The Systematic Development of a Mobile Phone Delivered Brief Intervention for Hazardous Drinking in India

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Abstract

The treatment gap for alcohol use disorders (AUD) in India is the highest amongst all mental and substance use disorders. Despite evidence of the cost effectiveness of Brief Interventions (BIs) for hazardous drinking, implementation in low- and middle-income countries (LMICs) is rare due to several human resource related barriers. This paper describes the processes and outputs of a study aimed at systematically developing a mobile phone delivered BI to overcome such barriers.

Mixed methods study with four steps. Review of the existing relevant evidence base by extracting data from studies cited in two recent, relevant and high-quality systematic reviews (Step 1). In-depth interviews (IDIs) with 11 national experts in addictions research and practice, and 22 hazardous drinkers (Step 2). Delphi survey (2 rounds) to identify components for the intervention package through consensus building (Step 3). Content and intervention development workshops with a range of stakeholders to develop the intervention package (Step 4).

72 journal articles were sourced from two selected systematic reviews. Key content areas extracted from the studies included facts and statistics about health related to drinking behaviour, self-reflection, goal-setting messages, motivational messages, and skills to manage risky situations. Most of these were also endorsed in the IDIs with experts and hazardous drinkers. The Delphi survey achieved consensus on 19 content areas and examples of these included targeted recommendations, personalised feedback and information, goal management and coping skills. The content and intervention development workshops resulted in an intervention package delivered over eight weeks, with the following seven themes guiding the content of the weekly messages: Safe drinking/health education, alcohol reduction, drinking and risk management, drinking alternatives, situational content, urge management, and maintenance and relapse prevention.

Our study was designed to consider contextual factors while developing the intervention, which is important to ensure acceptability and feasibility. Interestingly, the contextually informed intervention components, had several commonalities with BIs developed and tested

in high-income countries.

Keywords: Intervention development; mHealth; Brief Interventions; hazardous drinking; India

1. Introduction

Between 1990 and 2017, global adult per-capita alcohol consumption increased from 5·9 Litres to 6·5 Litres, and is expected to reach 7·6 Litres by 2030 (Manthey et al., 2019).

Importantly, saturation of markets in high-income countries (HICs) is causing emerging economies to increasingly be seen as untapped markets for the alcohol industry. This is leading to rapidly increasing alcohol consumption in low- and middle-income countries (LMICs) where the annual growth rate of volume consumption per person (1997-2009) was 2.8% as compared to 1.1% in HICs (Moodie et al., 2013). India, one such LMIC, is experiencing a steady increase in alcohol consumption, as well as increasing levels of alcohol-related problems (Rabiee, Agardh, Coates, Allebeck, & Danielsson, 2017). Despite the higher prevalence of hazardous drinkers, compared to dependent drinkers (Rathod, Nadkarni, Bhana, & Shidhaye, 2015; Verenkar & Vaz, 2018) in the country, Indian health policy focuses predominantly on the latter, resulting in the former having inadequate access to appropriate help (Mattoo, Singh, & Sarkar, 2015). Hence, the treatment gap for alcohol use disorders (AUD) in India remains extremely high at 86%, the highest amongst all mental and substance use disorders (Gururaj et al., 2016).

~~Despite~~ There is extensive evidence of the cost effectiveness of early identification and Brief Interventions (BIs) for hazardous drinking (Joseph & Basu, 2016; Kaner et al., 2018), but implementation of ~~BIs~~ such interventions in LMICs is rare (Greene, Kane, Khoshnood, Ventevogel, & Tol, 2018). There are several barriers to implementation of BIs, mainly lack of financial and structural resources. Specialized services are limited or non-existent in LMICs (Rathod et al., 2017) and primary care professionals across the world experience barriers such as lack of resources, training, and support, and high workload which limit their potential as delivery agents (Johnson, Jackson, Guillaume, Meier, & Goyder, 2010).

Innovative strategies need to be deployed to overcome supply side barriers such as lack of person-power in low-resource settings. There is growing evidence about the utility of technology-based interventions in LMICs, where technology is providing increasingly new possibilities for delivering a range of interventions for mental health problems (Naslund et al., 2017). In many LMICs, there has been a technological leap with a ‘mobile-first’-based

approach to communications, and people are more likely to have access to a mobile phone than to clean water or a source of electricity (World Bank, 2016). As the market penetration of low-cost mobile devices increases in LMICs such as India, it provides a potentially transformative opportunity for increasing access to BIs. Finally, substantially more culturally sensitive research on BIs needs to be undertaken in LMICs, as not much is known about contextual influences on BIs, such as cross cultural variability, health system idiosyncrasies, or how existing evidence, primarily from HICs, may be generalised to other healthcare settings (Elliott et al., 2016; McCambridge, 2011).

AMBIT (Alcohol use disorders Mobile based Brief Intervention Treatment) aims to increase access to care for hazardous drinkers by developing a BI which is contextually relevant and delivered using a mobile phone interface and subsequently evaluate its impact. The specific objectives of AMBIT are to: a) Use a systematic methodology to develop and refine a BI package informed by global evidence to be delivered using mobile phone technology; b) Examine the feasibility of delivery and acceptability of the BI delivered through mobile technology in a LMIC context; c) Evaluate the preliminary impact of the BI on drinking outcomes; and d) Fine-tune procedures for a definitive Randomised Controlled Trial (RCT) of the BI. This paper describes the processes and outputs of the formative phase of AMBIT aimed at building the BI through a systematic intervention development methodology (Nadkarni, De Silva, & Patel, 2014).

