- 1 Supporting Addictions Affected Families Effectively (SAFE): A mixed methods
- 2 exploratory study of the 5-Step Method delivered in Goa, India, by lay counsellors.

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4 Running head: A mixed methods exploratory study of the 5-Step Method

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- 9 S. and Pednekar, S. (2017). Supporting addictions affected families effectively
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Supporting Addictions Affected Families Effectively (SAFE): A mixed methods exploratory study of the 5-Step Method delivered in Goa, India, by lay counsellors.

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Abstract

- Aims: To explore the effect of the relatives' drinking on their family members, and the preliminary impact of the 5-Step Method intervention on the adverse effect of the relatives'
- drinking on their family members.

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- Methods: In Depth Interviews were conducted with eligible Affected Family Members (AFMs)
- 67 (n=30) to understand the effect of the relatives' drinking on their family members.
- Subsequently, a different group of consecutive eligible AFMs (n=21) received the 5-Step
- 69 Method from lay counsellors, with outcomes measured at baseline and 3 months after
- delivery of the first session, to examine the impact of the intervention on AFMs.

71 Findings:

In the In Depth Interviews, the perceived impact of the relatives' drinking on the AFM included substantial physical/emotional abuse, financial difficulties, shame, poor health, impaired interpersonal relationships, and change in the AFM's role in the family. In the case series, for AFMs who received at least one session of the intervention, there was significantly increased engaged coping, increased stress, and increased professional social support; and in those who completed the intervention, there was significantly increased engaged scoping, increased strain, and increased informal social support.

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- Conclusions: Compared to developed countries, stresses experienced by AFMs in our study
 are somewhat qualitatively different. The impact of an un-adapted 5-Step Method
 intervention is less helpful than found elsewhere; hence an adapted version of the 5- Step
 Method which is responsive to the realities of the cultural context may be better suited to
- 84 Indian settings.

Supporting Addictions Affected Families Effectively (SAFE): A mixed methods exploratory study of the 5-Step Method delivered in Goa, India, by lay counsellors.

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Introduction

Well over 100 million family members worldwide are estimated to be affected by the addictive behaviours of a relative (Copello, Templeton, & Powell, 2010; Orford, Velleman, Natera, Templeton, & Copello, 2013). The experiences of living with a user makes them vulnerable to mood disorders, substance use disorders, trauma, stress related conditions, reduced quality of relationships, and family violence and abuse (Copello, Templeton, & Powell, 2010; Orford et al., 2013; Ray, Mertens, & Weisner, 2009).

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Over the past two decades, India has been witnessing an increase in alcohol availability and consumption, lowering of the age of drinking onset, disproportionately high alcohol use disorders among drinkers, and higher levels of alcohol-related problems (Benegal, 2005; Murthy, Manjunatha, Subodh, Chand, & Benegal, 2010; Pillai et al., 2014; Prasad, 2009). There are also particular features of how alcohol is consumed in India: it is predominantly a male activity; almost half of all drinkers drink hazardously; and the signature pattern is one of heavy drinking, daily or almost daily drinking, solitary drinking of mainly spirits, drinking to intoxication and expectancies of drink-related dis-inhibition (Benegal, 2005). Such a change in the epidemiological landscape of alcohol consumption will have caused a parallel increase in the prevalence of family members affected by their relatives' drinking (Affected Family Members-AFMs). However, the burden on AFMs remains largely hidden because AFMs are a 'silent group'- their perspectives and problems are largely neglected, and even if they suffer from a resulting diagnosable illness, this will often not be identified; and even if it is will rarely be linked to the relative's drinking (Orford et al., 2013). The limited number of studies from India demonstrate high burden from a relative's alcohol use on family members, including disruptions in family interactions and routines, and financial difficulties (Mattoo, Nebhinani, Kumar, Basu, & Kulhara, 2013). Spouses of drinkers have reported experiencing worry, financial hardships, domestic violence and stigma as a result of their husband's alcohol consumption (Gururaj, Murthy, Girish, & Benegal, 2011; Patel et al., 2006).

Globally, and in India, the focus of intervention strategies for alcohol-related problems has largely been on the 'substance misuser' (Benegal, Chand, & Obot, 2009; Copello, Velleman, & Templeton, 2005); and within alcohol-treatment services, the stance has traditionally been that family members may be one of the causes for the addiction (Orford et al., 2013). Furthermore, despite clear evidence of the burden of alcohol use on families, there is a lack of adequate support and targeted services for them (Orford et al., 2013). This is a particularly crucial 'missing piece' in the collectivist Indian society where priority is given to the family unit, family members are more involved in caregiving when alcohol consumption leads to physical ill-health in the drinker, and a large burden of this falls on the family (Chadda & Deb, 2013).

Evidence-based interventions can be beneficial to AFMs who are having to deal with a relative's alcohol use (Copello et al., 2005). One such intervention is the 5-Step Method, based on the Stress-Strain-Coping-Support (SSCS) Model (Orford et al., 2013), which empowers AFMs by providing access to information, and helping them explore options in relation to their coping and social support, thus helping them reduce the strain experienced by living with a relative who consumes alcohol problematically and reduce their symptoms of distress (Copello, Templeton, Orford, & Velleman, 2010). However, in Low-and-Middle Income Countries (LMICs) such as India, two major barriers exist to making such psychosocial interventions accessible: the lack and inequitable distribution of skilled staff for delivering such interventions; and concerns regarding the contextual appropriateness and generalizability of interventions developed in 'western' cultural settings. Two evidence-based ways of making such interventions accessible and acceptable in low resource settings are through 1) adaptation of the intervention to ensure contextual relevance, and 2) task-sharing (rational re-distribution of frontline healthcare tasks among healthcare teams) to address

trained human resource shortages.

