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Why do men with drinking problems change their behavior? A qualitative study nested in a randomized controlled trial in India

Urvita Bhatia [a, b], Richard Velleman [a, c], Abhijit Nadkarni [a, d, *], Sachin Shinde [a, e], Aarushi Shah [a, f], Vikram Patel [a, g]

[a] Sangath, Goa, India
[b] Department of Psychology, Health and Professional Development, Oxford Brookes University, Oxford, England, United Kingdom
[c] Department of Psychology, University of Bath, Bath, England, United Kingdom
[d] Centre for Global Mental Health, Department of Population Health, London School of Hygiene & Tropical Medicine, London, England, United Kingdom
[e] Department of Global Health and Population, Harvard T.H. Chan School of Public Health, Boston, MA, United States
[f] Mailman School of Public Health, Columbia University, New York, NY, United States
[g] Department of Global Health & Social Medicine, Harvard Medical School, Boston, MA, United States

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ABSTRACT

The aim of this qualitative study, nested in a randomized controlled trial, was to assess the mechanisms of the effects in both arms through examining perceptions of the participants about changes in their drinking behavior and their attributions for any perceived changes. We conducted semi-structured interviews with a sub-sample of trial participants. We used thematic analysis to analyze the data. Self-perceived change, mostly positive, was reported regardless of the objectively measured remission status. Participating in the trial itself was a major catalyst for change. Participants in both arms used a variety of similar strategies to make these changes; additionally, for those who received the intervention, both the style of the counselor (for example, the non-judgmental stance) as well as specific elements of the intervention were seen to influence change in drinking behavior. Absence of self-reported change was relatively uncommon and primarily related to the felt need for alcohol (e.g., drinking was perceived to be necessary to maintain good health), or the belief that one did not need to or want to change. Experiences of participating in a trial, the counselor style, and specific elements of a brief psychological treatment, play a role in influencing change in harmful drinking behaviors.

Introduction

Alcohol use disorders (AUDs) are a major public health concern in many low- and middle-income countries (LMICs) such as India, due to rapid changes in the patterns of alcohol use associated with an increase in availability and consumption of alcohol (Murthy, 2015). Although harmful drinking patterns are much more prevalent than dependence, the health policy and practice response in India focuses almost entirely on the latter (Benegal, Chand, & Obot, 2009; Prasad, 2009). Despite robust evidence about the effectiveness of brief psychological interventions for harmful drinking, access to such interventions in LMICs is limited due to both demand-side barriers, such as low recognition of these problems, and supply-side barriers, such as lack of human resources to deliver such interventions. These barriers are compounded by the limited contextual applicability of interventions primarily developed and tested in specialist health care settings in high-income countries (Benegal et al., 2009; Patel et al., 2016). All of these factors have resulted in a treatment gap for AUD approaching 90%, the highest among all mental and substance use disorders in India (Gururaj et al., 2016).

The PREMIUM program aimed to address these barriers by developing a brief psychological treatment for harmful drinking, which was based on global evidence adapted to optimize acceptability and scalability in the local context. The resulting treatment, called the Counselling for Alcohol Problems (CAP), was a manualized psychological intervention, utilizing a Motivational Interviewing approach (Box 1).

* Corresponding author. London School of Hygiene & Tropical Medicine, Keppel Street, London, WC1E 7HT, United Kingdom. Tel.: +44 (0)20 7636 8636.
E-mail address: abhijit.nadkarni@lshtm.ac.uk (A. Nadkarni).

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Box 1
Research in context.

Background: In the PREMIUM trial, we found that Counselling for Alcohol Problems (CAP), a brief intervention delivered by lay counselors, enhanced remission and abstinence over 3 and 12 months among male primary care attendees with harmful drinking.

Trial setting and arms: In the trial, 377 adult men with harmful drinking were enrolled from primary care settings, in Goa, India. Participants were randomized to receive either Enhanced Usual Care (EUC), i.e., usual care enhanced by providing the physician the results of the screening results and the WHO Mental Health Gap Action Programme guidelines for harmful drinking, or CAP plus EUC.

CAP intervention content and delivery: The treatment involved three phases: detailed assessment and personalized feedback, developing cognitive and behavioral skills and techniques, and managing relapse. CAP was delivered by lay counselors, members of the community with no professional training or qualification in the field of mental health, who were trained by experts. The lay counselors were recruited through advertisements in local media. The essential criteria for the recruitment were completion of 10th-grade education and fluency in local languages. The desirable criteria were having a higher education beyond 10th grade, lack of prior professional training in mental health, and a 2-year commitment to the pilot and future trial.' A maximum of four sessions were delivered on a weekly or fortnightly basis at the Primary Health Centre (PHC) or the participant's home. Participants also received a 'Patient Booklet' comprising information about alcohol and ways of reducing or stopping its use (Nadkarni et al., 2015).

Findings: CAP plus EUC was superior to EUC at the end of treatment (3 months) and over time (12 months), with higher remission and abstinence rates than among individuals who received EUC alone. CAP is suited for scale-up, particularly in low-resource contexts, to address alcohol use disorders, which are some of the leading contributors to the global burden of disease.

The key trial findings were that CAP in combination with enhanced usual care (EUC) was effective and cost-effective compared to EUC alone. Although participants in both arms of the trial improved, those in the CAP plus EUC arm showed greater improvements at 3 months, as well as greater sustained improvements at 12 months on a range of drinking outcomes such as remission, abstinence, and recovery (Nadkarni, Weiss, et al., 2017; Nadkarni, Weobong, et al., 2017). Seventy percent (n = 131) of those in the CAP plus EUC arm had a planned discharge and received a mean number of 2.18 CAP sessions (95% CI 2.7–3.0). Ninety-eight percent (n = 434) of CAP sessions were delivered face-to-face, and 33% (n = 84 of 257 sessions) of sessions from the second session onwards were home-based (Nadkarni, Weiss, et al., 2017; Nadkarni, Weobong, et al., 2017).