2. Material and methods

2.1 Ethics

AMBIT has been approved by the host institution's Institutional Review Board and the Indian Council for Medical Research. In the formative phase, all participants with hazardous drinking were provided a BI in the form of an information leaflet. All harmful or dependent drinkers who were identified, received the same leaflet and were also provided information about trained counsellors at the host institution.

2.2 Setting

Goa is a small state in Western India with a population of 1.4 million people. Alcohol is easily available and less expensive in Goa as compared to other states in India. Goa has low abstinence rates and high rates of problematic alcohol consumption reflected in a high burden of AUDs in primary care, workplaces, and young people in educational institutions (D'Costa et al., 2007; Silva, Gaunekar, Patel, Kukalekar, & Fernandes, 2003; Verenkar & Vaz, 2018).

2.3 Study design

The intervention development included four sequential phases as follows:

2.3.1 Step 1: Examination of the existing relevant evidence base

Two recent, relevant (i.e. synthesised effectiveness evidence of digital/mobile interventions for hazardous/harmful drinking) and high-quality (decided based on the robustness of methodology followed) systematic reviews were identified (Fowler, Holt, & Joshi, 2016; Kaner et al., 2017), and studies included in the review were extracted if they described mobile-based BIs for drinking problems. Using existing reviews to examine the evidence base is consistent with the UK Medical Research Council's guidance on developing complex interventions (Craig et al., 2008) , and is an especially useful tool in settings which have limited resources to conduct a new review. Using a recent review to extract data ensures that the effect of missing out on most recent evidence is minimised. A data extraction spreadsheet was used to collect relevant intervention details. Data collected from each of the relevant papers included in the reviews were then synthesised using a content analysis approach (DG, FH). In addition, the technological interventions described in the studies, such as websites, mobile applications and other online interventions were reviewed. They were reviewed on two parameters: perceived utility and adaptability of content to an SMS/Interactive Voice Response (IVR) based intervention. Finally, any services or interactive activities on each of the websites (e.g. a goal setting calendar, a risky situation prediction tool) described in the reviews and that

appeared potentially suitable for AMBIT were identified and discussed.

2.3.2 Step 2: In-depth interviews (IDIs) with national experts in addictions research and practice, and intended recipients of the program

The aims of this step were to a) Examine the content and form of BIs that might be perceived as useful and helpful by experts and intended recipients; b) Explore and define treatment expectations and desired outcomes for hazardous drinkers; and c) Use the data from these interviews to define intervention content, delivery and recruitment processes.

IDIs were conducted among national experts in the field of addictions and mental health (psychiatrists, clinical psychologists and social workers) working in five institutions in South India (Karnataka, Pondicherry and Tamil Nadu) and two in North India (New Delhi and Chandigarh). These were premier institutes of medical research and practice, public tertiary care hospitals and NGO-run health centres. Practicing mental health professionals, working specifically in the field of addictions and/or authors of relevant academic publications, were also included. A combination of purposive and snowball sampling strategies were used. First, experienced professionals in India were identified through known academic connections and at the end of their interview, they were asked to recommend and refer others whom they deemed appropriate for participation in this study.

For the IDIs with intended recipients, screening for AUDs was conducted in two colleges (one urban and one rural), one large agro-chemical industry, and one primary care facility. Eligibility criteria included adult ($\geq$18 years) males with an Alcohol Use Disorder Identification Test (AUDIT) (Saunders, Aasland, Babor, de la Fuente, & Grant, 1993) score between 8 to 15 (hazardous drinking), and in possession of a personal mobile phone. Although the overall prevalence of drinking among women in India is low, there is emerging evidence about the increasing prevalence of alcohol use in young women in educational institutions (Verenkar & Vaz, 2018). Hence, females aged 18-25 years in educational institutions, who fulfilled the other criteria described above were also recruited. In recognition of stigma around seeking treatment for problematic alcohol consumption, low participation rates were anticipated in the

educational institutions and workplaces. ~~Hence~~ To overcome this barrier, in those settings, 'Health and Wellness Camps' were conducted where the screening questions about alcohol use were combined with the International Physical Activity Questionnaire (IPAQ) (Booth, 2000), and Perceived Stress Scale (PSS) (Cohen, Kamarck, & Mermelstein, 1983).

After obtaining informed consent via email, the IDIs with experts were conducted over telephone or through video conferencing. Socio-demographic details of the participants, including their highest qualification and years of professional experience were collected. The interviews were conducted in English by trained researchers (SC, DG). The IDIs with intended recipients were conducted face-to-face in a private space at the study sites. The interviews were conducted in English or vernacular language (based on the participants' choice) by trained researchers (DG, SS, SP). All interviews for both set of participants were recorded on a voice recorder and later transcribed and translated into English (if the interview was conducted in the vernacular) for analysis. In both sets of IDIs, we stopped data collection once data saturation was reached.

For both sets of IDIs, the interview questions were informed by findings from the review of global literature and the research objectives of the study. The interview guides aimed at capturing opinions, perspectives and feedback on the development and delivery of a mobile-based treatment for hazardous drinking. The interview guides for the experts explored topics such as perceptions on the content and delivery styles to which the participants were most likely to respond positively, theoretical frameworks the intervention could be built upon, and ethical concerns around using mobile technology for mental health service delivery. The interview guides for the intended recipients sought to collect data about the individual's drinking pattern, their mobile phone usage, their level of comfort with different features of their devices, and their feedback on the content areas and specific features that could possibly be included in the proposed intervention package. For both sets of participants, a few sample BI content areas were presented and they were asked to comment on the perceived importance and usefulness of each of those component areas. After a few IDIs were completed, the

interview guides were iteratively revised to focus on some important areas that were emerging from the responses that had been received.

