Culturally Adapting and Piloting Brief Interventions for Alcohol Harm Reduction in Sri Lankan Health Care Settings

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A thesis submitted for the degree of Doctor of Philosophy of
The Australian National University

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Declaration

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university. To the best of the author's knowledge, it contains no material previously published or written by another person, except where due reference is made in the text.

The research reported in this thesis is my own original work, conducted under the guidance of my supervisory panel. I led the development of all study protocols, conducted the literature searches and updated them periodically throughout the candidature, and trained and supervised the field staff. I conducted all data analyses and wrote all chapters of this thesis. My supervisory panel provided feedback on analysis and draft chapters over multiple cycles of revision.

Several figures in this thesis were created using Claude (Anthropic, 2025-2026). It was an iterative process; the author provided instructions, and in some instances, hand-drawn sketches as references. Multiple versions were generated and refined. Some refinements/ corrections were done by the author manually, to ensure accuracy and better readability, before creating the version in the thesis. Claude was also used to assist with editing text for clarity, grammar, and structure. The author reviewed all outputs and takes full responsibility for the final content of the thesis.

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Abstract

In 2019, alcohol accounted for 4.7% of global deaths according to the WHO, and more recent Global Burden of Disease estimates rank alcohol as the 11th leading risk factor for disease burden in 2023, with people in low-income countries experiencing disproportionately higher harm per litre consumed. Sri Lanka exemplifies this burden: approximately 20,000 alcohol-attributable deaths annually, and 41% of male drinkers engaging in heavy episodic drinking—yet no systematic screening or intervention programme exists. Brief interventions (BIs) are effective in high-income settings, but evidence from lower-middle-income countries remains limited. There are several BI trials which have used different intensities in the same setting. Further, conventional BI research has neglected two Transtheoretical Model (TTM) constructs critical in behaviour change—processes of change and context of change—and outcome measurement has focused narrowly on consumption, overlooking broader harms to drinkers and the burden borne by family members.

This thesis aimed to: (1) culturally adapt WHO's alcohol BI—adapted brief intervention (ABI)—using Resnicow's framework operationalising TTM processes and context of change; (2) develop three hierarchically nested BI intensities deliverable by trained non-specialists; (3) test their feasibility and acceptability; (4) to assess different AUDIT-C cut-offs and how they capture risky drinking (defined as drinking at levels or in patterns that increase the risk of alcohol-related harms)—to determine an empirical AUDIT-C cut-off; (5) determine risky drinking prevalence and alcohol knowledge among primary care attendees; and (6) incorporate family member-reported outcome measures—a methodological innovation in BI research.

An iterative programme comprising three sequential studies was conducted, each informing the next. First, WHO's alcohol BI was culturally adapted, and an inpatient three-arm pilot (n=48) tested feasibility and acceptability of the ABI—a culturally sensitive, patient-centred discussion taking 15–30 minutes. The two less intensive arms—Feedback on AUDIT-C (FOA, ~3 minutes) and Unit of Alcohol education (UOA, ~5

minutes)—both involving one-way information provision—emerged as potential less intensive BIs. However, health-related abstinence limited the utility of the inpatient setting for determining effectiveness, prompting a shift to the outpatient department (OPD)—a state-run primary health care service.

Second, a cross-sectional study (n=3,700) at Teaching Hospital Peradeniya's OPD was conducted to determine risky drinking prevalence, to determine an empirical AUDIT-C cut-off to detect risky drinking, and to assess knowledge of unit of alcohol, low-risk drinking, and alcohol-related harms. Of male OPD attendees, 39.3% were risky drinkers (AUDIT-C ≥4), with 84% engaging in heavy episodic drinking. Knowledge deficits were profound: only 0.9% understood low-risk drinking, 3.4% knew what a unit of alcohol was, and fewer than 5% recognised increased accident risks with alcohol. AUDIT-C ≥4 captured 23.3% more heavy episodic drinkers (a drinking pattern associated with high risk) compared to AUDIT-C ≥5.

Third, a three-arm pilot RCT at the OPD (n=150 patients, n=79 family members) tested feasibility and acceptability of all three BI, and ability of outcome measures to detect change, including family member-reported burden. Each intervention was nested within the more intensive one, and all were delivered by trained non-specialist research assistants. High acceptability was demonstrated across all three BI intensities. Research assistants with no health sector experience successfully delivered interventions. Six-month retention was exceptional: 88.7% for patients and 93.7% for family members. All outcome measures showed trends toward improvement.

This thesis provides the first evidence on risky drinking prevalence, knowledge gaps, empirical AUDIT-C cut-off to be used in Sri Lankan primary care, and BI feasibility in Sri Lanka. High risky drinking prevalence (39.3%) combined with very low understanding of low-risk drinking (0.9%) identifies knowledge as a critical intervention target. The three BI intensities, grounded in TTM processes and context of change, proved feasible and acceptable when delivered by non-specialists—demonstrating task-shifting potential for resource-constrained settings. Outcome measures captured both broader harms to drinkers and family burden—dimensions that consumption-focused research overlooks.

This work provides the foundation for future research to address Sri Lanka's substantial alcohol-related burden.

List of Abbreviations

ABI – Adapted Brief Intervention
ACE-IQ – Adverse Childhood Experiences – International Questionnaire
AKQ – Alcohol Knowledge Questionnaire
APQ – Alcohol Problems Questionnaire
AUD – Alcohol Use Disorders
AUDIT – Alcohol Use Disorders Identification Test
AUDIT-C – Alcohol Use Disorders Identification Test – Consumption
BI – Brief Intervention
CONSORT – Consolidated Standards of Reporting Trials
FM – Family Member
FMQ – Family Member Questionnaire
FOA – Feedback on AUDIT-C
FRAMES – Feedback, Responsibility, Advice, Menu, Empathy, Self-efficacy
GDP – Gross Domestic ProductHED – Heavy Episodic Drinking
LKR – Sri Lankan Rupee
LMICs – Low- and Middle-Income Countries
LRD – Low-Risk Drinking
MI – Motivational Interviewing
NATA – National Authority on Tobacco and Alcohol
OARS – Open-ended questions, Affirmations, Reflective Listening, Summary
OPD – Outpatient Department
PI – Principal Investigator
PIS – Patient Information Sheet
PMCU – Primary Medical Care Units
RA – Research Assistant
RCT – Randomised Controlled Trial
RD – Risky Drinking
SAFER – Strengthen, Advance, Facilitate, Enforce, Raise
SEAR – South-East Asian Region
SLCTR – Sri Lanka Clinical Trials Registry
STROBE – Strengthening the Reporting of Observational Studies in Epidemiology
TLFB – Timeline Follow Back
TTM – Transtheoretical Model
UOA – Unit of Alcohol
WHO – World Health Organization

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Chapter 1: Introduction

1.1 Chapter Overview

Alcohol is the most harmful psychoactive substance when harms to the user and to others are taken together (1). Yet, treatment systems worldwide remain grossly underdeveloped relative to burden. Sri Lanka exemplifies this gap. An estimated 2.5 million people use alcohol, at an economic cost exceeding (Sri Lankan Rupees) LKR 335 billion annually (2.18% of Gross Domestic Product-GDP) and an estimated 20,000 alcohol-attributable deaths each year (2). Yet the country lacks a systematic alcohol-harm reduction strategy, and its non-communicable disease prevention programmes advocate only for abstinence (3)—a paternalistic approach—where the client is not given a choice but the health care worker directs the patient (4, 5) often with fear provoking messages (6)—shown to produce defensive responses rather than behaviour change when not accompanied by information that enhances the individual's ability to act (5). This thesis tests whether brief interventions (BIs)—culturally adapted using Resnicow's framework (Discussed in Chapter 4), informed by the Transtheoretical Model (Discussed in Chapter 2), and delivered by non-healthcare workers—are feasible and acceptable in a Sri Lankan health care setting. The research incorporates family member-reported outcomes alongside other measures of harm, an approach that captures the broader social costs that conventional consumption-focused outcome measures do not. This introductory chapter establishes the global and local context of alcohol-related harms, the evidence base for BIs, and the rationale for the research undertaken in this thesis.

The chapter is organised in three parts. Part I establishes the scale of alcohol-related harm globally and in Sri Lanka, including the health, social, and economic costs, and the structural challenges that perpetuate a mismatch between burden and response. Part II introduces harm reduction approaches and presents the evidence for BIs as a feasible response in resource-constrained settings. Part III operationalises the target population, adaptation of WHO's BI, describes the research evolution from inpatient to outpatient settings, and presents the aim, objectives, and the conceptual framework that synthesises the preceding arguments. Table 1.1 summarises this structure.

Table 1-1 Overview of Chapter 1: Problem, opportunity, and thesis response

THE PROBLEM (PART I)	THE OPPORTUNITY (PART II)	THIS PhD (PART III)
Global - No binding international framework - Stigma deters treatment seeking - Stigma/ anxiety of interventionists - Harm to others unmeasured (A neglected, but critical dimension) **LMICs** - Alcohol-harm paradox - Illicit liquor market - High proportion of unrecorded alcohol - Escapes regulation and taxation -Treatment Infrastructure - Limited specialist and health workforce **Local** - Policy implementation gaps - 2016 National Policy poorly implemented - New liquor licenses issued despite policy goals - No scalable intervention for at-risk drinkers	**Healthcare Infrastructure** - 55 million OPD visits/year - 700+ Healthy Lifestyle Centres - Population engaged with preventive care **Population Characteristics** - 92.7% adult literacy rate - Healthcare encounters as teachable moments **Evidence Base** - Brief interventions effective internationally - WHO framework available - Knowledge improvement reduces drinking - Task-shifting potential - Non-specialists can deliver brief interventions	**Harm reduction** - Focused on reduced consumption as opposed to total abstinence and reduced alcohol-related harms to the individual; and reduction of family burden **Adapted Brief Intervention** - Culturally adapted (Using Resnicow's principles) • TTM-informed design • Deliverable by non-specialists **Three Nested Arms** - Feedback on AUDIT-C (FOA) - UOA: FOA+ information on low-risk drinking and unit education - ABI (Full intervention): UOA+ patient centred, interactive discussion **Outcome Innovation** - Family member-reported outcome measure as an outcome in its own right **Conceptual Framework**

(Note: This PhD addresses a subset of the identified problems through pilot work. Policy reform, illicit liquor control, and system-level changes require broader governmental responses-not the focus of this thesis. OPD-Outpatient Department, FOA-Feedback on AUDIT-C, UOA-Unit of alcohol, ABI-Adapted Brief Intervention).

PART I: The problem

1.2 Alcohol and its harms

Alcoholic beverages contain ethanol, a psychoactive substance that has been consumed across virtually all human cultures throughout recorded history. Ethanol is lipid-soluble and readily crosses the blood-brain barrier where it interacts with multiple neurotransmitter systems including γ-aminobutyric acid (GABA), glutamate, dopamine, opioids, serotonin, and acetylcholine, affecting almost every tissue in the body (7). Alcohol exerts its primary effects through enhancement of GABA-mediated inhibitory

neurotransmission via GABA-A receptors and suppression of glutamatergic excitatory transmission via NMDA receptors (8), while simultaneously modulating dopaminergic reward pathways in the mesolimbic system, leading to increased dopamine release in the nucleus accumbens (9). These neurobiological mechanisms—combining sedation, reward activation, and disinhibition—explain alcohol's substantial potential for repeated use and the development of dependence.

Alcohol is recognized as a causal factor for more than 200 diseases and injury conditions in the International Classification of Diseases (10). Of these, 25 chronic disease codes in ICD-10 are entirely attributable to alcohol as a necessary cause. For many others including numerous cancers, neuropsychiatric conditions, and cardiovascular and digestive diseases, alcohol has a component-risk role (11). Alcohol is classified as a Group 1 human carcinogen by the International Agency for Research on Cancer—placing it in the same category as tobacco smoking and asbestos—with established causal relationships to breast, liver, head and neck, oesophageal, and colorectal cancers (12). Alcohol use disorders substantially increase dementia risk, with heavy drinking or alcohol dependence associated with a more than three-fold increased risk (13). As an immune suppressant, alcohol contributes to increase incidence of tuberculosis and has been causally linked to HIV/AIDS transmission and disease progression (12).

The J-shaped curve, which suggests that moderate drinkers have better health outcomes than abstainers, was first reported by Pearl (14), and became widely accepted in the late twentieth century (Marmot et al., 1981). Its interpretation remains contested. The Global Burden of Disease 2020 Alcohol Collaborators' analysis of 22 health outcomes across 204 countries, including both high- and lower-income countries, found that the burden-weighted relative risk curve was J-shaped in all regions for people aged 40 years and older. However, for those aged 15–39 years, the level of consumption that minimised health loss was close to zero (15). Furthermore, the apparent protective effect may be largely an artefact of confounding. Former drinkers who stopped because of ill health ("sick quitters") are often grouped with lifetime abstainers, which inflates the risk among abstainers (16). When higher-quality studies compared low-volume drinkers with lifetime

abstainers, the mortality advantage disappeared (17). The J-shaped curve may also not apply equally in lower-income settings. In the multinational PURE study, current drinking was associated with a lower risk of the composite outcome in high- and upper-middle-income countries, but not in lower-middle- and low-income countries (18). This is relevant to Sri Lanka, where drinking is characterised by heavy episodic patterns, under which any cardioprotective effect is unlikely. However, WHO states, 'the risk to the drinker's health starts from the first drop of any alcoholic beverage' (19). A systematic analysis of data from 195 countries and territories demonstrated that the risk of all-cause mortality, and specifically of cancers, rises with increasing levels of alcohol consumption, and that the level of consumption that minimizes health loss is zero (20). This evidence establishes that harm from alcohol begins from the first drink consumed, with no safe threshold of consumption. This evidence has implications for public health terminology: continued use of qualified terms such as 'harmful use of alcohol' or 'alcohol abuse' is problematic, as they imply that 'non-harmful use' exists, contradicting the evidence (See Chapter 7).Alcohol's adverse effects also extend far beyond the individual user. When assessing overall harm—considering both harm to the individual user and harm to others (Figure 1.1)—alcohol was rated as the most harmful substance among 20 drugs evaluated, with an overall harm score of 72 out of 100 (1). Global road traffic data illustrate this harm to others starkly: of 298,000 deaths from alcohol-related road crashes in 2019, 156,000 (52.3%) were caused by someone else's drinking (12).

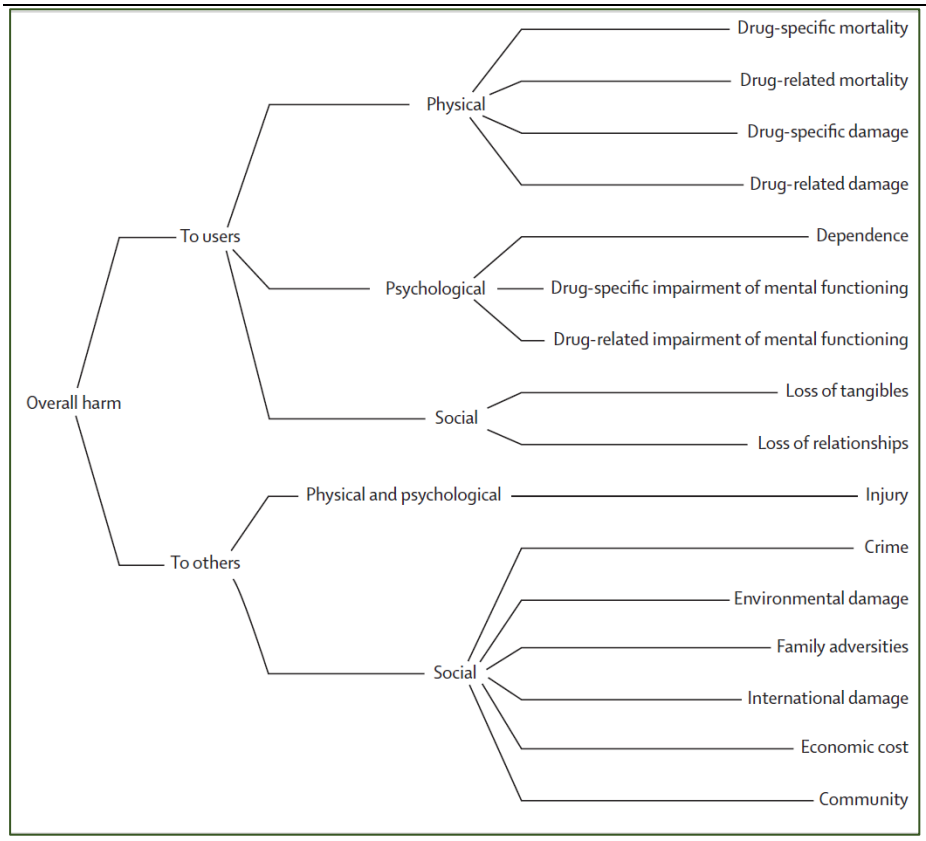

Figure 1-1 Alcohol-related harms to users and to others, grouped by physical, psychological, and social effects (1)

1.3 Global Burden of Alcohol

Globally, alcohol contributes to 3 million deaths annually and 5.1% of the global burden of disease, making it the leading risk factor for premature mortality among those aged 15-49 years (12). Importantly, most burden-of-disease coding systems capture only harms to drinkers themselves; they do not account for harms where alcohol's role is indirect—for example, injuries caused by an intoxicated assailant (21, 22). The true alcohol-attributable fraction is therefore higher than reported estimates.

Between 2010 and 2019, alcohol-attributable deaths declined by 20.2% globally, a reduction seen primarily in high-income countries and attributed partly to increased awareness of alcohol-related harms, despite poor treatment coverage (12). However, this progress has not reached low and middle-income countries (LMICs) or disadvantaged communities in high-income settings. The death rate per litre of alcohol

consumed is highest in low-income countries and lowest in high-income countries (23), a disparity explored further in Section 1.3.2.

The COVID-19 pandemic had mixed effects on alcohol consumption: some people drank less, while others drank more. A meta-analysis by Acuff et al. (24), which included 128 studies from 58 countries found that about a quarter of participants reduced their drinking and another quarter increased it. Increased drinking was more likely among those with children at home, those who had lost income, and those with depression. However, the meta-analysis focused on studies done during the early months of the pandemic, there is inadequate evidence on what happened after the pandemic and evidence on what happened afterwards remains limited, particularly outside high-income countries. In the US, national survey data showed that heavy alcohol use—(≥5 drinks on any day or ≥15 drinks per week for males, and ≥4 drinks on any day or ≥8 drinks per week for females— rose in 2020 and remained elevated in 2022 compared to 2018 (25). In Sri Lanka, a study in the North Central Province found that although overall alcohol consumption did not increase during the early COVID-19 restrictions, consumption of illicit alcohol did (26).

1.3.1 Drinking volumes and patterns

The relationship between alcohol consumption and health harm is shaped by two distinct dimensions: the volume of alcohol consumed over time, and the pattern in which it is consumed. These dimensions operate through different biological mechanisms and produce different categories of harm. Volume of consumption drives chronic disease risk—including liver cirrhosis, several types of cancers and alcohol use disorders—through cumulative toxic exposure (22). Patterns of consumption, particularly heavy episodic drinking (HED)—defined as consuming 60 grams or more of pure alcohol on a single occasion—independently increase the risk of acute harms including injuries, interpersonal violence, and cardiac arrhythmias, even among individuals whose overall weekly consumption may not be considered high (22, 27). Critically, two individuals consuming the same weekly volume of alcohol can face markedly different risk profiles depending on how that alcohol is distributed across occasions (22).

The evidence consistently shows that there is a dose-response relationship between the volume of alcohol consumed, and the patterns of consumption—Figure 1.2, from a systematic review of reviews and meta-analysis (22) demonstrates this. The figure illustrates that while volume of consumption increases risk for all major disease categories, heavy drinking occasions exerts an additional independent effect on injuries, and ischaemic heart disease, over and above what volume alone predicts .

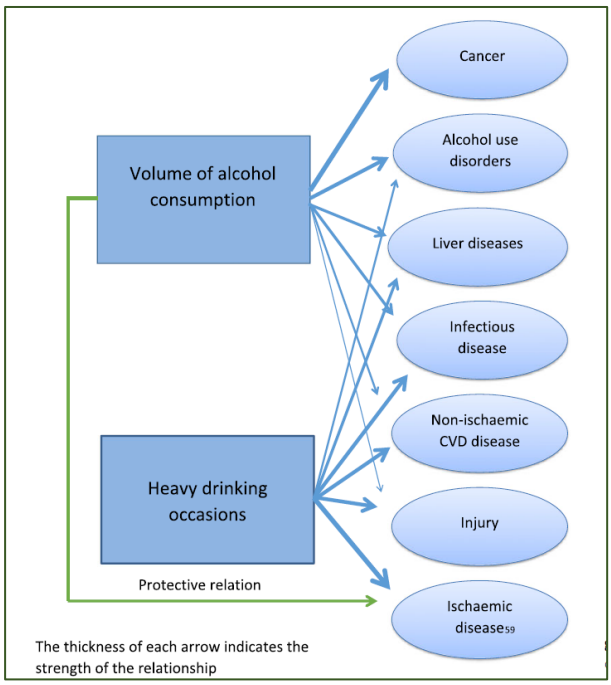

Figure 1-2 The impact of volume of alcohol use and heavy drinking upon major attributable disease outcomes (22)

Figure 1.2 shows the strength of the relationship—indicated by arrow thickness based on relative risks—for alcohol-attributable diseases and injuries with volume of alcohol consumption and heavy drinking occasions. A combined analysis of 599,912 current drinkers across 83 prospective studies, Wood et al. (28) found that all-cause mortality risk increased above approximately 100 grams per week, with the risk relationship steepening at higher consumption levels—Figure 1.3 illustrates this relationship between volume of alcohol consumption and hazard ratios for all-cause mortality.

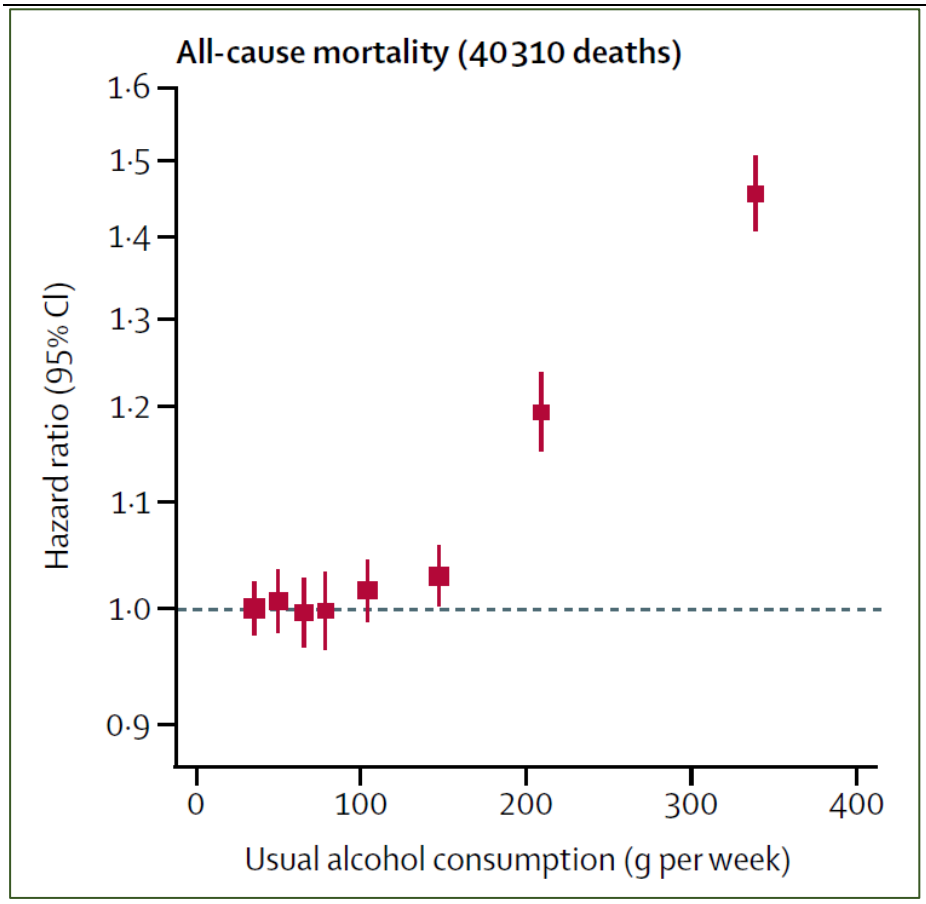

Figure 1-3 Associations of usual alcohol consumption with all-cause mortality (28)

Given these dose-response relationships, one might expect alcohol-related harm to track consumption levels proportionally across populations. However, the evidence reveals a more complex picture—one in which socioeconomic position profoundly modifying the relationship between consumption and harm.

1.3.2 The alcohol-harm paradox

Evidence consistently finds that people of lower socioeconomic status are disproportionately affected by alcohol-related harms (29, 30). This phenomenon is referred to as the alcohol-harm paradox (31)—those in lower socioeconomic conditions experience alcohol-related harm at disproportionately greater rates than those in more affluent circumstances, even when the amount of alcohol consumed is the same or less. Table 1.2, compiled from the WHO Global Status report in 2024, demonstrates this paradox. While per capita alcohol consumption and the percentage of drinkers are higher in upper-middle income and high-income countries, age-standardised alcohol-

attributable mortality per litre of per capita consumption is 4.5 times higher in low-income countries than in high-income countries (23).

Table 1-2 Alcohol attributable deaths and World Bank income groups (23)

Income Category	APC *(litres)*	% of current drinkers	Mortality Rate*	Deaths per litre of alcohol consumed**
Low-income	4.0	24.6	42.1	13
Lower-middle-income	5.1	26.1	46.2	9.8
Upper-middle-income	7.2	54.8	39.5	5.3
High-income	9.8	70.4	27.1	2.9

*(Note: APC- Alcohol Per Capita consumption, *per 100,000 population, **per 100,000 population per litre of pure ethanol consumed)*

The discrepancy is stark even in deprived areas of high-income countries—in Scotland, for example, the risk of alcohol-attributable admission or death for excessive drinkers was 10.22 times higher in deprived areas compared to 6.12 times in advantaged areas, relative to light drinkers (30).

A systematic review of studies from high-income countries found that socioeconomic inequalities in harm are partly explained by quantity per drinking occasion or frequency of HED (32). Findings of a population based Health-Survey in England also suggest that high levels of HED seen among those living in low socio-economic conditions partially explain this paradox (33). This disparity is compounded by clustering of other health risks including unhealthy diet, unsafe built environments that increase injury risk, smoking, physical inactivity and reduced access to health education and healthcare (34-36).

WHO emphasizes that the relationship between alcohol-related harms and socioeconomic inequalities extends to broader determinants of health—the conditions in which people are born, live and work. While alcohol policies, awareness campaigns and interventions can help address these inequalities, the underlying causes require multi-sectoral responses involving stakeholders beyond health alone (37).

1.3.3 Global Governance and industry challenges

Alcohol is the only psychoactive and dependence-producing substance that exerts a significant impact on global population health, that is not controlled at the international level by legally binding regulatory instruments (38). This regulatory vacuum limits the ability of governments to regulate alcohol distribution, sale, and marketing, and to protect alcohol policy development from commercial interference. Calls for a binding instrument modelled on the WHO Framework Convention on Tobacco Control have not achieved consensus among Member States (39). This governance gap is compounded by the shift of alcohol advertising to digital platforms and social media, which operate across national borders and circumvent traditional media regulation, with particular concern about reaching children and young people (12, 23). Meanwhile, the alcohol industry has positioned itself as a partner in achieving the Sustainable Development Goals through initiatives such as 'The International Alliance for Responsible Drinking' (40), a narrative that obscures the fundamental conflict between commercial alcohol interests and public health objectives.

1.3.4 Illicit alcohol

Globally, approximately 25% of alcohol consumption is unrecorded—produced and consumed outside regulatory oversight (41). This poses significant public health challenges, as unrecorded production frequently results in contamination with hazardous substances including methanol, leading to acute poisoning incidents (42).

1.4 Alcohol and Health: A broader perspective

1.4.1 Health beyond the individual drinker

WHO defines health as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' (43). A more recent definition states 'Health is the dynamic balance of physical, mental, social, and existential well-being in adapting to conditions of life and the environment' (44). When these definitions—particularly their emphasis on social well-being—are considered alongside the extensive harms alcohol inflicts on others—loss of relationships, family adversities, environmental

damage, and economic costs (1), it is doubtful whether there is anyone whose health has not been affected adversely by alcohol, either directly or indirectly. Yet both research and clinical practice have predominantly focused on the health of alcohol users themselves (45, 46) , while those affected by others' drinking remain largely invisible in alcohol harm reduction efforts. Krahn's concept of 'adapting to conditions of life and environment' (44) takes on particular significance for these individuals—family members, children, colleagues—whose adaptive capacities are under constant strain as they navigate volatile situations shaped by someone else's drinking. This relentless adaptive demand impairs their health yet rarely registers in alcohol harm reduction strategies.

1.4.2 Alcohol and sustained development

The United Nations introduced 17 sustainable development goals (SDGs) in 2015, and the third SDG— 'Health', aims to ensure healthy lives and promote well-being for all at all ages (47). WHO in its report on 'Alcohol consumption and SDGs' explicitly recognizes that 'a person's health and well-being are affected not only by disease and treatment, but also by social and economic factors such as housing, poverty and education'. Accordingly, WHO has documented how alcohol consumption undermines achieving 13 of the 17 SDGs, impacting indicators across child health, infectious diseases, road injuries, economic and social development, environment and equality (10).