Many well-powered trials, such as PREMIUM, have provided high quality evidence of the effectiveness of interventions, but their quantitative findings do not allow for a fine-grained understanding of the mechanisms through which change occurs. Qualitative research embedded in effectiveness trials provides an opportunity to understand (a) the mechanisms of change in both arms of the trial (as participants in both arms typically show improvements over the course of the trial), and (b) the extent to which self-reported change aligns with the objective outcomes on drinking behavior (Lewin, Glenton, & Oxman, 2009). A better understanding of the processes of change from the perspective of the participants in the trial can lead to improved intervention design, impact, and scalability (Craig et al., 2008).

Material and methods

The study described in this paper attempted to do this through a qualitative inquiry into the experiences of participants in both arms of the CAP trial. The aims of this study were to explore participants' perceptions about the changes in their drinking behavior, and their attributions for any perceived changes.

Sample

Fifty-one adult males (the trial only recruited men because the prevalence of AUD in women in India is extremely low) from both arms of the trial, who had completed their 12-month outcome evaluation. Participants were initially selected based on their remission status at 12 months (1:1, remitted vs. non-remitted), with remission defined as an AUDIT (Alcohol Use Disorders Identification Test) score of <8 (Saunders, Aasland, Babor, De la Fuente, & Grant, 1993). Subsequently, we oversampled participants from the CAP plus EUC arm to enrich the sample to understand the specific experiences of receiving the intervention. Recruitment of participants was done face-to-face and stopped after data saturation was reached.

Setting

The trial participants were recruited from ten primary health centers in Goa, India. Goa has a population of 1.6 million, and unlike most of India, it has a 'more liberal, wet culture' with the drinking patterns characterized by low rates of abstinence, and a high prevalence of hazardous drinking in men. The prevalence of high-risk drinking in men in the community is 14.8%, while that of hazardous drinking ranges from 15% in primary care male attenders to 21.3% in industrial workers (D'Costa et al., 2007; Pillai et al., 2013; Silva, Gaunekar, Patel, Kukalekar, & Fernandes, 2003).

Data collection

Semi-structured interviews were conducted by four undergraduate male and female field researchers within 8 weeks after the completion of the 12-month outcome assessment for the trial. The interview guide comprised two parts: 1) participants' perceptions of their drinking behaviors and related concerns (e.g., patterns of drinking and the impact it has on their lives), and 2) their experience of change over the course of the trial and attributions of change (e.g., facilitators of and barriers to change). The field researchers were trained to conduct qualitative interviews and were supervised fortnightly throughout the data collection period in order to assure the quality of the data collected and to identify new and unexpected themes as well as themes where data saturation had been reached, and to revise the interview guide accordingly. Interviews took place from February 2015 to July 2016, at the participants' preferred venue; only the field researcher and participant were present during the interview. There was no prior relationship established between the field researchers and participants. The field researchers were blinded to the treatment allocation (in the first part of the interview) and were unmasked unintentionally by

the participant volunteering such information during the interview, or deliberately at the end of the first part of the interview by opening a sealed envelope that contained the allocation arm. The field researchers had direct experience of the study setting but none were directly involved with the intervention delivery in the trial. The interviews lasted 30–45 min, were conducted in the vernacular language, were audio recorded, and were accompanied by interviewers' notes and memos.

Data analysis

The interviews were transcribed and then translated into English, with the notes and memos attached to the transcripts. Thematic analysis was used to examine the data in five stages (Braun & Clarke, 2006). First, two researchers familiarized themselves with the data by reading interview transcripts and listening to interview tapes. Then, five interviews were selected randomly and both researchers read them independently to generate initial codes through assimilating meaningfully similar data. Next, the codes were collated into potential themes and a code book was finalized, using NVivo version 11. Four researchers then double-coded these interview transcripts and discussed discrepancies with supervisors. This helped assess inter-rater reliability, which was found to be 85%. All four researchers continued 'coding' the remaining interviews against the code book. Then, data were 'charted' according to their relevant thematic framework. Charts were created for each theme to include data from different participants. In the final stage of analysis, each chart was examined separately, and a process of mapping and interpretation was undertaken, i.e., the completed charts were used to explore the range and nature of experiences and any emerging associations between sub-themes were identified to explain the findings.

The aim of the analysis was to develop a model of change following treatment for drinking problems, grounded in participants' accounts. This paper presents an analysis of clients' explanations for either any positive changes, or the lack of any change, that they reported had occurred in their drinking during the previous 12 months. For the purpose of our study, we defined 'positive changes' in two ways: first, participants reporting noticeable positive change in their drinking habits; and second, change in relation to the impact of drinking behaviors on their lives. Similarly, 'lack of change' was defined as no or little change in their drinking habits, and no or little change in the impact of drinking behaviors on their lives. These definitions of change align with accounts of people with drinking problems in the study setting. In our formative research, we found that reduction or cessation in drinking, improved family relationships, improved emotional/physical well-being, and better occupational functioning were the most desired treatment outcomes (Nadkarni et al., 2013). In addition to the themes, we also present illustrative quotes that are identified by the age of the participant, the arm of the trial, and their remission status at 12 months.

Ethical considerations

Assent for the qualitative interviews was taken at the time of the final trial outcome assessment at 12 months. Participants who assented were included in the sample for random selection in the study as described above. Written and audio-taped consent was obtained from participants. Ethical approval for the study was obtained from the host institution in India and the lead institution in the United Kingdom.

Results

Three hundred sixteen participants completed their 12-month outcome assessment, of which 51 participants consented and were interviewed; 33 were from the CAP plus EUC arm (20 remitted) and 18 were from the EUC arm (9 remitted) (Table 1). The average age of the participants was 45.18 years (SD 11.36). Thirty-eight (74.5%) were married and 40 (78.4%) were employed, with the most common occupations being daily wage labor, domestic work, and farming (n = 27, 67.5%). The sample was representative of the trial sample (Nadkarni, Weobong, et al., 2017) in terms of the sociodemographic characteristics of the participants.