The IDIs were translated (wherever appropriate) and transcribed. The transcripts were then analysed using a thematic analysis approach to identify emerging content areas. Two independent coders (DG and FH for data from experts; AJ and SC for data from intended recipients) completed analysis using version 11 of the N-Vivo software. The analysis involved generation of codes from raw data, followed by deriving themes by retrieving pieces of data pertaining to codes and examining their meaning in relation to the research questions (preferences related to the content and delivery of the mobile-based intervention, expectations and anticipated outcomes from the mobile-based intervention).

2.3.3 Step 3: Delphi study with international experts

The potential BI content areas arising from steps 1 and 2 were rated for effectiveness and generalisability using pre-defined criteria as follows:

EFFECTIVENESS (Data from systematic review)		**GENERALISABILITY**			
STRENGTH	**SCORE**	**CONTEXT (Data from systematic review)**	**SCORE**	**ENDORSED BY (Data from IDIs)**	**SCORE**
>1 RCT	++	Hazardous drinking	1	Experts	1
1 RCT	+	LMIC	2	Educational institutions	1
Other Designs	-	Adults	1	Workplaces	1
				Primary Care	1

Each content area was scored on strength of effectiveness based on one of the three categories in which it fit. Areas were then scored for generalisability to each of the three domains within ‘context’, and the four related to by whom it was ‘endorsed’. The score for

LMIC was weighted higher than the other domains as that was the most important generalisability criterion for our purposes. A hypothetical example of how the scoring would be done is as follows. If a particular content had been shown to be effective in one RCT, had been tested in hazardous drinkers in Brazil, and was endorsed by experts and participants in educational institutions, its score would be '+' on 'strength' and 5 on 'generalisability. Potential content areas that met one of the following criteria were shortlisted for the Delphi survey: 1) ++ effectiveness score, irrespective of the generalisability score, 2) + effectiveness score and generalisability score of ≥2, 3) generalisability score of ≥4 irrespective of the total effectiveness score. In the hypothetical example above the content area would be shortlisted for the Delphi survey as it would fulfil criterion number 2 above.

The selected potential content areas were formally named and defined. Content areas with definitional overlap were collapsed (e.g. 'resource information' and 'health resources' were collapsed into health seeking information/resources). A total of 33 content areas were identified and of these, 31 met the criteria for inclusion in the Delphi. 'Test for compliance' and 'attractive caption' did not meet the criteria because they each had a generalisability score of <2. After collapsing overlapping content, 26 content areas were included in the Delphi.

Potential participants were identified either through personal knowledge of at least one of the Investigator team, whereupon they were sent an invitation email directly, or due to their membership of an international group of BI practitioners and researchers, where an invitation was sent to the entire mailing list of that group. These included individuals with expertise in research and/or delivery of BI or other psychological interventions for alcohol problems, addictions research, or more specifically mHealth interventions, including text-messaging interventions. Individuals who chose to participate were asked to provide consent through an online survey interface.

Each content area was presented in the Delphi survey and participants were asked to rate

each area for the extent to which they felt the content area should be included in a mobile based BI for hazardous drinkers using a five-point Likert scale (1 – Strongly disagree to 5 - Strongly agree). Participants were also given the option to provide qualitative feedback about each of the content areas in addition to their rating in Round 1. Round 2 included group response data from the preceding round in the form of a histogram, mean rating, and the standard deviation. Respondents were asked to re-rate each content area given the new information about the group's responses. Participants re-rating a content area more than 1.0 rating point from the previous round's mean were asked to provide qualitative support for their rating.

While consensus is a common standalone criterion for Delphi analyses, some commentators also recommend using a second criterion, stability (Giannarou & Zervas, 2014; Scheibe, Skutsch, & Schofer, 2002). However, logistical reasons meant that we decided to simply focus on consensus. Quantitative analysis was performed using Stata IC 15.

2.3.4 Step 4: Synthesis of findings to inform content development for the first version of the intervention

After the final intervention content areas were identified, a content development workshop was conducted, which included representatives from our technology partner, our researchers, and members of the local community (e.g. college students, parents, teachers recruited through social media). The goals of this workshop were to solicit community and technology partner feedback on the content areas and to develop preliminary intervention message content. It included facilitated activities with the community members focused on learning what types of messages were most likely to be effective among our target audience. Activities included brainstorming sessions on generating different types of content formats (e.g. narrative stories, gamified content) and activities such as script writing of sample messages.

Using the feedback and information obtained from this workshop, a second content development workshop was conducted to develop the design/framework of the intervention. The AMBIT project team, as well as other staff from the host institution with clinical psychology backgrounds, worked in two independent groups to brainstorm on the structure of the intervention, developed potential frameworks, and then presented their design to the larger group. In addition to developing a framework, each group was given the opportunity to add and/or eliminate content areas from the final intervention if they were able to provide reasonable justification.

3. Results

3.1 Step 1: Examination of the existing evidence

72 journal articles were sourced from two selected systematic reviews- Fowler et al. (2016) and Kaner et al. (2017) (Fowler et al., 2016; Kaner et al., 2017). These studies were conducted in 15 countries including USA (n=41), Netherlands (n=6), Sweden (n=5), and Australia (n=3). The participants in these studies mostly included school and university students. Most studies described findings from RCTs (n=70). Details of the studies that were included in our analysis are provided in Appendix 1. The key emergent themes from the studies included those related to the content and delivery of the BI messages and are summarised as follows.

