on experience of previous intervention development projects, feasibility of recruitment and adequacy to meet study objectives.

Procedures

Consenting participants from primary care were assessed by the LHWs for preliminary eligibility (Appendix 2) to undergo home-detoxification. The primary care physician determined the final eligibility for home-based detoxification based on clinical examination and laboratory tests (Appendix 3). The eligibility criteria for home detoxification are listed in Box 1. Participants who were not eligible to undergo home-detoxification at either of these assessments were referred to the de-addiction centre for inpatient detoxification. For participants eligible for home detoxification, the LHWs assessed the drinking history (Appendix 4), explained (verbal and written) the detoxification process to the patient and designated carer and obtained informed consent from both. The primary care physician then prescribed medications for home detoxification as per protocol, which was then monitored by the LHW.

LHWs

Six female LHWs and one supervisor (also an LHW) participated in the study. They had no formal qualifications in the field of mental health, but had completed at least secondary school education. They underwent training in the home detoxification intervention and relapse prevention intervention for three days each. They also underwent a refresher training of four days, six months after the initial training. The training was delivered primarily by an experienced psychologist and psychiatrist. It was designed around the intervention manuals and included didactic lectures, videos, demonstrations and role plays. Some of the learning goals in the home detoxification training included understanding the features of alcohol dependence and alcohol withdrawal, learning how to do a detailed assessment of a person with alcohol dependence, understand the role of various medications used in the alcohol detoxification process, learning how to measure blood pressure, pulse and temperature, learning how to identify nystagmus, ophthalmoplegia and ataxia, and learning how to check for orientation to time, space and person. The relapse prevention counselling training focused on learning goals such as learning how to enhance motivation to change, identifying relapse triggers, helping the patients to deal with the triggers using skills such as handling peer pressure, and dealing with lapses and relapses. They received weekly peer-group supervision, which involved rating of randomly selected recorded sessions on the CONTAD Therapy Quality Scale (Appendix 5) developed specifically for the study.

Interventions

The interventions described below were delivered according to specific protocols developed for the program (http://www.sangath.in/contad/). Home-detoxification involved once or twice daily home visits as per need, daily monitoring using the Clinical Institute Withdrawal Assessment for Alcohol, revised version (CIWA-Ar) (Sullivan et al., 1989), monitoring of pulse, blood pressure, temperature, nystagmus, ophthalmoplegia, ataxia, dehydration, orientation, sleep, level of sedation, symptoms of delirium, side effects of medications, compliance with medications, and continued abstinence.

The designated carer and patient could contact the LHW over the phone or access the nearest hospital in case of any emergency, such as a seizure. For patients undergoing home-detoxification, relapse prevention counselling was commenced on completion of detoxification or as soon as the patient was physically comfortable during the course of the detoxification. For alcohol dependent patients who were currently not consuming alcohol and those who had completed detoxification at the de-addiction centre, the counselling was started as soon as the patient consented to participation. The counselling was delivered over 4-8 weeks through up to 4 sessions, each lasting 30-60 minutes. The content of the sessions included reviewing the patient's drinking history and presenting personalised feedback, preparing to avoid a lapse by learning how to identify and deal with triggers, learning how to deal with a lapse, and learning what to do if a lapse turned into a relapse. A participant was classified as a `planned discharge' if at least one of the following criteria were met: participant's exit from treatment was decided in collaboration with the LHW or the maximum of four sessions was completed.

Ethics

The study was approved by the ethics committees at the implementing organisation, the Indian Council of Medical Research, and the state Directorate of Health Services. Anyone screening positive for hazardous or harmful drinking was provided a leaflet which specified the signs and risks associated with drinking problems, and listed self-help strategies to manage drinking.

Data

The following data were collected during the course of the study.

(1) *Process indicators*: Data was collected on patients who screened positive, patients accepting treatment, those who refused treatment, and those who completed treatment. Information was also collected on adverse events, and dropouts. Serious adverse events were defined as any of the following: death due to any cause, attempted suicide, and unplanned hospitalisation.

(2) *Clinical indicators*: Number of sessions, location of session delivery, duration of session, and number of days between sessions.

(3) *Outcome assessment*: Alcohol (in gms) consumed in the two weeks preceding the outcome assessment, heavy drinking days, and Short Inventory of Problems (SIP) score. The SIP is a 15-item questionnaire that measures physical, social, intrapersonal, impulsive, and interpersonal consequences of alcohol consumption. The SIP is a validated tool (Feinn et al., 2003) that has been used in the study setting (Nadkarni et al., 2017b). Alcohol consumption in the past two weeks and heavy drinking days were measured using the Time Line Follow Back (TLFB), a calendar tool supplemented by memory aids to obtain retrospective estimates of daily drinking over a specified time period. The TLFB is a validated instrument (Sobell and Sobell, 1992) that has been used in the study setting (Nadkarni et al., 2017b). The TLFB was used to calculate mean daily alcohol consumption and percentage days of heavy drinking (PDHD). These assessments were conducted at baseline and three months post recruitment.