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SAFE (Supporting Addictions Affected Families Effectively) was a formative research project which aimed to use a systematic methodology (Nadkarni et al., 2015) to contextually adapt the 5-Step Method, to make it acceptable, safe and feasible to be delivered to AFMs by lay counsellors (LCs). We chose to work with LCs to deliver the intervention because the huge shortage of specialist manpower would otherwise mean that, even if effective, the 5-Step Method could never be implemented on a wide scale. This is consistent with emerging evidence of effectiveness of psychosocial interventions delivered by non-specialist health workers in LMICs (van Ginneken et al., 2013). In this paper we report the findings from two critical steps of the intervention adaptation process (findings from other steps and resulting adaptations to the 5-Step Method will be presented in separate papers). The aims of these steps were as follows: 1) To examine the perceived impact of the relatives' drinking on their family members, and 2) To estimate the preliminary impact of the 5-Step Method in India. Thus in this paper we describe findings from two separate studies from the intervention adaptation process, namely a) a qualitative study exploring the impact of the relatives' drinking on their family members, and b) a quantitative study examining whether, in India, the 5-Step Method can reduce the adverse impact of the relatives' drinking on their family members. Our project is the first such project related to the 5-Step Method in India, and one of very limited studies in LMICs examining the impact of interventions to support AFMs (Rane et al., 2017).

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Methods

191 Setting

Goa, in western India, is one of India's smallest states with a population of just over 1.4 million people, 62% of which live in urban areas. Alcoholic drinks are easily available here at cheaper rates than neighbouring states, due to lower excise duties (Patel, Dourado, De Souza, & Dias Saxena, 2001) and local production of alcohol from the cashew fruit. Hence,

unlike most of India, Goa has a more liberal attitude towards drinking and this is reflected in lower abstinence rates (D'Costa et al., 2007; Pillai et al., 2013; Silva, Gaunekar, Patel, Kukalekar, & Fernandes, 2003). Risky drinking patterns in Goa are associated with intimate partner violence (Pillai et al., 2013), reports of diversion of essential household funds to drinking, and mental ill-health in spouses (Gaunekar, Patel, & Rane, 2005). Except for Al Anon, which has a limited reach, there is no structured support available specifically for AFMs in Goa. Finally, there is substantial evidence for the effective use of LCs for delivery of a range of psychosocial interventions in Goa (Nadkarni et al., 2017; Patel et al., 2010).

Study design

Mixed methods study with multiple steps: qualitative in-depth interviews (IDI) in step one were followed by an intervention cohort with before and after design in step two.

Sample

AFMs were defined as any adult (≥18 years) family member of a drinker, who lives in the same house as the relative or has face-to-face contact with him/her at least three times a week, where the drinking has been a source of distress for the family member, in the last 6 months. Potential participants were excluded if they themselves had a substance use problem and/or a physical/mental health problem that might interfere with participation, and/or was not able to converse in any vernacular languages used at the study site or English.

Participants were recruited through referral by community gatekeepers (e.g. community health workers, village council members) or self-referral in response to media advertisements. Extensive networking was done in the community to establish strong links with the gatekeepers and enhance referrals. For the IDIs, 30 participants were selected through purposive sampling to ensure maximum variability. As this was a qualitative study these numbers were not derived from sample size calculations and the data collection was stopped once data saturation was reached i.e. no new themes emerged. For the intervention

cohort the first 21 participants consenting to participate were recruited. The samples for these two steps of the project were independent of each other. As the intervention cohort was a feasibility study the sample size was not informed by formal sample size calculations but based on the pragmatics of recruitment; and met the recommendations for sample size for pilot studies being 10-40 participants (Hertzog, 2008).

Data collection

Qualitative data: Data were collected through IDIs, a technique that allows for detailed indepth probing of subject matter and provides information on context (how experiences are linked to each other) (Legard, Keegan, & Ward, 2003). The interview questions were designed to explore specific research objectives and the data reported here relate to questions focused on the impact of the relative's drinking on the AFM (data related to other questions about topics such as coping and support are reported elsewhere (eg Bhatia et al, in preparation)).

Quantitative data: a) Socio-demographic data, b) Process data about recruitment (e.g. how many AFMs referred) and intervention delivery (e.g. how many sessions delivered), c) Outcome tools administered at baseline and three months after the delivery of the first session. These consisted of the following, each of which measures one element of the SSCS Model: 1) Symptom Rating Test (SRT) (Kellner & Sheffield, 1973)- to assess the extent of mild-to-moderate physical and psychological ill health. This examines 'strain' as a sum of all items to produce a total symptom score or, by calculating two sub-scales scores (psychological symptoms and physical symptoms), 2) Coping Questionnaire (CQ) (Orford, Templeton, Velleman, & Copello, 2005)- to measure ways of coping by the AFM. It can be used to generate a total coping score or by calculating three sub-scale scores corresponding to three ways of coping (standing up to the problem or engaged coping; putting up with it, or tolerant-inactive coping; and withdrawing and gaining independence or withdrawal coping), 3) Family Member Impact Questionnaire (FMI) (Orford et al., 2005)- to measure the extent

and type of impact on the AFM as a total impact score, or by producing two sub-scale scores reflecting two different aspects of family impact (worrying behavior and active disturbance), and 4) Alcohol, Drugs and the Family Social Support Scale (ADF-SSS) (Toner & Velleman, 2014)-to assess the perceived functional social support received by AFMs as an overall social support score as well as subscales for functional support (informal social support from friends and relatives), positive alcohol, drugs and families specific support (formal social support received from professionals/friends/family or through information found in books etc), and negative alcohol, drugs and families specific support (unhelpful support such as non-supportive interactions with friends/family). All these measures have been validated previously (although not in India) and all were translated and back translated using rigorous procedures for use in Goa.