A couple of examples of content types were ‘health information’ and ‘goal setting’. Health information included facts and statistics about health related to drinking behaviour, which could be personalised based on inputs or responses from the participant. Certain messages had content that compelled the participants to engage in self-reflection by encouraging them to observe, assess and analyse their drinking behaviour in the context of their life and interests, and accordingly set goals to change their drinking behaviour. The goal-setting messages supported participants in setting and modifying goals related to abstinence or moderation, including messages that challenged them to incrementally decrease their drinking. Other types of content included motivational messages that helped participants cope

with the stress of making a behaviour change, and gave them advice based on their reported behaviour. Participants in some studies also received messages about managing risky situations where they would be tempted to drink more than they intended. Techniques that focused on the delivery of the BI included customization of the message by giving recipients options about a) length and number of messages over a period of time, b) language of message delivery, c) frequency and timings during the day to receive the messages, and d) choice of termination.

Across the two reviews, 24 technological interventions were described and these included six mobile applications and 18 websites. We conducted a web search for the mobile applications and were able to locate five. Three of them were paid and/or inaccessible, one was only a risk assessment app, and one was only a Cost Benefit Analysis app. Since the mobile applications were either inaccessible or not relevant to AMBIT's goals, we examined the websites for their content and features. Most of the websites were risk assessment portals that did not provide enough in-depth engagement about alcohol consumption. Of the three websites that appeared to be promising, we excluded one as it was inaccessible without a Norwegian phone number. We reviewed the remaining two viz, Downyourdrink and Vetchange (Brief et al., 2013; Wallace et al., 2011). Vetchange, a web-based intervention for US veterans with problem drinking and PTSD symptoms, had a balance of self-driven and directive content, allowed high level of personalization, and enabled help-seeking by providing links to services/options for referral. Downyourdrink, a web-based screening and BI for anyone concerned about their drinking, was based on the Stages of Change model (DiClemente, Schlundt, & Gemmell, 2004), and provided an intervention after categorizing participants based on their stage of motivation.

3.2 Step 2: In-depth interviews (IDIs)

We interviewed 11 experts (four females). The mean age of the participants was 44.8 (SD=10.1) years and average years of work experience was 17 (SD=9.6) years. Two were psychologists, one was a psychiatric social worker and eight were psychiatrists; eight had an MD and three had a PhD. Details of the experts are provided in Appendix 2. We interviewed

22 intended recipients: five males in primary care, six males in the workplace, and 11 participants (five females) in the educational institutions. Mean age of the participants was 30.7 (SD=13.3) years and the mean AUDIT score ranged between 9.17 (SD=1.17) to 9.8 (SD=1.92) for the three sites. Both sets of participants were asked about the development and delivery of the BI messages.

Key themes from the expert interviews included those on

a) Content of the messages: factual information about different alcoholic beverages, biological effects of drinking, guidelines on safe drinking limits, and contact details of local health services such as de-addiction centres.

b) Skills based support: tips on prevention, risk reduction and coping methods; setting and maintaining goals; and adherence.

c) Engaging social support system: involving the participant's family, friends or peers in supporting adherence to the treatment.

d) Enhancing the participant's experience in the treatment though messages that increased their trust and engagement with the treatment.

e) Personalised content delivered in an interactive format.

f) Customising delivery of the intervention: messages to be sent 2-3 times a week, with the language and tone modified to match the context of the participant; and for IVR, the voice could be a friendly voice that conveys respect and warmth and is not judgmental.

Key themes that emerged from the interviews with the intended beneficiaries included the following:

a) Content focused on changing the participant's behaviour: building self-awareness by assessing personal alcohol use habits, acknowledging problem drinking, and increasing self-motivation to change.

b) Information about reducing current alcohol intake rather than encouraging abstinence.

c) Tips on safe drinking, anticipating common situations involving alcohol consumption and

overcoming cravings for alcohol.

d) Messages that helped in setting goals for reducing alcohol consumption and that recommended alternatives to drinking e.g. exercising or spending time with family

e) Informational messages: negative health effects of alcohol consumption, information about local health facilities that can provide personalised care for alcohol-related injuries and alcohol use disorders.

f) Both SMS and IVR were perceived to be acceptable platforms for delivery of the intervention messages, although it was suggested that different media such as videos or photos be shared through web links. The intervention messages could be shared on a weekly basis in the evenings on weekends, post 8 PM. For the IVR calls, the responses regarding the voice of the speaker delivering the content varied, with no consensus emerging on whether the voice should be male or female, or young, middle-aged or old. Further, the message giver could be a doctor, family member, friend or celebrity. Shorter messages (less than 5 sentences) and shorter calls (less than 5 minutes) were preferred.

3.3 Step 3: Delphi survey

We received 34 responses in Round 1 of the survey. Two responses were incomplete and subsequently eliminated. In Round 2 we received 30 responses. The data from 30 participants with complete responses from both Delphi rounds, were used for analysis. A majority (63.3%) of the participants were male, with a mean age of 46.5 (SD=12.1) years. The mean experience of the group was 18.3 (SD=9.9) years and half of them had a PhD.

Appendix 3 shows the outcome of the rating of the content areas on effectiveness and generalisability. At the conclusion of Round 1, out of 26 content areas, 18 reached consensus and at the end of Round 2, 22 reached our consensus criteria (Appendix 4). While qualitative data was obtained in each round, analysis did not elicit any emergent themes.

Although Delphi studies typically conclude after consensus is met for each content area, we concluded our Delphi after two rounds for logistical reasons, particularly time constraints. The 22 content areas which were selected for inclusion into the intervention and further developed through two content development workshops are listed in Box 1.