Analyses

Process indicators of the screening, and treatment process are presented as proportions and means as appropriate. Socio-demographic characteristics of the sample are summarised as means and proportions as appropriate. The median pre and post scores on the outcome tools were compared using the Wilcoxon signed-rank test. Sub-group analysis was conducted based on treatment completion, and type of treatment (detoxification and relapse prevention vs relapse prevention only). Analyses were conducted using Stata14.

Results

Feasibility of screening in primary care and acceptability of recruitment procedures to patients in primary care

Participants were recruited through a sequential process (Fig 1). We gained access to 7013 patients, 1000 (14.3%) in the private-sector clinics and 6013 (85.7%) in the public-sector clinics, through universal screening or referrals. Of these, 5006 (71.4%) agreed to be assessed for eligibility for screening, and 3251 (64.9%) were eligible for screening. Of the 3251 screened, 2225 (68.4%) were ever drinkers and

1414 (43.5%) were current drinkers. Two thirds (63.6%) of the ever drinkers were current drinkers. The mean AUDIT score amongst current drinkers was 8.5 (SD=7.4) and the prevalence of alcohol dependence amongst current drinkers was 140 (10.1%).

35 harmful drinkers were also screened using the additional questions and based on that 22 (62.9%) were diagnosed to have alcohol dependence. Additionally, seven participants were recruited in the public-sector clinics immediately after inpatient detoxification in the tertiary care de-addiction centre. One participant did not agree to the consenting process. Of the remaining 168 with alcohol dependence, 38 (22.6%) consented to participate in the study. Despite screening positive for alcohol dependence on the AUDIT, 27 were currently abstinent and did not have any acute withdrawal symptoms (seven after a recently completed inpatient detoxification), and 11 were currently consuming alcohol. The former were directly recruited to receive relapse prevention counselling, and the latter were recruited to receive home detoxification followed by relapse prevention counselling.

There were no statistically significant differences between those who consented to participate and those who did not; and amongst those who consented to participate there were no significant differences between those recruited from the public sector clinics and those recruited from the private sector clinics (Supplementary tables 2 and 3).

Acceptability, feasibility, and safety of medically assisted detoxification by LHWs in patients' homes

11 participants started detoxification. Their mean age was 38.2 (SD=10.6) years and mean AUDIT score was 24.9 (SD=9.0); the predominant proportion had at least some education (81.8%), were employed (81.8%), married (81.8%) and recruited in the public sector clinics (81.8%) (Supplementary Table 5). One participant (9.1%) was excluded after day four as he re-started consuming alcohol. Six participants completed detoxification on day five, and two participants each completed detoxification on day six and day seven respectively.

Table 1 describes the CIWA-Ar scores and figures 2a and 2b describe the clinical indicators through the course of the detoxification. The severity of withdrawal was predominantly mild to moderate, and the severity steadily decreased over the course of the detoxification. All clinical parameters that were assessed either remained within the normal range (Pulse, BP, temperature) or normalized if it was abnormal (ataxia, dehydration, disorientation, sleep) over the course of the detoxification.

During the course of the detoxification, two serious adverse events were reported, both unplanned hospitalisations. In one case the admission was for severe tremulousness, which was misinterpreted by the carer as a seizure. An assessment of the other serious adverse event could not be made as the patient did not agree for a formal evaluation of the serious adverse event by a specialist, despite multiple requests.

Acceptability and feasibility of relapse prevention counselling by LHWs

Of the 38 who entered relapse prevention treatment, 15 (39.5%) completed treatment or had a planned discharge. There were no statistically significant differences on intake variables between those who completed treatment or had a planned discharge compared to those who dropped out of treatment (Supplementary table 4). There were no statistically significant differences on intake variables between those who received detoxification and relapse prevention compared to those who received only relapse prevention (Supplementary table 5).

Details of the relapse prevention counselling are described in Table 2 and Table 3. Of the 38 participants who entered treatment, 2 (5.3%) dropped out before starting relapse prevention counselling, 10 (26.3%) completed all four sessions, 8 (21.1%) completed three sessions, 5 (13.2%) completed two sessions, and 13 (34.2%) completed one session. The mean number of sessions was 2.4 (SD=1.3) after excluding the two who did not get a single session. Those who had a planned discharge received on an average 3.7 (SD 0.5) sessions and those who dropped out received on an average 1.4 (SD 0.8) sessions. There were no significant

differences in mean number of sessions and mean duration of treatment between those who received detoxification and relapse prevention compared to those who only received relapse prevention. The mean duration of sessions reduced from session 1 to session 3 before increasing again in the final session. The highest proportion of session 1 was conducted in the clinic and this proportion gradually reduced over the duration of treatment, with the highest proportion of session 4 conducted in the patients' homes. Finally, the mean number of days between sessions increased as the treatment progressed from session 1 to session 4 (from 16 to 31 days).