The baseline quantitative assessments in the intervention cohort were conducted by either research workers or the counsellors (who later provided the counselling). All other quantitative and qualitative data were collected by the research workers. Permission to record the IDIs on a digital recorder was sought by the research worker prior to each IDI, and to record the intervention sessions was sought by the LC from each participant prior to the first intervention session and confirmed at the start of each subsequent session. Interviews and intervention sessions were conducted in the vernacular language. The audio-recordings of both the IDIs and the intervention sessions were first transcribed and then later translated into English. The quality of data from the IDIs was monitored on an ongoing basis through the following mechanisms: the research coordinator examined the incoming data for richness/completeness, quality and interviewing style, and feedback was provided to the relevant research worker with suggestions for improvement.

Intervention

The 5-Step Method (developed and tested in the UK and other parts of the world), is a psychosocial intervention based on the principles of the Stress-Strain-Coping-Support model

(Copello, Templeton, Orford, et al., 2010). The 5 steps include: 1) Exploring stresses and strains, 2) Providing relevant information, 3) Exploring and discussing coping behaviors, 4) Exploring and enhancing social support, and 5) Exploring additional needs, and further sources of help, and ending the intervention. The intervention is usually delivered over five sessions (with a booster session added on for SAFE), with a frequency of one session every 1-2 weeks. The booster session was typically delivered a month after the completion of treatment, most often as a telephonic conversation and in some cases a home visit. The purpose of the booster session was to 1) ascertain the AFM's current health status, 2) assess helpfulness of strategies learnt during treatment, and 3) assess for continuing progress. The intervention is delivered in settings based on convenience of the participant (home, health centre, etc.).

Adapting the Intervention

At the outset of this work in India, we collected various data about the ways that the 5-Step Method might need adaptation to make it culturally appropriate for Goa, and wider India. Part of the IDIs in step one (above) described the 5-Step Method to the AFMs being interviewed, and investigated the ways that these AFMs thought it might need adapting for the local context. Similarly, a number of intervention development workshops were held with various stakeholder groups (intervention providers, lay counsellors, AFMs, etc) asking similar questions. Many suggestions were forthcoming about issues such as the location of sessions and methods of contacting AFMs, but there was a great consensus that all five of the Steps were completely appropriate to the local context, and that no additions needed to be made. Therefore, except for the addition of a booster session, all the other adaptations made before the intervention cohort component of the research were all surface ones (for example, materials were translated into local vernacular languages; and the settings where AFMs might be seen were revised).

Counsellors: The intervention was delivered by Lay Counsellors (LCs) i.e. local community members with no previous mental health-related professional qualifications, recruited through local advertising. Eligible LCs underwent rigorous training over 3 days in general counselling skills and two weeks in the 5-Step Method. This is much longer than the more usual 2- or 3-day training provided to experienced practitioners, because these LCs had never received any previous training in, nor had any previous experience in delivering, psychosocial interventions, and hence needed to undergo a relatively long training to be able to deliver the 5-Step Method to the required competency-based standard. Ten LCs underwent the training and at the end of the training seven LCs who achieved predetermined competency standards were selected to deliver the intervention in the intervention cohort.

Supervision

Supervision of LCs was informed by a rigorous protocol and consisted of regular monitoring of intervention delivery through listening to session audio-tapes, direct observation of sessions, review of clinical notes and related documentation, and maintenance of skills through refresher trainings, and debriefing sessions. Supervision included a combination of group-based and individual-based supervision. Performance of the LCs was measured through a standardized tool for measuring competency in the 5-Step Method and general counselling, and feedback was given by supervisors (UB and SP) and peers. The 5-Step Method experts (RV and GV) commented on (and rated) 20 translated transcripts of sessions and feedback was provided to the LCs.

Analyses

All audio-recorded IDIs were first transcribed verbatim and then translated into English. Qualitative data were analysed by SC and UB under AN's supervision. Data were analysed using Thematic Analysis, which is a method for identifying, analysing, and reporting patterns (themes) within data (Braun & Clarke, 2006). The researchers read the transcripts to

immerse themselves in the data and then generated initial codes through coding parcels of data in a systematic fashion. Based on the coded data, we defined and collated codes into potential themes which were then used to code the entire data set and the meaning of the themes was examined in relation to the research question (impact of relative's drinking on AFM). Patterns were derived by comparing similarities and differences between participants on these themes or by examining how the themes or codes were connected to or interacted with one another. Each theme was assigned a name and a descriptive phrase that best explained their meaning and united its individual codes on consistency. The themes were supported by excerpts from transcripts to demonstrate that themes were as close to the data as possible and reflected the words used by the participants themselves.

Process indicators of the screening, and intervention process are presented as proportions and means as appropriate. Socio-demographic characteristics of the sample are summarised as means and proportions as appropriate. The mean pre and post scores on four outcome tools were compared using the paired t-test.