Although we selected the participants for this qualitative substudy on the basis of their 'objective' remission status as shown by their AUDIT scores (and later, as per arm), we were interested in participants' own accounts and understanding of whether or not they had made any positive changes. While the majority of participants whose AUDIT scores had shown remission did also report a positive change, this was also observed, albeit to a lesser degree, among participants whose AUDIT scores did not show such improvement (Table 2). Analyses of the descriptions and attributions was undertaken separately for these two broad groups of participants and Models of Change for each group were derived. These are elaborated below.

Positive changes

The narratives revealed that, even for many of the participants who had not remitted on the AUDIT, there were still significant changes reported to their drinking and related behavior. Reduced drinking behavior ranged from stopping drinking entirely, to reductions in frequency or quantity.

> ….. *he* (counsellor) *advised me to either reduce drinking gradually or stop directly at once. So, I thought if I reduce it gradually, I won't be able to stop it completely and my drinking might increase again. That's why I stopped it completely.* (53 years, CAP, remitted)

> *I had decided to reduce the quantity of consumption gradually and then give up totally …. I am going to stop eventually. Everybody is advising me for my wellbeing. I will reduce drinking step by step and then stop. It is almost a year now.* (35 years, CAP, not remitted)

Some participants who would have liked to quit entirely felt that this was unacceptable and/or unattainable, for example because of their fear of an adverse outcome following complete cessation or because of their perception that they would need to drink occasionally at social or other occasions.

> *I had told her* (counsellor) *that it won't be possible for me to quit alcohol. I will reduce it gradually, for example if I drink one quarter* (peg of 180 ml) *then another day I will drink ½ quarter. If I stop directly then anything can happen to me on the spot.* (30 years, CAP, remitted)

Some participants' aim was to reduce drinking to a level that would reduce or stop the problematic aspects of drinking, for example, the amount of money spent or the problems drinking caused them at home. There were many reports of improvements in physical health, including reductions in aches and pains, improved appetite, etc. There were also reports of improved mental health, including 'feeling better', reduced suicidal thoughts, feeling

Table 1
Sociodemographic and other characteristics of participants.

	CAP plus EUC arm (n = 33)	EUC arm (n = 18)	Total (n = 51)
Mean age (years, 95% CI)	45.64 (41.58–49.7)	44.33 (38.62–50.04)	45.18 (41.98–48.38)
Marital status	Married (75.75%) Never married (21.21%) Widowed (3.03%)	Married (72.22%) Never married (27.77%)	
Employment status	Unemployed (18.18%) Laborer/domestic worker/farmer (48.48%) Trader/business (18.18%) Clerical/secretarial work (12.12%) Professional (3.03%)	Unemployed (27.77%) Laborer/domestic worker/farmer (61.11%) Trader (11.11%)	
Mean number of sessions completed (95% CI)	2.18 (2.7–3.0)	NA	2.18 (2.7–3.0)
AUDIT score at 12-months outcome assessment (95% CI)	8.18 (5.51–10.85)	8.50 (4.90–10.21)	8.29 (6.22–10.36)
Remission (%)	20 (60.61%)	9 (50%)	29 (56.86%)

Note: AUDIT: Alcohol Use Disorders Identification Test, CAP: Counselling for Alcohol Problems; CI: Confidence Interval; EUC: Enhanced Usual Care.
Remission = AUDIT score of <8 at 12-months outcome assessment.

Table 2
Comparisons of self-reported change and trial outcome assessment of remission.

	Numbers reporting positive change	Numbers reporting no change
AUDIT[a] remitted (n=29)	26	3
AUDIT NOT remitted (n=22)	16	6

[a] AUDIT: Alcohol Use Disorders Identification Test; Remitted: AUDIT score of <8 at 12-months outcome assessment.

less stressed or 'tensed', experiencing fewer negative thoughts, and having a more positive attitude toward resolving stressors. Participants also experienced positive changes in lifestyle, including an increase in the time spent with their family, greater engagement, particularly with their children, and fewer fights. There were also more positive and amicable relationships with friends and neighbors, better work functioning, and improved reputation in the community, with some describing how they felt that they had earned a renewed sense of respect in the community due to the changes that had occurred.

Participants' attributions for positive change

The model of change for these participants is presented below (Fig. 1). The model highlights how specific intervention and trial-related experiences alongside personal factors led to positive change on the participants' drinking behaviors and overall health.

Three major sub-themes were identified in attributions of positive change in participants in both arms. First, for many participants, the initial catalyst for change was the trial procedures, i.e., screening and baseline assessments that occurred as they were waiting to see a doctor at the primary health center (PHC) and their subsequent decision to participate in the trial.

> *Now I am fine. It's like a fresh day. Do you know why I am fresh now? She* (screener) *told me the impact of drinking alcohol. Ultimately what happens is that your drinking problem will directly affect your family's life. Thinking constantly about my children affected my brain, so I used to drink a lot in the last year. But since I met her, my stress level started getting subdued. Now I consume one peg of alcohol.* (37 years, EUC, remitted)

> *That day when I was waiting in a queue to visit the PHC doctor, they* (counsellor) *called me on the top floor for counselling. That time I thought about completely quitting drinking because I was wasting my money on drinks and there were fights at home due to my drinking habits.* (61 years, CAP, remitted)

Second, participants attributed change to the role of the primary care doctor, perceiving both the advice and prescribed medications as the primary reasons for change in their drinking behaviors. Some key themes in the advice given by primary care doctors included the adverse impact of drinking, and sometimes the ways in which drinking behaviors can be changed (e.g., suggesting a gradual decrease in consumption).