Box 1. Content areas achieving consensus in Round 2 of the Delphi survey

1. Targeted recommendations
2. Assessment
3. Personalised feedback and information
4. Goal-setting messages
5. Personalisation
6. Goal management
7. Personalised content
8. Coping
9. Standardised content
10. Situational content
11. Self-reflection messages
12. Motivation
13. Self-awareness
14. Maintenance
15. Risk management
16. Craving management
17. Drinking management
18. Safe drinking
19. Interactive approach
20. Alcohol reduction
21. Help-seeking options/resources
22. Drinking alternatives

3.4 Step 4: Content development workshops

After reviewing the content areas, six were excluded by the participants in the content development workshops (Table 1).

Table 1: Content areas excluded in the content development workshops

Content area	**Justification for exclusion**
Assessment	Assessment can be done during intake. Doing so will simplify the intervention and will allow participant information that can be used to guide which content they receive to be entered into the technology partner's database from the beginning of the intervention.
Human interaction	Human interaction is likely not feasible with the desired sample sizes for the case series and RCT and will be even less feasible when scaling up.
Personalised content	This content area was poorly defined (supported by qualitative comments obtained in both rounds of the Delphi) and has strong overlap with other content areas.
Coping	There is a strong overlap with other content areas e.g. drinking alternatives
Maintenance	Not necessary for hazardous drinkers. Also, as brief interventions are focused on increasing knowledge about risky behaviour, any knowledge obtained from the intervention is likely to be retained and does not need to be re-taught
Targeted recommendations	As defined, this content area nearly defines the intervention itself.

Upon completion of the content development workshops, the frameworks developed by each group were reviewed by a member of the research team and comparisons were drawn. Similarities among the proposed frameworks were identified and a final intervention framework was designed that incorporated major components from both frameworks. Figure 1 is the

graphical representation of the final merged framework of the intervention. Further elaboration on the content of the various components in the framework is provided in Table 2. Seven themes guide the content of the weekly messages over the eight week intervention period: Safe drinking/health education, alcohol reduction, drinking and risk management, drinking alternatives, situational content, urge management, and maintenance and relapse prevention. Except for the last theme which guides the last two weeks, the rest guide the messages for one week each. The messages will be a mix of push and pull messages. Everyone will receive the push messages (e.g. 'self-awareness') while only some will receive the pull messages based on the information they provide (e.g. 'actionable feedback' for urge management).

Table 2: Description of components in the final intervention framework

Intervention component	**Description**
Safe drinking	Specific safe drinking tips. e.g. pacing drinking or eating before drinking
Self-awareness	Recommendations to assess their personal alcohol use habits, acknowledge problem drinking, and increase self-motivation to change
Alcohol reduction	Content encouraging drinkers to reduce alcohol intake
Goal-setting	Prompts to identify and modify their progression towards goals for making changes to drinking behaviour
Situational content	Relatable narrative information outlining common situations involving alcohol consumption and how to respond in a healthy manner
Self-reflection	Questions that help them observe, assess, and analyse drinking behaviour in the context of their life and interests, in order to decide their next steps

Drinking management	Content that focuses on prevention, risk reduction, and coping methods within the context of hazardous drinking
Risk management	Content to guide users in planning how to avoid and strategise for specific risky drinking situations that may prevent them from reaching their drinking goals
Motivation	Content that incentivises, cheers, and encourages to continue with healthy behaviour adoption and maintenance
Drinking alternatives	Information recommending alternatives to drinking that can help to reduce their desire to consume alcohol. e.g. exercise, spending time with family, or working
Review	Series of questions that seek to assess the user's drinking behaviour in previous week
Information about other resources for help	Information about supportive health resources available
Urge management	Information regarding skills to overcome drinking urges
Actionable feedback	Concrete and useful tips/information that influence future health behaviour
Maintenance and relapse prevention	Assignments to help them practise and maintain their goals for healthier drinking behaviours over the long term
Goal management	Content that helps setting and maintaining goals and provides rewards for goal achievement
Check- in messages	Short check -in messages to ensure participant is moving towards the desired drinking goal

Figure 1: Merged Intervention Framework

Engagement and personalization strategies

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Weekly theme	**Safe drinking, Health education**	**Alcohol reduction (Health education)**	**Drinking and Risk Management**	**Drinking alternatives (Health education)**	**Situational content**	**Urge management (Health education)**	**Maintenance and Relapse prevention**	**Maintenance and Relapse prevention**
Content of messages	Self-awareness (including tips)	Goal setting	Motivational	Review of drinking	Self-reflection	Motivational	Self-reflection	Review of drinking in previous week
		Self-reflection (including facts)		Self-awareness	Information about other resources for help	Actionable feedback (including tips)	Information about other resources for help	Actionable feedback
								Motivational messages on relapse prevention
	Check-in (on goal management) every alternate week							

4. Discussion

Our paper describes the process of development of a mobile phone delivered brief intervention (BI) for hazardous drinking delivered using text messaging or IVR in India. We have also used this process to describe a systematic methodology for the development of a technology-enabled intervention in settings with a great shortage of healthcare human resources, limited 'tech literacy', high treatment gap for alcohol use disorders, and reliance on biological models of care for any sub-type of AUDs: all in contrast to high income country settings. The intervention we have developed at the end of this process is designed to overcome the first two barriers and in doing so, attempt to increase access to care for hazardous drinking through a contextually appropriate non-biological intervention.