Ethical issues

The Institutional Review Board at Sangath reviewed and approved the study. Written informed consent was taken individually from all participants. Anonymity was assured to each participant and informed consent given by those interviewed.

Results

Sample

The participants in the IDIs (n=30) were predominantly females (93%), aged more than 30 years (90%), and wives of drinkers (63%). The majority of the participants were literate (87%), and employed (60%). Four (13%) had not completed primary education, 18 (60%) had completed at least primary schooling, and 8 (27%) had completed higher secondary or above.

In the intervention cohort, of the 44 AFMs referred (33 by gatekeepers, 11 through self-referral) 36 (81.8%) could be approached and 25 (69.4%) could be screened for eligibility. 22 (88.0%) were eligible, with reasons for ineligibility being: not being a resident in the catchment area for the duration of the program, relative was not drinking alcohol, and drinking relative had died. Of these, one (4.5%) did not consent to participate and 21 entered the case series. Of these, 18 (85.7%) entered the intervention and the rest did not start the intervention. One AFM did not give a reason for not entering the intervention after consenting and the reasons for the other two AFMs were a) Husband (drinker) died before she could start the intervention, and b) AFM wanted an intervention for the drinker and not herself.

AFMs who entered the intervention had a mean age of 44.4 years (SD=2.6), and were predominantly female (n=16; 88.9%), employed (n=11; 61.1%), and literate (n=14; 77.8%). 4 (22.2%) had not completed primary education, 11 (61.1%) had completed at least primary school, and 3 (16.7%) had completed higher secondary or above.

- Table 1 describes the characteristics of the consented participants in the IDIs and intervention cohort.
- 372 (Table 1 about here)

Effect of the relatives' drinking on their family members

In the following section we describe the common strands that run through the impact of the relatives' drinking on various domains of the family members' lives. These include experiencing abuse, health problems, financial difficulties, shame, relationship problems, and changed role in the family.

1. Abuse when drinking: AFMs reported experiencing physical and mental abuse by the drinker and/or witnessing another family experiencing such abuse. Abuse was common and inflicted mainly on women; however sometimes males and children were also at the receiving end of abusive behaviour. The violence was very serious in some cases and involved the use of weapons such as iron rods. Another key aspect of their lives was the neglect that they had to go through, because the drinker was not able to fulfill his family role.

'He (son) has hit me many times. He hit with metal rod once, once he hit me with a rock' (Mother, 46)

'Despite my health issues he (husband) wanted to have sex with me. He did not care even that I was unwell; if I wanted a glass of water or vomited he would tell the children to tend to me. But he never tended to me himself.' (Wife, 49)

'He (husband) started harassing and beating me, began to keep me hungry. He used to put me out of the house. When he did that, I used to spend nights surviving on tap water from the neighbourhood tap. He used to put me out of the house even when it was raining' (Wife, 37)

'He (son) has broken my teeth by punching me ...he has slapped me ...he has kicked his father ... he has broken his brother's hand and punched him in the eye...We have suffered a lot because of him' (Mother, 50)

2. Impact on health

Almost all AFMs reported experiencing a deterioration of physical and mental health, sometimes very severe. They reported experiencing burden due to increased responsibility and worry for a drinking relative, often causing them to neglect their own wellbeing. Disturbed sleep, 'tension' (stress), and worrying was commonly reported. For many, these

eventually led to decreased self-confidence and in some cases AFMs reported active suicidal ideation. Physical problems such as headaches, high blood pressure, as well as pain from where they had been beaten, were also commonly reported by AFMs; with those who had the least support reporting the most problems. 'Her (drinker's mother) BP fluctuates, physical appearance has changed. It has changed significantly due to tension, disturbed sleep and disturbed mind and worries.' (Sister in law, 37) 'Now that he (Son) has reduced his drinking, living here is bearable. Earlier it was impossible to live in the same house with him. I was fed up with life and contemplated suicide. I even told the police that I would kill myself and implicate him as an abettor to my death. It was unbearable' (Mother, 50) 3. Financial difficulties A direct consequence of a relative's drinking was the diversion of funds from necessary household expenses. As the drinking relative was often the major financial provider (even when the AFM was employed), family members often experienced worry and anxiety over how they would get money for food, treatment and to provide for their children. 'Once we had lots of property and money. He spent all of it on drinking; he even sold his mother's gold, a large size necklace, he sold it to a jeweller. When he needed the money (to buy alcohol) he even sold it. He is not concerned about his property. As a result he has destroyed everything' (Wife, 49) 'I was also worried that I was not working, and my children are small. I did not have money

to pay utility bills or buy food for my children.' (wife, age 38)

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437 4. Shame and being blamed Societal stigma appeared to be an important factor in shaping how female AFMs 438 experienced the consequences of their male relative's drinking. Furthermore, AFMs were 439 made to believe that the relative's drinking was a consequence of their own incapability to 440 441 maintain a home environment that would stop him from drinking. 442 443 'I was mentally disturbed thinking about him (the drinker). I did not know how I would manage when my husband was drinking and what people would say.' (wife, age 38) 444 445 446 'I feel ashamed when the doctors or the nurses shout at me; they look at me with doubt 447 ...what kind of a lady is she? One nurse said to me he "drinks so much and you are not with 448 him in the house. You should have controlled him and not let him drink so much" (Wife, 47) 449 450 5. Impact on relationships 451 Some AFMs (spouses) were regarded with suspicion by the drinker and accused of being 452 unfaithful. Furthermore, the inability of the drinker to financially contribute to the household 453 and their abusive behaviour often led to a break-down in communication in the family. 454 455 'My cousins do not talk about this (relative's drinking) and don't interfere in this matter. One 456 of my brothers in law has stopped coming to our house' (Sister, 34) 457 AFMs attempted to keep a relative's behaviour hidden from the rest of the world. This led to 458 459 several difficulties and the eventual breakdown of relations between the AFM, and wider family members and others outside the family. The relative's unruly behaviour such as 460 fighting and swearing when intoxicated, caused AFMs to avoid attending events and 461 462 stopped them from inviting guests to their house.