> *The doctor suggested to me that 'drinking is not good for your health* (but) *you shouldn't stop consuming alcohol all of sudden. You should stop by decreasing the amount day-by-day, gradually. If you stop immediately, it will affect your brain.' And thus, I have reduced my alcohol consumption.* (62 years, CAP, remitted)

> *The doctor told me that he needed to give me medical treatment because he wanted me to be cautious regarding the harmful effects of drinking on health. He also made me realise that I have to think about my family, and who would take care of my family if something happened to me. After thinking a lot about this, I decided that I will quit drinking. Earlier I used to spend Rs 500 on my drinks but now I am saving money. Now I also have my meals properly. This advice was very helpful for me.* (42 years, EUC, not remitted)

Third, participants attributed their changes to their own decision-making, often triggered by their trial entry and motivated by their reflections on the type of person that they wanted to be, or to pressure from significant others, in part due to the shame associated with the drinking problem.

> *They* (relatives) … *talk about my drinking habit. Actually, they are concerned about me. They feel that I am a good person and I should quit drinking. As a result, I have decided to quit drinking. I have reduced my consumption of drinks. (30 years, CAP, not remitted)*

> *I have even observed and understood that in front of normal people, we* (people with alcohol problems) *look odd among them; they are good and fresh in appearance but we aren't and we stink of alcohol, fully. So, out of embarrassment, I had to reduce my consumption of alcohol.* (46 years, EUC, not remitted)

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Participants said that these changes had a positive domino effect on their well-being, financial status, and work and social functioning and that these, in turn, reinforced their motivation to maintain their changed drinking behavior.

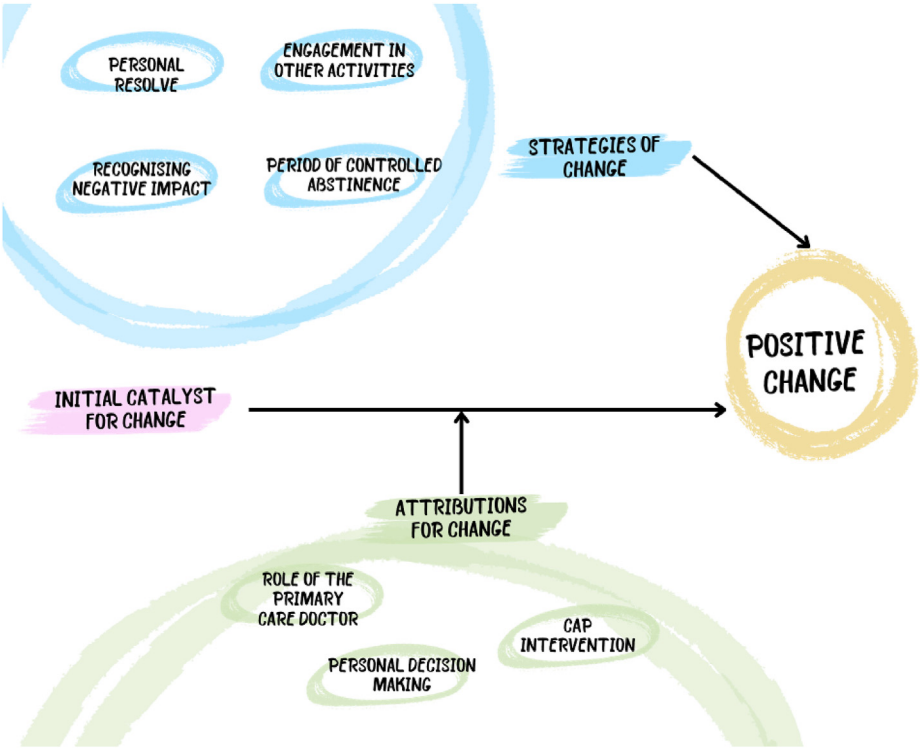

Fig. 1. A Model of Change from the participants' perspective

Earlier I was having arguments with others … that has changed a lot …. Now everything is fine at home …. It (this change) *is because I reduced drinking because person talks out of his sense when he is under influence of alcohol, he even gives bad words to others, but if you are stable then your mind doesn't get affected. (62 years, CAP, not remitted)*

I stopped worrying about my tensions … I spent all the money (which I used to spend on drinking) on household repairs. I bought all the necessary household appliances like fan, table, and television for the home. (31 years, EUC, not remitted)

I am able to maintain a good relationship with my wife and children, and my mother is also happy that I have reduced drinking. My health has also improved. The tremors have stopped. Earlier I used to think only about drinking. (32 years, CAP, not remitted)

Additionally, those from the CAP + EUC arm attributed further stimulus to change to the CAP intervention. The counseling treatment had been useful in helping them both to recognize their unhealthy patterns of drinking and to overcome any barriers preventing them from changing.

My drinking habit, tensions, thoughts reduced after listening to the counsellor and my sleep improved ….it (counselling) was helpful to stop my drinking habit. It even helped me financially. It helped me to regain the respect as I stopped drinking. Now my daughters and son in law are good to me … …My life came on the right track after taking your treatment. (62 years, CAP, remitted)

The suggestions given by the counsellor benefitted me with regards to my family and health problems. I am able to maintain a good relationship with my wife and children, and my mother is also happy that I have reduced drinking. My health has also improved. The tremors have stopped. Earlier I used to think only about drinking. (32 years, CAP, not remitted)

Strategies used to modify drinking behavior

As well as the strategies introduced to those in the CAP plus EUC arm, participants in both arms commonly mentioned four strategies that they used to make positive changes. First, was the ability to control drinking through personal resolve, typically described as "*strong will power*" or "*making up my mind*". Perceiving the control of alcohol consumption as a challenge to oneself was seen to be effective for changing drinking behaviors.

…. .I stopped because of my own motivation. For 1–2 days, I restricted myself in terms of going to the bars. And in this way, I quit drinking. (55 years, EUC, remitted)

I had firmly decided that I was going to quit my alcohol habit. I had even decided that if anybody insisted, then I would not get influenced and accept their wishes; and when I get tremors in the morning I would not touch alcohol. (30 years, CAP, remitted)

Second, participants reminded themselves of the negative impact of one's drinking on one's health or social functioning, such as family life and work.