1.5 Alcohol in Sri Lanka

Sri Lanka, an LMIC, has the highest human development index and highest mean years of education in the South-Asian region, alongside other impressive population health indicators (48). However, when it comes to alcohol-related harms, the situation is concerning, although a majority of the population (65% of those aged 18-69 years) are lifetime abstainers (49). The 2024 WHO global status report on alcohol suggests emerging patterns of risky ways of drinking (23). Table 1.3 compares data from the 2018 (50); and 2019 (23) Global Status Report on alcohol to summarise emerging trends—increasing trends of HED among all drinkers, and especially among females and also among adolescents.

Table 1-3 Sri Lanka's alcohol use—volume and patterns (23, 50)

Indicator	2016	2019	Change
Population aged 15+ years			
Total APC (litres pure alcohol)	4.3	2.8	↓
Recorded APC	2.7	2.6	↓
Unrecorded APC	1.6	0.3	↓
Beverage: Spirits / Beer / Other (%)	85/ 13/ 2	89.8/ 8.5/ 1.4	Spirits ↑
Past-12-month drinkers (%)	28.7	37.3	↑
— Males	40.6	48.7	↑
— Females	17.9	27.0	↑
Heavy episodic drinking (%)	9.1	12.4	↑
— Males	16.6	18.8	↑
— Females	2.4	6.7	↑
Population aged 15–19 years			
Current drinkers (%)	-	18.3	
— Males	-	19.9	
— Females	-	16.7	
Heavy episodic drinking (%)	7.0	8.3	↑
— Males	12.4 *(47.8% among current drinkers)*	9.3 *(46.9% among current drinkers)*	↓
— Females	1.6 *(16.4% among current drinkers)*	7.0 *(41.7% among current drinkers)*	↑

(Note: APC- Alcohol Per Capita Consumption, ↓- downward trend, ↑- upward trend)

Per capita alcohol consumption was 2.7 litres of pure alcohol per person aged 15 years and older in 2022 (4.8 litres among males), one of the highest in the South Asia region (49). This measure is widely accepted as the best indicator of population-level alcohol exposure and of effectiveness of population-based prevention efforts to reduce the harmful use of alcohol. It also is a key indicator for estimation of alcohol-attributable disease burden and deaths (51). But this is not a reliable indicator of alcohol related harms for countries like Sri Lanka where the proportion of the population who are abstinent is high (See Section 1.9).

Like other countries in the South-East Asian region (SEAR), Sri Lanka shows a marked gender disparity in alcohol use. Recent nationally representative data revealed that 53% of men and 2% of women were current drinkers (past-year use) (48)—higher than the 48%

and 1.2% respectively reported a decade earlier (52). The low prevalence among women reflects strong cultural barriers, with religion, family upbringing, and social pressure cited as the primary reasons for abstinence (53). Within these gender-specific patterns, sociodemographic profiles differ. Among men, secondary education and middle wealth quintile predict higher alcohol use; among women, the predictors are tertiary education and the highest wealth quintile (48).

While comprehensive research on alcohol's negative impacts in Sri Lanka remains limited, existing studies have documented how alcohol drives multiple serious harms across health, social and economic domains.

1.5.1 Health harms

Road traffic injuries show substantial alcohol involvement: a study of deaths among vulnerable road users—those who are unprotected by an outside shield— found 52% of postmortem reports had blood alcohol levels above the legal limit, with 45% of these being pedestrians (54). A six-month study across three hospitals in North Central Province attributed 14.8% of injuries to alcohol (55). The association with suicide and self-harm is particularly strong: almost two-thirds of male suicides involved alcohol-related problems, while one-tenth of female suicides were linked to a family member's alcohol use (56). Alcohol use disorders have been implicated in nearly one-third of non-fatal self-poisoning among men (57), with a case-control study finding an odds ratio of 21.4 for deliberate self-poisoning among those aged 30 years or older with alcohol use disorders (58). Further, a community-based study found that one-third of spouses of men with 'problem drinking' experience depressive disorder (59).

1.5.2 Social harms

Alcohol is a common factor in domestic violence (60-62) and contributes to child abuse through multiple mechanisms: household violence, neglect when parents drink, economic strain on families, and increased physical and sexual abuse when parental self-control and protection is impaired (63-65). Post-pandemic reports indicate

significant increases in domestic violence and child abuse, with alcohol identified as a contributing factor (66). Beyond the household, a WHO multi-country study (21) found that 27% and 3% of Sri Lankan adults experienced mild and severe harms respectively from strangers' drinking each year—including harassment, feeling frightened, sleep disruption, and feeling unsafe in public places. Given Sri Lanka's large abstainer population, these figures suggest harm from others' drinking is relatively widespread.

1.5.3 Economic burden

A qualitative study across different regions, income levels and ethnic groups found alcohol to be a major contributor to poverty—encompassing economic, material and social dimensions (67). Using WHO cost-of-illness methodology, Ranaweera et al. estimated the economic cost of alcohol at LKR 119.6 billion in 2015, equivalent to 1.07% of GDP, with road injuries representing the highest cost category and indirect costs (lost earnings from absenteeism and premature mortality) accounting for 56% of total costs (68). A 2023 UNDP investment case estimated substantially higher annual costs of LKR 335 billion, equivalent to 2.18% of GDP (2, 49).

This burden falls heavily on the public sector: since Sri Lanka's free healthcare system—covering approximately 50% of outpatient and 90% of inpatient admissions (69)—is funded by taxpayers, alcohol-related healthcare costs represent a direct transfer from public resources to treating preventable harms. A recent political economy analysis confirmed that alcohol-related costs far outweigh tax revenue (70).

1.5.4 Challenges faced by Sri Lanka

Sri Lanka's challenges must be understood within the regional context. SEAR, consisting entirely of LMICs, has experienced gradual but significant increases in alcohol consumption, with particularly concerning trends among adolescents, youth, and women (71). The authors further note that spirits account for 70% of total alcohol consumed in the region; and that SEAR has become an emerging target market for the alcohol industry .

1.5.4.1 Favourable conditions to increase alcohol consumption?

Sri Lanka has endured multiple recent compounding crises within the period from 2020-2025, including the COVID-19 pandemic, the country's worst economic crisis since independence, and recurrent severe flooding. The pandemic resulted in increasing poverty rates, from 9.2% to 11.7%, and over 70% of the informal workforce experienced job losses or severe income reductions (72). The subsequent economic crisis led to inflation peaking at 69.8% in September 2022, near-depletion of foreign exchange reserves and acute shortages of essential goods and medicines (73). Severe flooding in four consecutive years from 2021 killed hundreds, displaced hundreds of thousands and destroyed agricultural livelihoods and property (74, 75). International evidence suggests complex effects: economic crises typically reduce overall population-level alcohol consumption due to budget constraints, but simultaneously increase high-risk drinking among vulnerable subgroups, particularly unemployed men and those with lower education levels (76, 77).

The simultaneous occurrence of economic collapse, pandemic disruption, and repeated natural disasters creates an unprecedented scenario with potentially compounding effects on alcohol consumption patterns, demanding improving health literacy on low-risk guidelines and alcohol-harms; pre-emptive strengthening of alcohol screening; intervention capacity; and surveillance systems.

1.5.4.2 Increasing number of outlets/ licenses

Despite the economic crisis and stated government commitments to alcohol control, the number of licensed alcohol outlets continued to increase. By January 2024, the government had issued 5,730 liquor licenses, an increase of 214 licenses from January 2023 (78). However, increased licensing did not translate to increased legal alcohol sales. Legal alcohol production declined from 43.3 million litres in 2022 to 35.1 million litres in 2023—an 8.2% drop in production and a 19% decline in sales—with particularly sharp decreases in smaller bottle sizes commonly consumed by lower-income groups (78). This divergence between expanding retail infrastructure and declining legal sales

suggests a shift toward illicit alcohol consumption, since recent studies on consumption did not show overall declining pattern in drinking (48, 79).

1.5.4.3 Illicit alcohol market

Illicit alcohol—primarily kasippu (moonshine)—accounts for 40-65% of total alcohol consumption in the country (80). Beyond economic implications, illicit alcohol poses severe health risks through methanol contamination—in 2008, 10 consumers died and about 50 became severely ill in the Gampaha district of Sri Lanka (81), and eight died in Puttalam district in early 2026 (82) from methanol poisoning. Heavy taxation on legal alcohol—where excise, value added tax, and other levies constitute a substantial share of the retail price (83)—combined with political patronage of illicit liquor operations perpetuates this market (80).

1.5.4.4 Resource allocation mismatch

The National Authority on Tobacco and Alcohol (NATA) Act No. 27 prohibits the sale or supply of alcohol to anyone under 21 (84), yet WHO data (23) indicate this provision is poorly enforced (See Table 1.3), and NATA's education and prevention efforts targeting young people appear inadequate. By contrast, the National Dangerous Drugs Control Board (NDDCB)—mandated for illicit drug control—conducts intensive preventive work among school children (85). The agency most actively engaged in school-based prevention is thus focused on illicit drugs, while the agency responsible for alcohol control has not matched this effort—despite adolescent alcohol use exceeding illicit drug use (86).

The same disparity is evident in treatment. The government operates multiple dedicated drug rehabilitation facilities, with 80% of drug treatment occurring at state-run facilities (87). However, no dedicated government-funded alcohol treatment centres exist.

The mismatch is stark: alcohol affects substantially more Sri Lankans and causes greater harm than illicit drugs, yet both prevention and treatment resources remain directed primarily at illicit drugs, leaving alcohol largely unaddressed at the systems level.

1.6 Knowledge deficits and the normalisation of drinking

The preceding sections have documented the scale of alcohol-related harms; the systemic failures in governance, treatment infrastructure, and policy implementation that perpetuate it. Beyond these structural drivers, people's perceptions of alcohol's effects and harms directly influence their drinking behaviour and willingness to reduce consumption. Lack of knowledge about alcohol-related harms and low-risk drinking is an independent predictor of risky drinking (88). Unlike genetic predisposition, and more readily than socioeconomic or household conditions, knowledge is modifiable—yet in Sri Lanka, no systematic mechanism exists to deliver alcohol-related health education to the population at risk.

This knowledge deficit does not exist in a vacuum—it is actively sustained by the normalisation of drinking through media and marketing. Although alcohol promotions are legally prohibited under the NATA Act No. 27 (84), analysis of Sri Lankan media content from 2019–2020 revealed that tobacco and alcohol portrayals remained abundant in locally produced films and television series, with a particular focus on female drinking and substance use among young people (89). Social media platforms similarly featured promotional content presenting drinking 'in a positive and attractive light, repeatedly highlighted as normal and a pleasurable act.' These findings suggest that the alcohol industry's marketing strategies in LMICs—particularly targeting youth and women through portrayals of alcohol as symbolic of social freedom and modernity—have gained traction in Sri Lanka despite regulatory frameworks (90). The transnational media influence from Indian cinema, where alcohol consumption is increasingly portrayed as aspirational and normalised, compounds this effect. The result is a population exposed to sustained pro-alcohol messaging through multiple channels, with negligible counter-messaging about harms and risks.

That this knowledge deficit is not inert—but actively drives consumption—is confirmed by international and local evidence. Analysis of six waves of Australia's National Drug Strategy Household Survey (2001–2016) demonstrated that individuals with greater

knowledge of low-risk drinking guidelines had lower alcohol consumption, with this association strongest among social, heavy, and binge drinkers (91). In Europe, reductions in alcohol consumption have been linked to increasing awareness of negative health and social consequences, in addition to strict alcohol policies (23). In rural Sri Lanka, where baseline prevalence of risky drinking (i.e.: those who scored ≥8 on full AUDIT) was approximately 65%, a cluster-randomised community intervention trial demonstrated that educating people about the harmful effects of drinking and about low-risk drinking reduced risky drinking, with sustained reductions in both frequency and volume at six and 24 months (92).

Where people lack accurate information about what constitutes risky drinking and how alcohol affects their health, families, and livelihoods, the motivation to reconsider drinking behaviour cannot take hold. In a media environment that normalises alcohol consumption while health education remains absent, the knowledge deficit described above is both predictable and self-reinforcing—positioning it as a foundational, modifiable determinant of risky drinking in Sri Lanka. Raising awareness of alcohol harms is a strategy prioritized by the WHO to reduce alcohol-related harms (38).

1.7 Adverse childhood events

Adverse childhood experiences (ACEs), also referred to as childhood adversities, encompass a broad range of experiences: emotional, physical and sexual abuse; emotional or physical neglect; and household dysfunction, such as parental separation or divorce, a family member with mental illness, and domestic violence (93). These experiences are difficult to separate because they are often interrelated. For example, a child growing up in a household with violence is also likely to experience emotional abuse and neglect.

Alcohol use disorders (AUDs) are associated with genetic and environmental factors, co-existing mental illness, and adverse experiences in childhood. The association with childhood adversity is supported by many studies, which emphasise the importance of enquiring about early childhood trauma in all patients with AUDs. One review concluded

that early childhood trauma is common among people with alcohol dependence and described the neurobiological mechanisms that increase vulnerability to later dependence (94). Similarly, Enoch (95) proposed that early life stress can cause lasting changes in neurohormonal systems, leading to later alcohol- and drug-related problems. The review also emphasised gene–environment interactions and identified relationships with family and peers as important protective factors.

Parental alcohol misuse is itself an ACE: household substance abuse was one of the categories in the original ACE study, in which people exposed to multiple ACEs had a markedly higher risk of alcoholism in adulthood (96). Children of parents with alcohol problems are therefore both "affected others" and at increased risk of developing alcohol problems themselves, which highlights the intergenerational relevance of family-focused interventions.

1.7.1 Prevalence of childhood adversities in Sri Lanka

The prevalence of ACEs in Sri Lanka is not known. A case–control study of the association between ACEs and self-poisoning reported that 75.7% of cases and 56.3% of controls had experienced at least one adverse event in childhood (97). In 2017, the Weekly Epidemiological Report of the Epidemiology Unit, Ministry of Health, Nutrition and Indigenous Medicine, reported that 15% of 10–19-year-olds had low parental engagement and 39% had been bullied in the 30 days before the survey. Both groups had a higher prevalence of alcohol use than those with good parental engagement or who had not been bullied (98). In a study done in southern Sri Lanka,14% of the screened children were reported to have been sexually abused (99). This evidence suggests that experiencing ACEs is not uncommon in Sri Lanka.

PART II: The opportunity

1.8 Harm reduction approaches

1.8.1 From abstinence to harm reduction

The approach to addressing alcohol-related harms has evolved from an exclusive focus on complete abstinence to a broader harm reduction framework that recognises the benefits of reducing consumption levels, and adopting low-risk patterns of drinking, even without achieving total abstinence. This paradigm shift is supported by robust evidence demonstrating a continuous, dose-dependent relationship between alcohol consumption and mortality risk (22, 28), forming the basis for the WHO's recommendation to use consumption reduction—rather than abstinence—as a measure of success in treatment trials for alcohol use disorders (100, 101). This patient-centred strategy recognizes that substantial reductions in drinking represent meaningful treatment success and are more readily achievable than complete abstinence, thereby increasing treatment acceptability among patients and caregivers (102).

Importantly, alcohol consumption is not an isolated behaviour—population-level drinking patterns affect rates of alcohol-related problems across that population. When mean consumption increases, the proportion drinking above harmful levels also increases (103, 104). This 'total consumption model' has significant implications for intervention targeting: focusing not only on those with alcohol use disorders but also on those who do not meet diagnostic criteria yet drink at levels that increase risk of harm, offers greater potential for population-level harm reduction. At population level, the majority of alcohol-related harms arise not from the relatively small number of individuals with alcohol use disorders, but from the far larger group drinking at levels that increase risk (105). Addressing this majority therefore has the potential to confer greater population-level benefits than focusing exclusively on those at highest individual risk. The former group is also more amenable to opportunistic interventions (106). BIs, which are opportunistic interventions (102), targeting the full risk spectrum may therefore achieve greater population-level harm reduction than focusing resources exclusively on those meeting dependence criteria. This is particularly relevant in Sri Lanka, where HED

prevalence is high, specialist alcohol services are limited, and the few resources that exist are directed exclusively at treating dependence.

The public health urgency is underscored by rising trends in LMICs, where the alcohol-attributable burden of disease continues to increase (107). In this context, harm reduction strategies that promote risk awareness and consumption reduction represent pragmatic, evidence-based approaches to mitigating alcohol's substantial health and social costs.

1.8.2 Why people drink

Motivations for alcohol consumption vary substantially across cultures and contexts, shaped by social, psychological and individual factors. Social influences include descriptive norms (perceptions of how much others drink) and injunctive norms (perceptions of peer approval), which together create powerful influences on drinking behaviour—individuals who overestimate both prevalence and approval among peers are more likely to engage in heavy consumption (108, 109). Learned cultural expectations about behaviour under alcohol's influence differ dramatically between societies and can either constrain or facilitate harmful drinking patterns (67, 110).

Psychological factors also play a significant role. Mental illness, poor coping strategies, and the self-medication hypothesis—whereby individuals use alcohol's rapid anxiolytic effects to manage emotional distress—are well-documented drivers of consumption, particularly those with pre-existing mental health conditions (111-113). In Sri Lanka specifically, peer pressure and lack of social skills have been documented as the main risk factors for drinking initiation among adolescents and youth (114).

Genetic factors also contribute to drinking behaviour, with twin and adoption studies estimating the heritability of alcohol use disorders at approximately 49% (115). However, this estimate is complicated by gene-environment interplay: children of heavy drinkers inherit not only genetic susceptibility, but also adverse family environments characterised by reduced parental monitoring, social learning of drinking behaviours,

and exposure to childhood adversity—factors that independently increase alcohol use disorder risk and may amplify genetic vulnerability (116).

1.8.2.1 Knowledge as a modifiable factor

Of the risk factors discussed above, genetic predisposition cannot be altered, and socioeconomic conditions require systemic change beyond the scope of healthcare encounters. Knowledge, however, can be addressed opportunistically within existing health system contacts. As established in Section 1.6, poor knowledge about alcohol-related harms independently predicts risky drinking, is actively reinforced by normalisation through media, and—critically—responds to intervention. This positions knowledge improvement as the logical entry point for BIs in resource-constrained settings.

1.8.3 Harms to others: A neglected dimension

Lifetime risk of death from alcohol-related causes increases exponentially with average daily consumption, with a 48% reduction in intake producing approximately 76% risk reduction (117, 118). Critically, these estimates quantify only harms to drinkers themselves. Rehm et al. (22) argued that harms to others must be included in assessing alcohol's total attributable burden. When such harms—to families, communities, and society—are factored in, even modest consumption reductions may translate to substantially greater total harm reduction at the population level. Yet when interventions target drinkers, harms to others remain largely unmeasured as an outcome, with research continuing to prioritise individual drinking outcomes over the broader social costs that alcohol uniquely imposes (119, 120).

How this research addresses this gap through family member-reported outcomes is discussed in Section 1.10.1.

1.8.4 Cost-benefit analysis of effective interventions

The economic burden of alcohol in Sri Lanka is substantial (See Section 1.5.3) and provides a compelling case for policy action. Of the estimated LKR 335 billion in annual

losses, 21% comprised direct costs and 79% indirect costs, the latter driven by decreased labour force participation (56%), absenteeism (21%), and presenteeism (2%) (2). This represents a powerful counter-narrative to government perspectives that prioritise revenue generation through alcohol taxation over public health considerations. Although there is no source that combines all alcohol-related tax revenue for direct comparison, excise duty on liquor in 2018 was approximately LKR 114 billion (121), representing only about a third of the LKR 335 billion in estimated economic losses (2)—and excise duty constitutes the largest component of alcohol taxation.

WHO (49) advocates implementation of the SAFER package (19)—a technical package comprising five population-based interventions to reduce alcohol related harms, with the third intervention being 'Facilitate access to screening, BI and treatment'. The economic argument for implementing SAFER is compelling: the UNDP projects that full implementation over 20 years would yield a return on investment of 12.2:1, with economic benefits (LKR 643 billion) significantly outweighing implementation costs (LKR 53 billion) and would save 104,000 lives (2). A study in the US provided onsite evidence that emergency department and inpatient costs were significantly less at six months for those who received BI in comparison to who did not (122).

An economic analysis demonstrated high returns on investment for best buys in alcohol control—every additional US$1 invested in the WHO-recommended most cost-effective interventions per person per year will yield a return of US$ 9.13 by 2030, a return that is higher than a similar investment in tobacco control (US$7.43) or prevention of physical inactivity (US$2.80) (123). Organisation for Economic Co-operation and Development estimates show that every US$1 invested in a comprehensive policy package—combining pricing policies, police enforcement, primary care counselling, and child protection measures—yields a return of up to US$ 16 in economic benefits over a 30-year period (124).

Opportunistic interventions in primary care—one component of this cost-effective package—is the focus of this thesis, with particular relevance to Sri Lanka where alcohol-

related costs account for 2.18% of the GDP (49), and recorded 55 million visits to primary care (125)—outpatient departments in Sri Lankan setting—giving ample opportunity to intervene .

1.8.4.1 Screening for hazardous use of alcohol

Brief tools such as the AUDIT-C detect unhealthy drinking in primary care with acceptable accuracy, although specificity varies widely across studies (126). However, no trials have tested whether screening itself improves outcomes or causes harm, but it is recommended in primary care, together with behavioural interventions to reduce alcohol abuse (126). Its value therefore depends on the intervention that follows, and that evidence is modest (127).

AUDIT cut-offs are a further concern. Most LMIC studies use non-WHO thresholds without validating them (128). In Sri Lanka, only the 10-item AUDIT has been validated, in a community sample of Sinhalese married men (129)

1.9 Brief interventions

1.9.1 Why BIs

Several psychosocial approaches have demonstrated effectiveness for risky drinkers, including cognitive behavioural therapy (130), Alcoholics Anonymous and other 12-step programmes (131), contingency management (132), and BIs (102). However, most of these approaches require specialist training, multiple sessions, or established treatment infrastructure—resources scarce in LMICs like Sri Lanka.

A meta-analysis of patient-level interventions in LMICs found consistent evidence of effectiveness for BIs, recommending them as the most feasible approach in resource-constrained settings (133). BIs align with the harm reduction approach outlined in this chapter: they emphasise a shift from diagnosis-dependent treatment to population-level risk awareness and consumption reduction. As Nutt and Rehm (134) argue, effective intervention should not require medical professionals to diagnose alcohol use disorders before action can be taken. A numeric approach—focusing on grams of alcohol

consumed rather than disease categories—parallels successful public health strategies already established for calories, cholesterol, and blood pressure (127).

1.9.2 Task shifting potential

Internationally, healthcare providers consistently report lack of knowledge, training, and discomfort discussing alcohol as major barriers to implementing screening and BIs (135, 136). Providers may avoid exploring patients' alcohol disclosures due to concerns about harming therapeutic relationships, patient resistance, or stigmatising patients (137). These barriers are compounded in LMICs by shortage of specialist manpower and limited awareness of alcohol-related problems among healthcare workers themselves (138).

However, these workforce constraints have catalysed an important innovation: task-shifting BIs to non-specialist personnel. Growing evidence demonstrates that trained non-specialists—including lay counsellors, peers, and community workers—can effectively deliver brief alcohol interventions, sometimes with outcomes comparable to or better than specialist-delivered care. A systematic review of BIs in primary healthcare found nurse-delivered interventions were most effective at reducing alcohol consumption (139), while studies from non-clinical settings show that properly trained non-health staff can engage clients effectively, potentially with reduced stigma (140, 141).

The most compelling LMIC evidence comes from the PREMIUM study in India, which demonstrated that lay counsellors with no prior health sector experience could deliver a brief psychological treatment—effectively a BI according to WHO definition (102)—for harmful drinking that achieved sustained remission and was cost-saving from a health systems perspective (142). This finding is particularly significant: if trained lay counsellors can achieve such outcomes in primary care, the scalability implications for resource-constrained settings are substantial. A meta-analysis of mental health interventions delivered by lay counsellors across LMICs confirmed medium effect sizes for various conditions including alcohol use (143).

Several characteristics make BIs particularly amenable to task-shifting. Their structured nature separates *what* to deliver from *how* to deliver it: FRAMES (Feedback, Responsibility, Advice, Menu, Empathy, Self-efficacy) specifies the components to include—content that specialists can standardise—while OARS (Open-ended questions, Affirmations, Reflections, Summaries) provides communication techniques that non-specialists can be trained to use (102). Evidence suggests that intervention content and structure may matter more than total delivery time, with even single five-minute sessions demonstrating effectiveness (144). This finding has significant implications for workforce planning: if effectiveness does not require specialist training or extended consultation time, BIs become feasible within existing primary care staffing models.

Task-shifting also addresses a practical barrier identified in implementation research: non-specialist staff may actually achieve better client engagement due to reduced social distance and perceived stigma compared to clinical specialists (140). In Sri Lanka, where government OPDs serve as the principal primary healthcare provider with over 55 million visits annually (145), trained non-specialist workers could dramatically extend the reach of alcohol screening and intervention beyond the limited specialist workforce.

This evidence base underpins the present research, which specifically tests BIs designed for delivery by non-healthcare workers.

1.9.3 Sri Lanka's opportunity

Sri Lanka possesses infrastructure that could support BI implementation. The preventive health system demonstrates both accessibility and population engagement—87% of adults with hypertension have had their blood pressure measured, and over 700 Healthy Lifestyle Centres provide comprehensive screening (146). In addition, much of Sri Lanka's curative primary care is provided by the outpatient departments of government hospitals . The volume of visits, about 55 million a year for a population of 22 million, further highlights this opportunity (145).

The country's high literacy rate of 92.7% (147) provides an important foundation for health education initiatives. While basic literacy and health literacy are distinct concepts (See

Chapter 7), research demonstrates that basic literacy skills are necessary prerequisites for developing health literacy competencies (148, 149). In populations with high basic literacy, health education interventions can more effectively use written materials and health information resources—capacities essential for screening and BI programmes.

However, a gap exists: while the WHO BI framework provides an evidence-based foundation, its feasibility and acceptability in the Sri Lankan cultural context remain unknown—and critically, whether it can be delivered effectively by non-healthcare workers who could extend reach beyond the formal health system.

PART III: This PhD

1.10 Risky drinking

The evidence presented in Part I reveals a central tension: while aggregate per capita consumption in Sri Lanka appears modest and declining, the proportion of drinkers, the prevalence of HED, and the dominance of spirits are all increasing (See Tables 1.2 and 1.3)—trends actively reinforced by media normalisation of alcohol despite regulatory prohibitions (See Section 1.6). These patterns are masked by per capita figures diluted by Sri Lanka's large abstinent population and compounded by the alcohol-harm paradox (See Section 1.3.2) in which each litre consumed inflicts disproportionately greater harm in lower-income settings. Any intervention targeting alcohol-related harm in Sri Lanka must therefore first define what constitutes 'risky' drinking—and that definition must account for the dominant HED patterns, spirits-heavy pattern that characterises Sri Lankan consumption, rather than relying on volume-based thresholds developed in populations with very different drinking profiles.

1.10.1 Defining risky drinking

As established in Section 1.3.1, alcohol-related harm is determined by both the volume consumed over time and the pattern of consumption—particularly HED—which operate

through different biological mechanisms and produce different categories of harm (22). These two dimensions are central to defining risky drinking.

Risky drinking is a term used frequently in alcohol literature to denote: drinking above recommended limits in terms of both volume and pattern (150, 151); consuming above binge drinking limits only (152); and when validating AUDIT-C—the shorter version of Alcohol Use Disorders Identification Test of the WHO to identify the risky patterns of consumption (102)—cut-offs for a particular setting; 'validated cut-off for AUDIT-C to identify risky drinking' (151, 153). The term encompasses all individuals who use alcohol in a way that increases their health risk—including those who fulfil ICD or DSM criteria for an alcohol use disorder and, critically, those who do not yet meet diagnostic thresholds, but drink in harmful ways. The latter group accounts for the majority of alcohol-related population-level harms (105). Given that alcohol causes the most overall harm of any psychoactive substance (See Section 1.2), early identification of such drinkers is essential. However, this is not straightforward: low-risk drinking guidelines vary substantially across more than 20 countries, reflecting differing interpretations of the same evidence base, and the threshold separating 'low-risk' from 'risky drinking' differs depending on whether the outcome of interest is chronic disease, acute injury, or alcohol use disorders (154).

The reliance on per capita consumption as a population-level indicator is particularly problematic for Sri Lanka, as mentioned in Section 1.5, a country where the majority are abstinent and those who drink tend to binge heavily. Several authors have questioned the validity of this approach in such settings, where per capita figures mask the true extent of harm (155, 156). A ten-country comparative study confirmed that Sri Lankan drinkers consumed at a single, uniformly heavy quantity level with no variation across occasions (157).For this thesis, risky drinking is defined as drinking at levels or in patterns that increase the risk of alcohol-related harms—both acute and chronic (154), operationalized using an AUDIT-C total cut-off appropriate for Sri Lankan drinking behaviour (See Chapter 5). The AUDIT-C—through its questions on frequency (Question 1), typical quantity (Question 2), and HED frequency (Question 3)—directly captures this pattern, unlike volume-based measures which systematically underestimate

consumption in HED-dominant populations (157). The 10-item AUDIT is considered too long for routine use in busy clinical settings (158). The AUDIT-C performs comparably to the full AUDIT in identifying hazardous drinking (159) and was therefore used in this study.

Defining heavy episodic drinking

Of the three AUDIT-C questions, Question 3—which assesses frequency of consuming six or more standard drinks on a single occasion—is of particular importance for this thesis. This question directly measures HED (102), a consumption pattern responsible for a disproportionate share of alcohol-related harms in LMICs , including injuries, violence, and cardiovascular events (12), as discussed in 1.3.2. In populations where most drinkers are not dependent but drink heavily when they do drink, and live in deprived social circumstances—as in Sri Lanka—(23), HED is a primary driver of population-level harm (12).