463 'Then I noticed that my office colleagues maintained a distance from me. They felt that I always had a sad face, that I always have problems and sent negative vibes. That could be 464 what they thought' (Wife, 47) 465 466 467 'But if anyone visited us, he (husband) used to take Rs 500 from me to keep quiet, or else he threatened to create a ruckus. I plead to people not to come to our house because of 468 469 such things' (Wife, age 49). 470 471 6. Role in the family 472 The relatives' drinking and the consequent financial difficulties meant that AFMs often found 473 themselves having to adapt their roles within the household to manage a variety of tasks. 474 Managing finances, taking care of the relative when he is frequently unwell because of his 475 drinking, and managing the increased demands of the drinker, were all tasks that AFMs had 476 to take on as a result of lack of support. 477 478 'I have a son who is 8 years and my husband works abroad. So, if I have to take him 479 (drinking relative) to the doctor it is an additional responsibility as I have to manage my son 480 as well. As my son cannot manage things on his own at this age I have to take care of his 481 needs, manage the home, as well as adjust with his (drinking relative) hospitalization.' 482 (Sister in law, 37). 483 To summarise, the relatives' drinking affected their family members at several levels, namely 484 485 at the personal level (experiencing abuse, and physical and emotional health problems, and financial difficulties), interpersonal level (impaired relationships, and change in traditional 486 487 roles in the family), and societal level (stigma). 488

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Impact of the 5 Step Method

For those who entered the intervention, the relationship of the AFM to the drinker was wife (n=14; 77.8%), father (n=2; 11.1%), and mother (n=2; 11.1%). The AFMs (wives) were married to the drinker for an average of 15.3 years (SD=5.8). The AFMs were living with the drinker for an average of 17.6 years (SD=8.3). On average, the AFM's relative was reported to have been drinking for 13.4 years (SD=8.8) and drinking problematically for 7.1 years (SD=5.2).

Two (11.1%) AFMs (both wives of drinkers) dropped out after first and third sessions respectively, with the rest completing the intervention (n=16; 88.9%). Sessions were predominantly delivered in the community clinic (61.8%). Other places where the sessions were delivered included the church (12.4%), AFM's home (10.1%), neighbour's house (10.1%), and other sites such as local school (5.6%).

Baseline data were available for all AFMs who entered the intervention. Outcome data were available for 17 (81%) of the 21 who consented, and 16 of the 18 who entered the intervention. So baseline and outcome data were available for 16 AFMs who entered the intervention (received at least one session); and for 14 AFMs who completed the intervention. Multiple attempts were made to schedule appointments with all the remaining AFMs, but all were unsuccessful.

In AFMs who received at least one session of SAFE there was a significant increase in the engaged style of coping (the three forms of coping measured by the Coping Questionnaire are described in the methods section, above), increased stress (increased score on FMI scale), and increased professional social support related to alcohol, drugs, and families (Table 2). In AFMs who completed the intervention there was a significant increase in the engaged style of coping, increased strain (increased total score on SRT and its psychological sub-scale), and increased total and informal social support (increased total score on the SSS and its Positive Functional Support subscale).

(Table 2 about here)

Discussion:

To summarise, our findings from the IDIs show that the perceived effects of the relatives' drinking on their family members include physical and psychological abuse, financial difficulties, shame and stigma, poor physical and mental health, poor interpersonal relationships within and outside the family, and changes to the traditional family roles. In the intervention cohort we found that, following intervention with the 5-Step Method, there was an increase in one coping style and in social support but worsening of stress and strain.

Consistency with other qualitative work internationally

Research conducted in various parts of the world on the impact of a relative's drinking and drug taking on their family members include relationships becoming disagreeable, and sometimes aggressive, conflict over money and possessions, uncertainty because of the unreliability of the relative's presence in the home, worry and concern about their relatives, depletion of the family's financial resources, family members (often women) having to support the family economically. They also experienced a denting of their self-confidence and a range of emotions such worry, anxiety, helplessness, despair, guilt, anger, resentment, and fear (Orford, Velleman, Copello, Templeton, & Ibanga, 2010).

Although most of these elements are universal, as can be seen from our findings and discussed, for example, in Orford et al (2005), there are finer differences in the pre-dominant concerns based on the cultural context. Orford et al. (2005) showed that, in a LMIC such as Mexico, a major impact on AFMs was financial instability caused by excessive drinking, when families are already living in poverty; but in White English family members, the prominent perceived impact was on family members' individual autonomy. On the other

hand, in the Pakistani-Kashmiri community in England, a dominant feature was greater exposure and dishonor due to the greater social support afforded by a close-knit community (Orford et al., 2010). In Australian Aboriginal families one of the major concerns for the family as well as the wider community was the link between excessive drinking and violence (Orford et al., 2005). What comes out strongly from the IDIs in this present, Indian, study is the feeling of being trapped in an extremely difficult situation (often with quite extreme levels of violence) which allows no escape. This could be due to the desire not to disrupt the perceived sanctity of the family in a socio-centric culture and also the limited financial independence of a large majority of women from India. Instead the AFMs attempt to maintain stability in the family by taking up the roles traditionally fulfilled by the man (who is now not able to do that because of his drinking).