I was able to reduce intake of drinks as everybody in the house would grumble because of my drinking habit and secondly, I would waste money by spending it on my drinks. So, I thought of reducing my consumption of alcohol. Every month I would spend approximately Rs 2,000 to 3,000 on drinks, which now I have been able to save. (57 years, CAP, not remitted)

The obvious reason to quit consuming alcohol was the fear of the medical report, which would have declared me as an unhealthy person and I would have had to quit my job … (39 years, EUC, remitted).

Third was engagement in other activities, most often family-focused or recreational.

What I *liked was keeping myself busy with family members …. helping my wife with some work and playing with the children ….and when I am busy with any work, my drinking is in control. (32 years, CAP, not remitted)*

I thought about what he (counsellor) *said and then decided to spend my time with children, watching TV with children … Since the time I met your team members I had changed my mind and decided to stop drinking.* (32 years, CAP, remitted)

The final strategy was periods of controlled abstinence, either during periods of religious importance (such as during the month of *Shravan*, a holy month in the Hindu calendar during which Hindus eat vegetarian food and refrain from consumption of alcohol), or during specific days of the week (e.g., abstinence on every Monday). Paradoxically, some participants reported drinking even greater quantities before the religious period, which was seen as a strategy to help prepare for short-term abstinence.

I did not experience any problem if I did not consume alcohol for some days. I have stayed without alcohol for 9 days when we have a religious fast. But once the fast was over then again, I wanted it routinely. (53 years, *CAP, remitted)*

I try to quit alcohol only during Shravan month. Otherwise, my drinking pattern has not changed … What I *do is, before Shravan begins, I keep heavy stock of liquor in the refrigerator. Then for 2 to 3 days I drink continuously. After heavy drinking of 2-3 days, I don't feel* (the need) *to drink anymore right at the beginning of Shravan.* (50 years, CAP, not remitted)

No change in drinking patterns

We defined 'no change' if participants reported that there had been no noticeable change, or worsening, in their drinking habits (that is, no reduction, or even an increase, in the frequency of alcohol consumption), or if there were no changes or worsening in their social functioning, or health status. Participants' attributions or explanations for no change (Fig. 2) are grouped into two main categories.

The first was that they did not want to, and did not see the need to, change their drinking. Some were clear that they did not want to reduce their drinking, or felt that their drinking was under their control and caused them no harm or created no problems. Nearly all the nine participants who reported 'no change' made no acknowledgement of any relationship between their drinking behavior and their health. A majority of these participants had strongly asserted that their drinking was (and always had been) under control and was therefore not detrimental to their health or lifestyle. A few openly admitted to not being interested in changing their habits and being indifferent toward whatever had been offered them in either arm of the trial, because they felt they did not have an "addiction".

No, I did not face any health problems due to my drinking habit. My drinking is under control. I only consume our homemade feni (a locally produced spirit). *Besides this I don't consume any other alcohol drink.* (43 *years, CAP, not remitted)*

The counsellor asked me whether I had any problems due to my drinking e.g. *do I have any family problems, or whether my children have any problems due to my drinking). But I don't have any problems as such ….* (39 years, CAP, not remitted)

The second category comprised participants who did recognize that their drinking might be problematic and might relate to adverse consequences, but who still felt that they needed to continue to drink at harmful levels. Three themes stood out. One related to the use of alcohol to help them cope with life's eventualities such as ageing, stressful life experiences or situations, frustration, boredom, loneliness, and so on:

am drinking only one quarter, but now I am not going to reduce more than this. You know why I can't? Because now I am ageing and I might pass away anytime. I have consumed alcohol since my childhood and will continue till my death takes us apart. (64 years, CAP, not remitted)

I don't want to drink alcohol. Sometimes I get frustrated so I have to drink. Even that bar guy (pub owner) *says to me that "Why you want to drink? Quit drinking, it's not good for health." I say I am going to die, let me die. I am alone at home, and I get upset. Sometimes at home I sit and watch TV programs and in between if anybody comes home, then they too take me out, to the bar* (pub). (50 years, CAP, not remitted)

Sometimes when I come back home from work I feel bored as I don't have anything to do, especially on Wednesdays when we prepare chicken at home, that time I feel like going down to have a drink. (53 years, CAP, not remitted)

A second theme related to the perceived role of alcohol in avoiding physical problems if they were to stop, such as withdrawal symptoms.

If I do not drink I experience health problems. I need to drink alcohol. Currently I am not getting tremors as I had had a little amount of alcohol, but if I do not drink I get tremors. If I consume alcohol, I do not experience any health problems. By God's grace I do not have any other ailments. I feel fine after I consume alcohol, and if not then I get tremors (participant showed hand tremors). (55 years, EUC, not remitted)

If I don't drink for 15 days, I feel very weak. When I drink, I feel better. You might say that if I reduce or stop drinking then my health will improve, but what I have experienced is that if I don't drink then I feel very weak and feel like I do not have energy to do any work. (51 years, CAP, not remitted)

The third theme related to the perception that alcohol enabled a person to function 'normally' – to retain appetite or enable him to work:

…. I realised that drinking is harmful for my health. I had decided to quit it completely. The only thing is that even now I need some amount of alcohol before having food, to get a good appetite. (32 years, EUC, not remitted)

I need to drink regularly. That way I regularly go to work. (39 years, CAP, not remitted)

A number of participants discussed how they did make changes in their drinking behavior at various times in the 12 months since entering the trial, only to then relapse. Sometimes this was