Despite its significance, there is no internationally agreed threshold for defining HED. The WHO defines HED as consuming ≥60 grams of pure alcohol on a single occasion (23). The United States National Institute on Alcohol Abuse and Alcoholism (NIAAA) defines binge drinking as a pattern that raises blood alcohol concentration to ≥0.08 g/dL, which typically corresponds to five or more drinks for men and four or more for women within approximately two hours (160), with a US standard drink containing 14 g of pure alcohol. These discrepancies arise partly from the lack of a universal standard drink size and partly from differing approaches to defining risk—whether based on grams of ethanol, blood alcohol concentration, or number of drinks.

Emerging evidence supports a lower threshold of ≥5 standard drinks of 10 g each (≥50 g of pure alcohol) per occasion, to define HED. The WHO Regional Office for Europe, reporting data from the Eurobarometer survey, defined HED as 'five or more drinks on one occasion, or 50 g alcohol' (161). Connor et al. (162), in a national cross-sectional study in New Zealand, explicitly defined HED as consuming ≥50 g of alcohol on a single occasion and demonstrated that this pattern was associated with a threefold increase in alcohol-involved intimate partner violence.

On this basis, this thesis adopts a threshold of ≥5 standard drinks of 10 g each—the standard WHO measure of a drink (102)—per occasion to define HED, and incorporated this to the question 3 of the AUDIT-C. This threshold aligns with the WHO European regional definition and is more conservative than both the WHO global threshold (≥60 g) and the NIAAA threshold (≥70 g for men). In this thesis, the term HED is used throughout. Although 'binge drinking' is frequently used interchangeably in the literature, HED is preferred as it is consistent with WHO terminology.

1.11 Research evolution and design

Informed by the evidence reviewed in the preceding sections, this thesis evolved adaptively in response to the findings of successive studies (Figure 1.4). Specifically, the scarcity of BI evidence from LMICs, the lack of culturally adapted interventions, and the limited attention to harms experienced by family members shaped the decision to adapt the WHO BI, evaluate screening thresholds locally, and include family-member outcomes.

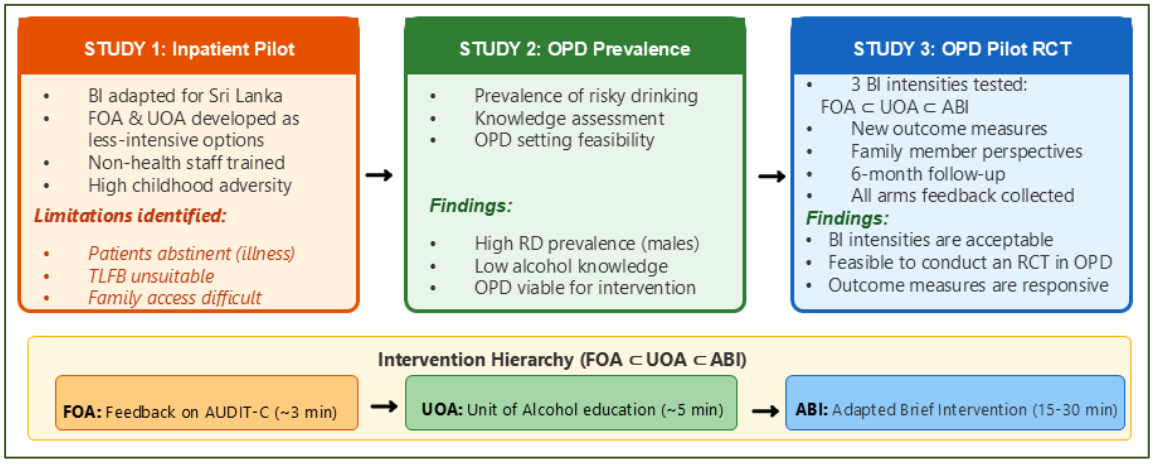

Figure 1-4 Evolution of the thesis

(Note: BI- Brief Intervention, FOA- Feedback on AUDIT-C, UOA- Unit of Alcohol, ABI- Adapted Brief Intervention, OPD- Out Patient Department, TLFB-Timeline Follow Back, RD- Risky Drinking)

The initial inpatient pilot tested the feasibility and acceptability of a culturally adapted BI, hypothesising that hospitalisation would create 'teachable moments' when patients are particularly receptive to health behaviour change (163).

The pilot established acceptability of the adapted brief intervention (ABI) and identified Feedback on AUDIT-C (FOA) and Unit of Alcohol education (UOA) as potential lower-intensity alternatives warranting further testing. However, it also revealed important setting and outcome limitations: many patients were abstinent at both recruitment and follow-up due to ongoing illness, making it impossible to assess intervention effects on drinking behaviour; the Timeline Follow Back method proved unsuitable; and hospital visiting hour regulations created barriers to family member engagement (See Chapter 4).

These findings prompted a shift to the outpatient department (OPD) setting: the state-run, main primary health care facility in Sri Lanka. Before proceeding to an OPD pilot, a prevalence study determined an empirical AUDIT-C cut-off (≥4) to detect risky drinking, characterised risky drinking patterns and knowledge deficits among OPD attendees and established the feasibility of this setting (See Chapter 5). The subsequent OPD pilot tested the acceptability and feasibility of three BI intensities (FOA, UOA, ABI), with new outcome measures, and extended follow-up to six months (See Chapter 6). This responsive, formative approach allowed each study phase to inform the next, developing context-appropriate interventions rather than imposing models from high-income settings.

1.11.1 The innovation: Family member perspective

This research addresses a neglected dimension of harm reduction by incorporating family member perspectives as outcome measures, in interventions delivered to the drinker. As established earlier in this chapter, alcohol causes greater harm to others than any other psychoactive substance (1), yet intervention research has overwhelmingly focused on the drinker's self-reported outcomes as the index of effectiveness. This represents a significant methodological limitation (164).

Family member reports capture dimensions of harm that patients themselves may not fully recognise or report, including violence, psychological trauma, economic hardship, and family disruption (21). By systematically incorporating family member

perspectives—through Family Member Questionnaire (165), this thesis assesses harm reduction in its truest sense—measuring not only changes in the individual's consumption and health, but also reductions in the broader familial and social impacts that constitute a substantial proportion of alcohol's total harm burden.

1.11.2 Additional methodological features

Two further methodological features strengthen this research.

First the use of Alcohol Problems Questionnaire (166) captures harm reduction beyond consumption changes—a patient may experience fewer alcohol-related problems (reduced conflict, improved work attendance, better family relationships); and change risky patterns (e.g., HED) even without changing drinking quantity, representing meaningful harm reduction in its own right.

Second the patient information sheet, answered by all patients, gathers contextual information while potentially triggering the 'question-behaviour effect' (167)— whereby answering questions about one's behaviour can itself prompt reflection and change; and creates a sense of ‘intimacy’ (45)—See Chapter 7, as the interventionist enters the conversation already informed about the patient's circumstances, enabling a more personalised and efficient discussion.

These methodological approaches address a critical gap in alcohol intervention research internationally and are discussed in detail in Chapter 6 and 7.

1.12 Research aims and objectives

1.12.1 Overall research aim

To adapt and evaluate the feasibility and acceptability of BIs for risky drinkers in Sri Lanka using Resnicow's cultural adaptation framework (168) and the transtheoretical model (169), evaluate its feasibility and acceptability when delivered by non-healthcare workers, and incorporate both patient and family member perspectives as outcome measures.

1.12.2 Research objectives

1. Adapt the WHO BI framework for the Sri Lankan context, specifically for delivery by non-healthcare workers
2. Assess the feasibility and acceptability of BIs of varying intensity (FOA, UOA and ABI)
3. Evaluate outcome measures for assessing intervention effects from patient perspectives
4. Establish the feasibility of family member-reported burden as an outcome measure
5. To describe variations in drinking patterns captured by different AUDIT-C cut-offs
6. To determine the prevalence of risky drinking in a primary care setting of a tertiary care hospital, and
7. To describe knowledge on low-risk drinking, unit of alcohol and alcohol-related health hazards in primary care

Together, these studies provide foundational evidence for the future integration of brief alcohol interventions into routine healthcare delivery in Sri Lanka. The research includes all risky drinkers identified through screening, without excluding those with more severe alcohol use disorders—a pragmatic approach reflecting the reality that in settings without established treatment pathways, any contact represents an opportunity for intervention.

The cross-sectional study determined an empirical cut-off to detect more risky drinkers, which will be an additional burden on already stretched resources in health care settings. Therefore, alongside this, the research assessed the feasibility and acceptability of three nested BIs that can be scaled up through delivery by trained non-healthcare personnel. The research also establishes the feasibility of measuring outcomes beyond consumption alone, recognising that patients may experience improvements in alcohol-

related problems independent of consumption changes, and that reductions in family burden represent meaningful harm independent of changes in drinking behaviour.

1.13 Practitioner-research approach

The research described in this thesis used a practitioner-researcher approach, which integrates the principal investigator's professional experience as a source of insight and hypothesis generation while maintaining methodological rigour to minimise bias (170). The research design was strongly informed by my experience as a psychiatrist working with patients presenting with issues directly or indirectly related to alcohol—from individual patients to the broader community—over about two decades, including two years' experience in Australia and 18 years in Sri Lanka.

Prior to this doctoral research the study I conducted during my specialist training (59), which included data collection at patients' households, was an eye-opener: the 'untold and unseen' stories of alcohol harms towards family members far exceeded what we typically heard in clinical settings and read in literature. It also confirmed research findings that family members' behaviours can worsen drinking behaviour and vice versa (171, 172)—a bidirectional relationship that prompted me to include family member perspectives as an independent outcome.

Clinical experience across diverse settings revealed important cultural differences. Australia is a more individualistic society, while Sri Lanka is a collectivist society characterised by enmeshed family systems where boundaries between members are permeable and interdependence is normative (173, 174). In such systems, one member's problem becomes the family's problem to a greater extent than in individualist cultures. Women appear most affected—as partner, mother, or daughter. Sri Lankan culture positions the mother/wife as the family's pivot, expected to 'tolerate' a drunken, abusive husband for the sake of 'family' or 'the children's sake'—and at times appear to be accused of being the 'reason for his drinking'.

While no comparative research has formally tested whether collectivist family structures amplify alcohol's harm to others, the WHO Harm to Others project—which included Sri

Lanka—documented substantial harm across collectivist societies, noting that political, cultural, and religious ideologies and family-centred worldviews shape how harm is experienced and distributed (21). Epidemiological research from India suggests that although abstinence rates are high, those who do drink often present with problematic patterns that place significant burden on families (175, 176).

My clinical observations over two decades treating patients with alcohol use disorders in Sri Lanka consistently revealed that family members—particularly spouses—presented with significant burden, often appearing more distressed than the patients themselves. The enmeshed nature of Sri Lankan family systems meant that one member's drinking became the family's problem in ways that appeared qualitatively different from descriptions in Western literature. This clinical observation informed the decision to include family member-reported outcomes as a primary measure in this PhD—capturing harm to others as a distinct measure of intervention effectiveness, rather than merely a collateral data source.

My clinical experience and professional clinical training also suggested that patients who were approached empathetically and non-judgmentally responded to simple education about units of alcohol, low-risk drinking, and alcohol-related harms—contrary to the popular local belief that 'teaching them how to drink will increase their drinking', the reason for including a third arm, UOA arm, in both pilot studies. In Sri Lankan settings, patients are usually accompanied by a family member even after recovery. Addressing the family member, allowing them to describe the impact of the patient's drinking and simply ventilate their emotions, appeared to help them cope better, which in turn seemed to benefit patient outcomes.

The main disadvantage of the practitioner-researcher approach is the potential for bias. However, several safeguards minimised this risk: a supervisory panel whose members brought expertise across public health, social anthropology, epidemiology, psychiatry, and alcohol research, including two experienced psychiatrists with knowledge of alcohol-related issues in both Sri Lanka and Australia; in-depth literature reviews to

ground methodological decisions in existing evidence rather than clinical assumptions; feedback from five psychiatrists on adapting the BI, ensuring the intervention reflected broader clinical judgement rather than a single practitioner's perspective; and delivery and outcome assessments conducted by trained research assistants rather than the principal investigator, separating the roles of intervention designer and outcome assessor. Together, these measures were intended to reduce the risk that while the practitioner-researcher's clinical knowledge informed the research design, it did not compromise the integrity of data collection or interpretation.

Another possible source of bias was the power differential between me, as a specialist psychiatrist, and the participants, as patients. This may have led participants to under-report on their alcohol consumption and to answer outcome questionnaires in a socially desirable direction. However, this risk was likely reduced because I had no direct contact with participants in any of the three studies, participants were told at the outset that their responses would not affect their care, and standardised questionnaires were used. Further research assistants who collected data were not hospital staff, and they were from equal socio-economic background as many participants were, which may have improved the rapport.

1.14 Conceptual framework

Figure 1.5 synthesises the relationships between risk factors, alcohol-related harms, and harm reduction responses that frame this thesis. Alcohol-related harms—affecting both drinkers and those around them—arise from the interplay of individual risk factors and social risk factors. Individual risk factors include adverse childhood experiences, role modelling, genetics (177, 178); poor coping, self-medication, co-morbid mental illness (111-113), male gender (12), and limited awareness of harms (88, 91). The social risk factors include (38) availability, price, drinking norms, media portrayal, myths about alcohol, and low socio-economic status. Policy-level and individual-level responses offer pathways to reducing these harms. This thesis focuses on individual-level responses: opportunistic interventions. However, implementing these responses in Sri Lanka faces specific barriers—stigma surrounding alcohol problems, limited resources

and trained workforce, absence of a proper screening tool, and lack of a culturally adapted BI. This thesis addresses these implementation gaps.

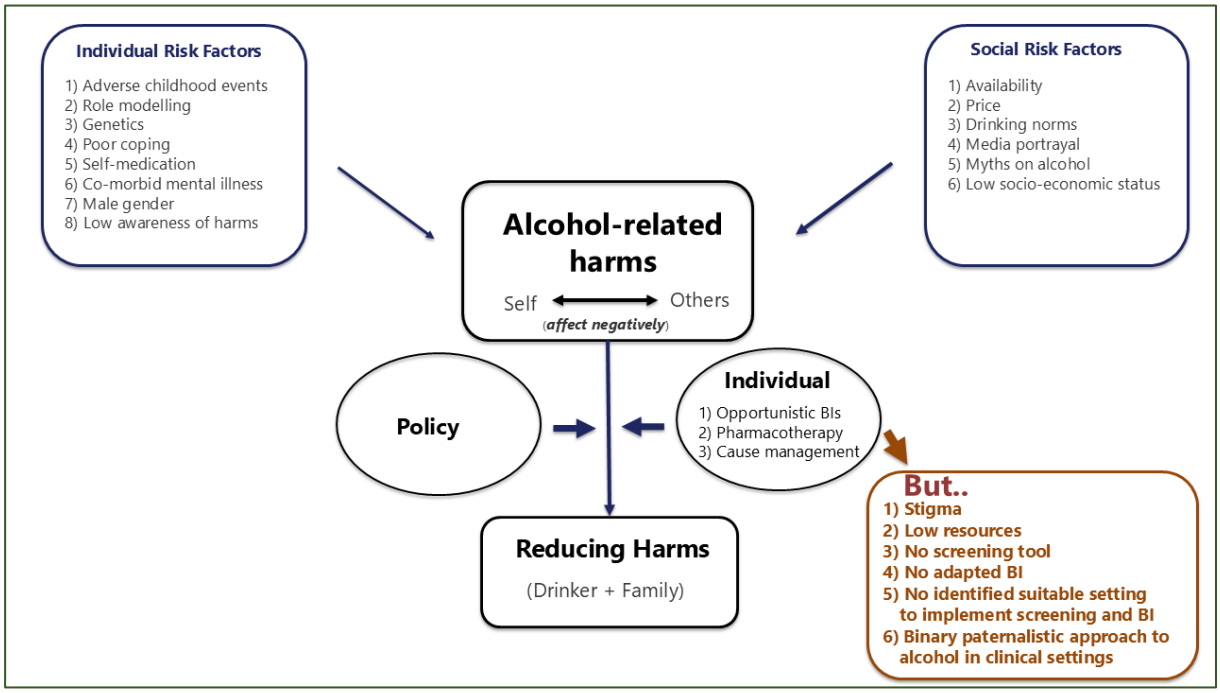

Figure 1-5 Conceptual framework

1.15 Structure of the thesis

This thesis comprises seven chapters.

Chapter 1: Established the global and local context of alcohol-related harm, the need and the opportunity for BIs in Sri Lankan health care setting, and the rationale for this research programme.

Chapter 2: Presents the Transtheoretical Model (TTM) as the conceptual framework underpinning this thesis. It describes the core constructs of TTM—stages of change, processes of change, decisional balance, self-efficacy and temptation, and context of change—examines their application to alcohol use and critically evaluates the model's strengths and limitations. The chapter concludes by explaining how TTM constructs were operationalised in the design of the interventions reported in subsequent chapters.

Chapter 3: Reviews the evidence base for BIs in alcohol harm reduction. It traces the historical development of BIs, examines systematic reviews and primary studies from both high-income countries and LMICs, and critically appraises methodological limitations identified in the literature—including heterogeneity in intervention content and delivery, reliance on self-reported outcomes, and insufficient attention to mechanisms and tailoring.

Chapter 4: Reports the inpatient pilot study: a three-arm parallel-group pilot randomised controlled trial conducted at Teaching Hospital Peradeniya. This study adapted the WHO alcohol BI to the Sri Lankan context using Resnicow's cultural adaptation framework, tested the feasibility and acceptability of three intervention intensities (FOA, UOA, and ABI) delivered by trained non-specialist research assistants, and was the first to include family member-reported burden as an outcome measure of an intervention delivered to the drinker. This Chapter has been published (179)

Chapter 5: Presents a cross-sectional study of alcohol use patterns and alcohol-related knowledge among patients attending the outpatient department (OPD) of Teaching Hospital Peradeniya. The study described variations of AUDIT-C cut-off for identifying risky drinking in Sri Lankan primary care, established the prevalence of risky drinking, and revealed substantial deficits in knowledge of units of alcohol, low-risk drinking, and alcohol-related harms. These findings confirmed the OPD as a viable setting for screening and BI.

Chapter 6: Reports the OPD pilot study, which tested the feasibility and acceptability of all three BI intensities in the outpatient setting. This study addressed the limitations identified in the inpatient pilot by testing new outcome measures from patient perspectives, collecting feedback from patients in all intervention arms and from family members, and extending follow-up to six months, and provided the foundation for a future adequately powered randomised controlled trial.

Chapter 7: Synthesises the findings across all studies, integrating them within Nutbeam's health literacy framework and the Transtheoretical Model. It discusses the

theoretical and methodological contributions of this thesis—including the patient information sheet as a methodological innovation, the systematic operationalisation of TTM constructs beyond stages of change, and the incorporation of family member perspectives as an outcome measure. The chapter considers limitations, implications for policy and practice, and directions for future research.

Chapter 2: Conceptual Model of the Thesis: Transtheoretical Model

2.1 Introduction

Changing health-related behaviours is difficult. Despite knowing the risks, people continue to smoke, drink excessively, eat poorly, and remain sedentary. Understanding *why* behaviour change is difficult—and *how* it occurs when it does—is essential for designing effective interventions. This chapter presents the Transtheoretical Model (TTM) as the conceptual framework underpinning this thesis and its approach to alcohol harm reduction in Sri Lanka.

A theoretical framework serves two purposes in intervention research (180). First, it provides a lens for understanding the phenomenon under study—in this thesis, how individuals change their alcohol-related behaviours. Second, it guides intervention design by identifying the mechanisms through which change occurs and the conditions under which interventions are likely to succeed or fail. Without such a framework, interventions become atheoretical—a collection of techniques without a coherent rationale for why they should work or for whom. Further, the lack of a proper framework makes the intervention non-reproducible.

Several behaviour change theories exist, including the Health Belief Model, Theory of Planned Behaviour, and Social Cognitive Theory. The Transtheoretical Model was selected for this thesis for three reasons. First, TTM explicitly addresses the temporal dimension of change—recognising that behaviour change is a process that unfolds over time, not a single event; and that people can move back and forth in the process. This is particularly relevant for alcohol use, where the journey from problematic drinking to sustained change may span months or years. Second, TTM integrates constructs from multiple theoretical traditions, offering a comprehensive account of both the cognitive-motivational and behavioural aspects of change. Third, TTM has been applied extensively in addiction research, including alcohol interventions (although to a lesser extent than in

smoking cessation research), providing an existing evidence base against which findings can be compared and interpreted (181).

This chapter is structured as follows. It begins with an overview of TTM's historical development and evolution. The core constructs of the model—Stages of Change, Processes of Change, Decisional Balance, Self-Efficacy, and Context of Change—are then described. Following this, the chapter examines TTM's application to alcohol use specifically, before presenting a critical evaluation of the model's strengths and limitations. The chapter concludes by explaining how TTM informed the design of the studies reported in subsequent chapters and how it will be used to interpret their findings, and to design future RCTs.

2.1.1 Dark logic considerations

Public health interventions, including behavioural interventions, can sometimes cause serious harms. Examples include psychological harms, such as stress caused by false-positive screening results; social harms, such as labelling individuals identified as at risk; and opportunity harms, where patient diversion could happen from more effective interventions to possible less effective intervention being tested (182). As a behavioural intervention, BI could potentially cause such harms if not delivered carefully. Several steps taken in this study may have minimised this risk. To avoid low-risk drinking guidance being interpreted as endorsement of drinking, participants were advised that not drinking carries the lowest risk. Patients who believed that disclosing their drinking to a family member would worsen problems at home could decline family involvement. Patients who appeared to be alcohol dependent were offered referral to psychiatric services, the more appropriate management for them, rather than BI alone. Information disclosed by a patient or family member was not shared with each other unless this was essential, and in such cases, consent was obtained after discussing the need. The feedback from patients, family members and research assistants (discussed in sections 6.3 and 6.4) will help minimize potential harms further in future trials. The need to understand behaviour change

The global burden of noncommunicable diseases (NCDs) is substantial. According to the World Health Organization, 18 million people died prematurely—aged 70 or below—from NCDs in 2021, with 82% of these deaths occurring in low-and middle-income countries (LMICs) (183). Four behavioural risk factors contribute disproportionately to this burden: tobacco use, unhealthy diet, harmful use of alcohol, and insufficient physical activity (183).

These statistics underscore a fundamental challenge: knowing that a behaviour is harmful does not automatically lead to its cessation. If knowledge alone were sufficient, public health campaigns providing information about risks would be universally effective. They are not. Something more is required—an understanding of the psychological processes through which awareness translates into intention, intention into action, and action into sustained change (184, 185).

Behaviour change, as DiClemente (186) noted, can take three forms: initiation of a new healthy behaviour (such as regular exercise), modification of an existing behaviour (such as reducing dietary salt or moderating alcohol intake), or cessation of a harmful behaviour (such as quitting smoking or abstaining from alcohol) (Figure 2.1). Each pattern presents distinct challenges. Initiation requires establishing new routines where none existed. Modification demands ongoing self-regulation to maintain behaviour within acceptable limits. Cessation involves not merely stopping a behaviour but sustaining that cessation against the pull of habit, craving, and environmental cues.

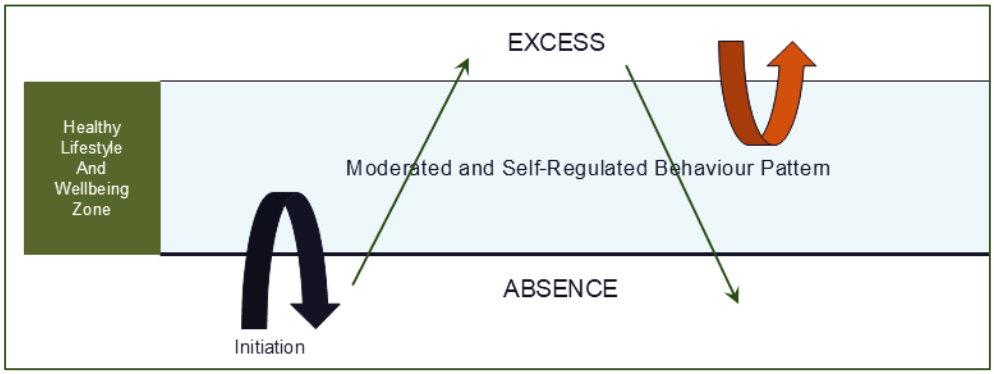

Figure 2-1 Different patterns of behaviour change (186)

For alcohol, the picture is further complicated by the fact that both modification and cessation may be appropriate goals depending on the individual's circumstances. Unlike tobacco—where cessation is unambiguously the goal—alcohol interventions may aim for reduced consumption, low-risk drinking patterns, or complete abstinence. A useful theoretical framework must accommodate this complexity.

2.2 Why the Transtheoretical Model?

The Transtheoretical Model emerged from a simple but important observation: different psychotherapeutic approaches, despite their radically different philosophies, produced roughly equivalent outcomes. In the late 1970s, over 250 distinct forms of therapy had been identified, yet none demonstrated clear superiority (187). This suggested that common processes might underlie successful change regardless of the specific treatment modality.

Simultaneously, research on smoking cessation revealed that many smokers quit successfully without any formal treatment. Self-quitters did not differ systematically from treatment-assisted quitters in personality characteristics or locus of control (188). If people could change on their own using the same underlying processes as those in therapy, then understanding these processes—rather than specific treatment techniques—became the priority.

TTM was developed to address this priority. Rather than advocating for a single therapeutic approach, it sought to identify the common principles and processes that facilitate change across different contexts and interventions. The name "transtheoretical" reflects this integrative ambition—drawing on constructs from psychoanalytic, behavioural, cognitive, and humanistic traditions rather than aligning with any single school (186).

Three features make TTM particularly suited to alcohol intervention research in resource-limited settings:

First, TTM recognises that most people presenting to healthcare settings are not ready for immediate action. A study of 15 health risk behaviours among Health Maintenance Organization members found that 40% were in precontemplation, 40% in contemplation, and 20% in preparation (See Section 2.6.1)—meaning 80% were not prepared for immediate action (189). Action-oriented interventions, which assume readiness to change, are therefore mismatched to the needs of most patients. TTM provides a framework for engaging individuals regardless of their current readiness, making it applicable in general healthcare settings where patients have not self-selected into treatment.

Second, the integration of processes of change with stages of change has direct clinical implications. Health promotion benefits from shifting from an action paradigm—where all interventions assume readiness—to a stage paradigm, where interventions are matched to the patient's current stage. Further, when processes are mismatched to stages, patients remain stuck and treatment failure rates increase (190). TTM specifies the processes through which change occurs, not merely the stages through which people progress. This process focus has direct implications for intervention design. Different processes are theorised to be more effective at different stages, suggesting that interventions should be tailored accordingly. For brief interventions (BIs) delivered in busy clinical settings, this specificity is valuable—it suggests *what* to do, not merely *that* something should be done.

Third, TTM acknowledges that change is rarely linear. People may progress, regress, recycle through stages, or remain stuck. The spiral model of change (191)—Figure 2.2—accommodates relapse as a normal part of the change process rather than as treatment failure. For alcohol use—where relapse rates are high—this realistic framing is both clinically and ethically important.

2.3 Scope of this chapter

This chapter provides the theoretical foundation for the empirical studies that follow. It does not attempt a comprehensive review of all behaviour change theories, nor does it

claim that TTM is without limitations—indeed, criticisms of the model are discussed explicitly. Rather, it presents TTM as a useful framework for understanding how individuals change their alcohol-related behaviours and for interpreting the outcomes of interventions designed to facilitate such change.

The chapter draws primarily on foundational TTM literature, particularly the work of Prochaska, DiClemente, and colleagues, supplemented by more recent applications and critiques. Where relevant, the chapter notes how specific TTM constructs informed the design of the studies reported in this thesis; however, detailed methodological descriptions and empirical findings of each study are reserved for subsequent chapters.

The following section describes the historical development and evolution of TTM, tracing its origins in smoking cessation research to its current formulation as a comprehensive model of intentional behaviour change.

2.4 Evolution

In the early 1970s, there was increased interest in how people quit smoking— some even on their own. Some were engaged in different types of therapies which used 'radically different philosophies and approaches', but the results were equal. Further, smokers who quit on their own or while on treatment did not differ in their smoking habits, locus of control and measures on personality (188). In 1976, Horn hypothesized that there are four stages associated with health related behaviours; contemplation—people are aware that there is a problem and are seriously considering about overcoming it; preparation—people are planning to overcome the problem behaviour; action—people modify their behaviours to overcome the problem behaviour; and maintenance—people concentrate on consolidating what they have achieved (192).

In 1984, an expert group gathered in Scotland to contribute to the development of a comprehensive treatment model for addictive behaviours integrating appropriate therapies. It focused on wide variation in ways people chose to change, from intensive therapies, self-help manual, to self-quitters. A comprehensive model was expected to cover the full course of change; from the moment one becomes aware of his problem to

quitting it altogether, complexity of changing the behaviour and also to acknowledge that change is a dynamic and open phenomenon (193).