Consistency with other 5 Step Method work internationally

Except for one randomized controlled trial in primary care, all 5-Step Method research studies have been intervention cohort studies (Copello, Templeton, Orford, & Velleman, 2010). In all studies (with one exception: a small (N=15) feasibility study in a UK statutory substance misuse service), there was a significant reduction in strain (total symptoms, physical symptoms and psychological symptoms on SRT) after the intervention (Copello et al., 2010). Results are mixed with regard to impact on coping behaviors. In most studies there have been significant reductions in engaged and tolerant coping. However, in the UK British Minority Ethnic (BME) study there were no significant changes in coping (Orford et al., 2009), and in the Italian study, although engaged coping did reduce, the only significant change was a reduction in tolerant coping (Velleman et al., 2008), suggesting that there might be cultural influences on how coping changes.

The 5-Step Method is based on the Stress-Strain-Coping-Support (SSCS) model which proposes the following mechanism for the effect of a relative's drinking on the AFM (Orford,

Copello, Velleman, & Templeton, 2010). When a relative has a serious drinking problem it is highly stressful to close family. A direct consequence of such a stressful set of circumstances is 'strain' i.e. effects on a family member's health. The AFM then finds ways of buffering the stress and reducing strain on themselves and other members of the family and these ways of responding are collectively referred to as 'coping'. Finally, informal and formal support, which may come from a number of different directions, is an important component of this buffering.

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In our study there was an increased engaged style of coping and support but a worsening of stress and strain. It is possible that there was no change in the other two styles of coping in the direction which has been found in some other studies (a reduction of 'putting up with it' and an increase in 'becoming independent') as those might not be realistic in a patriarchal Indian society where a woman, especially a married one, is dependent on a man for support, or does not feel empowered to make autonomous decisions. The differential change in coping and support without any change in stress and strain could be because the intervention first has a positive effect on proximal components of the SSCS model, and three months might be too early to see a change in the more distal components. On the other hand, it could also mean that, in this particular cultural group, the intervention is not able to reduce stress and strain through changes in coping strategies and improved support alone; and that a more focused intervention directly targeting cognitions, emotions and behaviours related to psychological and physical symptoms might be needed. The worsening of both stress and strain could possibly be because engagement in the intervention process might be increasing AFMs knowledge and understanding about their situation, without them feeling empowered to make changes in their situation. This increase in knowledge could therefore increase their worrying, and especially their pre-occupation with getting help for the drinker and changing his drinking patterns, and exacerbate their other psychological and physical symptoms. Furthermore, the intervention could have created a set of expectations for the AFM that they would be able to create change in the family situation (for instance, by actively seeking help for the drinking relative), which may have resulted in stress and strain if the expected outcome wasn't achieved (i.e. the relative stopping drinking). Further, the actual process of talking about the problems might have made the AFMs feel worse about their lives, if they also felt powerless to make changes to alleviate the situation. For example, financial difficulties were one of the major issues experienced by AFMs, yet these are more or less 'permanent' in AFMs lives: realising that the intervention was not going to change this could also help explain their worsening rates of stress and strain.

Previous studies of the 5-Step Method support the hypothesis that a reduction in tolerant-inactive and/or engaged-emotional coping is associated with improvement in health, and underline the importance of the AFM a) becoming more assertive, resisting, setting limits and making rules, b) increasing the focus on his/her own life and needs, becoming more detached from the relative's behaviour, and understanding the effect it is having on him/herself, and c) no longer keeping the relative's drinking problem and its impact secret (Copello & Orford, 2002). However, it is quite likely that such responses might not be realistic options in Indian settings because of the structure of families, the relatively disempowered role of women in large sections of Indian society, and the strong stigma associated with drinking behaviours. One other finding (that there was an increase in professional social support related to alcohol, drugs, and families) is most possibly an artefact caused by the AFM's reporting the support received from the LCs as professional social support.

Finally, it is possible that, in India, the problems are so intractable, and sometimes overwhelmed by a more serious phenomenon such as severe domestic violence, that a brief intervention such as the 5-Step Method is not sufficient to make any positive changes. A larger study that we are currently conducting in the same setting would possibly provide more evidence to support or refute these speculations.

Strengths and weaknesses

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This is a first study from India testing the impact of an intervention directed at supporting family members affected by their relative's drinking. Its strengths lie in its mixed methods approach, community-based approach to recruitment, innovative delivery method, and high intervention completion rate. The study has several 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 means that we cannot attribute any changes in the outcome measures directly to the intervention. The tools used to measure the impact of the intervention have not been validated in Indian settings and despite face validity they might not be measuring the construct appropriately in a cultural setting distinct from the one in which they were originally developed. However, the advantage of formative research such as the one reported in this paper is that it allows the examination of such issues so that they can be corrected before deployed in larger effectiveness trials. Finally, while interpreting the findings and their generalisability one also needs to consider the systematic contextual differences between Goa and the rest of India; and also the characteristics of our sample. The former include differences in social and economic parameters, which have the potential to influence critical components of a program such as ours e.g. uptake and acceptability. The latter (i.e. middle aged, educated, employed, spouses of drinkers) represent a sub-set of AFMs and it could well be that the experiences and response to the intervention of AFMs with a different set of socio-demographic characteristics will be distinct from our findings.