The intervention development process is heavily influenced by a peer reviewed framework that we developed for use for the development of contextually appropriate psychosocial interventions to be used in low-resource settings (Nadkarni et al., 2014; Nadkarni et al., 2015). The process started with mapping the existing global evidence base for effectiveness of technology-enabled BIs for AUDs. This was supplemented with contextual knowledge gleaned through examining the explanatory models and coping strategies used by individuals with hazardous drinking, and treatment strategies used by national experts working with such individuals. These steps allowed us to identify potential component strategies for our BI, which were reviewed and filtered in consultation with a group of international experts for inclusion in our draft intervention. Finally, through a participatory process we assembled these components into a draft intervention to be further tested for acceptability and feasibility in our settings.

The active components of the intervention would be building awareness through information, enhancing self-awareness through reflection on one's drinking in relation to the information received and subsequently setting drinking goals, actionable feedback through evidence-based

strategies for reducing problematic drinking behaviour, enhancing motivation, goal monitoring through regular check ins, and skills to maintain change and prevent relapse. Figure 2 illustrates the various components of our intervention and the potential mechanisms through which they could lead to the eventual treatment goals.

The information and awareness provided is postulated to increase self-awareness about the drinking directly or through increased reflection. The increased self-awareness, by itself or in combination with increased reflection and enhanced motivation, will lead to the consolidation of a drinking goal. Once that happens, the skills learnt through actionable feedback, enhanced motivation, and monitoring of the goal will help achieve change in drinking behavior. A constant monitoring of the goal will also help to sustain motivation, and along with relapse prevention skills help to maintain the change that has been achieved.

This intervention development experience demonstrates that despite a very clear focus on intervention components which are contextually informed, most content in the final intervention package has several commonalities with BIs developed and tested in HIC countries. ~~Despite that~~ Following a systematic process of intervention development enhances our confidence in the likelihood of our intervention being feasible to deliver using text messaging and acceptable to the target population. Additionally, since our approach grounded in both global and contextual evidence ultimately led to an intervention consistent with the widely used and evidence-based BIs, it indicates the universal applicability of BIs and also strengthens our confidence in how they can be generalised across cultural contexts. Our findings are consistent with the experiences of other investigators who have adapted psychological treatments for use in culturally diverse settings (Chowdhary et al., 2014). A systematic evaluation of these paradigms of contextual relevance of our intervention was subsequently done through a mixed-methods uncontrolled treatment cohort, followed by a pilot RCT.

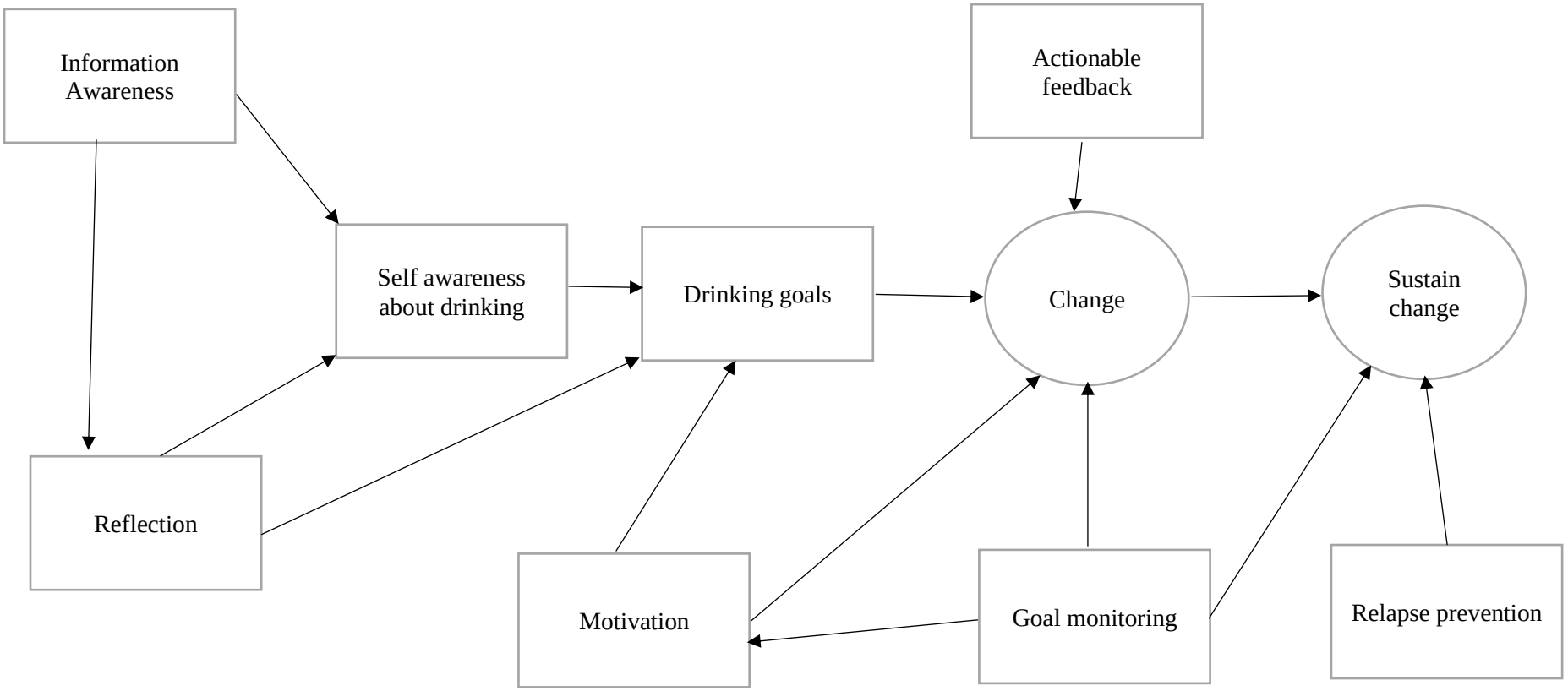
We would like to examine some limitations of our intervention development process. The evidence examined in the reviews in Step 1 was published in English language journals and might exclude contextually relevant literature in other languages. However, this may not be a significant limitation as most peer-reviewed public health and social sciences publications from South Asia are in English. A criticism of contextually developed interventions is that their utility is overstated as it assumes that cultural groups are a homogenous entity, when in fact in a large country like India there is extensive heterogeneity subsumed within a single culture. However, the advantage of a technology enabled intervention like ours is that its content and decision rules can be easily tailored depending on the needs of particular cultural subgroups. Finally, one could argue that such a lengthy process of intervention development is a major limitation in an environment where research funding for mental health is limited, and that time and resources should rather be spent on the evaluation of the intervention. Conversely, one could also argue that a rigorous treatment development process ensures that scarce resources are not wasted on evaluating interventions that might not work for lack of adequate formative work. A rigorous treatment development process leads to an intervention that is better designed, easier to evaluate, more likely to be effective, and worth implementing. Finally, while acknowledging the strengths of m-health in overcoming access barriers, we also need to be mindful of its limitations in LMICs, such as the reach and quality of mobile telecommunication network infrastructure, low-literacy levels and consequent variability in patients' ability to comprehend message content, and concerns around privacy and data security.