2.5 Constructs of TTM

2.5.1 Stages of Change

Prochaska and DiClemente (194) developed the stages of change construct from their comparative analysis of smoking cessation. In their 1982 study comparing self-changers with therapy-changers, they identified distinct phases through which smokers progressed when quitting. This work established five discrete, categorical stages: *precontemplation* (not considering change within the next six months), *contemplation* (considering change within the next six months), *preparation* (intending to take action within the next month), *action* (actively modifying behaviour, lasting up to six months), and *maintenance* (sustaining change from six months to five years) (190). Stages of change describes a temporal dimension of when shifts in attitudes, intentions and behaviours occur. In the same year as Prochaska and DiClemente's initial work, Schachter (195) demonstrated that successful self-quitters made an average 3-4 action attempts before becoming long-term maintainers—an early indication that progression through stages was neither linear nor guaranteed.

Originally, people were supposed to progress linearly through these stages. However, in their 1992 article providing a comprehensive summary of the transtheoretical model, Prochaska et al. acknowledged that linear progression is rare. They proposed a spiral model of the stages of change (Figure 2.2), where those who relapse do not revolve endlessly in circles regressing to where they started, but can return to any prior stage. The spiral nature also accommodates people jumping several stages at once. The article concludes: 'probably the most important and direct implication of our research is the need to assess the stage of a client's readiness for change and to tailor interventions accordingly—i.e. ‘doing the right things (processes) at the right time (stages)' (196).

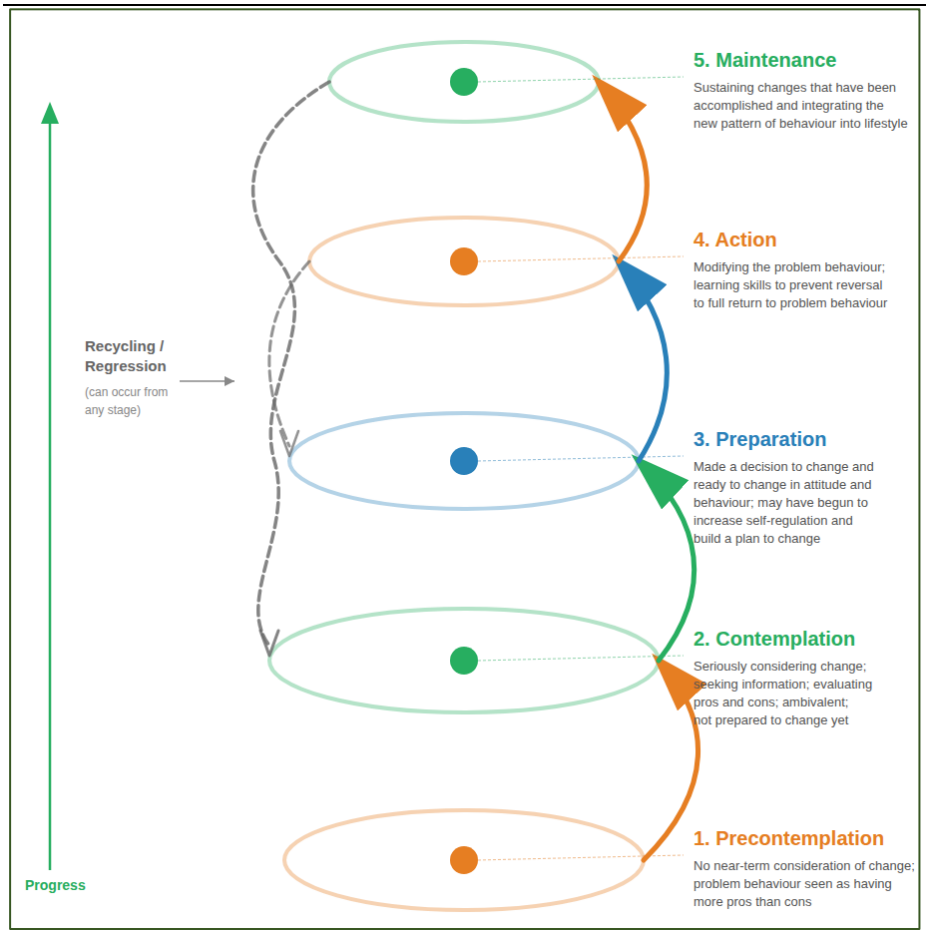

Figure 2-2 Spiral model of stages of change

In 1997, Prochaska and Velicer added a sixth stage—*termination*—where individuals have zero temptation and 100% self-efficacy. However, they acknowledged that these criteria are too strict and termination is not a practical reality for most people. Consequently, they gave little emphasis to this stage in later work (190), suggesting that the developers themselves recognised this construct had limitations in real-world behaviour change.

In his 2023 presentation at Grand Rounds of Western Viginia University on 'Understanding the Journey: Stages, Mechanisms, and Moderators of Health Behaviour Change,' DiClemente clarified that stages should be understood as tasks to be accomplished rather than boxes to jump between (186). He emphasised that not everyone progresses sequentially, but the framework makes the journey non-stigmatising. The shift from labelling people ('precontemplators' implying resistant or unmotivated) to describing their current state ('in precontemplation') is clinically significant. DiClemente frames this

as moving 'from resistance to readiness'—stages represent critical tasks, not permanent categories. This distinction matters for clinical practice: a patient in precontemplation is not failing; they simply have different tasks to accomplish than someone in action (Table 2.1).

Table 2-1 Role of the therapist in each stage of change (186)

Stage	Therapist's role
Precontemplation	Raise doubts about continuing problematic behaviour and increase the clients awareness of associated risks
Contemplation	Help the client to voice reasons for change and risks of not changing to facilitate the shifting the balance from cons to pros of changing
Preparation	Help the client to develop an effective, personalized and accessible plan
Action	Adjust the plan as needed and develop strategies to prevent relapses
Maintenance	Help the client to identify their strengths and to support them to achieve desired health outcomes.

2.5.2 Processes of Change

Stages of change is about 'when' shifts in attitudes, intentions and behaviour occur, processes of change describe how these shifts occur (196). Prochaska's comparative analysis of 18 psychotherapy theories identified common processes through which therapeutic systems produce change (187). However, these processes lacked empirical validation until DiClemente and Prochaska's (1982) study among smokers (194). These processes represent covert and overt activities and experiences people use when they attempt to change their behaviours and can be used within or between or without therapy sessions. The model identifies 10 processes (Table 2.1). These processes are categorized into two—experiential/ cognitive: consciousness raising, dramatic relief, environmental re-evaluation, social liberation, self-re-valuation; and behavioural: helpful relationships, stimulus control, counter conditioning, reinforcement management, self-liberation (191).

Table 2-2 The processes of change and representative interventions (196)

Process	Definitions: Interventions
Consciousness raising	Increasing information about self and problem: observations, confrontations, interpretations, bibliotherapy
Self-reevaluation	Assessing how one feels and thinks about oneself with respect to a problem: value clarification, imagery, corrective emotional experience
Self-liberation	Choosing and commitment to act or belief in ability to change: decision-making therapy, New Year's resolutions, logotherapy techniques, commitment enhancing techniques
Counterconditioning	Substituting alternatives for problem behaviors: relaxation, desensitization, assertion, positive self-statements
Stimulus control	Avoiding or countering stimuli that elicit problem behaviors: restructuring one's environment (e.g., removing alcohol or fattening foods), avoiding high risk cues, fading techniques
Reinforcement management	Rewarding one's self or being rewarded by others for making changes: contingency contracts, overt and covert reinforcement, self-reward
Helping relationships	Being open and trusting about problems with someone who cares: therapeutic alliance, social support, self-help groups
Dramatic relief	Experiencing and expressing feelings about one's problems and solutions: psychodrama, grieving losses, role playing
Environmental reevaluation	Assessing how one's problem affects physical environment: empathy training, documentaries
Social liberation	Increasing alternatives for nonproblem behaviors available in society: advocating for rights of repressed, empowering, policy interventions

Findings of longitudinal studies described how people in each stage use different process/es of change to move to the next stage (Table 2.2) (196). People used more experientially/ cognitively oriented processes of consciousness raising, dramatic relief and self/ environmental re-evaluation in the contemplation stage, and counterconditioning, stimulus control, reinforcement management and helping relationships, and more behavioural processes in the action and maintenance stages. (196).

Table 2-3 Use of different processes in different stages of change (196)

Precontemplation	Contemplation	Preparation	Action	Maintenance
Consciousness raising				
Dramatic relief				
Environmental reevaluation				
	Self-reevaluation			
		Self-liberation		
			Reinforcement management	
			Helping relationships	
			Counterconditioning	
			Stimulus control	

Although there is evidence to support these 10 processes across many types of behavioural change, some behaviours do not support all 10 processes, suggesting that some behaviours may need fewer processes (190).

The integration of stages of change and processes of change was supported by a study done in Texas and Rhode Island among smokers (197) and in a naturalistic study on attendance and outcome in a work site weight control programme (191). TTM emphasizes that processes of change are the 'change engine and the key mechanisms' of behaviour change. However, the 1982 study found no differences between maintainers and recidivists on any processes of change (194), a finding that raised questions about whether processes alone explain maintenance. This observation aligned with emerging work by Marlatt and colleagues arguing that maintenance requires distinct treatment approaches (198), and with Bandura's (1977) proposal that self-efficacy operates as a separate mediator of sustained behaviour change (199).

2.5.3 Decisional balance

When people have to make vital decisions, they weigh pros and cons of changing—four categories of pros—instrumental gains to self and others, and approval from self and others, four categories of cons—instrumental costs to self and others, and disapproval from self and others (200).

In 1985, a study was carried out to determine the decisional balance measure for assessing and predicting smoking status. Two scales were identified and were labelled as 'pros of smoking' and 'cons of smoking'. The authors concluded that these two scales were successful in differentiating between the 5 stages of change in the quitting process, in predicting outcome at six-month follow-up and that it is a powerful construct in behaviour change (201).

A study investigating TTM's generalizability across 12 problem behaviours (202), supported the internal validity of the two-factor model of decisional balance: pros and cons. Across 12 problem behaviours studied, there was a remarkable predictability when decisional balance was matched with stages of change across all behaviours—cons of changing the problem behaviour outweighed the pros for those in precontemplation for all behaviours and the opposite was true for people in action stage (except for cocaine abuse). A cross over of pros and cons occurred in contemplation stage. Moreover, the

study provided strong support for the generalizability of transtheoretical constructs of stages of change and decisional balance across a variety of problem behaviours. The paper reiterates the importance of being sensitive to culture when applying TTM, although the same constructs can be used. Migneault et al. (181) confirmed that decisional balance is consistently associated with stages of change for substance use behaviours, shifting as individuals progress through stages.

2.5.4 Contextual factors

TTM includes five components within context of change construct (186):

Current life situation – current concerns, symptoms, housing, stresses
Beliefs and attitudes – religious, political, familial, cultural
Interpersonal relationships – significant others
Social systems – family, work, legal, societal
Enduring personal characteristics – personality, identity, implicit attitudes

These factors are critical in addressing substance abuse—current life situation, beliefs, and peer relationships help explain why certain people start to use substances while others do not. Social systems and enduring personal characteristics influence why some continue to use and experience associated harms, and these same factors help explain why some people respond to interventions while others do not (203, 204). For example, an adolescent following a relationship break-up may start to self-medicate his negative affective state with alcohol (perhaps influenced by his alcohol using peers, due to his belief 'I can forget problems when I am drunk' or modelling his parents or TV idols who take alcohol after facing a problem), while another adolescent following a break-up turns to his trusting parents. Further, a cross-sectional analysis of patients in general practice revealed that the presence of comorbid anxiety and depression was significantly related to later stages of change in TTM—those who had depression or anxiety had higher temptation to drink and lower self-efficacy to abstain from drinking (205).

Despite substantial evidence of how these contextual factors affect substance initiation and subsequent outcomes, there is limited research on how these factors could be incorporated into interventions. Unlike stages (206, 207), processes (208, 209), decisional balance (210), and self-efficacy—which all have validated measurement

instruments—the context of change construct lacks standardised assessment tools for alcohol populations.

2.5.5 Self-efficacy and temptation

Self-efficacy, derived from Bandura's (199) social cognitive theory, refers to an individual's confidence in their ability to abstain from a behaviour across different situations. DiClemente (211) first applied this construct in 1981 to smoking cessation, demonstrating that self-efficacy significantly differentiated maintainers from relapsers at five-month follow-up. The construct was subsequently integrated into TTM, where it reflects confidence to resist engaging in the problem behaviour when faced with high-risk situations (e.g., an individual reducing alcohol consumption resisting pressure from drinking peers to drink more).

Temptation is the converse of self-efficacy—it reflects the intensity of urges to engage in the problem behaviour when in difficult situations (212). The authors describe common high-risk factors—negative affective states (e.g., following a relationship break-up), positive social events (e.g., Christmas celebrations), and craving or withdrawal symptoms.

Self-efficacy and temptation have a dynamic relationship: temptation dominates in early stages of change while self-efficacy dominates in later stages (213).

2.6 Contemporary TTM

Contemporary TTM comprises six constructs: stages of change, processes of change, context of change, decisional balance, self-efficacy, and temptation (186) (Figure 2.3). DiClemente emphasizes that TTM addresses "client-focused intentional behavioural change" and recognizes that health behaviours are multi-dimensional—requiring initiation, modification, or cessation—with varying frequencies, intensities, and levels of commitment.

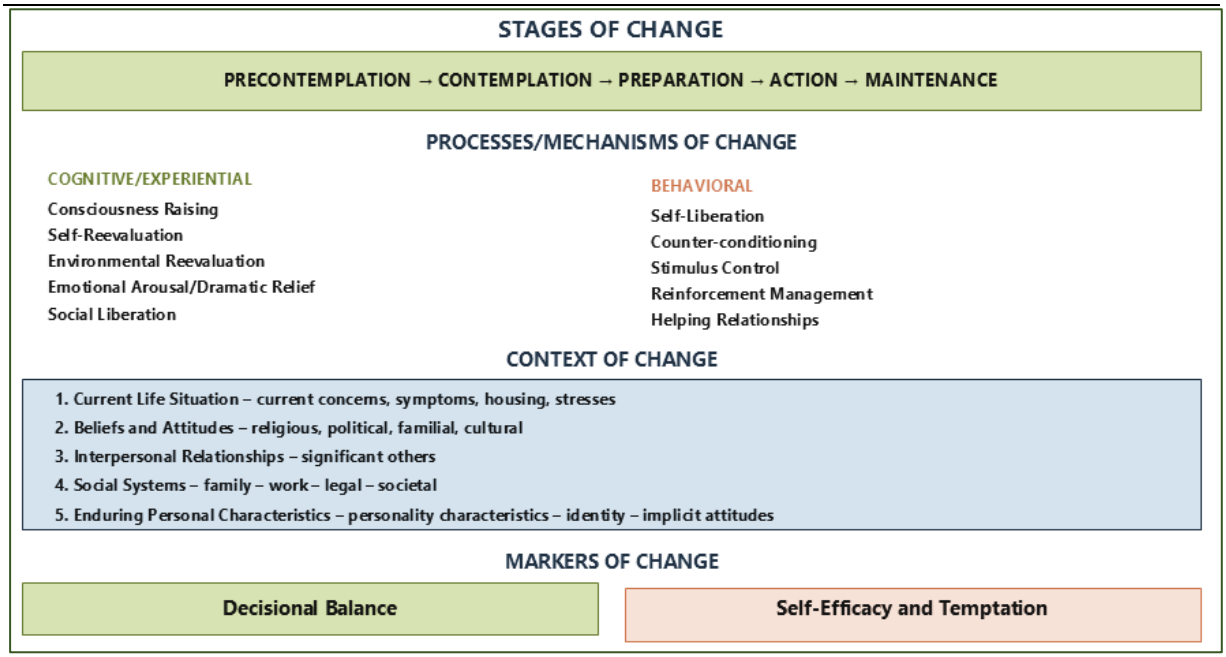

Figure 2-3 A client focused model of intentional behaviour change

The stage-task distinction is central to modern TTM. Stages represent tasks to be accomplished rather than static categories (186). For those in precontemplation, the task is building awareness of the problem. For those in contemplation, the task is resolving ambivalence. For those in preparation, it is developing an actionable plan. This framework helps practitioners recognize patient ambivalence as a normal stage of change rather than resistance and reduces stigma around not being ready for immediate action or experiencing relapse—particularly important in alcohol interventions where social stigma may already be high. This task-oriented view makes TTM particularly applicable to alcohol interventions, where both reduction and cessation may be appropriate goals depending on the individual's circumstances and preference.

The model helps the practitioner to recognize the ambivalence of the patient and provides means to address it and pushes him towards the right direction (214, 215). The transtheoretical model also may facilitate a less judgmental view of people not ready for change or who relapse, as in common with addictions (216).

2.7 Critiques of TTM

TTM has been both supported and criticised since its proposition by Prochaska and DiClemente (187). Systematic reviews provide evidence for its effective use in changing health behaviours such as physical activity, diet, and smoking cessation (217). Yet the model has also attracted substantial criticism. Sussman et al. (2022) note that TTM 'has been discredited to a large extent by several in the health behaviour research community' while continuing to enjoy popularity among clinicians—(218) a paradox that is essential to examine given TTM is central to this thesis.

The critiques centre on several interconnected problems. First, the stage boundaries are arbitrary, and these are pseudostages—points on a continuum rather than qualitatively distinct categories. The six-month timeframe for contemplation and 30-day criterion for preparation were decreed rather than empirically derived (219). Sussman et al. (2022) observe that these time courses 'vary a great deal across studies and may not be necessary'(218). West (2005) (220), in his provocatively titled editorial 'Time for a change: putting the Transtheoretical (Stages of Change) Model to rest,' noted that 51% of quit attempts in smokers were unplanned (221). Sussman et al. (2022) extend this: individuals can 'move cognitively between precontemplation, contemplation, and preparation in a matter of minutes as well as move from precontemplation to action in a matter of moments' (218). 'Third, stage-matched interventions show limited effectiveness, and Riemsma et al. (2002) cautioned against its use by practitioners (222). Fourth, contrary to the assumption that specific processes of change correspond to distinct stages, individuals use multiple processes simultaneously across stages, with usage patterns varying by the target behaviour (223).

A more fundamental problem is the model's assumption of rational, deliberate decision-making. Sussman et al. (2022) (218) put it directly: The transtheoretical model assumes that people are inherently rational and plan things out. However, actual changes occur through a chaotic process. Implicit cognitive processes may steer behaviour, particularly under periods of stress. TTM also neglects external factors: life events such as health

crises, births, or divorce can trigger change without prior motivation. Also, if someone is mandated to attend treatment, they will change regardless of their stage (216).

Prochaska (2005) responded to these criticisms existing at the time, arguing that critics confuse the construct with the assessment. Problems with staging algorithms do not invalidate the underlying phenomenon. Stages should be understood as tasks to be accomplished rather than categorical labels to assign. Making any psychological concept operational is inherently arbitrary—this applies equally to depression, anxiety, or addiction (169). Before TTM, clinicians might intuitively sense a patient was not ready for change but lacked a systematic framework for responding appropriately. Patients were treated uniformly regardless of readiness, and treatment failure was attributed to the patient "lacking motivation." TTM systematized how to assess readiness and match interventions to each stage. The criticism targets how TTM has been operationalized and tested, not the core insight that readiness for change matters.

Importantly, much of the critique has been generated from smoking research. Evidence from alcohol treatment is more supportive. Heather and McCambridge (2013), using United Kingdom Alcohol Treatment Trial (UKATT) data, found that post-treatment stage of change (measured as pre-action versus action) was a better predictor of outcome than pre-treatment stage (224). This contradicts findings of the ‘Project Matching Alcoholism Treatments to Client Heterogeneity (MATCH)’, where baseline readiness predicted drinking outcomes, but end-of-treatment readiness did not (225). DiClemente's own analyses (226) of Project MATCH (225) and trial ‘Combining Medications and Behavioural Interventions for Treatment of Alcoholism (COMBINE)’ (227) data showed that while different treatment modalities produced similar outcomes, TTM process dimensions discriminated between drinkers who did well and those who did not. Therefore, constructs have prognostic utility even when stage-matching does not produce differential effects.

Davidson (2002) observes that criticism of stage models follows a predictable trajectory: initial uncritical acceptance, followed by guarded sympathy, escalating to outright hostility, and ultimately achieving "grandfather status"—retained for historical reference

but no longer generating productive research. He contends that TTM had not yet reached this terminal phase (228). Sussman (2022) added it is 'best considered a clinical heuristic, which may assist in decreasing patient stigma and possibly enhance recovery but may not yield fruitful prospective scientific findings as a coherent theoretical model', and suggest that it is a good tactic to move TTM away from strict stages, to work on processes of change that can move people out of precontemplation, when costs are higher of not changing a particular behaviour, and those which can move patients from short-term maintenance to long-term maintenance (218). It also helps to understand that addictions and behavioural problems are not easily remedied, therefore encouraging patience and persistence in change efforts (216), both in the patient and the therapist.

There is a case to be made that TTM's limitations in smoking research may not generalise to alcohol. Nicotine dependence involves approximately 200 reinforcements daily (229), with nicotine reaching the brain within 10-20 seconds of each puff (230)—arguably the worst possible test case for a model assuming deliberate, planned change. Alcohol use disorder has a longer trajectory from risky drinking to dependence (231), creating more observable precontemplation and contemplation phases. The model's clinical utility may be greatest precisely where deliberation actually occurs—and that may be alcohol rather than smoking. In fact, this is what research suggests: research in the developed world showed that using TTM in alcohol interventions is effective (232, 233).

A review of the literature reveals that TTM constructs have been predominantly validated in high-income country populations, with limited application in low- and middle-income settings. There is one study, done in Iran, an LMIC, which had used stages of change to profile alcohol abuse (234).

Despite these criticisms, TTM remains appropriate for this thesis for several reasons. First, the most substantive critiques—arbitrary stage boundaries, limited effectiveness, and assumptions of rational decision-making—derive predominantly from smoking cessation research; whereas evidence from alcohol treatment is more supportive, as explained earlier. Second, this thesis adopts the approach advocated by DiClemente (186): rather than relying on strict stage classification, it focuses on activating processes

of change—the mechanisms through which behaviour change actually occurs—and systematically operationalises context of change, a construct largely neglected in prior TTM-alcohol research. Third, TTM's recognition that change is a process, not an event, and that relapse is a normal part of the change process rather than treatment failure, makes it particularly suited for opportunistic interventions in primary care settings in LMICs.

2.8 How TTM constructs have been operationalized in the current thesis

This section demonstrates how TTM constructs—particularly processes of change and context of change—were operationalized in the current research. It argues that alcohol interventions require a fundamentally different application of TTM than smoking cessation research, because both modification and cessation are legitimate goals for alcohol, whereas smoking research has focused almost exclusively on cessation. While TTM has been applied extensively to alcohol treatment, particularly in high-income settings (226, 233, 235), no study, to the best of our knowledge, has described how a culturally adapted alcohol BIs systematically operationalizes TTM processes and context where both modification and cessation represent valid endpoints.

Behaviour change can be initiation of a desired behaviour or modification or cessation of an undesired behaviour (186). As noted in Section 2.3, this tripartite distinction has direct implications for how TTM should be applied to different health behaviours. Unlike tobacco—where cessation is unambiguously the goal and TTM research has consequently focused on commitment to abstinence—alcohol interventions must assess and support decisions across a spectrum from harm reduction to complete abstinence. Contrary to earlier convention about ‘safe drinking’, all recent research evidence indicates that ‘zero drinking’ is the safest (20). However, research also says that reduction of drinking improves health outcomes (134). Therefore, when it comes to alcohol—the problematic behaviour explored in this thesis—there must be policies and interventions to prevent people from drinking at amounts which increase their risks (modification) or to support complete abstinence (cessation). People who are already

drinking either should modify their consumption to lower-risk levels or abstain. The focus of my study was to determine the acceptability and feasibility of WHO's BIs adapted to Sri Lanka, aiming either to reduce alcohol amount, modify alcohol-related harmful behaviours, or achieve cessation.

Figure 2.4 summarizes the constructs of TTM and illustrates how the tools and interventions used in this thesis operationalize these constructs.

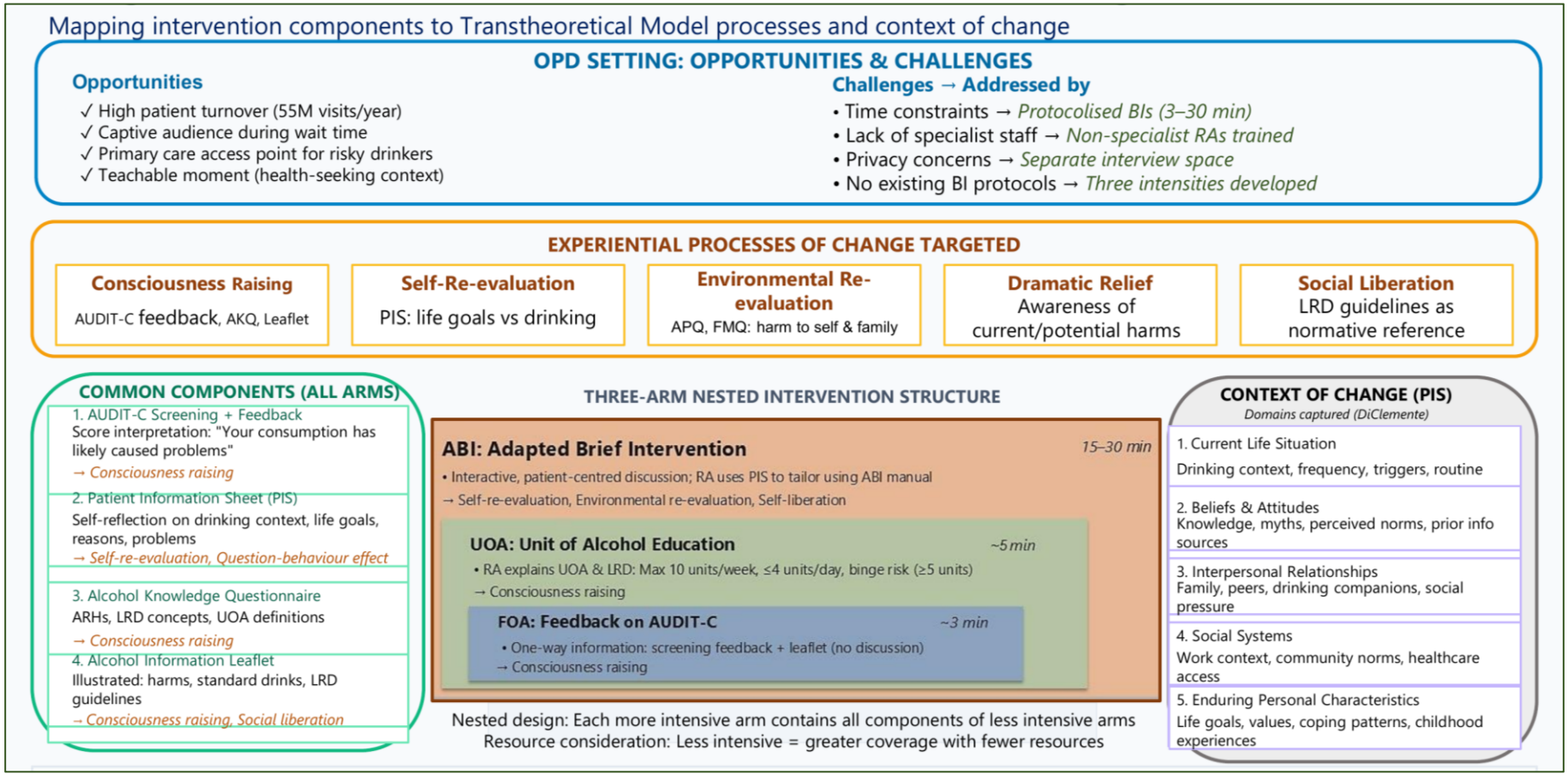

Figure 2-4 Integration of TTM constructs into the current thesis

(Note: Stages of change not formally assessed. Interventions designed to activate processes appropriate across the precontemplation-contemplation spectrum)

2.8.1 TTM processes targeted in this thesis

The intervention was designed to activate processes of change appropriate across the precontemplation–contemplation–preparation spectrum. Consistent with the opportunistic nature of BIs in general healthcare settings, we did not formally assess stage of change at recruitment. This reflects the reality that most patients in such settings are unlikely to be in action or maintenance stages (189), and that stage assessment instruments may artificially categorize what is often a fluid state of readiness.

The processes of change—consciousness raising, self-re-evaluation, environmental re-evaluation, emotional arousal and self-liberation— have been shown to be effective in the early stages in the journey to recovery. Rather than attempting to match specific processes to assessed stages, the research tools were designed to activate multiple experiential processes simultaneously, recognizing that in opportunistic healthcare encounters, the goal is to move patients toward greater readiness regardless of their precise starting point.

Screening using Alcohol Use Identification Test-C (AUDIT-C) (236) could serve as a 'wake-up call' to those who believe they are drinking 'at low-risk levels' or 'socially'. Similarly, the alcohol knowledge questionnaire (See Chapter 4 and Appendix C), which addresses alcohol-related health problems, low-risk drinking, and units of alcohol, raises awareness. The Alcohol Problems Questionnaire (See Chapter 6 and 7; and Appendix C) and Family Member Questionnaire (See Chapter 4, 6 and 7; and Appendix C) make the patient aware of the harms caused to himself and to family members by alcohol, which may prompt deliberation about alcohol consumption and what to do about it. This design reflects the TTM principle that experiential processes—particularly consciousness raising and, self and environmental re-evaluation—are most effective for individuals in precontemplation and contemplation stages (196).