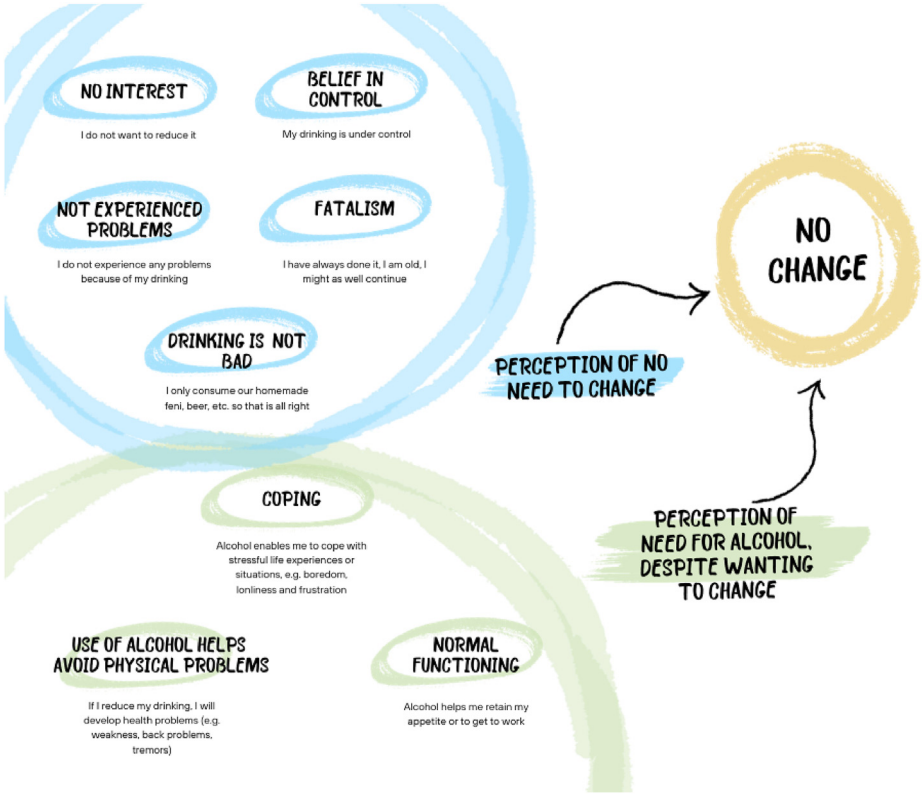

Fig. 2. A Model of 'No-Change' from the participants' perspective

attributed to external events (e.g., stressors) that triggered the relapse:

> *I liked that they* (counsellors) *were telling me "you can try to reduce your drink in a little way". So, I started reducing but I came back to routine* (i.e. excessive consumption) *…. because of my son, he lost my mobile worth Rs 8,000. The expenditure was too much for my son's college fees and other such things. So, because of this stress I started drinking more.* (50 years, CAP, not remitted)

Specific experiences of the CAP intervention

Although our models of change examine experiences of participants in both arms of the trial, we observed some specific experiences relating to the mechanism through which the CAP intervention effected change, as well as challenges and barriers in engagement and impact for a smaller group of participants (Table 3).

Part of the CAP intervention included discussion and specific training in a number of potentially helpful cognitive and behavioral skills and techniques for cutting down or stopping drinking and managing relapse. For each of the major themes outlined above, those in the CAP plus EUC arm mentioned utilizing these techniques to assist them in making these changes, including 'controlling one's urges to drink alcohol', achieved through keeping oneself busy, consuming soft drinks instead of alcohol, avoidance where possible of 'potentially dangerous situations', and utilizing 'drink refusal skills' to firmly refuse drinks offered by friends.

> *I wasn't drinking even when I was getting urge. I was replacing my urge to drink alcohol with consuming soft drinks. Generally, if you see me now, I don't get urges until and unless my friends insist at a party, and even if I go with my friends to the bar, I don't drink at all …. now I have quit drinking alcohol.* (30 years, CAP, remitted)

As well as these specific skills and techniques, those receiving the CAP intervention also identified both the stance and style of the counselor as being especially positive experiences. The collaborative and friendly approach of the counselor and the discussions about drinking goals and clarifications about the impact that drinking was having on areas of their lives were often mentioned, in particular where the counselor was reported to be encouraging and providing hope and assurance through focusing on the positive impact of change, consistent with the motivational interviewing stance of the intervention. The counselor was perceived to be understanding, objective, knowledgeable, friendly, and non-judgmental, unlike family members (in some cases), or other professionals they had consulted previously, which influenced their intentions to engage in treatment and achieve positive changes in their life. Participants also highlighted the flexibility of the delivery of the intervention, in terms of the venue for sessions and their timing.

> *He spoke nicely to me and provided me with valuable information so I went to the PHC after eight days to meet him again. He asked me whether I can quit my drinking habit. I replied yes. He then asked me how I am going to quit my drinking habit, directly or gradually …. I thought if I reduce it gradually, I won't be able to stop it completely and my drinking might increase again. That's why I stopped it completely. (53 years, CAP, remitted)*

> *She would come to my place and would make me understand about my problem. Many family members had told me to leave alcohol, but not in the way how that lady made me understand. She would ask me certain questions and accordingly I would respond. I would give her very frank answers as I know I should not lie to her as she was talking to me for my goodness … frankly speaking I did get benefit from this treatment. (30 years, CAP, remitted)*

Table 3
The elements of the CAP intervention that were seen as being helpful/unhelpful.

Helpful elements	Unhelpful elements
Intervention content-related	**Intervention content-related**
Detailed assessment	Literacy
Personalized feedback	**Intervention delivery-related**
Behavioral strategies	Time-related barriers
Motivational interviewing – informed content and motivational interviewing approach	Conflicting work schedules
	Gender of the counselor
Patient booklet	
Intervention delivery-related	
Flexible approach	
CAP Counselors were seen positively	

I liked the way they (counsellors) talk because my mind would feel relaxed when they were talking to me … I feel the family always supports *us during our difficult situations. That is quite obvious. But when you get* support *from someone outside, who is unknown to you, then it is totally different. Family members often get angry with us due to our misbehaviours. But when some unknown person advises you regarding your problems, then we tend to take it differently.* (30 years, CAP, remitted)

The specific content of the intervention that influenced change started with the first session of the intervention, which focused on the personalized feedback, followed by discussions about the advantages and disadvantages of their drinking, particularly its effects on their health, interpersonal life, and finances, and ways in which reduced consumption might improve health and well-being.