Over the years, several models have been proposed to guide the development of contextually suitable interventions and despite being developed independently they appear to have several convergence points (Kumpfer et al., 2008; Wingood and DiClemente, 2008), and none of these have clear advantages over the others. One defining feature of these models is that they integrate existing theory and procedures ("top-down" elements), with input from contextually relevant

stakeholder groups (“bottom-up” elements) to arrive at a version that can then be rigorously evaluated. Our evidence-based model developed and tested in the context (Vellakal and Patel, 2015) broadly defines sequential stages consisting of (a) information gathering, (b) preliminary adaptation design, (c) preliminary adaptation tests, and (d) adaptation refinement, the first two stages of which have been described in this paper. Finally, this intervention development approach is flexible and if there are significant resource and time constraints, the steps can be limited to workshops with international and local experts in the first phase, and case series with specialists, and case series and pilot trial with counsellors in the second phase (Vellakal and Patel, 2015).

If our intervention is found to be acceptable to the target population and feasible to be delivered through text messaging, the next step will be a cost effectiveness evaluation through a definitive RCT. If found to be cost effective, such an intervention delivered using a basic technological innovation would greatly help to reduce the treatment gap for hazardous drinking in India and similar settings where there is a shortage of human resources in the healthcare system but high, and constantly increasing, mobile tele-density.

Figure 2: Proposed mechanism of change



References

Booth, M. (2000). Assessment of physical activity: an international perspective. *Res Q Exerc Sport,* 71(sup2), 114-120.

Brief, D. J., Rubin, A., Keane, T. M., Enggasser, J. L., Roy, M., Helmuth, E., Hermos, J., Lachowicz, M., Rybin, D., Rosenbloom, D. (2013). Web intervention for OEF/OIF veterans with problem drinking and PTSD symptoms: A randomized clinical trial. *J Consult Clin Psychol,* 81(5), 890-900.

Chowdhary, N., Jotheeswaran, A., Nadkarni, A., Hollon, S., King, M., Jordans, M., et al. (2014). The methods and outcomes of cultural adaptations of psychological treatments for depressive disorders: a systematic review. *J Psychological Medicine*, 44(6),1131-46.

Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. *J Health Soc Behav*, 24(4), 385-396.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*, 337, a1655.

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.

DiClemente, C. C., Schlundt, D., & Gemmell, L. (2004). Readiness and stages of change in addiction treatment. *Am J Addict,* 13(2), 103-119.

Elliott, J. C., Delker, E., Wall, M. M., Feng, T., Aharonovich, E., Tracy, M., Galea, S., Ahern, J., Sarvet, A. L., Hasin, D. S. (2016). Neighborhood-Level Drinking Norms and Alcohol Intervention Outcomes in HIV Patients Who Are Heavy Drinkers. *Alcohol Clin Exp Res,* 40(10), 2240-2246.

Fowler, L. A., Holt, S. L., & Joshi, D. (2016). Mobile technology-based interventions for adult users of alcohol: a systematic review of the literature. *Addict Behav,* 62, 25-34.

Giannarou, L., & Zervas, E. (2014). Using Delphi technique to build consensus in practice.

International Journal of Business Science & Applied Management, 9(2), 65-82.

Greene, M. C., Kane, J. C., Khoshnood, K., Ventevogel, P., & Tol, W. A. (2018). Challenges and opportunities for implementation of substance misuse interventions in conflict-affected populations. *Harm Reduct J,* 15(1), 58.

Gururaj, G., Varghese, M., Benegal, V., Rao, G., Pathak, K., Singh, L., et al. (2016). National Mental Health Survey of India, 2015-16: Summary. *Bengaluru, National Institute of Mental Health and Neuro Sciences, NIMHANS Publication*(128).

Johnson, M., Jackson, R., Guillaume, L., Meier, P., & Goyder, E. (2010). Barriers and facilitators to implementing screening and brief intervention for alcohol misuse: a systematic review of qualitative evidence. *J Public Health,* 33(3), 412-421.