Even the act of consenting to participate in alcohol screening may itself represent an initial openness to addressing drinking behaviour. This phenomenon—termed 'assessment reactivity'—suggests that the assessment process itself can trigger change

(237, 238). From a TTM perspective, assessment reactivity can be understood as consciousness raising: completing screening instruments forces individuals to confront information about their problematic behaviours that they may have previously been ignorant of, avoided or minimized; and participants' response to avoid being judged by giving a socially desirable response—which has been observed in alcohol research (239) . Some studies have shown that people who consent to be study participants have more alcohol-related problems than those who decline (240). However, a study among young males in Switzerland revealed that 'late respondents' use higher amounts of substances than 'early respondents' (241)—although this may be affected by the culture, like in Sri Lanka, where alcohol use is met with significant stigma.

2.8.2 The patient information sheet: Operationalizing processes and context of change

In the pilot study done in the OPD, we administered the patient information sheet—a tool we developed in this thesis (Appendix A), further discussed in Chapter 6 and Chapter 7—to all patients, which gave them the opportunity to actively think of aspects related to their consumption. These 'aspects' represent both processes of change and context of change—rarely investigated but crucial constructs of TTM in alcohol interventions, especially in preventing relapses (see Sections 2.1 and 2.6.4). The patient information sheet represents a methodological innovation in BI research: a single instrument designed to simultaneously activate multiple TTM processes while gathering contextual information essential for intervention tailoring.

The patient information sheet included questions on demographics, income, drinking companions, occasions of consumption, context/ emotions of consumption, relationship status, children, reasons for drinking, issues faced due to alcohol, and sources of prior alcohol knowledge or advice. The patient information sheet raised awareness (consciousness raising), aroused emotions (dramatic relief), and encouraged self and environmental re-evaluation. It simultaneously explored contextual factors across TTM's context of change domains: current life situations (problems experienced due to alcohol—health, financial and any other, drinking context, life goals); beliefs and attitudes (reasons for drinking, alcohol myths, prior alcohol information); interpersonal

relationships (drinking companions, drinking to socialize, relationship status); and social systems (drinking context). This dual function—activating processes while capturing context—addresses a practical challenge in resource-limited settings: the need to gather sufficient information for personalized intervention within time constraints that preclude separate assessment sessions.

In all arms, answering these questions raised awareness, aroused emotions, and prompted self and environmental re-evaluation. In the adapted brief intervention arm, this information additionally provided the interventionists with the patient's context, enabling them to incorporate processes of change tailored to the individual, in the discussion that followed.

2.8.3 The three intervention arms and their TTM components

Each intervention arm operationalized TTM constructs at different levels of intensity, creating a hierarchy from minimal to extended intervention:

2.8.3.1 Feedback on AUDIT-C score (FOA arm)

The patient was educated about what his AUDIT-C score means—that he is either already experiencing harmful consequences of his drinking or is likely to experience them in the future. Patients received alcohol information leaflet (Appendix A) prepared for the study, which included information on harms of alcohol, low-risk drinking, and unit of alcohol. The leaflet carried illustrations to enhance understandability and included a measure showing a unit of alcohol in commonly used alcoholic beverages in Sri Lanka. From a TTM perspective, the FOA arm primarily activates consciousness raising through personalized feedback and educational material.

2.8.3.2 Education of unit of alcohol and low-risk drinking (UOA arm)

The patient was educated about what his AUDIT-C score means, and the research assistant explained what unit of alcohol and low-risk drinking mean using the alcohol information leaflet. This arm extends consciousness raising by adding verbal explanation to written materials, potentially enhancing comprehension and personal relevance.

2.8.3.3 Adapted brief intervention (ABI arm)

The WHO's alcohol BI (102), was adapted using Resnicow's principles of cultural adaptation (168) and FRAMES (Feedback, Responsibility, Advise, Menu, Empathy and Self-efficacy) of WHO (102) (See Chapter 4).

The adaptation process explicitly integrated Resnicow's cultural sensitivity framework (168) with TTM's context of change construct—a theoretical bridge that, to our knowledge, has not been previously articulated in the literature. Resnicow describes two dimensions critical for culturally sensitive interventions: surface structure and deep structure. Resnicow et al. (2000) argue that while surface structure increases the receptivity or acceptance of messages, deep structure conveys salience—the intervention must address the cultural, social, and psychological forces actually influencing the target behaviour. This distinction maps directly onto TTM's context of change construct (186), which specifies precisely these forces: current life situation, beliefs and attitudes, interpersonal relationships, social systems, and enduring personal characteristics.

Surface structure—which includes language, product brands, and location or context of use—was addressed through non-stigmatizing language, culturally modified dialogues drawing on the principal investigator's extensive psychiatric experience with alcohol use disorder patients, and unit of alcohol illustrations depicting locally consumed beverages. Deep structure—which includes beliefs, myths, knowledge, and resistance to paternalistic approaches—was addressed by incorporating alcohol myths identified through the patient information sheet, acknowledging demographic factors associated with drinking patterns, and addressing stigma that emerged from patient responses. The patient information sheet was specifically designed to elicit information across TTM's context of change domains, enabling the ABI to fulfil Resnicow's deep structure requirements.

Resnicow also describes 'cultural competence—the capacity of individuals to exercise interpersonal cultural sensitivity' (242)—when adapting interventions. This concept

relates to interventionist qualities rather than intervention materials, describing how interventionists should incorporate processes of change, decisional balancing, enhancing self-efficacy, and reducing temptations when directing the patient toward change. The principal investigator, who has extensive experience in in-depth conversations with patients and their families, contributed substantially to improving cultural sensitivity of the intervention materials and messages while ensuring cultural competence in the training of research assistants.

The patient had a 20–30-minute discussion with the research assistant using the manual prepared by the principal investigator, tailored to the patient's stated intention: to not do anything about current drinking, to reduce drinking, or to abstain. The discussion in the ABI arm is geared towards enhancing self-efficacy and resisting temptations—the TTM constructs theorized to be most critical in action and maintenance stages, and therefore essential for patients who express readiness to change during the intervention.

2.9 Summary: A Comprehensive TTM-Informed Intervention Design

In summary, the research design operationalizes TTM constructs at multiple levels. The screening and assessment tools (AUDIT-C, Alcohol Knowledge Questionnaire, Alcohol Problems Questionnaire, Family Member Questionnaire) activate experiential processes appropriate for early-stage change. The patient information sheet simultaneously captures context of change domains while continuing to activate processes of change. The intervention arms represent a hierarchy of intensity: FOA provides consciousness raising through feedback; UOA extends this through education; and ABI incorporates the full range of TTM constructs—processes of change, decisional balance, self-efficacy, and temptation reduction—within a culturally adapted framework that addresses both surface and deep structure requirements.

This design addresses several criticisms of previous TTM-informed intervention research. First, by not requiring formal stage assessment, it avoids the measurement problems associated with staging algorithms (219) while retaining the clinical utility of matching interventions to readiness. Second, by integrating Resnicow's cultural adaptation

framework with TTM's context of change, it provides a theoretically grounded approach to cultural adaptation that extends beyond surface modifications. Third, by testing three intervention intensities within a single study, it enables comparison of TTM-informed interventions rather than simply comparing a TTM-informed intervention against treatment as usual. Finally, by designing for an LMIC setting where both modification and cessation are pragmatically necessary goals, it extends TTM application beyond the cessation-focused paradigm that has dominated the model's development and testing.

The discussion chapter (Chapter 7) will examine how the empirical findings of this thesis illuminate both the strengths and limitations of TTM.

Chapter 3: Brief Intervention

3.1 Approach to literature review

This chapter presents a narrative review of the BI literature. A narrative approach was chosen because the aim was to trace the conceptual development of BIs and critically examine debates about their effectiveness and implementation, rather than to estimate a pooled effect. Literature was identified through searches of PubMed, the Cochrane Library. Connected Papers and Google Scholar using combinations of terms including brief intervention, alcohol, primary care, screening, low-and middle-income countries supplemented by citation tracking of key papers and reviews. Searches were conducted between 2022 and 2026. Priority was given to systematic reviews and meta-analyses, Cochrane reviews and large trials, with seminal historical papers included to trace the development of the field. Studies from LMICs were specifically sought, given the focus of this thesis. As a narrative review, no formal quality appraisal or exhaustive screening process was undertaken, and the review is not intended to be comprehensive. Over the past two decades, a substantial body of systematic reviews and meta-analyses have examined BI effectiveness. A review of reviews identified 24 systematic reviews published between 2002 and 2012, which consistently reported BI to be effective for hazardous and harmful drinking in primary care, particularly among middle-aged men, while noting gaps for women, younger and older drinkers, minority ethnic groups, and developing countries (144). Section 3.5.2 focuses on the most comprehensive and recent of these reviews. History of Brief Intervention

Historically, people afflicted with alcohol-related problems were treated inhumanely, institutionalized, and considered as having bad morals (243). They caused considerable harm to those who were around them, the economy, and the society at large. The temperance movement– which promoted teetotalism, prohibition of alcohol marketing, and education of alcohol harms–began in the early 1800s in the United States and became popular in other English-speaking countries (244). This led to the prohibition of alcohol in some countries in the early 1900s, including the United States. Prohibition was later repealed, as it had fuelled the rise of organised crime through an expanding illicit

alcohol market, corrupted law enforcement agencies that proved unable or unwilling to implement the law, and growing recognition during the Great Depression that a legalised alcohol industry could provide much-needed tax revenue and employment (245, 246).

Two physicians from the United States (247) and Great Britain (248) first recognized excessive alcohol consumption as a medical condition. In 1960, Jellinek coined 'the disease concept of alcoholism' (249), which accelerated the medicalization of what had previously been viewed as drunkenness—a moral failing rather than a medical condition. A few years earlier, in 1956, the Board of the American Medical Association passed a resolution urging hospitals to admit patients with alcoholism (246, 250). Even though they were admitted to hospitals, they were treated with disdain and prejudice (251).

Chafetz, who was a newly qualified psychiatrist, commenced work at around the same time in a newly established government-funded alcohol treatment centre at Massachusetts General Hospital in Boston. He recognized his own attitudes towards the patients then labelled 'alcoholics'—'my own ignorance and prejudice'—particularly those from Skid Row (areas of urban destitution) who arrived in crisis, disturbed and disturbing, dragged to the hospital emergency department by the police. They were subsequently referred to the alcohol rehabilitation clinic, but none turned up. He suspected that these alcoholics' non-acceptance of the treatment offered, and complete avoidance of clinic follow-up, could mainly be due to the dismissive, prejudiced, and hostile attitudes of those who were around him, including clinical staff. His team hypothesised that if these alcoholics were treated with optimism and respect, they might accept treatment. In the late 1950s, they created a welcoming environment in the emergency department and considered this visit as the starting point of rehabilitation. They commenced their initial work in the unit, which led to a two-arm RCT with 100 alcoholics in each arm. This intervention included a psychiatrist and a social worker meeting alcoholics at the emergency care visit with understanding, empathy, and attention to their expressed needs. This intervention was expected to increase their presentation to out-patient alcohol treatment (viz., not meant to address their alcohol consumption). The control arm received 'usual care'. As anticipated, the number of alcoholics who presented for initial and follow-up alcohol clinic visits was greater in the

intervention group, compared to care as usual (243). Once he realized that the first trial included only a very socially isolated group of alcoholics, the team conducted a similar RCT, this time with less socially isolated alcoholics. The findings were similar (252). In a subsequent study, the team demonstrated that the caring and concerned tone of the emergency care doctor did matter in the alcoholic's decision to attend the alcohol clinic later (253). These studies, although focused on encouraging the alcoholic to engage in treatment (viz., not on modifying their drinking), are considered as the first to demonstrate the principles of brief interventions (BIs)—immediate, respectful, brief, and empathetic contact to engage the patient (254).

Around the same time as Chafetz's work, the main goal in treatment for alcoholism remained abstinence. But this contention was challenged by Davies' study in 1962, which reported that alcoholics could return to *normal drinking* (as it was called in those days) (255), [although this study was later heavily criticized for its methodological flaws (256)]. Over the next few decades, 'controlled drinking' was also accepted in Australia, Canada, and in some European countries (257-259) as an option for those who did not want to abstain from alcohol. However, controlled drinking was not accepted as a goal in alcohol programmes in the United States (260).

3.2 Brief interventions as treatment for alcoholism

In 1977, Edwards et al. in an RCT demonstrated that both groups of alcoholics seeking help—one that received one counselling session and another receiving several months of inpatient and outpatient treatment—showed similar proportions of improvement at one year (261). This was a very influential study which proved that many with alcohol problems could benefit from cost-effective, brief, and minimal professional input offered in out-patient settings (254).

In 1983, Kristenson et al. randomized men identified as 'heavy drinkers' through elevated gamma-glutamyl transferase levels, to either a counselling group—monthly counselled by a nurse on their repeated gamma-glutamyl transferase levels; or to a control group—informing drinkers about their increased gamma-glutamyl transferase results with

requests to reduce alcohol. Although, gamma-glutamyl transferase levels decreased significantly in both groups, the intervention group showed greater improvement in terms of absenteeism, sick days, and days hospitalized (262).

Around the same period, there were emerging epidemiological findings characterising alcohol consumption and problems as distributed in different degrees of severity across the entire drinking population in a roughly normal distribution, but skewed towards the heavier end (104). These findings, together with the WHO's directives to emphasize the role of primary care in relation to health promotion (263) marked a major shift away from traditional approaches to alcohol treatment, which were resource intensive, to approaches which needed minimal time and resources. Heavier drinkers were the key target population for early intervention to prevent more severe problems later (263). As the first step, the Alcohol Use Disorders Identification Test (AUDIT) was developed in a six-country collaborative project as a reliable screening tool for alcohol problems (264). The second phase commenced in 1985 (265) as a test of the potential usefulness of screening when it is combined with methods of BIs for identified alcoholics. The investigators characterized the existing findings from previous studies on BIs into three dimensions before planning the study.

1. The timing of the intervention in the patient's drinking history: early vs. late, meaning intervening before the onset of more severe alcohol problems
2. Intensity of the intervention: brief vs full—meaning minimal investment of patient and professional resources, but with therapeutic or preventive effect
3. The goal of the intervention: total abstinence vs. moderated drinking or broader changes in lifestyle or mental health

The trial was multi-centre—included hospital settings, primary health care clinics, worksites and educational institutions; and cross-national—Costa Rica, Australia, the United Kingdom, Norway, Mexico, Kenya, Bulgaria, the former Soviet Union, Zimbabwe and the United States of America. The clinical trial included male and female at-risk drinkers and was carried out to determine the influence of simple advice, brief counselling, and extended counselling, on the frequency and quantity of drinking, the moderating role of reduced consumption on the prevention of alcohol related problems,

and to evaluate the cross-national generalizability of BI techniques. Although there was variation in the intervention outcomes, the study concluded that BI received widespread dissemination for use with heavy drinkers in primary care across multiple health care settings and socio-cultural groups. Furthermore, it concluded that five minutes of simple advice was as effective as 20-minute brief counselling for men. However, women showed comparable reductions in drinking even after screening with or without advice (265).

After reviewing many studies on BI, Miller and Sanchez (266), deduced that effective BIs generally focused on raising awareness of the problem and advising change. Consequently, they enumerated six elements commonly included in BIs that had been shown to be effective, summarized by the acronym FRAMES:

Feedback—Of the risks and impairments to instigate change

Responsibility—Drinking is their own responsibility and choice. 'No one can decide for you. What you do about drinking is solely up to you'

Advice—Clear written or verbal advice on how to reduce or stop drinking

Menu—Alternative strategies are given, for the client to choose from

Empathy—Warm, reflective, empathic, and understanding counselling style

Self-efficacy- Emphasizing the client's ability to change and enhance optimism

3.3 What constitutes brief interventions?

Brief interventions are 'short conversations aiming in a non-confrontational way to motivate individuals to think about and/or plan a change in their drinking behaviour in order to reduce their consumption and/or their risk of harm' (102). These interventions are heterogeneous in content, duration of engagement with the client, and the mode of delivery. There are different terms used in place of 'BI'—'brief lifestyle counselling', 'screening and brief intervention', 'screening, brief intervention and referral to treatment, 'identification and brief advice', 'brief motivational interviewing', 'extended brief intervention', 'brief advice', 'brief lifestyle counselling', and 'health behaviour change counselling' (102). Therefore, BI is essentially an umbrella term covering a wide range of interventions included in the broad definition (Figure 3.1).

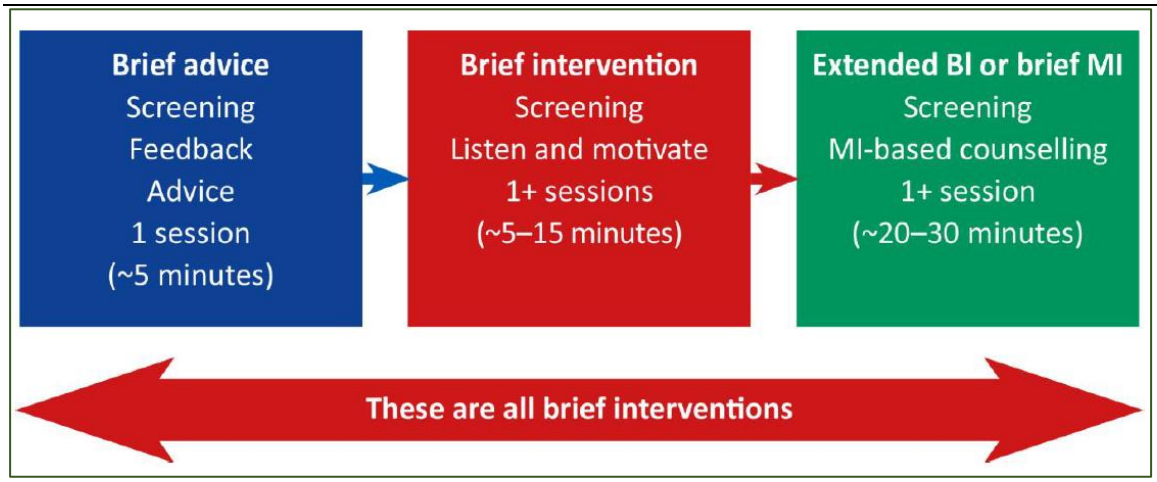

Figure 3-1 A continuum of brief interventions (102)

However, the common goal of all BIs is to identify potential or real alcohol problems and motivate the individual to do something about them, by recommending low-risk patterns of drinking and minimizing associated harmful behaviours. Although the initial focus of BI was as treatment for problem drinking, later it became broadened to include heavy drinkers to prevent them from developing problems later, making it a more preventative approach (254).

The empathic counselling style emphasized in FRAMES was later enhanced by incorporating communication skills from Motivational Interviewing (MI), particularly OARS—Open-ended questions, Affirmations, Reflective Listening, and Summary—to improve the delivery of BIs (267).

3.3.1 The conflation of Motivational Interviewing (MI) and Brief Intervention (BI)

MI and BI are conceptually distinct. MI is a client-centred counselling approach defined by its communication style and spirit (partnership, acceptance, compassion, evocation); BI is defined by its setting, duration, target population, and delivery context. The incorporation of MI techniques such as OARS into BI practice reflects the adoption of effective communication strategies rather than a merging of the two concepts.

The terminological diversity in the BI definition itself demonstrates the conflation problem. The WHO's inclusion of 'brief motivational interviewing' alongside 'brief advice'

treats MI as merely another variant of BI, rather than as a distinct counselling approach that may be incorporated into BI delivery. Systematic reviews have perpetuated this confusion by routinely including MI studies under the BI umbrella (268, 269). Even Platt et al. (139), in an otherwise rigorous meta-regression, groups MI and MI-plus interventions as 'content categories' within brief alcohol interventions—reinforcing rather than challenging the conceptual conflation.

This conflation has two important consequences. First, it may inflate the evidence base for BI—if trials demonstrating effectiveness actually delivered MI rather than BI, the apparent support for BIs may partly reflect the effectiveness of a more intensive approach. Second, it creates confusion about training requirements: MI demands extended training, whereas BI is designed for delivery by non-specialists with minimal preparation. Failing to distinguish between them risks both overstating what BI can achieve and underestimating what its implementation requires.

3.4 Research/ Reviews on BI

3.4.1 Early evidence

Bien et al. (270) reviewed BI literature published up to 1993. The studies they reviewed had two outcomes: either improved referral to specialist care or reduced drinking among high-risk drinkers towards a low-risk pattern of drinking. Eleven out of 12 studies in the former category found significant effects of BI in increasing referral or retention in specialist services. In the latter category, the authors identified 32 controlled trials published between 1977 and 1993, enrolling nearly 6,000 participants. Thirteen of these compared BI with more extended therapies, including cognitive behaviour therapy, marital therapy and standard inpatient/outpatient alcoholism treatment. Few differences were observed between treatments, leading the authors to conclude that BI has an overall impact comparable to that of more extensive counselling, and yields significantly better outcomes than no treatment. The review identified the target group as those with low to moderately severe alcohol problems and emphasized the need for 'immediate' intervention without waiting for scheduled appointments.

The review also pointed out that primary care agents were not confident enough to intervene, had pessimistic expectations of outcomes, and were reluctant to interfere with what they perceived as a voluntary behaviour. The authors elaborated on areas requiring attention in future research: lack of description of the actual intervention; lack of manuals; lack of supervision to evaluate counsellor compliance; lack of information on the characteristics of those delivering interventions; lack of identification of active ingredients of BIs; and lack of understanding of optimal responder characteristics (i.e., age, sex, education, social support, co-morbidity, neuropsychological impairment, and severity of alcohol problems).

3.4.2 Evidence from high-income countries

3.4.2.1 Primary trial using three intensities of BI:

Two trials carried out in the emergency departments and the probation setting using three-step intervention ladder (leaflet, 5-minute brief advice and 20-minute brief lifestyle counselling) for hazardous users found that longer and more intense BIs do not provide additional advantage over screening and simple feedback (271, 272).

3.4.2.2 Systematic reviews and meta-analysis

A comprehensive review on alcohol BIs was published in the Cochrane database of systematic reviews (273). The review included RCTs on BIs—conversations comprised of ≥5 sessions of brief advice or brief lifestyle counselling with a total duration of ≤60 minutes—conducted in general practice or emergency care. It did not include digitally delivered BIs. The review included 69 studies from multiple countries, though the vast majority were from high-income countries (34 from the USA, 10 from the UK, and others from Western Europe and Australia), with only a small number from low- and middle-income countries (LMICs) (Kenya, Brazil, Thailand, and South Africa). It provided moderate-quality evidence that BIs are effective for both men and women in reducing alcohol consumption; and, that there was little evidence of a dose-response effect, either in duration or intensity. Further, it pointed out that the effect sizes tend to diminish when gamma glutamyl transferase levels were taken as the outcome measure over self-

reported outcomes, emphasizing the need to use different means to gauge the effectiveness of BIs. Given the predominance of high-income country data, the review emphasized the need for research in LMICs, among younger people, and also to standardize outcome measures used. The review recommended key areas to focus on:

1. A comprehensive training programme for primary health care staff to enhance their knowledge on drinking guidelines and self confidence in delivering BIs, and in recognizing non-symptomatic risky-drinkers.
2. To enhance skills to recognize and advise at-risk drinkers in the primary health care
3. To provide materials for easy and efficient delivery of BI
4. Engage key stake holders in the implementation process
5. Facilitate research in LMICs on how BI could be used in these areas

Several meta-analyses have been published since the Kaner et al. review, extending the evidence base in important ways. A network meta-analysis by Hennessy and colleagues (274) specifically examined BIs among college students, a population with high rates of heavy episodic drinking. The review, which included studies through April 2016, found that while BIs may be effective in the short-term for reducing problematic alcohol use among this population, their effectiveness beyond three months remains unclear. This finding highlights the challenge of sustaining behaviour change in younger populations and suggests the need for booster sessions or alternative intervention approaches for this demographic.

A more recent network meta-analysis by Beyer et al. (275) directly compared practitioner-delivered and digitally-delivered interventions in non-treatment-seeking hazardous or harmful drinkers. This comprehensive review included 201 randomised controlled trials with 94,753 participants, substantially expanding the evidence base. The analysis found that practitioner-delivered interventions reduced alcohol consumption more than digitally-delivered interventions at one month (-23 g/week) and six months (-14 g/week). However, at 12 months, there was no evidence of a difference between delivery modalities (-6 g of alcohol/week, 95% CI: -24g to 12g), suggesting that while face-to-face delivery produces faster results, digital interventions may achieve comparable outcomes

over the longer term. This has important implications for implementation in resource-limited settings where practitioner time may be constrained.

Additionally, Sohi et al. (276) updated a 2017 review examining digital interventions for reducing alcohol use in the general population. The updated systematic search identified RCTs published from January 2017 to June 2022, finding continued support for digital interventions compared to no intervention or minimal interventions. The review noted ongoing heterogeneity in intervention characteristics and outcome measures, echoing concerns raised in earlier reviews about standardisation.

3.4.2.3 . Recent primary studies

A notable trial published in 2023 after the above meta-analysis is worth mentioning. Scott et al. (277) examined whether adding recovery management checkups to standard screening, BI, and referral to treatment (SBIRT) in primary care centres improved outcomes. At 12-month follow-up, participants receiving the additional checkups were significantly more likely to report any substance use disorder treatment, more days of treatment, more days of abstinence, and fewer days of alcohol and cannabis use compared to SBIRT alone (Scott, Dennis et al. 2023). This finding suggests that the "single dose" model of BI may be enhanced by systematic follow-up contacts, consistent with chronic disease management principles.

3.4.3 Evidence from Low-and Middle-Income Countries

3.4.3.1 Studies from LMICs

Relatively few studies have been conducted in LMICs. A mixed method study carried out in South Africa evaluated the implementation SBIRT for risky substance use. Sixty-eight percent of the eligible participants used only alcohol. They evaluated the implementation outcomes according to feasibility, acceptability, adoption and appropriateness in an emergency centre setting. They concluded that SBIRT implementation and adoption were largely successful and recommended engaging stakeholders early to improve implementation readiness and programme compatibility in the emergency setting (277).

An RCT conducted in India (142) to determine the sustained effectiveness and cost-effectiveness of a BI counselling for alcohol problems, delivered by lay-counsellors, to males with harmful drinking, in primary care concluded that BI was significantly effective compared to usual care in maintaining remission at 12 months, and the health care cost incurred was offset over 12 months.

To determine the feasibility of BI delivered through text messaging as a way of overcoming human resource limitations, Nadkarni et al. completed a three-arm pilot RCT in India. The results of the pilot were encouraging—feasible and showing preliminary impact on alcohol consumption—as a potentially scalable first-line response to hazardous drinking in low-resource settings (278).

A systematic review and meta-analysis described patient-level alcohol interventions conducted in LMICs. It concluded that BIs were the most evaluated and had the most consistent positive effect on alcohol-related outcomes. (133). However, all six studies which used BI were conducted in South Africa.

3.4.3.2 Implementation considerations for LMICs

Nadkarni et al (138), in a review on barriers to implement BIs, pointed out the urgent need to look for cost-effective measures to reduce alcohol exposure in LMICs, considering the projected increase in harmful alcohol use in this region. Taking examples from Latin America and India, the review highlights the importance of implementation of BIs in primary health care and community settings to overcome barriers of lack of financial and structural resources together with lack of specialized staff in LMICs and proposes that it is important to use non-specialist health workers, including lay counsellors.

3.5 Critiques of BI/ Challenges of BI

Despite the evidence supporting BIs, significant critiques have emerged regarding their methodology, implementation, and applicability in contemporary contexts.

3.5.1 Methodological Challenges

The definition of BI itself allows for enormous heterogeneity. BIs described in the existing literature vary greatly: from opportunistic conversations on alcohol ranging from just asking about one's alcohol consumption to multiple sessions of counselling (279), and in total time spent: less than five minutes to about 135 minutes (139). This heterogeneity makes it almost impossible to compare between trials (254). The authors point out that lack of clear documentation regarding what exact intervention was delivered, the focus on efficacy rather than effectiveness (although this distinction is contested; See Section 3.5.4), and the absence of consensus on core components have hampered both replication and implementation.

Another challenge concerns the interpretation of trials claiming BI effectiveness for problem drinking. These trials have typically relied on self-reported consumption, which may inflate positive outcomes through social desirability bias—a claim supported by the absence of demonstrable effects on other outcomes such as injuries or use of acute health care (127).

3.5.2 Questions about mechanisms and tailoring

Beyond methodological concerns, fundamental questions remain about how BIs work and for whom they are most appropriate. McCambridge and Saitz (127) raise a critical question: is it the content of BIs or the counselling micro-skills that lead to improved outcomes? If the micro-skills—essentially MI techniques—are the active ingredient, this has major implications for training and implementation that the literature has largely failed to address. It also underscores the need to disentangle BI as an intervention framework from MI as a communication approach, rather than treating them as interchangeable, as discussed in Section 3.3.1.

Further, the authors point out that, though 'stepped care'—where treatment starts with the least intensive intervention likely to be effective, then steps up to more intensive treatments for those who do not respond adequately (280)—is recommended, there is no evidence to identify *a priori* which patients require which intensity of intervention. The Screening and Intervention Programme for Sensible drinking (SIPS) trial illustrates the broader uncertainty here: this pragmatic cluster RCT found no overall benefit of more intensive interventions (brief advice or brief lifestyle counselling) over a simple patient information leaflet (281). The authors suggested that stepped care might still be appropriate—reserving extended intervention for non-responders or those who request additional support—but this presupposes a capacity to identify such patients that the evidence base has not yet established.