Feasibility of measuring drinking and related outcomes (Tables 4a and 4b)

At baseline, TLFB was available for 36 (94.7%) participants and SIP was available for 32 (84.2%) participants. At follow-up, TLFB and SIP were available for 35 (92.1%) participants. There was no significant difference in daily alcohol consumption and PDHD between baseline and follow-up in the whole cohort and when segregated by treatment settings, severity of dependence, and number of sessions attended. However, there was a significant difference between baseline and follow-up in a) daily alcohol consumption in those who completed treatment (Median 20.7 vs 0, p=0.04), b) PDHD in those who received home detoxification and relapse prevention counselling (Median 35.7 vs 0, p=0.006), c) SIP scores in the whole cohort (24.5 vs 15.0, p=0.002), in those with milder alcohol dependence (Median 24.0 vs 10.0, p=0.02), those who attended more sessions (Median 26.5 vs 15.0, p=0.02), and those who dropped out of treatment (Median 24.5 vs 22.0, p=0.03).

Adaptations to the home detoxification manual

Some of the learnings during the course of the study that resulted in adaptations to the detoxification are described in Table 5.

Discussion

Our study examines the acceptability, feasibility, and safety of a contextually-adapted package for home detoxification and relapse prevention delivered by lay

health workers, the first such study from India. Our findings indicate that it is feasible to identify and recruit patients with alcohol dependence into a programme that delivers home detoxification and relapse prevention counselling through LHWs. Importantly, such a programme is acceptable to the recipients to some extent, is feasible and safe to deliver.

Our study had a low consent and a high dropout rate, with only 40% of those entering the programme completing treatment. Low rates of entry into and high dropout rates from substance misuse treatment are not unusual. In better resourced settings, such as in Europe, <20% of all AUD cases identified, receive treatment for their alcohol problems in the 12 months preceding identification (Manthey et al., 2016); and treatment contact is reported to be no more than 20% in the year of onset, even for alcohol dependence (Oakley Browne et al., 2006; Wang et al., 2005). Some common reasons for not entering treatment for AUD include beliefs that one should be strong enough to handle their drinking problem by themselves, that drinking problems resolve by themselves, and that one's drinking problem is not serious enough require treatment (Grant, 1997). High drop-out rates are not unique to AUDs, with rates being as high (31-60%) for a range of other mental health treatment programmes (Keil and Esters, 1982). More specifically, completion rates for standard outpatient adult alcohol treatment programmes are as low as 40% (Wickizer et al., 1994).

On the other hand, we observed high completion rates for the home detoxification component of our study. The detoxification process was largely clinically uneventful, patients and their carers adhered to the protocol, and there were no serious adverse events resulting directly from the detoxification. This is consistent with findings reported in other studies (Nadkarni et al., 2017a). The impact of home detoxification has been examined using a range of study designs. In experimental studies, those who underwent community detoxification (compared to patients undergoing facility-based detoxification) were more likely to be drinking less or abstinent (Nadkarni et al., 2017a). In non-controlled studies of home detoxification such as ours there was a significant reduction in quantity and frequency of drinking and also impact of drinking at follow-up (Nadkarni et al., 2017a).

The only other study that examined community detoxification in a LMIC was conducted in Brazil and compared conventional outpatient treatment for alcohol dependence with conventional outpatient treatment supplemented by home visits. (Moraes et al., 2010). The latter was superior with regard to a range of clinical outcomes. In the absence of an evidence base from LMICs, our study is crucial as it demonstrates the workability of a potential solution to bridging the AUD treatment gap in a low-resource setting. In our study there was a significant difference between baseline and follow up for daily alcohol consumption and heavy drinking in those who received both home detoxification and relapse prevention counselling, but not in those who received only the latter. We also observed a similar significant difference in the SIP scores, in the whole cohort, in those who had milder alcohol dependence, had a longer duration of treatment, and attended more sessions. All of these findings, combined with the low mean number of sessions received, indicate the need for ongoing care to improve outcomes in alcohol dependence. It is possible that when the same LHWs undertake both detoxification and relapse prevention counselling it is much more likely to be successful because these LHWs have been visiting the patient in their home, and have made positive therapeutic relationships with both the patient and their carer. On the other hand, if the patient is detoxed in a facility, separated both geographically and in its orientation with CONTAD, then there may be far less engagement with the relapse prevention counselling.