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Implications

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Our study has several clinical, research and policy implications. The findings raise several questions about the applicability of the 5-Step Method which, as described above, underwent only surface adaptations to increase acceptability and feasibility in Indian settings. Although our formative work suggested that there needed to be no changes made

to the basic structure and content of the 5-Step Method, these findings above imply that this may need to be re-thought. One such adaptation would have to be around the addition of an intervention component specifically designed to tackle the issue of domestic violence, given the frequency and serious level, which was reported in this context. Other potential adaptations could be around increasing the behavioural components of the intervention and reducing the cognitive components, and adding components which help to engage the drinking relative into addictions treatment services. The limited impact of the 5-Step Method in our case series, some of which is inconsistent with other 5-Step Method work, also raises questions about the suitability of this un-adapted intervention for delivery by lay counsellors. We are already testing the intervention in a pilot randomised controlled trial (RCT) and this should clarify some of the questions raised by this study.

Conclusion:

Our findings emphasise the distinctiveness of some of the experiences of AFMs in our study compared to those who have taken part in earlier studies in developed countries. The differences might be in the stresses experienced (e.g. extent and intensity of domestic violence is a powerful theme that runs across most narratives), or the circumstances of the AFMs' family lives (e.g. less opportunity for asserting independence), and hence their reactions to a surface-adapted 5-Step Method are less predictable and more inconsistent. Consequently, the findings of the various steps of this formative work are expected to result in a version of the 5- Step Method with deep adaptations, which would be contextually better suited to the idiosyncrasies of the Indian cultural setting. Once we have developed this more fundamentally adapted version, the next step will be to conduct a definitive RCT of this adapted intervention, to test its cost effectiveness. If found to be cost-effective, then the intervention would potentially be suitable for scaling up in India and other low resource settings as it is designed to be delivered by non-specialist health workers.

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References:

Benegal, V. (2005). India: alcohol and public health. Addiction, 100(8), 1051-1056.

Benegal, V., Chand, P. K., & Obot, I. S. (2009). Packages of care for alcohol use disorders in low-and middle-income countries. *PLoS Med*, *6*(10), e1000170.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Res Psychol*, *3*(2), 77-101.

Chadda, R. K., & Deb, K. S. (2013). Indian family systems, collectivistic society and psychotherapy. *Indian J Psychiatry*, *55*(S2), S299.

Copello, A., & Orford, J. (2002). Addiction and the family: is it time for services to take notice of the evidence? *Addiction*, *97*(11), 1361-1363.

Copello, A., Templeton, L., Orford, J., & Velleman, R. (2010). The 5-Step Method: Evidence of gains for affected family members. *Drugs: Education, Prevention and Policy, 17*(S1), 100-112.

Copello, A., Templeton, L., Orford, J., & Velleman, R. (2010). The 5-Step method: Principles and practice. *Drugs: Education, Prevention and Policy*, *17*(S1), 86-99.

Copello, A., Templeton, L., & Powell, J. (2010). The impact of addiction on the family: Estimates of prevalence and costs. *Drugs: Education, Prevention and Policy, 17*(S1), 63-74.

Copello, A. G., Velleman, R. D., & Templeton, L. J. (2005). Family interventions in the treatment of alcohol and drug problems. *Drug Alcohol Rev, 24*(4), 369-385.

D'Costa, G., Nazareth, I., Naik, D., Vaidya, R., Levy, G., Patel, V., & King, M. (2007). Harmful alcohol use in Goa, India, and its associations with violence: a study in primary care. *Alcohol Alcohol*, *42*(2), 131-137.

Gaunekar, G., Patel, V., & Rane, A. (2005). The impact and patterns of hazardous drinking amongst male industrial workers in Goa, India. *Soc Psychiatry Psychiatr Epidemiol*, *40*(4), 267-275.

Gururaj, G., Murthy, P., Girish, N., & Benegal, V. (2011). *Alcohol related harm: implications for public health and policy in India*. NIMHANS, Bangalore.

Hertzog, M. A. (2008). Considerations in determining sample size for pilot studies. *Res Nurs Health*, *31*(2), 180-191.

Kellner, R., & Sheffield, B. F. (1973). A self-rating scale of distress. *Psychol Med, 3*(01), 88-100.

Legard, R., Keegan, J., & Ward, K. (2003). In depth interviews. In J. Ritchie, J. Lewis, C. M. Nicholls, & R. Ormston (Eds.), *Qualitative research practice: A guide for social science students and researchers*. London: Sage.

Mattoo, S. K., Nebhinani, N., Kumar, B. A., Basu, D., & Kulhara, P. (2013). Family burden with substance dependence: a study from India. *Indian J Med Res*, *137*(4), 704-711.

Müller-Riemenschneider, F., Reinhold, T., Nocon, M., & Willich, S. N. (2008). Long-term effectiveness of interventions promoting physical activity: a systematic review. *Preventive Medicine*, *47*(4), 354-68.

Murthy, P., Manjunatha, N., Subodh, B., Chand, P. K., & Benegal, V. (2010). Substance use and addiction research in India. *Indian J Psychiatry*, *52*(7), 189-199.