3.5.3 Contemporary contextual challenges

Broader contextual and societal factors also challenge the effectiveness and implementation of BIs in the 21st century. McCambridge (46) draws attention to reducing effect sizes in trials, probably due to less publication bias towards negative outcomes and also to the 'alcogenic' environment of the 21st century—the emerging global trends of enhanced personal freedom over societal benefits, together with unregulated promotion and normalization of alcohol by alcohol industry. Rather than abandoning BIs altogether, McCambridge emphasizes the need to connect conversations about alcohol with existing health problems of the individual—rather than relying on universal screening. As Andreasson (282) argues, practitioners need 'smarter ways to initiate discussions about alcohol use' that are 'more related to clinical relevance and patient concerns, recognising that alcohol use contributes to much of the morbidity encountered in primary care'—but 'the right response is not to throw out the baby with the bathwater'.

Summarizing the 2019 INEBRIA (the international network for BI researchers) Nick Heather lecture, McCambridge (46), elaborates on several challenges facing BI in the 21st century. First, recommended forms of screening and BI are unappealing to key practitioner groups since they pay little or no attention to tailoring to individual concerns. Second, there remains a lack of understanding of mechanisms and mediators of

change—how BIs work, and for whom, particularly in terms of the level of drinking or extent of problems that might reasonably be expected to be amenable to such interventions. Third, existing BI strategies fail to address the global trend of normalising alcohol use, cultural aspects of alcohol, and social context in individual decision-making about alcohol use. Fourth, BI research has failed to incorporate other life domains of the drinker—family, work, environment, consumption and leisure—that would enable better control of drinking and overall health. Finally, McCambridge emphasises the importance of moving beyond binary thinking towards a continuum of severity of alcohol problems.

Stewart et al (45), voice similar concerns: that BI research has failed to address the changing landscape of alcohol; that current approaches promote an unhealthy dichotomy discouraging individuals from engaging in BI; and that there has been a failure to tailor BI to the individual.

3.5.4 Implementation challenges

Beyond questions of whether BIs work under trial conditions, a distinct set of challenges emerges when attempting to implement BIs within routine healthcare systems. The gap between the evidence base and routine delivery in real-world practice represents a fundamental barrier to realising the public health potential of BIs. One possible contributor to this gap is the trials themselves: when trials that test efficacy (effects under ideal, controlled conditions), rather than effectiveness (effects under routine practice conditions) may produce results that do not translate into practice. However, the extent to which BI trials reflect efficacy rather than effectiveness is widely debated. A Cochrane review of BI in general practice and primary care found no evidence of a difference in patients' drinking outcomes between efficacy and effectiveness trials, concluding that the literature is relevant to routine primary care (283). However, Heather later argued that the classification tool used in this review was not psychometrically tested; and measured clinical representativeness rather than the efficacy–effectiveness distinction itself (284). Moreover, none of the trials in the 2007 review were conducted in developing countries (283), and the 2018 update still drew mainly on high-income

settings, with no trials from South Asia (273). The question therefore remains unresolved, and evidence from low-income countries is still scarce.

A large-scale implementation trial in the United States demonstrates yet another challenge. Lee and colleagues conducted a stepped-wedge cluster randomised implementation trial across 22 primary care practices, involving over 333,000 patients. Critically, this was not a trial testing whether BIs reduce drinking *per se*; rather, it examined whether a multicomponent implementation strategy could increase the delivery of alcohol-related care in routine practice. The implementation intervention comprised three components: practice facilitation (external support to help clinics change their workflows), electronic health record prompts and decision support tools, and performance feedback to clinicians (Lee, Bobb et al. 2023).

The results revealed a stark pattern. The intervention dramatically increased alcohol screening rates, from 20.8% to 83.2% of patients. It also produced modest increases in brief preventive counselling (i.e., BI), new diagnoses of alcohol use disorders, and treatment initiation. However, the intervention did not increase patient engagement in ongoing alcohol treatment compared to usual care. In other words, while the implementation strategy successfully got clinicians to screen and briefly counsel patients, it failed to translate these activities into sustained behaviour change or treatment uptake at the patient level.

This finding has significant implications for the field. It suggests that even with substantial system-level supports—electronic prompts, dedicated facilitation, and feedback mechanisms—the pathway from screening and BI to meaningful treatment engagement remains problematic. The challenge may not be simply one of getting clinicians to deliver BIs, but of ensuring that those interventions lead to sustained patient outcomes. This echoes concerns raised in the methodological literature about the “single dose” model of BI and whether one-off conversations can produce lasting change without systematic follow-up.

These implementation challenges are compounded in low-resource settings. If well-resourced health systems with integrated electronic records and dedicated practice facilitators struggle to translate BIs into sustained outcomes, the barriers facing healthcare systems in LMICs are likely to be substantially greater. Staff shortages, competing clinical priorities, lack of referral pathways for patients requiring more intensive treatment, and absence of system-level supports for quality improvement all present additional obstacles. Understanding and addressing these implementation barriers is essential if the evidence base for BIs is to translate into population-level reductions in alcohol-related harm.

Despite the above-mentioned challenges, BI has shown effectiveness in reducing alcohol consumption in drinkers in various settings as discussed above. Its need for relatively low resources is appealing in Sri Lankan settings, as will be discussed in subsequent sections

3.5.5 Resource implications

Resource implications are central to whether BIs can be implemented at scale. A systematic review of economic evaluations concluded that screening and BI in primary care is cost-effective, but almost all included studies were from high-income countries, with a paucity of evidence for LMICs (285). The review also noted that delivery by nursing staff may reduce overall budget impact without impacting on the outcome. In LMICs, the existing evidence is encouraging: in India, a BI delivered by lay counsellors was cost-effective, with healthcare costs offset within 12 months (142).

At the population level, an updated global cost-effectiveness analysis, conducted to inform the revision of the WHO ‘best buys’, found pricing policies and restrictions on alcohol availability and marketing to be more cost-effective than brief psychosocial interventions, although the latter remained favourable in low-income settings (286). BIs are therefore best positioned as a complement to, rather than a substitute for, population-level alcohol policies, and their sustainability in LMICs depends on delivery models that make use of existing staff and infrastructure.

3.6 Rationale for Brief Interventions in Sri Lanka

As has been discussed in Chapter 1, a large proportion of Sri Lankans are lifetime abstainers (49), and those who drink, do so in a harmful manner, and heavy episodic drinking (HED) is prevalent. This pattern accounts for a greater share of population-level harm than that caused by dependent drinkers alone—a phenomenon known as the 'prevention paradox' (287), and contributes to alcohol-harm paradox (288). Ninety percent of alcohol consumption in Sri Lanka comes from spirits (23). Spirit-dominant consumption is causally linked to HED patterns: the high ethanol concentration of spirits facilitates rapid intoxication, and cross-national evidence consistently shows that spirit-drinking cultures are characterised by non-daily drinking with irregular HED episodes, in contrast to the daily moderate consumption typical of wine-drinking cultures (289, 290).

BIs, as discussed in section 3.4 above, have been proven effective for hazardous and harmful patterns of consumption—the predominant patterns in Sri Lanka. They have been shown to be effective in LMICs, require relatively little training, and are cost effective in resource limited setting (138).

Sri Lanka's healthcare infrastructure provides a favourable context for BI implementation. The country has a government-run outpatient department in each hospital, which delivers primary health care, free of charge. These facilities receive approximately 55 million visits annually for a population of 22 million (3), representing the primary target setting for BI delivery.

Given the epidemiological profile of alcohol use—high abstinence rates but harmful consumption patterns among drinkers—combined with the accessible primary care infrastructure, BIs represent an appropriate and feasible strategy for addressing alcohol-related harm in Sri Lankan primary healthcare, complementing alcohol polices.

3.7 Aims of the current thesis

Sri Lanka does not currently use BIs in routine clinical care, and the prevailing approach to individuals with alcohol problems is paternalistic, which has been shown to deter treatment-seeking behaviour (291). The first step in implementing BI is cultural adaptation, since culture plays a major role in the acceptability of behavioural interventions (168). This thesis aimed to adapt the WHO's alcohol BI (102) for delivery by non-specialist interventionists and to pilot test it while examining the acceptability of interventions of varying intensity, using a nested design (Figure 3.2).

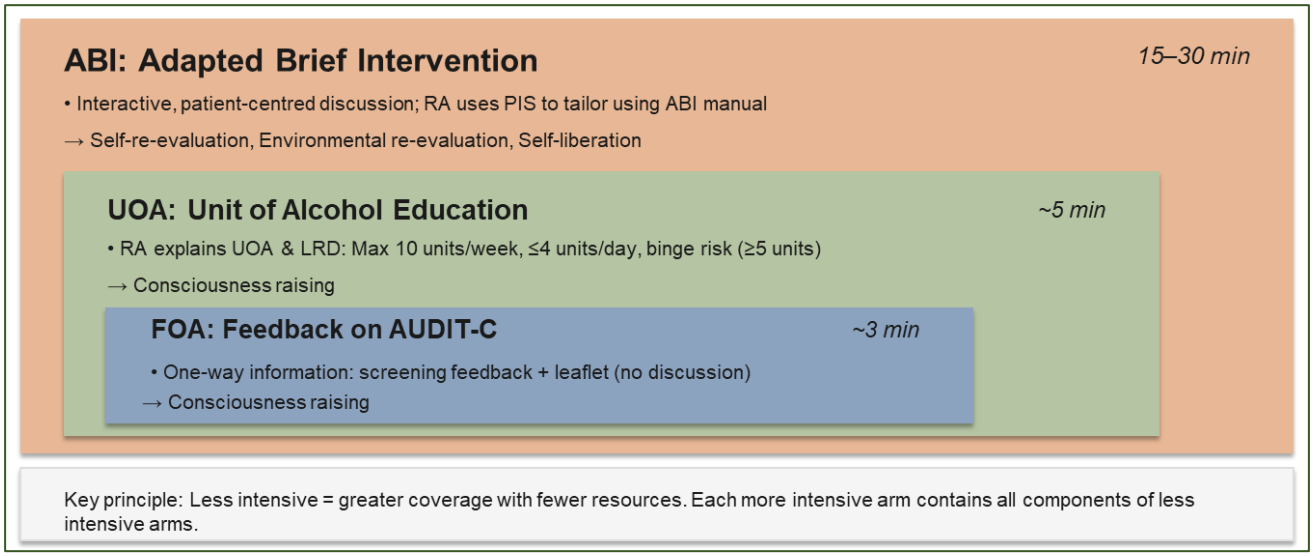

Figure 3-2 Three-arm nested design of brief interventions

The research proceeded in stages. The adapted intervention was first pilot tested in inpatient setting (See Chapter 4), where follow-up was more reliable and the intervention could be refined before deployment in busier outpatient settings. A prevalence study was then conducted to establish the burden of risky drinking among outpatients (See Chapter 5)—since no past data existed. The intervention was subsequently pilot tested in the outpatient department (See Chapter 6) and thesis overall outcomes evaluated in Chapter 7.

The adaptation process aimed to contextualize and tailor BIs to the individual—an area frequently critiqued in the literature—using the transtheoretical model of behaviour

change (See Chapter 2 and 7). Additionally, this thesis sought to examine BIs through a broader harm reduction lens, recognising that alcohol is the most harmful substance to others (1)—not only reduction of alcohol consumption—an approach adopted in this research but rarely employed in BI research.

Together, these chapters represent the first systematic attempt to develop, culturally adapt, and pilot test BIs for alcohol use within Sri Lankan primary healthcare settings.

Chapter 4: Feasibility and Acceptability of an Adapted WHO Alcohol Brief Intervention: Pilot of a Three-armed Randomized Trial in Sri Lanka

Preamble

Chapter 3 provided a comprehensive review of the evidence on alcohol brief interventions, highlighting their effectiveness in reducing risky drinking while also identifying key gaps in the literature—particularly the limited evidence from low- and middle-income settings, the need for cultural adaptation, and the absence of family-centred outcome measures. This chapter addresses these gaps—by adapting the WHO alcohol brief intervention for the Sri Lankan context, testing the feasibility and acceptability of delivering this culturally adapted intervention through non-specialist personnel in an inpatient hospital setting; while also evaluating the appropriateness of methodology and outcome measures for a future definitive RCT. Importantly, this pilot incorporated an innovative approach of assessing outcomes from family members' perspectives alongside patient outcomes. The findings from this chapter informed the subsequent refinement of the intervention and the selection of a more appropriate study setting, which is described in Chapter 6. Further, the tools used in the study are described in Table 4.1 and in Chapter 6; and the development of the alcohol knowledge questionnaire is detailed in the Chapter 5

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Author contribution: Dewasmika Ariyasinghe (DA) designed the study and Cathy Banwell (CB), Buddhima Lokuge (BL), Thilini Rajapakse (TR), Grace Joshy (GJ) and Kamalini Lokuge (KL) suggested improvements. DA drafted the manuscript and CB, BL, TR, GJ, SC and KL revised and made improvements.

P.S. Some sections and text were later added to the revised thesis following examiners' comments.

4.1 Introduction

Alcohol is ranked as the most harmful substance of abuse when combining harms to self and others, and the third most harmful substance to users (1). Users experience higher rates of malignancies, infections, metabolic syndrome, injuries, cognitive deficits, and poverty. Non-users are also affected by injuries, crimes, family adversities, and poverty to mention a few. Most alcohol-related harms are attributed to heavy episodic consumption, not to alcohol dependence (12).

Sri Lanka faces significant challenges with risky drinking (RD)—drinking at levels or in patterns that increase the risk of alcohol-related harms (154). Heavy episodic drinking affects 9% of those ≥15 years and 32% of drinkers, despite approximately half the population being lifetime abstainers. Ninety percent of drinkers consume spirits (23). Local research reveals the impact of alcohol misuse in depression among drinkers' spouses (59), domestic violence (61), suicide (57, 292), economic costs (68), accidents (54, 55), and child abuse (65).

Despite this high prevalence of RD and adverse consequences on the individual and the society, Sri Lanka lacks an effective behavioural intervention for opportunistic use with risky drinkers that is feasible for widespread implementation.

4.1.1 What are Brief Interventions?

The WHO endorses brief interventions (BIs) for harmful and hazardous alcohol use. BIs use non-confrontational conversations to motivate individuals to contemplate changing their drinking and related behaviours. BIs emphasize patient autonomy, patient-centred collaboration, and treating behaviour change as a process, not an event (102).

4.1.2 What is the importance of this pilot RCT?

Client-informed decision making facilitates change (293). Conversely, paternalistic approaches and abstinence demand—both common in Sri Lanka—deter behavioural change (279), highlighting the need for BI-centred approaches.

Opportunistic interventions—delivered to individuals not seeking alcohol-related help—enhance efficiency (291) but require numerous trained individuals. Given the limited availability of specialists, training non-health staff to deliver these interventions is essential if such interventions are to be accessible to all those in need. Several studies demonstrate that non-health staff can effectively deliver interventions after proper training to address RD in a range of settings, which also promotes better client engagement due to reduced stigma (140, 141).

Cultural adaptation is necessary given variation in drinking habits and cultural values, and it improves acceptability and effectiveness (108, 168). While unstructured unadapted BIs were previously used in Sri Lanka (92), culturally adapted structured interventions are needed, especially when implemented by non-specialist or non-health staff.

Previous research on BIs reveals several deficiencies: demonstrating efficacy rather than effectiveness; susceptibility to the Hawthorn effect (294)—the behavioural change due to an awareness of being observed or positive response to the intervention; over-reliance on self-reports; inadequately evaluated content (127); and limited evidence from lower-income settings (133, 295). Furthermore, studies typically measure effectiveness solely through consumption changes, overlooking improvements in family environment—important aspects in harm reduction. Addressing these requires widening inclusion criteria, using non-specialist interventionists (296), incorporating family perspectives as outcome measures, and developing structured, culturally adapted manuals.

WHO's BI manual encourages use of decisional balancing—exploring the pros and cons of continuing versus stopping or reducing alcohol consumption—in client-centred

discussions, an important construct in the transtheoretical model (102, 297). However, eliciting this information can be time-consuming, and non-specialists may struggle with raising such sensitive issues (140). BIs take about 25 minutes to administer (273). In resource-limited settings like Sri Lanka, this could significantly impact efficient implementation. Therefore, two less resource-intensive interventions were included with hierarchical structure: 'Feedback on AUDIT-C' (FOA) and 'Unit of Alcohol education' (UOA). FOA was the foundational component and was included within UOA, while UOA was a subcomponent of the ABI. If proven effective in future RCTs, these less resource intense interventions would be particularly valuable.

4.1.3 Adverse childhood experiences and knowledge of alcohol related harms as potential effect modifiers

Adverse childhood experiences increase the risk of alcohol use disorders through neurobiological (94) and permanent neuro-hormonal changes (95) and may affect intervention outcomes (298). Poor knowledge of alcohol harms and low-risk drinking (LRD) predicts RD (108), and knowledge reduces long-term harms (299, 300). However, evidence on how prior knowledge affects BI effectiveness is lacking (301). Determining whether these factors modify intervention effects is important for targeting and adaptation.

4.1.4 Study objectives

1) Adapt WHO alcohol BI for delivery by non-specialists in Sri Lanka.
2) Assess feasibility and acceptability of a) the adapted BI (ABI), b) targeted educational material (unit of alcohol education- UOA) and c) giving feedback on screening (FOA).
3) Evaluate methodology for a future RCT by (a) assessing the appropriateness of the study design and setting, (b) determine the appropriateness of outcome measures in both patient and family member perspectives, and (c) explore the feasibility of measuring adverse childhood experiences and alcohol knowledge to assess effect modification.

4.2 Methods

4.2.1 Phase 1: Adapting the BI

Cultural sensitivity is a key principle in public health (168). The Primary Investigator (PI) adapted the BI using Resnicow's cultural adaptation principles, focusing on surface and

deep structures (168), while preserving the OARS framework (Open-ended questions, Affirmations, Reflections, Summaries) of WHO (102), with enhanced contextualization (302). Five psychiatric specialists experienced in alcohol-related issues (two local, one Australia-based, and two former local specialists now working in Australia) provided written and online feedback through multiple refinement cycles .

4.2.2 Phase 2: Pilot RCT

4.2.2.1 Context

The study was conducted at Teaching Hospital Peradeniya (THP), a tertiary care centre in central Sri Lanka, which provides free health care to patients from diverse socioeconomic backgrounds. All male wards in the hospital were selected to recruit participants.

4.2.2.2 Participants and eligibility

Due to the marked gender differences in alcohol use disorders (AUD) prevalence in Sri Lanka (males 5.9%, females 0.7%) (303), only males were recruited.

Inclusion criteria:

1. Adult male inpatients from medical, neurology, surgical, orthopaedic, and toxicology wards
2. Risky drinkers - AUDIT-C score ≥5 (102) - Validated Sinhala AUDIT-C (129) was updated per recent guidelines (293).

Exclusion criteria:

1. Serious illness (Patients requiring high-dependency care, being clinically unstable, or having impaired consciousness or delirium that precluded informed consent or participation. Eligibility was confirmed with the treating medical officer)
2. Current AUD therapy or electing to access specialised care
3. Inability to communicate in the language the research assistants were conversant with (Sinhala)

4.2.2.3 Study design and procedure

A three-arm parallel group pilot study design included ABI, UOA and FOA arms (section 4.2.3). Consecutive sampling was used: all eligible male inpatients received study information; consenting patients completed screening. Eligible patients consented to

participation and family member contact (spouse, adult sibling, parent, or adult child). Family member consent was also sought. Participants and family members were reimbursed Rs. 2500 (~7.25 USD) per assessment for transport costs and their time to participate (304).

The five wards were divided by proximity into two study units, each with four research assistants (Figure 4.1). Screening RAs recorded eligible patients, then different RAs randomized those who consented using an ABC, BCA, CAB pattern in each unit. During real-world implementation, the same practitioner would likely complete screening and intervention delivery, utilizing any rapport developed during screening. However, only RAs allocated to the ABI arm were trained in ABI to prevent contamination—ensuring non-ABI RAs couldn't use ABI skills in their respective arms. Consequently, this approach, where the same RA delivers screening and intervention was only feasible for the ABI arm (Figure 4.1).

The four-week follow-up assessment used RA swapping between units to facilitate unbiased outcome assessment. Initial assessment blinding was impossible due to the nature of the intervention.

4.2.2.4 Sample Size

Data collection continued until each arm reached 15 patients.

4.2.2.5 Ethics

This study received ethics approval from the Ethics Review Committees of both the Faculty of Medicine, University of Peradeniya, Sri Lanka (2022/EC/56) and the Australian National University, Australia (2022/779). The trial was registered in Sri Lanka Clinical Trials Registry (SLCTR/2022/030). All participants provided informed written consent prior to enrolment. Participation or non-participation in the study had no influence on the healthcare services patients received from the hospital.

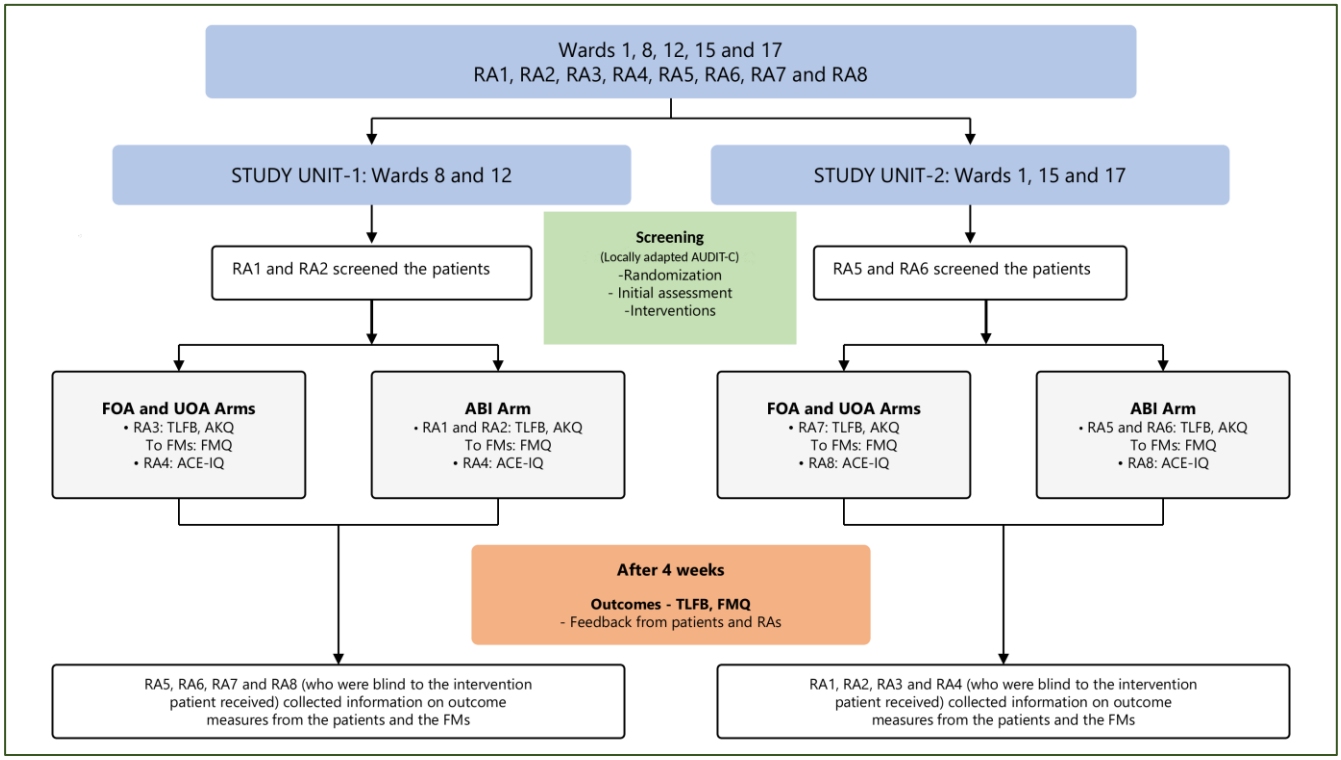

Figure 4-1 Allocation of research assistants, measures used and randomization in the two study units

(RA- research assistant, FMs- family members, FOA- Feedback on AUDIT-C, UOA- unit of alcohol, ABI- adapted brief intervention, AUDIT-C: Alcohol Use Disorders Identification Test-C, TLFB- Timeline Follow Back, AKQ-Alcohol Knowledge Questionnaire, FMQ-Family Member questionnaire, ACE-IQ-Adverse Childhood Experiences- International Questionnaire)

4.2.3 Interventions

4.2.3.1 FOA

RAs informed the patient about his AUDIT-C score meaning i.e. their consumption is likely to have caused problems already or is likely to cause problems in future. The alcohol leaflet, prepared for ABI, was then given to them. This involved the provision of only one-way information by the RA, with no interactive discussion with the patient.

4.2.3.2 UOA

In addition to all components of FOA, these patients received brief education from the RA on UOA and LRD (i.e.: maximum 2 units/day, activities to avoid after drinking, risks of HED ≥5 units/ occasion). There was no interactive discussion.

4.2.3.3 ABI

In addition to all components of UOA, RAs used the ABI manual and 'patient information sheet (PIS)' (section 4.3.1) to engage the patient in a discussion. This included a two-week text reminder as well.

4.2.4 Outcome measures

The study measured three main outcomes: (i) Feasibility and acceptability of the ABI, UOA and FOA, (ii) feasibility of the methodology, appropriateness of measures of intervention outcomes and (iii) feasibility of measuring effect modifiers. See columns 2 and 3 of Table 4.1.

4.2.4.1 Feasibility and acceptability of the interventions

For each arm, intervention duration was recorded by direct observation, and retention was assessed as attendance of patients and family members at the four-week follow-up. Acceptability of the ABI was assessed using a patient feedback questionnaire modified from a previously used questionnaire (305). It covered satisfaction with ABI content, setting, duration, RA qualities and perceived effectiveness, rated on a 5-point scale (completely disagree to agree completely), with two open-ended questions for suggestions and comments. RAs delivering the ABI completed an anonymous feedback questionnaire, modified from an intervention facilitator feedback tool (306), using the same scale. It assessed their perceptions of patient reception, adequacy of training, confidence in delivery, intervention duration and ABI components, again with two open-ended questions. Acceptability of the UOA and FOA was not assessed directly.

4.2.4.2 Feasibility of the methodology and appropriateness of outcome measures

Feasibility of the methodology was assessed using screening and consent records (patient and family member recruitment rates), attendance tracking (patient and family member follow-up rates), and the setting-related factors of time taken to recruit patients and abstinence rates at each assessment.

Two candidate measures of intervention outcome were evaluated for time taken to complete and comprehensibility, based on RA feedback. Alcohol consumption was measured with the Timeline Follow Back (TLFB), which retrospectively assesses drinking over periods of up to 12 months (307); this study used it for the 28 days preceding each assessment. Impact on family members was measured with the Family Member Questionnaire (FMQ), a 30-item interviewer-administered measure of the social, emotional, physical and financial effects of the patient's drinking on family members, together with their coping and support, rated on a 4-point scale (0 = never to 3 = often) (165) (Appendix C). Intervention effectiveness was defined as a reduction in "total family burden", combining the impact, symptom, emotional coping and tolerant-inactive coping domains. The FMQ was translated into Sinhala, back-translated and corrected.

4.2.4.3 Feasibility of measuring effect modifiers

Two potential effect modifiers were measured [at the initial assessment], and their comprehensibility and administration time were recorded. The Alcohol Knowledge Questionnaire (AKQ), developed by the PI and administered by RAs, assessed basic alcohol knowledge, including 13 alcohol-related harms from the WHO ABI manual (102) and awareness of UOA and LRD. Adverse childhood experiences were assessed with the translated and validated Sinhala version of the WHO Adverse Childhood Experiences International Questionnaire (ACE-IQ) (97).

4.2.5 Selection, training, allocation and supervision of research assistants

Eight RAs were selected through interviews, focusing especially on their communication skills. Communication skills were assessed at two stages. First, at the selection interview, conducted in Sinhala by a panel of the PI and a second psychiatrist, each applicant was given a case scenario and asked to convey specified information in Sinhala, allowing the panel to judge clarity, empathy and the ability to explain information in lay terms. Second, during the ten-day training, the PI observed the RAs' performance in role-plays, and the four judged strongest were allocated to ABI delivery.

None had substantial training/ work experience as health staff; some had done short counselling internships. The ten-day training by the PI included lectures, role-plays and hands-on sessions covering study purpose, basic alcohol knowledge, UOA and LRD concepts, alcohol-related societal harms and mental illness, research ethics, consent, and administering the study measures (Appendix D). Post-training, four RAs with better communication skills—a quality sought in previous non-specialist BI studies (141) - received ABI training and were assigned to ABI delivery, two RAs to FOA and UOA to minimize contamination, and two RAs to adverse childhood questionnaire administration. RAs handled screening, consent, randomization, data collection, and intervention delivery. The PI made regular visits to the wards to ensure RAs followed the study protocol and to help with any difficulties they faced. The PI also held weekly meetings with the RAs to discuss issues, and RAs could contact the PI by phone anytime.