Joseph, J., & Basu, D. (2016). Efficacy of brief interventions in reducing hazardous or harmful alcohol use in middle-income countries: systematic review of randomized controlled trials. *Alcohol Alcohol,* 52(1), 56-64.

Kaner, E. F., Beyer, F. R., Garnett, C., Crane, D., Brown, J., Muirhead, C., et al (2017). Personalised digital interventions for reducing hazardous and harmful alcohol consumption in community-dwelling populations. *Cochrane Database Syst Rev*, 9(9), CD011479.

Kaner, E. F., Beyer, F. R., Muirhead, C., Campbell, F., Pienaar, E. D., Bertholet, N., et al (2018). Effectiveness of brief alcohol interventions in primary care populations. *Cochrane Database Syst Rev,* 2(2), CD004148.

Kumpfer, K.L., Pinyuchon, M., de Melo, A.T., Whiteside, H.O. (2008). Cultural adaptation process for international dissemination of the strengthening families program. *Evaluation & Health Professions*, 31(2), 226-39.

Manthey, J., Shield, K. D., Rylett, M., Hasan, O. S., Probst, C., & Rehm, J. (2019). Global alcohol exposure between 1990 and 2017 and forecasts until 2030: a modelling study. *Lancet, 393(10190):2493-2502*.

Mattoo, S., Singh, S., & Sarkar, S. (2015). *De-addiction services in India*. In *Developments in Psychiatry in India* (pp. 405-416): Springer

McCambridge, J. (2011). Fifty years of brief intervention effectiveness trials for heavy drinkers. *Drug Alcohol Rev,* 30(6):567-8.

Moodie, R., Stuckler, D., Monteiro, C., Sheron, N., Neal, B., Thamarangsi, T., et al. (2013). Profits and pandemics: prevention of harmful effects of tobacco, alcohol, and ultra-processed food and drink industries. *Lancet,* 381(9867), 670-679.

Nadkarni, A., De Silva, M. J., & Patel, V. (2014). *Developing mental health interventions*. In Thornicroft, G. & Patel, V. (Eds.), *Global Mental Health Trials* (pp. 36-54). Oxford: Oxford University Press

Nadkarni, A., Velleman, R., Dabholkar, H., Shinde, S., Bhat, B., McCambridge, J., et al. (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.

Naslund, J. A., Aschbrenner, K. A., Araya, R., Marsch, L. A., Unützer, J., Patel, V., & Bartels, S. (2017). Digital technology for treating and preventing mental disorders in low-income and middle-income countries: a narrative review of the literature. *Lancet Psychiatry,* 4(6), 486-500.

Rabiee, R., Agardh, E., Coates, M. M., Allebeck, P., & Danielsson, A. K. (2017). Alcohol–attributed disease burden and alcohol policies in the BRICS–countries during the years 1990–2013. *J Glob Health,* 7(1), 010404.

Rathod, S., Pinninti, N., Irfan, M., Gorczynski, P., Rathod, P., Gega, L., & Naeem, F. (2017). Mental health service provision in low-and middle-income countries. *Health Serv Insights,* 10, 1178632917694350.

Rathod, S. D., Nadkarni, A., Bhana, A., & Shidhaye, R. (2015). Epidemiological features of alcohol use in rural India: a population-based cross-sectional study. *BMJ Open,* 5(12), e009802.

Saunders, J. B., Aasland, O. G., Babor, T. F., de la Fuente, J. R., & Grant, M. (1993). Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO Collaborative Project on Early Detection of Persons with Harmful Alcohol Consumption--II. *Addiction,* 88(6), 791-804.

Scheibe, M., Skutsch, M., & Schofer, J. (2002). *Experiments in Delphi methodology*. In Linstone, H.A., & Turoff, M. (Eds.), *The Delphi method: Techniques and applications* (pp. 257-281). Reading, Mass: Addison-Wesley Pub. Co

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.

Vellakkal, S., Patel. V. (2015) Designing psychological treatments for scalability: the PREMIUM approach. *PLoS One*, 10(7), e0134189.

Verenkar, Y. J., & Vaz, F. S. (2018). Prevalence and pattern of alcohol consumption using alcohol use disorder identification test among students at a medicalcollege in Goa, India. *Int J Community Med Public Health,* 5(7), 2935-2938.

Wallace, P., Murray, E., McCambridge, J., Khadjesari, Z., White, I. R., Thompson, S. G., et al. (2011). On-line randomized controlled trial of an internet based psychologically enhanced intervention for people with hazardous alcohol consumption. *PLoS One,* 6(3), e14740.

Wingood, G.M., DiClemente, R.J (2008). The ADAPT-ITT model: a novel method of adapting evidence-based HIV Interventions. *Journal of Acquired Immune Deficiency Syndromes*, 47, S40-S6.

World Bank. (2016). “World Development Report 2016: Digital Dividends.” Overview booklet. Washington, DC: World Bank.

Acknowledgements

The following institutions supported us through allowing access to their students, employees or patients: Smt. Parvatibai Chowgule College, Margao; Govt. College Quepem; Rosary College, Navelim; IHM, Porvorim; Zuari Agro, Pvt. Ltd; Longuinhos Beach Resort, Colva; and MPT Hospital, Vasco. Members of the INEBRIA network who participated in the Delphi surveys. Staff from Sangath who contributed to the interevention development workshops. Community members who participated in the various steps of the intervention development. AMBIT is funded by a grant from the Medical Research Council, UK (Grant number: MR/P020348/1)

Declarations of interest: None