Historically, treatments for AUD have been delivered for circumscribed duration or intensity, and are expected to produce impact lasting well beyond the end of treatment. However, this is in contrast to treatments of other chronic medical conditions which include acute care strategies followed by longer-term follow-up and strategies. Thus, in AUD, we may be missing opportunities to maximise the potential benefits of existing treatments by focusing on interventions delivered in a few sessions over a short period of time (McLellan, 2002). A more appropriate response for alcohol dependence would be to maintain therapeutic contact for extended periods of time and to adjust the intensity of treatment in response to changes in symptoms and functioning over time (McKay, 2005). A study from India in which the intervention group received weekly continued care in the

community, compared to routine hospital follow-up visits, showed that the former group had more non-drinking days and that they continued to maintain these gains while the control group showed a downward slide (Murthy et al., 2009). Thus one of the adaptations that will have to be made to the CONTAD relapse prevention intervention is to individualise treatment planning so that the length of follow up care can be matched to patient requirements in order to achieve sustained change in drinking outcomes.

The other major adaptation would have to be around strategies to engage and retain patients in treatment. These could include strategies implemented before treatment begins (e.g. reviewing potential barriers to adherence) and those implemented during treatment (e.g. calling up patients to check on their status on the same day that they miss a session) (Carroll, 1997). These are in addition to the strategies that are already specified in the manual, such as exploring ambivalence and encouraging the involvement of significant others. Finally, in our study, the primary care physicians were very well engaged with their tasks of examining the patient's eligibility for home detoxification and prescribing medications. However, they could potentially play a greater role in a collaborative care model where they contribute to other critical processes such as supervision of the LHWs. On the other hand, such compliance in dealing with alcohol withdrawal and detoxification certainly cannot be taken for granted, and it is very likely that a coordinated education and attitude-modification program would be needed in order to roll out methods such as these into routine clinical practice within primary care.

This is a first study from India examining the feasibility, acceptability, and safety of an intervention package for alcohol dependence delivered by LHWs in the community. Its strengths lie in its participatory methods used to design the intervention, primary care approach to recruitment, and innovative delivery method. Our study has weaknesses as well and these need to be considered while interpreting our findings. The sample size limits the precision of our findings and the absence of a control arm means that we cannot attribute any changes in the

outcome measures directly to the intervention. Another limitation is the use of AUDIT to identify alcohol dependence. The cut-off score to identify alcohol dependence has not been well validated, but a cut off score of 20 is in line with expert guidance on the use of this instrument, and dependence has been identified in primary care populations at lower scores (Johnson et al., 2013). This limitation was offset to a certain extent in our study by using additional questions which allowed us to use symptomatology to identify alcohol dependence that might have been missed by the AUDIT. Our stringent eligibility criteria ensured that only those with less severe alcohol dependence were included in the study. Although this limits the generalisability of our findings, it ensured that patients having complex alcohol dependence with the potential for adverse outcomes were not put at risk by undergoing detoxification in settings with limited medical supervision.

The evidence base for treatment of alcohol dependence, both for home detoxification and relapse prevention, is predominantly derived from high-income countries and is focused on specialist settings and delivery (Allen et al., 1997; Nadkarni et al., 2017a; World Health Organization, 2015; UKATT Research Team, 2005). Hence, CONTAD is unique as it is designed to be delivered by LHWs in primary care settings, making it potentially scalable in low resource settings with shortage of specialist healthcare professionals. Considering the feasibility, acceptability, and safety of CONTAD and the encouraging change in some outcomes in the positive direction, further research on CONTAD is warranted. This could include a trial of CONTAD, adapted based on the findings of this formative research. If effective, such a contextually-appropriate intervention for alcohol dependence could be a substantial achievement as it is the first comprehensive intervention for alcohol dependence developed in a LMIC and is designed to meet the acute care and longer term needs of those with alcohol dependence. Finally, if effectiveness of CONTAD is established, further implementation science research would help test the scalability of the intervention inherent in its suitability for non-specialist health worker delivery and processes such as peer-supervision. In conclusion, our findings warrant further research on CONTAD as it has the potential to bridge the significant treatment gap for alcohol dependence in LMICs.

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Disclosure

The authors have no conflict of interest and financial interest or benefit that has arisen from the direct applications of this research.

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Box 1: Eligibility criteria for home detoxification		
All these criteria to be fulfilled	Contraindications for home detoxification	
	Assessed by LHW	Assessed by primary care physician
Age ≥18 years Stable housing Designated carer available and willing to stay with the patient Patient agreeable for home visit/contact by the LHW Appropriate care arrangements put in place for any children and vulnerable adults	**Lifetime:** Seizures or severe confusion during a past detoxification History of hallucinations Unexplained loss of consciousness Seizures even when not withdrawing from alcohol or on treatment for epilepsy **Current:** Treatment for psychiatric disorder Use of any other substance of misuse (except tobacco) Head injury with loss of consciousness in the past one year Blood in the stool in the past one year Blood in vomitus in the past one year	**Lifetime:** Wernicke's encephalopathy Angina/coronary heart disease **Current:** On regular benzodiazepines Wernicke's encephalopathy Physical health problems requiring immediate medical/surgical attention Unstable medical/psychiatric conditions Signs of liver compromise Severely dehydrated Cerebrovascular accident in the past one year Recent cardiac event Untreated/uncontrolled hypertension Significant respiratory problems