Table 4-1 Summary of objectives, methods and results

Objectives	Construct	Methods	Results
Assess the feasibility and acceptability of			
a) the adapted BI (ABI)	Duration	Direct observation	15-30 minutes
	Retention	Follow-up attendance	Patient 70.6% (12/15), FM-85.7% (6/7)
	Acceptability	*Patient feedback questionnaire:* Modified from a previously used questionnaire (305), this assessed satisfaction with ABI content, setting, duration, RA qualities and perceived effectiveness, on a 5-point scale (Completely disagree, disagree, undecided, agree, agree completely), with two open-ended questions for suggestions and comments.	-10 patients completed the feedback questionnaire-Feedback was overwhelmingly positive. -All patients identified the ABI manual-guided discussion as the most helpful component over the leaflet and text reminding of their plan -Patients' suggestions for improvement - community implementation ('we have so many in our neighbourhood, who would benefit from this'), more frequent interactions ('we wish we had several meetings'). Several had commented 'I often think of this [the ABI] when I think of a drink'.
		RA feedback questionnaire: Modified from an intervention facilitator feedback tool (306), the questionnaire used the same 5-point scale, to assess RA perceptions of patient reception, training adequacy, delivery confidence, intervention duration and ABI components, with two open-ended questions for suggestions and comments. The feedback was given anonymously.	– Feedback was overwhelmingly positive in all components assessed with recommendations for a separate space to minimize disturbance by ward activities -Further, the information gathered from patient information sheet (PIS) had greatly facilitated the initial engagement with the patient.
b) targeted educational material (UOA)	Duration	Direct observation	~5 minutes

	Retention	Follow-up attendance	Patient 40% (6/15), FM – 50% (1/2)
	Acceptability	Not assessed	-
c) Feedback on AUDIT-C (FOA).	Duration	Direct observation	~3 minutes
	Retention	Follow-up attendance	Patient 68.8% (11/16), FM – 66.7% (4/6)
	Acceptability	Not assessed directly	Follow-up rates are encouraging
Explore the appropriateness of *a) Methodology*	Patient recruitment rate FM recruitment rate	Screening records Consent records	25.3% (48/190) 45.4% (15/33)
	Patient follow-up rate	Attendance tracking	60% (29/48)
	FM follow-up rate	Attendance tracking	73% (11/15)
	Setting	-Time taken for recruitment of patients -Abstinence rates	- Data collection was completed in nine days - 38% (17/45) were abstinent at the initial assessment -76% (22/29) were abstinent at follow-up
		-Family member recruitment rate	-It was hard to meet the family members due to incompatibility of hospital visiting hours and RA working hours

b) Outcome measures	Time taken to complete and comprehensibility	*Timeline Follow Back (TLFB):* Retrospectively assesses alcohol consumption over periods up to 12 months (307). This study used TLFB to estimate consumption in the 28 days preceding each assessment.	RAs feedback - Daily drinkers completed assessment quickly (~2 minutes) with accurate recall, while non-daily drinkers struggled significantly (up to 10 minutes) with poor consumption recall.
		Family Member Questionnaire (FMQ): Interviewer-administered 30-item assessment measuring social, emotional, physical, and financial impacts of patient drinking on family members, coping strategies and support, using a 4-point scale (0='Never', 1='Once or twice', 2='Sometimes', 3='Often'). Intervention effectiveness determined by reduced 'Total family burden' combining impact domains, symptoms, emotional coping, and tolerant inactive coping (165) (Appendix C). Questionnaire was translated into Sinhala, back-translated, and corrected.	RAs feedback -Family members understood the questionnaire well. Administration took 10-15 minutes. Several expressed relief for getting an opportunity to discuss their concerns and requested healthcare referrals. 'Total family burden' appeared to be high, but no statistical analysis was done.
c) Evaluate the feasibility of measuring adverse childhood events and alcohol knowledge as potential effect modifiers.		*Alcohol Knowledge Questionnaire (AKQ):* Developed by the PI the questionnaire assessed patients' basic alcohol knowledge, including 13 alcohol-related harms from the WHO ABI manual (102) and awareness of UOA and LRD. RAs administered the questionnaire	-Well-comprehended; administration took ~10 minutes. -Only 23.4% and 12.8% reported awareness of UOA and LRD respectively, though accuracy of their knowledge wasn't verified. While 90% recognized accident risk and 62% knew about weight gain, knowledge of other alcohol harms was below 38% each.
		Adverse Childhood Experiences: International Questionnaire (ACE-IQ): The translated and validated version of the WHO questionnaire (97) was used.	-Well-comprehended -Took ~ 20-30 minutes to complete. - 95.7% (45/47) reported at least one childhood adversity -Most common: community violence (78.7%), emotional abuse (72.3%), emotional neglect (70.2%). - Physical abuse affected 44.7%; sexual abuse, bullying and domestic violence each affected approximately 19%. (Table 4.2).

4.2.6 Analysis

Quantitative outcomes for each objective are defined in Table 4.1. Descriptive statistics (frequencies, percentages, means and standard deviations) were calculated using Stata/MP 17.0; age was compared between risky and non-risky drinkers using an independent-samples t-test. Qualitative data came from the patient information sheet and from the open-ended questions on the patient and RA feedback questionnaires, which included 5-point Likert items. Further analysis was not done due to the pilot nature of the study

4.3 Results

4.3.1 Final adapted brief intervention

The final ABI included an illustrated leaflet with information on alcohol and LRD, patient information sheet–PIS, and a manual. Initiating discussion on alcohol and acquiring information to tailor-make the discussion is time consuming and challenging, even for a health care professional (308). PIS - a questionnaire to gather information on the patient's income, who he associates with when drinking, reasons/ occasions he drinks, life goals, any alcohol-related problems he has faced if any, and whether he had received any information on alcohol prior - was developed to address this issue. The manual was to enable RAs to tailor discussions based on responses to PIS.

4.3.2 Study design

4.3.2.1 Methodology

Data collection was completed within nine days (Figure 4.2). Risky drinkers (AUDIT-C ≥5) were significantly younger than non-risky drinkers (45.47±14.03 vs. 53.98±19.04 years, p=0.005, 95% CI: 2.59-14.42). The study sample (n=48) had mean values of age 45.5±14.0 years, education 9.0±3.7 years, and AUDIT-C score of 7.4±1.9. Mean patient ages across FOA, UOA, and ABI arms were 47.3, 45.6, and 43.8 years respectively. Mean years of education were 9.7, 8.4, and 9.0 years respectively, while mean AUDIT-C scores were 7.4, 6.8 and 8.0 in the same order. The total AUDIT score was 13.6, 12.9, and 17.3 in FOA,

UOA and ABI arms respectively. Patient characteristics and outcome measures for each arm are detailed in column four of Table 4.1. The column also includes family member follow-up rates.

Notably, 38% (17/45) of participants at initial assessment and 76% (22/29) at follow-up were abstinent, with at least 50% and 32% of them respectively attributing it to ongoing illness. Other reasons cited were 'no money', 'did not have parties during the 28 days'.

The PIS revealed primary drinking motivations: socialization/happiness [n=34], coping with negative emotions [n=23], and habit [n=9]), along with common misconceptions about alcohol (that it eliminates negative emotions, improves eating/sleeping, and cannot be refused).

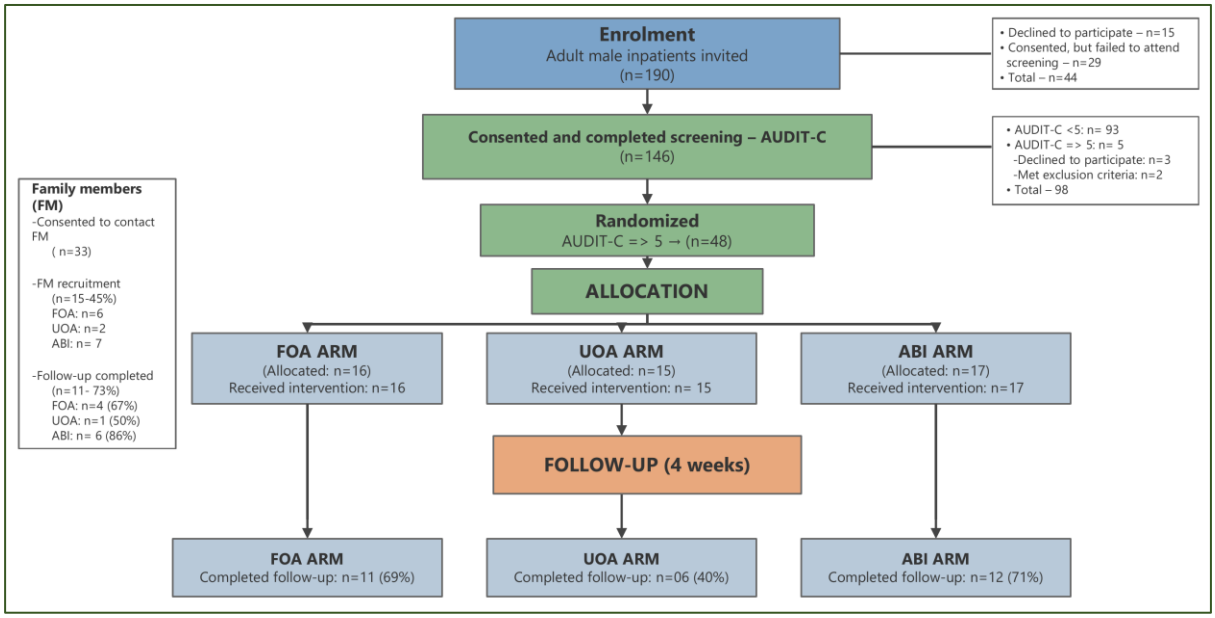

Figure 4-2 The CONSORT flow-chart of patient selection, randomization, and follow-up and information on family members

(FOA- Feedback on AUDIT-C, UOA- Unit of alcohol, ABI- adapted brief intervention, TLFB-Timeline Follow-back, FMQ- Family member questionnaire)

4.3.3 Outcome measures

Results are summarized in column four of Table 4.1. Overall follow-up rates were 60% for patients and 73% for family members. Childhood adversity details are shown in Table 4.2.

Table 4-2 Adverse childhood experiences of the patients (n=47)

Type of abuse	Frequency (%)	Remarks
Emotional abuse	34 (72.3)	Twenty-nine reported inadequate parental supervision during free time
Physical abuse	21 (44.7)	An object was used on 14 occasions
Sexual abuse	9 (19.1)	One instance of attempted rape
Violence against household members	9 (19.1)	
Living with household members who were substance abusers	4 (8.5)	
Living with household members who were mentally ill or suicidal	2 (4.2)	
Living with household members who were imprisoned	0 (0)	
Parental absence, separation, divorce or death	11 (23.4)	Ten had experienced parental death
Emotional neglect	33 (70.2)	
Physical neglect	6 (12.8)	
Bullying	9 (19.1)	
Community violence	37 (78.7)	Witnessing violence included: someone beaten (n=32), stabbed/shot (n=13), or threatened with a weapon (n=19)
Collective violence	7 (14.9)	

4.4 Discussion

To our knowledge, this study represents the first adaptation and piloting of an ABI for risky drinkers in Sri Lanka, using Resnicow's principles (168) and WHO guidelines (102). Resnicow describes surface structure as matching interventions to population characteristics for cultural 'fit', and deep structure as addressing cultural, social, historical, and psychological forces influencing health behaviours. This pilot study incorporated both: surface structure through non-stigmatizing language and culturally modified dialogues drawing on the PI's extensive psychiatric experience with AUD patients, plus UOA illustrations for clarity; and deep structure by addressing alcohol myths, demographic factors and stigma revealed by the PIS. This adaptation maintains impact (168) while preserving the WHO's OARS framework (Open-ended questions, Affirmations, Reflections, Summaries) and elements including personalized feedback,

advice, alternative options, moderate strategies, 'change talk', enhancing self-efficacy and role-playing to build patient assertiveness (102).

The three components of the ABI—leaflet, PIS, and the manual—work synergistically. Information from PIS provides a starting point to raise concerns, at which many interventionists are anxious in the first place (309), and also gives tailor-made direction for the ABI. Positive feedback from patients and RAs, combined with reasonable follow-up rates, confirmed acceptability and feasibility of ABI. Poor knowledge of alcohol harms and LRD emphasizes the importance of the leaflet in addressing these educational needs, both within interventions and for broader population health initiatives (299). The PIS efficiently captured drinking motivations and misconceptions, potentially reducing intervention time compared to sessions without this preparatory tool. Its comprehensibility, combined with Sri Lanka's high literacy rate (147), suggests patients could complete it while waiting to see practitioner. Overall implementation time matched international studies (273).

Both UOA and FOA arms were included - which could be considered as BIs (Figure 4.3) - because they require less time and resources than ABI. Despite UOA's lowest follow-up rate, its brief nature suits the local context and warrants inclusion in future RCTs. Despite being the least intense, follow-up rates of FOA for both patients and family members were encouraging. To maximize benefit, the PIS should also be given to patients in these arms in future powered RCT to encourage reflection—helping those in precontemplation reconsider their drinking through consciousness raising and self-re-evaluation (297).

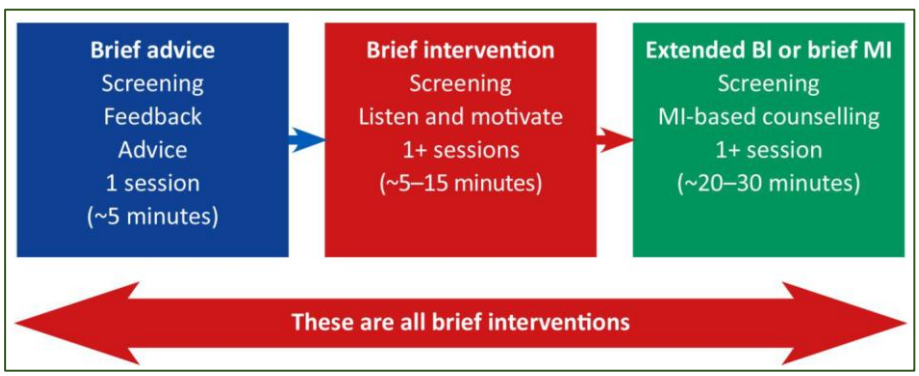

Figure 4-3 A continuum of brief interventions (102)
(Note: BI-Brief intervention, MI- Motivational interviewing)

Recruitment feasibility was demonstrated by a 25% eligibility rate and nine-day completion. However, high baseline and follow-up abstinence rates, with a considerable proportion citing illness-related factors as the reason, suggest future effectiveness studies should use primary healthcare settings where patients maintain their usual drinking patterns.

Regarding outcome measures, non-daily drinkers struggled with 4-week TLFB recall, indicating need for an alternative patient-outcome measure. The FMQ effectively captured family impacts and revealed valuable insights, with some requesting further care referrals. While initially burdensome for services, this likely improves overall outcomes - the bidirectional impact of RD and family member wellbeing is clearly documented (310) and is also an important factor described in the transtheoretical model of behaviour change (297). This aspect could be addressed in future outpatient-based RCTs, where family members typically accompany patients.

The AKQ and ACE-IQ were acceptable, though ACE-IQ was time-consuming. Poor alcohol knowledge and very high ACE prevalence may reflect broader public health concerns, highlighting their importance as potential effect modifiers in future trials and need for large-scale prevalence studies.

Risky drinkers were significantly younger than the non-risky drinkers, consistent with local (52) and international research (12), suggesting age as a useful screening factor.

4.4.1 Limitations

Several constraints affected this study—omission of polysubstance use and psychiatric comorbidity assessments to avoid overburdening hospitalized participants, though these are potential confounders; not evaluating RA micro-skills (listening, communication) using a proper tool, which may influence outcomes more than content itself (127). Family member recruitment was limited by scheduling difficulties, but conducting a future RCT in a primary health care facility will address this, since the patient is usually accompanied by a family member to the appointment. Further, patient

and RA feedback was not collected for the UOA and FOA arms, limiting direct assessment of their feasibility and acceptability. Feedback questionnaires for these arms will be added in the future RCT. Follow-up rates were moderate and need improvement strategies, like more reminder phone calls. Further, dropouts may sometimes occur when participants improve and do not see need for follow-up until relapse—a rarely researched, but perhaps a common clinical observation. Follow-up at least over the phone could be added in the methodology to investigate this aspect. Interventions were conducted only in Sinhala; adaptations will be needed for other Sri Lankan communities.

4.4.2 Strengths of the study

Our study attempted to address several limitations in BI research (127). Given the heterogeneity in duration, number of sessions, content and intensity—ranging from single sessions of ~5-30 minutes to multiple sessions, and from screening with feedback to screening and motivational counselling (Figure 4.3) (102), it is hard to compare ABI effectiveness studies. When setting, training level of practitioner and severity of alcohol consumption are added, comparing BI studies becomes nearly impossible. Poor intervention documentation further hinders reproducibility (269, 311). Our study clearly documented intervention time, content for each arm, structured ABI delivery, and RA selection, qualifications, and training. Selection of RAs with reasonably good communication skills ensured that each intervention is delivered optimally. Furthermore, designing a pilot study for a future RCT aiming to measure effectiveness, not efficacy, through broader inclusion criteria, and using non-specialists will increase generalizability (296).

Including family perspectives was a major innovation rarely implemented in alcohol intervention research, despite documented negative impact of drinkers on family members and vice versa, leading to unhealthy outcomes in both (165, 310). This dual-perspective methodology addresses two other significant limitations in traditional alcohol research: participant under-reporting, and failure to capture harm reduction in family dynamics (154), that may occur independently of changes in drinking—a meaningful outcome in itself. The study demonstrated feasibility of measuring family

member perspective as an outcome measure, thus enabling holistic assessment of intervention impacts beyond mere reduction of alcohol consumption.

We developed the ABI for the Sri Lankan context, designed for implementation by non-specialist personnel. Our RAs had no health sector work experience yet reported confidence and passion after 10-day training. This is quite promising considering issues raised in previous research—lack of knowledge and low confidence in delivering BI, unavailability of materials, along with concerns about raising alcohol-related issues with clients (309). Overwhelmingly positive patient feedback, rating discussions as most helpful, supports non-specialist training and intervention feasibility. Patient comments such as 'So many in our neighbourhood would benefit,' 'We wish we had several meetings,' and 'I often think of this when I think of a drink', further support this.

Incorporating different BI intensities in the same RCT proved feasible with clearly documented procedures. Conducting all interventions in the same setting is likely to eliminate contextual effects. These are initial steps in trying to untangle the confusion in terminology and reduce heterogeneity of BIs, thereby making it easier to make comparisons and to decide which BI is effective and resource efficient in what setting.

4.5 Conclusions

This pilot demonstrated ABI feasibility and acceptability among Sri Lankan male inpatients and their family members. Administering ABI by non-specialists with good communication skills is also feasible and acceptable. Using two less intense brief interventions -UOA and FOA- in the same study was also feasible. All outcome measures except TLFB were appropriate—the FMQ proved particularly valuable for capturing overlooked family perspectives. Alarming levels of poor knowledge of alcohol-related harms, UOA, and LRD, combined with very high levels of adverse childhood experiences are genuine public health concerns; their inclusion as potential effect modifiers in future ABI trials is feasible and essential. However, the inpatient setting proved sub-optimal for evaluating intervention effectiveness due to illness-induced abstinence and difficulty in meeting family members. A future RCT should target primary care settings where patients

continue typical day-to-day activities, including their usual drinking patterns, and where family member contact is easier, to better detect intervention effects.

Chapter 5: Patterns of Alcohol Use and Knowledge of Alcohol-related Harms Among Primary Care Patients in Sri Lanka: A Cross-sectional Study

5.1 Introduction

Alcohol-attributable conditions constitute one of the four primary causes of non-communicable disease mortality in Sri Lanka (312). Patterns of alcohol use and the harms it causes globally and in Sri Lanka are discussed in Chapter 1. Also discussed in Chapter 1 are the reasons why Sri Lanka needs to identify more heavy episodic drinkers to reduce the impact of this pattern of drinking, which often goes undetected in health care, especially in the primary care.

Lack of knowledge of alcohol-related harms and low-risk drinking are predictors of risky drinking (88)—defined as drinking at levels or in patterns that increase the risk of alcohol-related harms—both acute and chronic (154) (See Chapter 1). Frequency of drink counting and understanding of drinking limits (300) have been associated with a reduction of long-term harms. Recent reductions in alcohol consumption in Europe have been contributed by increasing knowledge of negative health and social consequences of alcohol use (301). This strategy is given highest priority in the WHO Global Action Plan (2022-2030) to reduce harms related to alcohol (37).

An RCT conducted in a rural Sri Lankan community, where baseline prevalence of alcohol use disorders was around 65%, concluded that educating people about the harmful effects of drinking and about low-risk drinking effectively reduces risky drinking (92). However, there are no local or large-scale international studies conducted in primary healthcare settings—settings which provide important opportunities for delivering health education, prevention, and early identification and intervention for risky drinking—which have assessed the association between understanding of 'unit of alcohol' (defined as 10 grams of pure ethanol) (102), the concept of low-risk drinking (293), and knowledge of alcohol-related harms on drinking behaviours. Further, there are no studies done locally using the AUDIT-C, an easily used brief and reliable screening tool for risky drinking (102).

The WHO recommend that AUDIT-C cut-off be ≥5 (102), However, lower cut-offs of AUDIT-C ≥4 for men and ≥3 for women are now widely recommended (313). Several studies support selecting the AUDIT-C cut-off according to the alcohol consumption patterns of the setting in which it is used (151, 314) (See Chapter 1), and systematic review of AUDIT cut-off in LMICs (128) points out the lack of such in these countries.

Therefore, the aims of the current study were to determine the following among patients presenting to the outpatient department (OPD) of a large hospital servicing rural and urban populations, Teaching Hospital Peradeniya, located in the central highlands of Sri Lanka:

1. To determine an appropriate AUDIT-C cut-off score for identifying risky drinkers among males in this population, by comparing the proportion classified as risky at two thresholds [≥4 (313) and ≥5 (102)].
2. To describe patterns of alcohol use by age, education and sex,
3. To determine prevalence of risky drinking,
4. To assess knowledge of alcohol-related harms, unit of alcohol, and low-risk drinking, and
5. To examine whether this knowledge was associated with risky drinking

5.2 Methods

This cross-sectional study was reported according to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines (315).

5.2.1 Study design, setting and period

This cross-sectional study was conducted from 23rd March to 21st April 2023 at the OPD of Teaching Hospital Peradeniya. OPDs are the main primary healthcare provider in Sri Lanka, serving predominantly for those with non-life-threatening conditions. A majority who present to OPDs in Sri Lanka are from lower-middle income groups, and they typically resume their routine activities, including their drinking patterns after a few days (316). The OPDs in Sri Lanka operate all weekdays from 8.00 AM to 4 PM, except on public holidays, and Saturdays from 8.00 AM to 12.00 PM.

5.2.2 Sampling and recruitment

Inclusion criteria: We employed consecutive sampling, approaching both adult males and females presenting to the OPD during this period. However, with only eight research assistants available, it was not possible to approach all 9,549 eligible patients who registered during the study period. Once a research assistant approached a patient and obtained consent, the research assistant administered the research questionnaires before approaching the next available patient (See Figure 5.1). This process meant that some eligible patients were seen by the medical officer and left before a research assistant became available. Importantly, the patients who were not approached were missed due to research assistant capacity constraints rather than any selection criteria, and therefore there was no systematic bias in recruitment. Eight research assistants were present from 9 AM until closing (4 PM) each day throughout the study period to ensure comprehensive recruitment. While the brief interval between OPD opening (8 AM) and research assistant arrival (9 AM) affected a small proportion of early-morning registrants, patients were approached while waiting to see the medical officer or while queuing at the pharmacy for prescribed medications. This meant that some patients who registered before 9 AM were typically still available for recruitment when RAs arrived, minimizing the number of missed patients. The principal investigator had daily meetings with the research assistants to ensure consistency in data collection.

Exclusion criteria: Patients requiring immediate hospital admission, inability to communicate in Sinhala (the language in which the study was conducted), or inability to provide informed written consent due to severe sensory or cognitive impairment.

Research assistants explained the study purpose, assured confidentiality, and obtained informed written consent from those agreeing to participate.

5.2.3 Research assistants and training

Eight research assistants who had previously received 10-day training (See Chapter 4) (179) collected data for the current study.

5.2.4 Data collection and tools

5.2.4.1 Sociodemographic Questionnaire

We collected information on age, sex, and years of formal education from all consenting participants; and for alcohol consumers, age at drinking initiation and types of alcohol consumed.

5.2.4.2 Alcohol Use Disorders Identification Test-C (AUDIT-C)

The AUDIT-C is a widely used three-item screening tool for risky drinking, derived from the full 10-item AUDIT (102). We used the first three questions of the AUDIT, which captures amount and patterns of consumption (i.e., AUDIT-C) of a culturally adapted 10-item AUDIT version with visual aids showing unit equivalents in commonly consumed local alcoholic beverages (arrack, beer, wine, 'kasippu—an illicitly brewed alcohol type', and toddy) (317). The three questions of the AUDIT-C are: 'How often do you have a drink containing alcohol?'; 'How many drinks containing alcohol do you have on a typical day when you are drinking'; and 'How often do you have ≥6 drinks on one occasion?'. The third question, which assesses heavy episodic drinking (HED), was modified to reflect updated evidence defining HED as ≥5 standard drinks per occasion (161, 162). Response options for each question, and the total AUDIT-C score remained unchanged—0 to 4 points respectively, yielding a total AUDIT-C score of 0–12 (102).

5.2.4.3 Alcohol knowledge questionnaire

Development and evaluation: Several alcohol knowledge questionnaires have been used in previous research, but none were suitable for the current study. One questionnaire designed for university students (318) was too complex for primary care settings, while others were not comprehensive enough, addressing only awareness of standard drink, hazardous drinking limit, and a few physical complications of alcohol (319, 320). Therefore, the 'Alcohol Knowledge Questionnaire' was developed by the principal investigator for this study to ensure clarity and comprehensiveness, to benchmark patient awareness of established clinical facts.

Content and structure: The alcohol knowledge questionnaire comprised 15 items: two items assessed awareness of ‘alcohol unit’ and ‘low-risk drinking thresholds’ (participants that responded 'Yes' were asked to specify the amounts separately in each instance), and 13 items evaluating knowledge of specific alcohol-related harms derived directly from the WHO Alcohol Brief Intervention Training Manual for Primary Care (102): forgetfulness, weight gain, tingling limbs, premature ageing, sexual problems, cancers, depression, nutritional deficiencies, frequent infections, accidents, heart diseases, dementia and foetal abnormalities. Deriving items from this WHO source ensured content validity by grounding the questionnaire in an internationally recognised, evidence-based framework of alcohol-related harms. The questionnaire was reviewed several times by the principal investigator—a consultant psychiatrist with 20 years of clinical experience in alcohol use disorder treatment—for face validity, clinical accuracy, and contextual appropriateness (321). Participants could respond 'Yes', 'No', or 'Don't know' to each item. ‘No’ and ‘Don’t Know’ responses were amalgamated to ‘No’, when analysing these 13 items.

Each item assessed factual knowledge of a discrete harm (i.e., whether the participant was aware that alcohol causes a specific condition) rather than measuring a latent psychological construct. The binary response format and factual nature of items meant that conventional internal consistency measures (e.g., Cronbach's alpha) were not applicable (322), as awareness of one harm (e.g., accidents) is not expected to correlate with awareness of another (e.g., foetal abnormalities)—these represent independent knowledge domains rather than indicators of a single underlying trait.

The alcohol knowledge questionnaire was previously administered by the research assistants in the inpatient pilot study (See Chapter 4) (179) to 48 inpatients. The research assistants—who subsequently collected data in the current study—reported that questions were clear and comprehensible, with no participant requests for clarification.

5.2.4.4 Administration Procedures

Both AUDIT-C and alcohol knowledge questionnaire were administered via face-to-face interview by the research assistants. Average completion time was 10-15 minutes.

5.2.5 Statistical methods

Outcome and exposure variables: The primary outcome was risky drinking (defined in Section 5.1) operationalised as an AUDIT-C score at or above the threshold selected as described below in Section 5.3.2. Prevalence ratios (PR) estimated from modified Poisson regression models were used to quantify variations in risky drinking according to sociodemographic and behavioural characteristics: age (18-29, 30-39, 40-49, 50-59, ≥60 years); years of formal education (≤11, 12-13, ≥14 years); age at drinking initiation (<21, ≥21 years)—categorized according to the national legal minimum age for sales of alcoholic beverages being 21 years (50); and type of alcohol consumed (spirits vs. non-spirits). To better understand associations between age at drinking initiation, type of alcohol consumed, and risky drinking, we additionally categorized age as a dichotomous variable (<50 vs ≥50 years). Analyses were undertaken using Stata version 17.0.

5.2.6 AUDIT-C cut-offs, heavy episodic drinking and risky drinking

Previous studies have used various AUDIT-C thresholds to define risky drinking: AUDIT-C ≥ 3 for both men and women in a population with high proportion with heavy drinkers (323); AUDIT-C ≥ 5 for men and AUDIT-C ≥4 for women in a UK sample who sought online help for their drinking (151); AUDIT-C ≥5 for men and AUDIT-C ≥4 for women for older adults (≥ 60 years) in Belgium. These findings highlight the need for selecting AUDIT-C cut-off scores according to both the purpose, and the population—a point reiterated by several authors (151, 323).

At the population level, most alcohol-related harms arise from HED rather than from alcohol dependence (12). We compared the proportion of people reporting HED at AUDIT-C thresholds of "≥4" and "≥5" (using Question 3 of AUDIT-C) and selected the threshold that captured the highest proportion of heavy episodic drinkers. As discussed

in Chapter 1, HED is the dominant consumption pattern among Sri Lankan drinkers and represents an important target for screening in primary care settings.

AUDIT-C score threshold of ≥3 was used to define risky drinking in females, based on the updated criteria (313). A similar analysis (to determine the percentage of HED identified by different AUDIT-C cut-off scores) was not performed for females due to the small number of female drinkers in the sample.

5.2.7 Ethics

This study received ethics approval from the Ethics Review Committees of both the Faculty of Medicine, University of Peradeniya, Sri Lanka (2023/EC/13) and the Australian National University, Australia (2022/779). All participants provided informed written consent prior to enrolment. Participation or non-participation in the study had no influence on the healthcare services patients received from the hospital.