The counsellor made me understand about my health situation and it gradually changed. Now I don't get thoughts of drinking. I have understood how to deal with it, how to say 'no' to it and in this way my health situation has slowly changed. (26 years, CAP, remitted)

She (counsellor) spoke to me about my drinking. She asked me "Why do you drink?" I told her that I do understand that drinking creates many problems. She asked me "Why don't you reduce drinking?" I had told her that I can reduce it gradually. As drinking affects my health, I have now started controlling my drinking habit a lot, compared to earlier …. (53 years, CAP, not remitted)

Participants often reported the benefits of learning cognitive and behavioral skills and techniques for cutting down or stopping drinking and managing relapse, such as controlling one's urges to drink alcohol, achieved through keeping oneself busy or consuming non-alcoholic drinks in social situations, and utilizing drink refusal skills such as avoidance of '*potentially dangerous situations*' and firmly refusing drinks offered by friends.

Whenever an urge to drink alcohol developed, she advised me to go to the temple or to drink soda or cola, and to avoid alcohol … She said that whenever I did not have any work, to go to the temple and sit there or else to watch television … and while returning home, to come back with good friends and not with friends who consumed alcohol. (35 years, CAP, not remitted)

He (counsellor) said that if I had the urge of drinking, then I should divert my attention to some other thing. For instance, I should keep myself busy with some activity or play with my kids, or I should focus on my work … He advised me not to pay much attention to drinking. If anyone insisted for me to drink, then I should say 'no' to it. (26 years, CAP, remitted)

Some participants also reported that the Patient Booklet was useful.

After reading the book I learned that having tobacco can cause cancer and I got additional information about alcohol. Consumption of alcohol damages the kidneys and it also creates infertility problem …. I took the decision to reduce drinking because I wanted to do something positive in life and lead a good family life. (32 years, CAP, not remitted)

However, a few participants expressed dissatisfaction with the intervention or experienced barriers in engagement. The reasons ranged from being unclear that the intervention constituted a 'treatment' to the fact that the intervention did not address the contextual life difficulties that were maintaining the problem drinking.

First of all, they did not give me any treatment. They used to sit with me for about an hour and ask me the same things, for instance, they used to ask whether I get any suicidal feelings or such type of unnecessary questions. Why would I get such thoughts in my mind and what should I tell them about my thoughts? (39 years, CAP, not remitted)

She (counsellor) advised me to stop drinking. I tried to quit drinking but I cannot because of my family problems. My sons are not normal and secondly my wife is not so smart and clever. Everything I have to do for my family. This is the reason that I cannot quit drinking … I did everything, but I am not convinced with the techniques (that the counsellor suggested) *because of my family issues.* (65 years, CAP, not remitted)

A few respondents reported structural barriers related to attending sessions, for example due to competing work commitments, and the lack of engagement of family members.

First of all, I don't have proper transport here to go to the PHC.… buses do not operate on time here, hence I either have to arrange a private vehicle or pilot (motorcycle taxi). If I hire a pilot, then I have to pay 100 rupees while going and 100 rupees while coming back. After that they (PHC staff) take two hours to locate the case papers and then doctors do the check-up. After that she (counsellor) takes 1 hour for the session. So, I was spending most of my time to complete all these procedures. (62 years, CAP, not remitted)

As the counselors were predominantly women, a few participants cited how difficult it was to become comfortable with the counselor, owing to gender differences; one participant suggested that these factors interacted with his social anxiety.

I am scared of closed rooms (participant laughs). *I was a bit nervous to sit in the closed room along with that girl* (counsellor). *I don't know the reason but I feel somebody would harm me. I felt scared.* (56 years, CAP, remitted)

Discussion

Our study explored the experiences of participants in both arms of a randomized controlled trial evaluating a brief psychological treatment for harmful drinking delivered by lay counselors in primary care in India. The trial findings indicated a high degree of acceptability of the psychological treatment (indicated by high levels of treatment engagement and completion) and effectiveness of the treatment in changing drinking behavior. The primary goal of

this nested qualitative study was to assess the pathways to change (or lack of change). From these accounts we developed a model of change (Fig. 1), as well as of 'no change' (Fig. 2).

The initial catalyst for positive change was linked with the trial procedures themselves, i.e., screening, recruitment into the trial, and the subsequent meeting with the primary care doctor. For some participants, this was sufficient to kick-start the process of change, often through consolidating the motivation to change that was triggered, and subsequent self-directed strategies to modify drinking behavior in response to the screening results and advice from the doctor. A key element was the internalization of the need to change, perceiving the control of alcohol consumption as a challenge to oneself, and support to facilitate the decision to change. Indeed, these mechanisms that operated in both arms of the trial were the main ones that accounted for the relatively high rates of change in the control arm. This is not a surprising finding, considering that 'assessment reactivity' or simply answering research questions related to drinking has been shown to lead to significant changes in drinking behavior (McCambridge & Kypri, 2011).