Table 1: Clinical indicators of home detoxification

	Day 1	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
	N=11	**N=11**	**N=11**	**N=11**	**N=10**	**N=4**	**N=2**
Mean CIWA-Ar score (SD)	8.5 (5.0)	5.5 (4.1)	4.8 (4.7)	3.5 (4.3)	2.4 (3.2)	0 (0)	0 (0)
CIWA-Ar ≤8 (mild withdrawal) n (%)	5 (45.5)	8 (72.7)	9 (81.8)	10 (90.9)	10 (100.0)	4 (100.0)	2 (100.0)
CIWA-Ar 9-15 (moderate withdrawal) n (%)	4 (36.4)	3 (27.3)	2 (18.2)	1 (9.1)	0 (0)	0 (0)	0 (0)
CIWA-Ar >15 (severe withdrawal) n (%)	2 (18.2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Clinical Institute Withdrawal Assessment of Alcohol Scale, Revised (CIWA-Ar), Standard Deviation (SD)

Table 2: Details of relapse prevention counselling

Session	Number of participants n (%)	Mean duration in minutes (SD)	Location n (%)		Mean number of days after previous session (SD)
Session 1	36 (94.7)	49.6 (19.3)	Clinic	22 (61.1)	
			Home	14 (38.9)	
Session 2	24 (66.7)	40.2 (11.9)	Clinic	11 (45.8)	15.5 (15.7)
			Home	13 (54.2)	
Session 3	18 (72.0)	34.7 (7.7)	Clinic	7 (38.9)	19.8 (14.0)
			Home	10 (55.6)	
			Phone	1 (5.6)	
Session 4	10 (55.6)	41.8 (12.3)	Clinic	2 (20.0)	30.8 (20.6)
			Home	7 (70.0)	
			Phone	1 (10.0)	

Standard Deviation (SD)

Table 3: Number of relapse prevention sessions and duration of treatment

	All participants	**Dropped out**	**Completed treatment or planned discharge**	**p**	**Relapse prevention**	**Detoxification and relapse prevention**	**p**
	N=38	**N=23 (60.5%)**	**N=15 (39.5%)**		**N=27 (71.1%)**	**N=11 (29.0%)**	
Mean number of sessions (SD)	2.3 (1.3)	1.4 (0.8)	3.7 (0.5)	<0.001	2.3 (1.3)	2.4 (1.5)	0.83
Mean duration (minutes) of treatment (SD)	69.0 (38.7)	76.7 (40.8)	57.2 (33.3)	0.13	73.4 (37.3)	58.1 (41.9)	0.27

Standard Deviation (SD)

Table 4a: Comparison of drinking and its impact at baseline and follow up

		All participants N-=38	**p**	**Relapse prevention N=27 (71.1%)**	**p**	**Detoxification and relapse prevention N=11 (29.0%)**	**p**	**Dropped out N=23 (60.5%)**	**p**	**Completed treatment or planned discharge N=15 (39.5%)**	**p**
Median daily alcohol consumed in gms (Range)	Baseline	24.9 (0-281.5)	0.67	13.3 (0-149.3)	0.17	44.8 (15.7-281.5)	0.005	33.0 (0-149.3)	0.25	20.7 (0-281.5)	0.04
	Follow up	14.4 (0-135.3)		32.5 (0-135.3)		4.1 (0-69.9)		47.9 (0-135.3)		0.0 (0-96.2)	
Median PDHD (Range)	Baseline	28.6 (0-100)	0.64	17.9 (0-100)	0.21	35.7 (14.3-100)	0.006	28.6 (0-100)	0.42	21.4 (0-85.7)	0.05
	Follow up	7.1 (0-100)		7.1 (0-100)		0.0 (0-100)		42.9 (0-100)		0.0 (0-92.9)	
Median SIP score (Range)	Baseline	24.5 (3-44)	0.002	24.5 (5-44)	0.02	25.0 (3-42)	0.04	24.5 (3-42)	0.03	26.5 (10-44)	0.05
	Follow up	15.0 (0-41)		22.0 (0-41)		12.5 (0-39)		22.0 (0-41)		12.5 (0-39)	

Percentage days heavy drinking (PDHD), Short Inventory of Problems (SIP)