Nadkarni, A., Weobong, B., Weiss, H.A., McCambridge, J., Bhat, B., Katti, B., et al. (2017). Counselling for Alcohol Problems (CAP), a lay counsellor-delivered brief psychological treatment for harmful drinking in men, in primary care in India: a randomised controlled trial. *Lancet*, 389(10065), 186-95.

Nadkarni, A., Velleman, R., Dabholkar, H., Shinde, S., Bhat, B., McCambridge, J., Murthy, P., Wilson, T., Weobong, B., Patel, V. (2015). The Systematic Development and Pilot Randomized Evaluation of Counselling for Alcohol Problems, a Lay Counselor-Delivered Psychological Treatment for Harmful Drinking in Primary Care in India: The PREMIUM Study. *Alcohol Clin Exp Res*, 39(3), 522-531.

Orford, J., Copello, A., Simon, A., Waheed, H., Fazil, Q., Graham, H., Mahmood, M., McNeil, S. and Roberts, G. (2009). Offering a service to BME family members affected by close relatives' drug problems. In: S. MacGregor (Ed). *Responding to Drug Misuse: Research and Policy Priorities in Health and Social Care*. Chapter 14. London: Routledge.

Orford, J., Copello, A., Velleman, R., & Templeton, L. (2010). Family members affected by a close relative's addiction: The stress-strain-coping-support model. *Drugs: Education, Prevention and Ppolicy*, 17(S1), 36-43.

Orford, J., Natera, G., Copello, A., Atkinson, C., Tiburcio, M., Velleman, R., Walley, G. (2005). *Coping with Alcohol and Drug Problems: The Experiences of Family Members in Three Contrasting Cultures*: Taylor & Francis.

Orford, J., Templeton, L., Velleman, R., & Copello, A. (2005). Family members of relatives with alcohol, drug and gambling problems: a set of standardized questionnaires for assessing stress, coping and strain. *Addiction*, *100*(11), 1611-1624.

Orford, J., Velleman, R., Copello, A., Templeton, L., & Ibanga, A. (2010). The experiences of affected family members: A summary of two decades of qualitative research. *Drugs: Education, Prevention and Policy, 17*(S1), 44-62.

Orford, J., Velleman, R., Natera, G., Templeton, L., & Copello, A. (2013). Addiction in the family is a major but neglected contributor to the global burden of adult ill-health. *Soc Sci & Med*, 78, 70-77.

Patel, V., Dourado, R., De Souza, N., & Dias Saxena, F. (2001). *The State of Goa's Health*. New Delhi: VHAI.

Patel, V., Kirkwood, B. R., Pednekar, S., Pereira, B., Barros, P., Fernandes, J., Datta, J., Pai, R., Weiss, H., Mabey, D. (2006). Gender disadvantage and reproductive health risk factors for common mental disorders in women: a community survey in India. *Arch Gen Psychiatry*, 63(4), 404-413.

Patel, V., Weiss, H.A., Chowdhary, N., Naik, S., Pednekar, S., Chatterjee, S., et al. (2010). Effectiveness of an intervention led by lay health counsellors for depressive and anxiety disorders in primary care in Goa, India (MANAS): a cluster randomised controlled trial. *Lancet*, 376, 2086-95.

Pillai, A., Nayak, M. B., Greenfield, T. K., Bond, J. C., Hasin, D. S., & Patel, V. (2014). Adolescent drinking onset and its adult consequences among men: a population based study from India. *J Epidemiol Community Health*, 68(10), 922-927.

Pillai, A., Nayak, M. B., Greenfield, T. K., Bond, J. C., Nadkarni, A., & Patel, V. (2013). Patterns of alcohol use, their correlates, and impact in male drinkers: a population-based survey from Goa, India. *Soc Psychiatry Psychiatr Epidemiol, 48*(2), 275-282.

Prasad, R. (2009). Alcohol use on the rise in India. Lancet, 373(9657), 17-18.

Rane, A., Church, S., Bhatia, U., Orford, J., Velleman, R., Nadkarni, A. (2017). Psychosocial interventions for addiction-affected families in Low and Middle Income Countries: A systematic review. *Addict Behav*, 74, 1-8.

Ray, G. T., Mertens, J. R., & Weisner, C. (2009). Family members of people with alcohol or drug dependence: health problems and medical cost compared to family members of people with diabetes and asthma. *Addiction*, *104*(2), 203-214.

Silva, M. C., Gaunekar, G., Patel, V., Kukalekar, D. S., & Fernandes, J. (2003). The prevalence and correlates of hazardous drinking in industrial workers: a study from Goa, India. *Alcohol Alcohol*, *38*(1), 79-83.

Toner, P., & Velleman, R. (2014). Initial reliability and validity of a new measure of perceived social support for family members of problem substance users. *Addict Res Theory*, *22*(2), 147-157.

van Ginneken, N., Tharyan, P., Lewin, S., Rao, G. N., Meera, S. M., Pian, J., et al. (2013). Non-specialist health worker interventions for the care of mental, neurological and substance-abuse disorders in low-and middle-income countries. *Cochrane Database Syst Rev*, *11*(11), CD009149.

Velleman, R., Arcidiacono, C., Procentese, F., Copello, A. and Sarnacchiaro, P. (2008) A 5-Step intervention to help family members in Italy who live with substance misusers. *Journal of Mental Health*, 17(6), 643-655.