Additionally, those who received the psychological treatment attributed much of the experienced change to the counseling that they received, identifying both the 'non-specific' elements of the therapeutic encounter (such as the non-judgmental and motivational interviewing stance of the counselor), as well as the specific elements of the treatment (such as the personalized feedback and cognitive and behavioral techniques). The narrated experiences with the counselor validate the helpfulness and usefulness of a therapeutic relationship and learning of specific coping and other skills in treatment. Regarding the former, our findings are consistent with the observation that the therapist–patient relationship has been known to improve clinical outcomes (Project MATCH Research Group, 1998; Velez, Nicolaidis, Korthuis, & Englander, 2017). Also, we found that the strategies that are highlighted as beneficial map well onto the framework of the CAP treatment, particularly skills to manage problem drinking behaviors (Nadkarni et al., 2015). Although CAP included a range of cognitive as well as behavioral strategies, our experience suggested that both counselors and participants worked better with behavioral strategies (e.g., using distraction to handle drinking urges) than cognitive strategies, suggesting that the former may be considered more contextually acceptable. The preference of behavioral over cognitive strategies can be assumed to be for various reasons, for instance, their more tangible nature.

Those who did not change provided many different explanations. These explanations are grouped into two main categories: on the one hand there was a lack of interest in reducing their drinking despite having agreed to participate in a trial aimed at modifying their drinking behavior, as they felt that their drinking already was under control and caused them no harm; on the other hand, while some could see that their drinking might be problematic, they felt that they needed to drink to enable them to cope with life eventualities or to offset the advent of physical discomfort. Additionally, some did not find the CAP treatment to be at all helpful. One reason for this relates to the challenge of introducing talking therapies in environments where illnesses and their treatments are often seen narrowly conceptualized as biological models, and/or where there is a high burden of social stressors that might necessitate further intervention or alternative support sources.

Although we selected the participants for this qualitative substudy on the basis of their 'objective' remission status as shown by their AUDIT scores, we were interested in participants' own accounts and understanding of whether they had made any positive changes. While there was a high degree of concordance between the self-reported perception of positive change and reduction in AUDIT scores, many who were deemed 'not remitted' in terms of their AUDIT scores still considered that they had made positive changes to both their drinking and their related lifestyles. Indeed, even among the few participants who did not make positive changes, no one worsened. While this discordance speaks to potentially significant limitations on the utility of objective measures in trials of alcohol consumption and the need to incorporate self-reported change in outcome assessments, we must be cautious in assuming that self-reported change necessarily aligns with improved health outcomes because some of the men with harmful drinking may either not have had any adverse consequences of drinking on health to begin with or might simply not acknowledge any link between the two. Thus, some participants vehemently claimed that their drinking was under control and thus did not need to be "treated". Even in the few instances where treatment was considered potentially useful, dissatisfaction with the treatment also extended to concerns that it did not involve a specific medical intervention or that it failed to address contextual stressors.

Notwithstanding these relatively uncommon perceptions, it is notable how well-received this treatment was by the majority of participants, in the light of the fact that psychological treatments are extremely unusual in the context in which it was delivered. Public primary health care in India is primarily accessed by people with relatively low incomes and relatively lower levels of education, and the care that people receive is predominantly pharmacological. Counseling or 'talking therapies' are extremely rare and the large majority of people entering the trial would never have been exposed to any type of psychological treatment – most would not have heard of such a treatment option. Many would solely expect either directive and authoritarian instruction or medication from their primary care doctor. One important finding, therefore, was that receiving this 'talking treatment' counseling grounded in motivational interviewing was perceived as being beneficial and acceptable in this context. Very few participants reported barriers to accessing or engaging with the treatment, the most common one being related to the time constraints due to competing social and work commitments. The assessment of such barriers at the outset of the treatment and discussion on how these can be mitigated, for example, through the use of remote delivery, may further improve upon the already high levels of acceptability of the treatment (Im, Yoo, Kim, & Kim, 2007; Pal, Yadav, Mehta, & Mohan, 2007).

We note a number of limitations with this study. The interviews might have been biased as they were undertaken by researchers working for the same organization that had implemented the study. The 'demand characteristics' of situations where participants form an interpretation of the interviewer's purpose and wishes and then change their responses to fit that interpretation, are well known (McCambridge & Kypri, 2011). Also, the influence of trial participation could have impacted the participants' reported changes in drinking behaviors. However, the researchers were blinded to the arm allocation status for the first part of the interview and the emphasis of the training was on understanding participant experiences rather than the impact of the intervention. On the other hand, it is also possible that respondents were more comfortable in a more intimate qualitative interview than they might have been in the more formal outcome assessment, and hence were more open and honest. Another limitation is that of recall bias; many participants found it difficult to recall treatment content and specific strategies that they had learned to deal with drinking behaviors because the interviews were conducted more

than a year after recruitment in the trial and the completion of the actual intervention. A final limitation impacting the generalizability of our findings was that our sample only included males, a reflection of the sociodemographic group that has a higher rate of consumption and alcohol-related problems in this context (Gururaj et al., 2016; Murthy, 2015). On the other hand, this study is unique in that it is, to our knowledge, the only qualitative study exploring perceptions of change in drinking behavior nested in a randomized controlled trial evaluating a lay counselor-delivered psychological intervention in a LMIC. We used a systematic and rigorous methodology, using the 'PREMIUM approach' (Vellakkal & Patel, 2015), to conduct the qualitative work, and recruiting a sample representative of the trial population. Finally, there are several research and policy implications of our positive findings for the contextual relevance and effectiveness of CAP, making the intervention ideally suited for scaling up to reduce the treatment gap for alcohol use disorders.

Conclusions

A major conclusion to this study relates to the overall acceptability and perceived effectiveness of a brief psychological intervention delivered in primary care settings. Participants highlighted how formal psychological support in primary care catalyzed change in their drinking behaviors and personal lives. For many participants, this was the first time that they had received structured help from the health sector for their drinking problems. Simply being recruited in a trial was sufficient for many individuals to modify their behavior, though this effect was further enhanced by the psychological intervention. At the very least, this indicates the value of universal screening and personalized feedback for harmful drinking and the potential additional value of brief psychological interventions based on motivational interviewing and simple cognitive and behavioral elements, delivered by non-specialist providers in routine health care settings in LMIC as an acceptable approach to bridge the massive treatment gap for AUDs.

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Declaration of competing interest

None.

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