Table 4b: Comparison of drinking and its impact at baseline and follow up

		Baseline AUDIT[a] ≤26	**p**	**Baseline AUDIT[a] >26**	**p**	**Attended up to 2 sessions**	**p**	**Attended >2 sessions**	**p**
		N=16 (42.1%)		**N=15 (39.5%)**		**N=18 (50%)**		**N=18 (50%)**	
Median daily alcohol consumed in gms (Range)	Baseline	25.2 (0-105.9)	0.07	13.3 (0-281.5)	0.29	35.0 (0-149.3)	0.42	18.2 (0-281.5)	0.19
	Follow up	2.8 (0-135.3)		51.4 (0-119.1)		42.3 (0-135.3)		0.0 (0-96.2)	
Median PDHD (Range)	Baseline	28.6 (0-100)	0.07	14.3 (0-85.7)	0.09	32.1 (0-100)	0.70	21.4 (0-100)	0.32
	Follow up	0.0 (0-100)		39.3 (0-92.9)		35.7 (0-100)		0.0 (0-100)	
Median SIP score (Range)	Baseline	24.0 (3-44)	0.02	30.0 (17-42)	0.1	22.0 (3-42)	0.10	26.5 (10-44)	0.02
	Follow up	10.0 (0-38)		25.5 (5-41)		22.0 (0-41)		15.0 (0-39)	

Alcohol Use Disorder Identification Test (AUDIT), Percentage days heavy drinking (PDHD), Short Inventory of Problems (SIP) [a]Excluding 7 participants who were eligible by virtue of having completed inpatient detoxification just prior to recruitment

Table 5: Adaptations made to the detoxification manual

Observation	Adaptation
Although past history of seizure was a criterion for exclusion from home detoxification we unknowingly included one patient with such a history as the patient and his carer assured us that he had never had 'fits' before. It became obvious that everyone in the target population did not clearly understand how a seizure presented.	Instead of asking the patient and carer whether the former ever experienced a 'fit' we started asking them the following: '*Have you ever observed or has anyone reported an event where* (the patient's*) limbs became stiff and then started shaking violently, after which you lost consciousness, involuntarily passed urine, frothed at the mouth, bit your tongue and became unconscious*?'
Certain medications (e.g. Omeprazole, Chlordiazepoxide) that we had specified in our original manual, based on the evidence and treatment development workshops, were not available in the public sector clinics.	We revised the protocol to ensure that alternative medications already available in the clinic (e.g. Ranitidine, Diazepam) were specified for the primary medications if the latter were not available.
Certain eligibility criteria for home detoxification that the doctors had to check for were too vague for the doctors and they communicated that to us e.g. 'Currently unstable medical conditions'	The criteria which were reported to be vague were made more specific to make them clearer.
Patients and their carers found it difficult to negotiate the dosing schedules of the various medications.	We used small envelopes with the tablets to be taken at particular times of the day and details of the medications were written on the envelope.

Figure 1: Flow diagram of progress through the phases of the treatment cohort

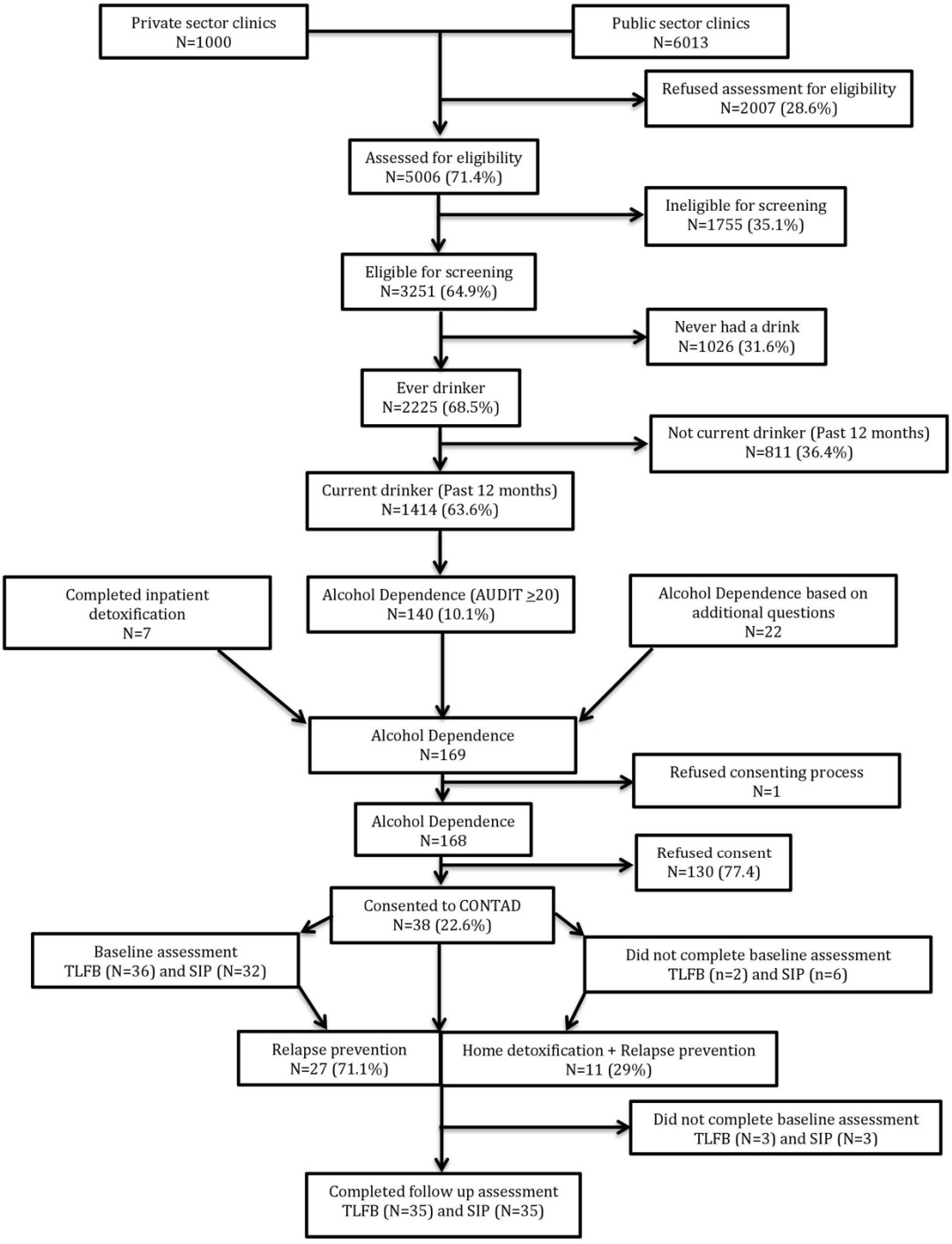


Figure 2a-Clinical parameters during home detoxification

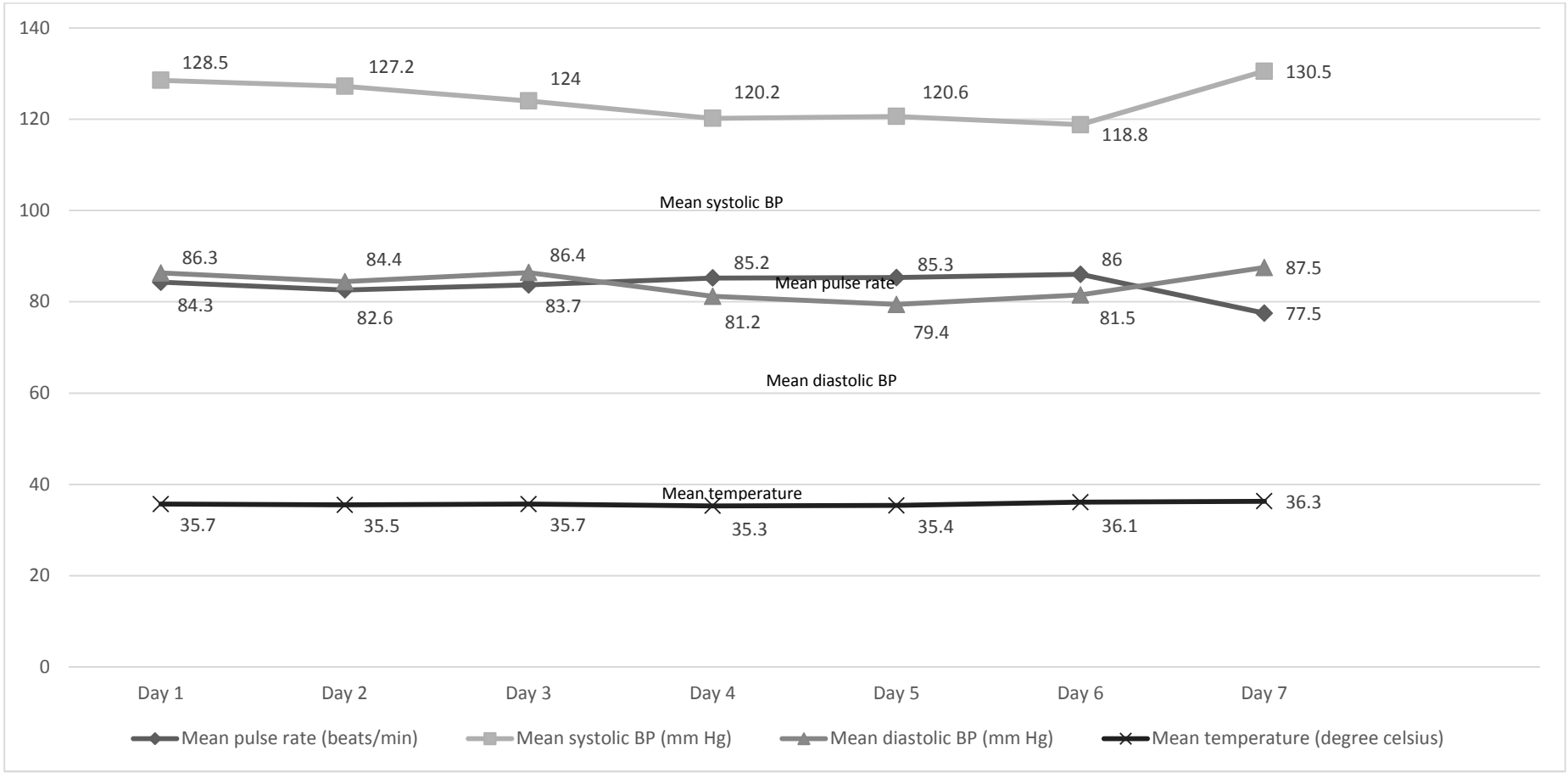
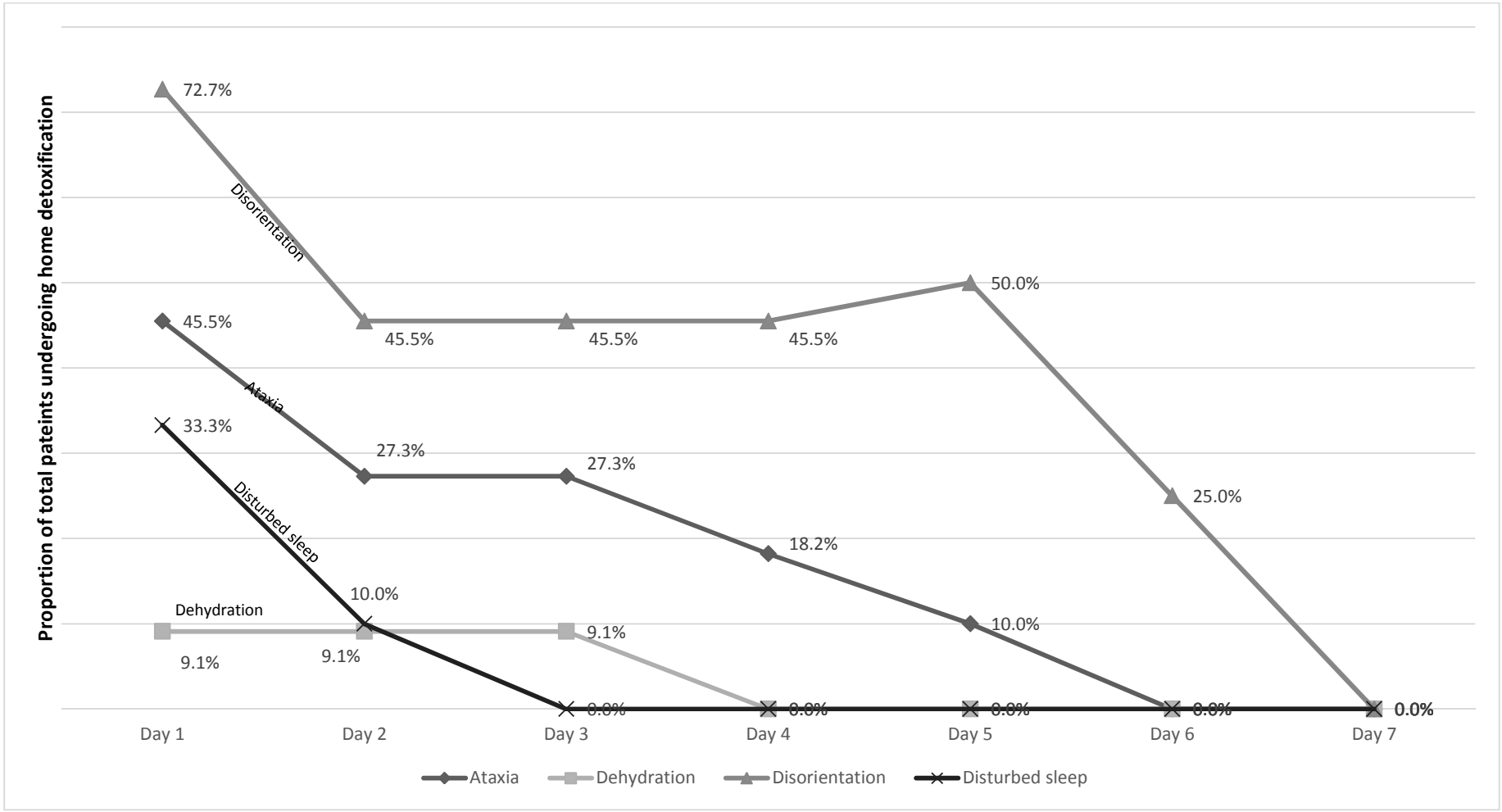


Figure 2b-Clinical parameters during home detoxification



-Alcohol detoxification can be safely delivered at home by LHW
-Entry and retention into treatment for alcohol dependence (AD) is modest
-LHW delivered interventions for AD could potentially reduce the impact of the AD