As duty of care, all participants received an educational leaflet (developed by the principal investigator as a component of the adapted brief intervention (BI)—See Chapter 4) hoping to trigger cognitive dissonance and initiate favourable behavioural change (324)—reduce drinking or abstain from drinking. Further, risky drinkers were informed about their drinking level and advised to seek assistance from the psychiatry unit at Teaching Hospital Peradeniya.

5.3 Results

5.3.1 Sample characteristics

During the study period, 9,549 eligible patients registered at the OPD. Eight research assistants approached 4,446 patients, of whom 3,700 (83%) consented to participate (Figure 5.1). Males comprised 38.2% (n=1,414) of the final sample. The mean age was similar between sexes (males: 45.0 years, SD 16.9; females: 43.5 years, SD 15.3), as were mean years of education (males: 11.6 years, SD 6.7; females: 11.9 years, SD 2.8).

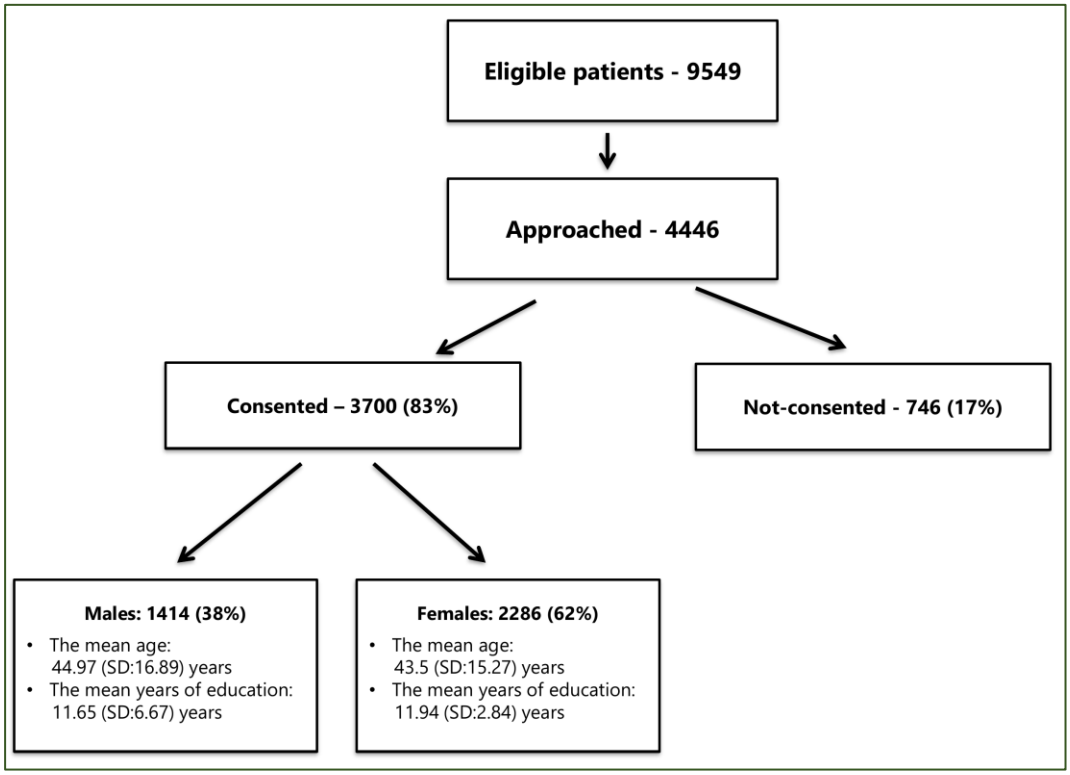

Figure 5-1 Characteristics of the study sample

5.3.2 Determining risky drinking based on AUDIT-C score

Of the 1414 males, 746 reported alcohol consumption in the previous year. 627 (i.e.: 84% of all drinkers) reported HED at some point over the previous year (scored ≥1 for question three of AUDIT-C). The mean and median AUDIT-C score was 5.33 (2.75) and 5.0 (IQR 3–7), respectively.

AUDIT-C score threshold of ≥4 identified 85.6% (n=537) of male heavy episodic drinkers, while the AUDIT-C score threshold of ≥5 identified only 62.4% (n=391). Among the 119 males reporting no HED, 15.1% (n=18) and 4.2% (n=5) had AUDIT-C scores of ≥4 and ≥5 respectively (Table 5.1). Given the better identification of HED, all subsequent analyses use an AUDIT-C score threshold of ≥4 to determine risky drinking in males.

Table 5-1 AUDIT-C score thresholds of ≥4 and ≥5 by heavy episodic drinking among males who reported alcohol consumption in the previous year

	Heavy episodic drinking		
AUDIT-C score	Yes	No	Total
≥4	537 (85.6%)	18 (15.1%)	555 (74.4%)
<4	90 (14.4%)	101 (84.9%)	191 (25.6%)
≥5	391 (62.4%)	5 (4.2%)	396 (53.1%)
<5	236 (37.6%)	114 (95.8%)	350 (46.9%)
Total	627	119	746

5.3.3 Patterns of drinking among males and females

Among all participants, 2,883 (77.9%, 95% CI: 76.5%, 79.2%) remained abstinent during the previous year. The prevalence of risky drinking in the study sample, as defined in section 5.3.2, was 15.5% (95% CI: 14.4, 16.7) (Table 5.2).

Among males, 746 (52.8%, 95% CI: 50.2%, 55.4%) reported alcohol consumption in the previous year, with 555 (74.4% of male drinkers, 95% CI: 71.1%, 77.5%) classified as risky drinkers, representing 39.3% (95% CI: 36.7%, 41.8%) of all male participants. Among females, 72 (3.1%, 95% CI: 2.5%, 4.0%) reported alcohol consumption in the previous year, with 19 (0.8%, 95% CI: 0.5%, 1.3%) classified as risky drinkers (Table 5.2). Females aged 18-39 years accounted for 48 (66.7%) of female drinkers and 11 (57.9%) of female risky drinkers.

Of the 818 people who consumed alcohol, 500 (61.1%) consumed spirits. Among all drinkers (i.e., males and females taken together), 574 (70.2%, 95% CI: 66.9%, 73.3%) were classified as risky drinkers. Given the small number of female risky drinkers, subsequent analyses were restricted to male participants (n=1414).

Table 5-2 Drinking patterns in the study population

	Males N (%)	Females N (%)	Total N (%)
All participants	1414	2286	3700
AUDIT-C scores			
AUDIT-C ≥5	396 (28.0)	N/A	N/A
AUDIT-C ≥4	555 (39.3)	N/A	N/A
AUDIT-C ≥3	N/A	19 (0.8)	N/A
Risky Drinking*	555 (39.3)	19 (0.8)	574 (15.5)
Participants who reported alcohol consumption in the previous year	746 (52.8)	72 (3.1)	818 (22.1)
HED (≥5 drinks per occasion)**	627 (84.0)	20 (27.8)	647 (79.1)
HED ≥ once a month**	319 (42.8)	8 (11.1)	327 (40.0)

*(Note: * Risky drinking, defined as AUDIT-C score threshold of ≥4 for males and ≥3 for females.*
***Amongst people who reported alcohol consumption in the previous year, HED – Heavy episodic drinking, N/A- Not Applicable)*

5.3.4 Factors associated with risky drinking in males

5.3.4.1 Age

Risky drinking was more common in middle aged men, with the point estimates ranging from approximately 43% to 50% in men aged 30-59 years, and slightly lower (30% to 33%) in the youngest and oldest age groups (18-29 years and ≥60y) (Table 5.3). Compared to the 18-29 age group, prevalence of risky drinking was 26% to 49% higher in all age groups except in those ≥60 years. Similar overall patterns of risky drinking were observed in men who reported consuming alcohol in the previous year, but prevalence was higher with around 73% to 82% men aged 30-59 engaged in risky drinking.

Table 5-3 Prevalence of risky drinking among males by age group

Age (y)	All Males			Males Drinkers		
	n	RD (%)	PR (95% CI:)	n	RD (%)	PR (95% CI:)
18-29 [a]	341	33.7%	1.00	175	65.7%	1.00
30-39	244	42.6%	1.26 (1.03, 1.56)	127	81.9%	1.25 (1.09, 1.42)
40-49	256	50.4%	1.49 (1.23, 1.81)	160	80.6%	1.23 (1.08, 1.40)
50-59	229	45.4%	1.35 (1.10, 1.65)	142	73.2%	1.11 (0.96, 1.29)
≥60	344	29.9%	0.89 (0.29, 1.39)	142	72.5%	1.10 (0.95, 1.28)
Total	1414	39.3%	-	746	74.4%	-

(Note: [a] The reference group, RD- risky drinking, PR- Prevalence Ratios)

5.3.4.2 Years of education

The prevalence of risky drinking varied by education category among males (Table 5.4). risky drinking was more common among males with fewer years of education, with the point estimate rising from 24.2% among those with ≥14 years of education to 36.1% among those with 12–13 years and 44.7% among those with ≤11 years. Compared to the ≥14-year category, prevalence was 49% higher among those with 12–13 years of education and 85% higher among those with ≤11 years. A similar pattern was observed among male drinkers, with risky drinking prevalence rising from 55.1% among those with ≥14 years of education to 77.5% among those with ≤11 years of education.

Table 5-4 Relationship between drinking and risky drinking among males and years of education

Education (y)	All Males			Male Drinkers		
	n	RD (%)	PR (95% CI:)	n	RD (%)	PR (95% CI:)
≥14[a]	157	24.2%	1.00	69	55.1%	1.00
12–13	499	36.1%	1.49 (1.10, 2.01)	241	75.0%	1.36 (1.08, 1.70)
≤11	741	44.7%	1.85 (1.38, 2.46)	427	77.5%	1.41 (1.13, 1.75)
Total	1397	39.3%	-	737	74.4%	-

(Note:[a] The reference group, RD- risky drinking, PR- Prevalence Ratios)

5.3.4.3 Age of initiation of drinking

Among younger males (≤49 years), those who initiated drinking before age 21 had a 14% higher prevalence of risky drinking compared to those who initiated at 21 years or later (PR 1.14; 95% CI: 1.02, 1.28). A similar but weaker association was observed among older males (≥50 years) (PR 1.09; 95% CI: 0.95, 1.25).

5.3.4.4 Knowledge of unit of alcohol, low-risk drinking and alcohol-related harms

Knowledge of alcohol-related harms varied across items. The lowest knowledge was regarding accident risk (<5% for both males and females), while the highest knowledge was regarding weight gain (49.2% among males and 44.6% among females).

Among males, 300 (21.2%) indicated they had heard of unit of alcohol and 243 (17.2%) indicated knowledge of low-risk drinking; however, only 48 (3.4%) and 13 (0.9%) respectively correctly identified the appropriate amounts. Knowledge scores varied by drinking status: abstainers had the lowest scores across most items, low-risk drinkers had the highest knowledge among the three groups, and risky drinkers fell between these groups. Figure 5.2 shows knowledge of alcohol-related harms among male participants by drinking status. Seven percent of low-risk drinkers were aware of increased accident risk.

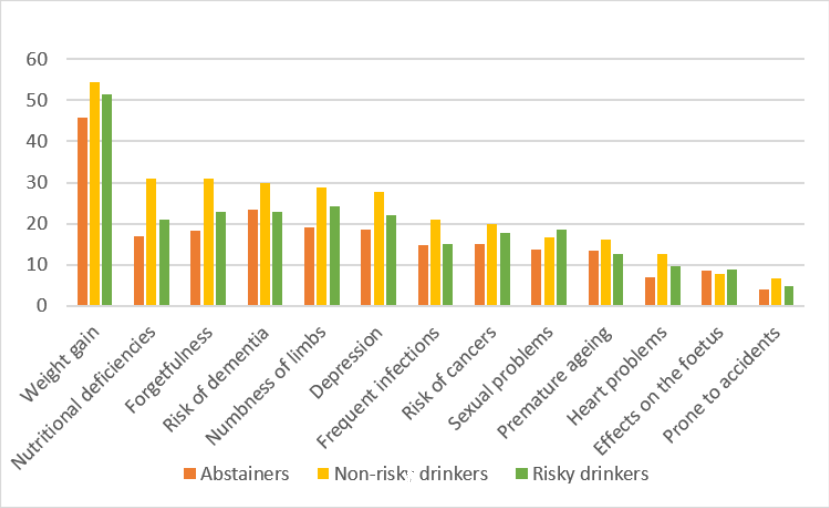

Figure 5-2 Knowledge of alcohol related harms among all male participants

Further, the alcohol knowledge questionnaire had a near-complete response rate [3,697/3,700, (99.9%)].

5.3.5 Preference of beverage type (spirits vs non-spirits)

Older adults (≥50 years, N=277) had higher spirits consumption than younger adults (<50 years, N=441) (PR 1.54, 95% CI: 1.40, 1.70). Among younger risky drinkers, 37.4% consumed non-spirits compared to 12.3% of older risky drinkers (RR=3.04, 95% CI: 2.04, 4.49). Compared to males with ≥12 years of education, those with <12 years had higher spirits consumption (PR 1.20, 95% CI: 1.08, 1.35).

5.4 Discussion

This study quantified alcohol consumption patterns and preferences among Sri Lankan males presenting to primary healthcare. The study used an empirical AUDIT-C score threshold to screen for risky drinking and to report the prevalence of risky drinking; and established level of knowledge regarding low-risk drinking, unit of alcohol, and alcohol-related harms among primary care patients in Sri Lanka.

5.4.1 AUDIT-C cut-off for Sri Lanka

Our empirically determined AUDIT-C cut-off of ≥4 for men identified 23.3% more heavy episodic drinkers than the WHO-recommended cut-off of ≥5. Given that HED is associated with higher risk of acute alcohol-related harms (See Chapter 1), and primary care screening should prioritise identifying all individuals who might benefit from intervention, we suggest the AUDIT-C≥4 threshold for males in Sri Lankan primary care.

This lower threshold is particularly appropriate for the Sri Lankan context, where HED is the dominant consumption pattern. WHO data indicate that 37.9% of male drinkers reported HED episodes in the previous 30 days (23), while our findings from this clinical sample suggest that the prevalence is as high as 84% among drinkers (over the preceding 12 months). The empirically determined AUDIT-C cut-off of ≥4 captured 23.3% more heavy episodic drinkers than the cut-off of ≥5—identifying risky drinkers, as defined in Chapter 1, to whom opportunistic BIs could be offered (See Chapter 6). This is particularly important in a country where the majority who drink do so to get drunk (110).

A more sensitive screening threshold will inevitably identify individuals at lower severity levels. In this population, however, such identification is warranted on two grounds. First, any level of drinking carries health risks (20), and early identification through screening provides an opportunity to intervene before the onset of more severe alcohol-related problems—a foundational rationale of screening and BIs in primary care (See Chapter 3). Second, knowledge of alcohol-related harms in this population is near-absent: only 0.9% of males understand low-risk drinking guidelines and fewer than 5% recognise alcohol's contribution to accident risk. Because BIs include an educational component (See

Chapter 3), even individuals identified at lower-risk thresholds stand to benefit from information about harms and low-risk drinking that they would not otherwise receive.

The additional burden of the lower threshold appears modest relative to its yield. In our sample, moving from AUDIT-C ≥5 to ≥4 identified an additional 159 males (approximately 11% of male attendees), of whom 146 (92%) reported binge drinking; only 13 (0.9% of male attendees) were non-binge drinkers (Table 5.1). Most additional interventions would therefore be delivered to heavy episodic drinkers missed by the higher threshold. Screening and brief intervention in primary care has been shown to be cost-effective in modelling studies, even in low-income settings (286). This should be weighed against the economic burden of alcohol-related ill health in Sri Lanka, estimated at LKR 335 billion annually (2.18% of GDP), comprising direct health-care costs and productivity losses due to alcohol-attributable diseases and injuries among drinkers themselves (2); harms to others were not included, so this is likely to be an underestimate. Nevertheless, the workload and cost implications of the lower threshold in Sri Lankan primary care have not been formally evaluated, and future studies should include economic evaluation.

5.4.2 Patterns of alcohol consumption and risky drinking

Our findings revealed substantial gender disparity in drinking, with 15.5% overall prevalence of risky drinking (39.3% among males and 0.8% among females). High prevalence of abstinence among females, male-predominant consumption, preference for spirits, and high HED proportions reflect consumption patterns observed in previous Sri Lankan studies (48, 79) and across the South-East Asian Region (SEAR) (325).

The prevalence of risky drinking was high among males across all age groups, with the highest rates in middle age (50.4% among 40–49-year-olds) and the lowest among those ≥60 years. This age distribution aligns with previous findings showing peak levels in young adulthood and middle age with reduction in older adults (326).

Our findings suggest an inverse association between educational attainment and risky drinking. A community-based study in Sri Lanka similarly found that years of schooling

reduced the risk of alcohol use disorders (327), and a population-based study in India reported lower educational attainment as a risk factor for harmful alcohol consumption (328). However, the cross-sectional design of these studies precludes causal inference. The observed association may reflect: 1. protective effects of education (329); 2. selection effects where alcohol use predicts lower educational attainment (330); and/or 3. socioeconomic background which predicts both alcohol consumption and education (331). However, a British cohort study found higher educational attainment associated with increased odds of problem drinking (332), indicating potential cultural differences in how education influences drinking behaviours. Nonetheless, over half of the most educated male drinkers (55%) in our study engaged in risky drinking which underscores that harmful drinking patterns affect all educational strata and that educational attainment alone is insufficient to prevent risky drinking in the Sri Lankan context as well.

Of particular concern is high prevalence of HED among drinkers, with 43% of male drinkers HED ≥ once per month over the previous year. The WHO in 2018 reported HED among 41% of male and 13% of female drinkers in Sri Lanka (50). Although direct comparison with WHO data is limited by methodological differences, both studies confirm that a substantial proportion of drinkers engage in risky drinking patterns. Additionally, 53% of male drinkers in our study initiated alcohol consumption before age 21, suggesting that legal age restrictions on alcohol purchase have limited effect on initiation. Given that early initiation of drinking is associated with higher prevalence of risky drinking (333)—a finding confirmed in the present study; and its adverse effects on brain development (334), targeted prevention of underage drinking should be prioritized.

Our finding that 61% of male drinkers consume spirits represents a potentially positive trend compared to the 85% reported in 2018 (50), since spirit consumption is associated with more risks compared to non-spirit-consumption (12). If observed elsewhere in the country, this shift away from spirits could reduce alcohol-related harms (335). However, the finding that young risky drinkers are three times more likely to consume non-spirits compared to older drinkers may signal an emerging concerning trend—one where the

perception of non-spirits as less harmful may lower the threshold for drinking initiation and normalise consumption among younger populations (See Section 5.4.5)

5.4.3 Knowledge of alcohol-related harms

Perhaps the most concerning finding of our study was the alarmingly poor knowledge of alcohol-related harms and low-risk drinking among participants. Only ~ 1% correctly understood low-risk drinking guidelines, and only 3% of males understood what constitutes a unit of alcohol. These findings are consistent with community studies from Ireland and Sweden, which reported very low knowledge of low-risk thresholds, and also have high prevalence of risky patterns of drinking similar to Sri Lanka (88, 319).

Most surprisingly, knowledge that alcohol increases accident risk was extremely low (<5%), despite alcohol-related road traffic accidents being widely reported in Sri Lankan media. Given that 12% of road deaths in Sri Lanka are attributable to alcohol (50), and 52% of vulnerable road users had blood alcohol concentrations above the legal driving limit (54), this knowledge gap represents a significant public health concern.

Knowledge scores were universally low across all drinking categories—abstainers, low-risk drinkers, and risky drinkers. Given the cross-sectional design, the direction of this association cannot be determined; better knowledge may support lower-risk drinking, or may follow from it (for example, through health advice received when reducing consumption).

In contrast, abstainers demonstrated the lowest knowledge scores among the three categories. This group, defined as no alcohol consumption in the previous year, is likely to be heterogeneous, comprising lifetime abstainers and former drinkers, some of whom may have stopped for health reasons—the 'sick quitter' effect (16) that has been proposed to contribute to the J-shaped relationship between alcohol consumption and mortality (Section 1.2). As these groups were not distinguished, findings for abstainers should be interpreted with caution. Low knowledge among abstainers suggests that factors other than health knowledge may contribute to abstinence—one likely being Sri

Lankan culture that traditionally condemns alcohol use (336). However, these cultural beliefs are changing across SEAR countries, potentially driving increased consumption among adolescents, youth, and females (337) (See Chapter 1).

The knowledge deficit we observed is not unique to Sri Lanka. An Australian poll revealed confusion about what constitutes low-risk versus high-risk consumption (338), and in India, 44% of medical interns believed alcohol consumption was safe (339). Evidence suggests that knowledge of alcohol-related harms can influence consumption patterns. As mentioned in 5.1, the observed reduction in alcohol consumption in Europe and some high-income countries has been linked to increasing knowledge of alcohol-related harms (301). Knowledge initiates cognitive dissonance and attitude change, which may lead to behaviour change (324). This is particularly relevant given the current emphasis on drinking patterns rather than total consumption in assessing alcohol-related harms (88).

5.4.4 Contextual factors affecting alcohol consumption in Sri Lanka

Several contextual factors, discussed in Chapter 1, hamper efforts to reduce harmful alcohol use in Sri Lanka. These include the large proportion of illicit liquor consumption (40–60%) that falls outside regulatory reach (340), increasing numbers of licensed liquor outlets (340) and alcohol industry marketing strategies targeting youth and women in the South-East Asia Region that seek to normalise consumption (71). Together, these factors create a challenging environment for harm reduction efforts.

5.4.5 Implications for policy and practice

Our findings highlight the critical need for public education about alcohol-related harms and low-risk drinking. This need is particularly urgent given the alcogenic culture that exists globally, where the alcohol industry promotes the notion that 'alcohol can cause problems only in the hands of a small number of users–who are by nature abusive and reckless' (341) while simultaneously perpetuating false claims that certain types of alcohol improve health (342)—claims contradicted by systematic evidence showing no safe level of alcohol consumption (20).

In Sri Lanka, this problematic messaging is compounded by recent trends including a marked rise in sensationalized and normalized portrayals of alcohol use by young males and females in media, cinema and social platforms (89). Sørensen et al. report that rural and semi-urban young men think it is ‘acceptable to drink in moderation, and that remaining abstinent is feminine and that abstainers lack social skills’ (110). Our finding that male participants have almost zero knowledge of low-risk drinking and unit of alcohol, combined with very poor knowledge regarding alcohol-related harms, aligns with these concerning attitudinal shifts. The shift towards non-spirit consumption among younger risky drinkers (See Section 5.4.2)—likely reflecting perceptions of such beverages as 'healthy and acceptable'—reinforces this concern.

When considered alongside Sørensen et al.'s observations about changing male drinking attitudes (110) and increasing alcohol promotion targeting young males and females (89), these findings suggest an alarming trend toward increasing risky alcohol consumption in Sri Lanka.

Improving individual risk perception is essential for achieving sustained reductions in risky drinking patterns, even with supportive government policies (343). The WHO recognizes "raising knowledge of health and social problems caused by harmful use of alcohol" as a key strategy to reduce alcohol-related harm (23).

Using AUDIT-C with alcohol knowledge questionnaire in primary care before the patient meets the healthcare professional leverages the 'question-behaviour effect—whereby answering questions about one’s behaviour can itself prompt reflection and change (238). Given Sri Lanka's high literacy rate (147), self-administered AUDIT-C and alcohol knowledge questionnaires could feasibly be completed while patients wait to see the healthcare professional—a low-cost approach that, based on evidence from the question-behaviour effect literature (238), warrants evaluation as a strategy to reduce risky drinking in resource-constrained primary care settings.

5.4.6 Strengths and limitations

This study has several strengths. To our knowledge, this is the largest study conducted in a primary healthcare setting globally to assess knowledge of low-risk drinking, unit of alcohol, and alcohol-related harms and their associations with risky drinking prevalence. Knowledge of these three areas is important for reducing alcohol-related harms yet has been rarely examined in previous studies. Our study achieved a high response rate (83%), enhancing the reliability of our findings. The alcohol knowledge questionnaire used in this study was developed and tested in a previous study (179) and proved to be an appropriate tool for assessing knowledge and initiating conversations about this sensitive topic in clinical settings. However, a formal psychometric validation (e.g., test-retest reliability, criterion validity) was not conducted; this is acknowledged as a limitation.

The research assistants had previously received extensive training for a pilot alcohol intervention study (179), which likely enhanced their ability to obtain accurate information on this sensitive topic in a non-judgmental manner while establishing good rapport with patients.

The study sampled primary care patients and not the general population. However, government OPDs are the principal primary healthcare provider in Sri Lanka, recording 55 million visits in 2024 for a population of 22 million (125) . While OPD attendees may over-represent lower and middle-income groups, these groups constitute the majority of the population—the bottom 80% of the population shares less than half (48.6%) of total household income (344)—and are the population most reliant on free government healthcare. Moreover, this over-representation may strengthen rather than limit the relevance of these findings: the alcohol-harm paradox as discussed in Chapter 1 demonstrates that those in lower socioeconomic conditions experience disproportionately greater alcohol-related harm even at comparable levels of consumption (31), a disparity compounded in LMICs by higher rates of HED and limited access to treatment (36). In Sri Lanka, alcohol has been identified as a major contributor to poverty across regions, income levels and ethnic groups (67, 345). The sheer volume of utilisation, combined with the concentration of alcohol-related harm in this

population, suggests these findings are relevant to a substantial proportion of the Sri Lankan adult population—and particularly to those most in need of intervention. Therefore, primary care settings represent important opportunities for delivering health education, and these results provide primary healthcare professionals with evidence-based insights to initiate alcohol discussions using tools like the AUDIT-C and alcohol knowledge questionnaire—an approach that warrants further evaluation.

Our study has several limitations. While the threshold comparison in this study supports AUDIT-C ≥4 as more appropriate for Sri Lankan primary care, formal validation against an independent criterion (such as the full AUDIT or a clinical interview) was not conducted. The stigma associated with alcohol consumption, particularly among females, may have led to underreporting, however thorough training of research assistants (Appendix D)—on empathy, non-judgmental approach—might have minimized this. Additionally, as this is a cross-sectional study, we cannot establish causal relationships between knowledge and drinking behaviours. The single-site design may limit generalizability, and it is important that similar studies are carried out in other primary care settings. Finally, while the alcohol knowledge questionnaire demonstrated good comprehension, with consistent response patterns across all items with no systematic missing data, provided evidence of adequate face validity across both clinical settings—outpatient and inpatient (See Chapter 4) . However, it is a limitation that it has not undergone formal psychometric validation.

5.5 Conclusions

Our findings reveal a high prevalence of risky drinking among males across all age and education categories in Sri Lanka, coupled with alarmingly low knowledge of alcohol-related harms, unit of alcohol, and low-risk drinking. These knowledge deficits may contribute to the high prevalence of risky drinking. While formal education appears to offer some protection, targeted educational interventions about alcohol-related harms and low-risk drinking are urgently needed to reduce this burden in Sri Lanka.

The combined use of AUDIT-C and alcohol knowledge questionnaire represents a dual-purpose approach: identifying at-risk individuals while simultaneously leveraging the question-behaviour effect. AUDIT-C≥4 captured 85.6% of heavy episodic drinkers compared to 62.4% at the WHO-recommended ≥5 cut-off, making it more appropriate for primary care screening in this setting. Together, these tools offer a potentially cost-effective strategy to reduce risky drinking for resource-constrained primary care settings, though future studies are needed to formally validate the AUDIT-C cut-off and the alcohol knowledge questionnaire.

Chapter 6: A Pilot Study of Culturally Adapted Brief Interventions for Alcohol Misuse in a Sri Lankan Outpatient Department

6.1 Introduction

Alcohol causes harm to drinkers, those around them, and society at large, ranking as the substance with the highest overall harm burden (1), and even minor reductions in consumption confer health benefits (28, 134). Harm reduction is therefore a valid goal alongside abstinence—and a more achievable one for many drinkers (See Chapter 1).

Among many effective behavioural interventions to minimise risky drinking, brief interventions (BIs) emerge as cost-effective, non-confrontational, and feasible for use as opportunistic interventions. However, research in this area has repeatedly highlighted deficits that impair interpretation of findings (127), and there is very limited evidence on how BIs perform in the South Asian region (133)—an area with distinct cultural characteristics, and showing a trend towards increasing use of alcohol especially among youth and females (37) (See Chapters 1 and 3).

Sri Lanka has no adapted brief interventions (BIs) available for use—a significant gap given the country's substantial burden of alcohol-related harms. In a pilot study in an inpatient unit (see Chapter 4) we adapted the WHO's BI to the Sri Lankan context; and pilot testing the intervention proved that it is acceptable and feasible. Further, the two less intensive interventions—Feedback on Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) (FOA); and Unit of Alcohol (UOA)—emerged as potential less intensive BIs. However, the inpatient setting was unsuitable for a future RCT: illness-induced abstinence was common—38% at recruitment and 76% at follow-up—with at least half of patients who reduced their drinking attributing their abstinence to ongoing illness rather than any intervention effect. This confounding meant that a setting where patients maintain their usual drinking patterns was essential for reliable testing of BIs.

Outpatient departments (OPDs) of government hospitals are the primary point of healthcare access for most Sri Lankans, recording 55 million visits in 2024 for a population of 22 million (145, 346). This volume presents both opportunity and challenge: BIs delivered in OPDs could reach a substantial proportion of the population but must be feasible within the time and resource constraints of this demanding environment. The urgency of identifying effective, low-resource interventions is underscored by the findings of the cross-sectional study, that 39% of adult males presenting to OPDs meet criteria for risky drinking (see Chapter 5). The same interventions used in the inpatient pilot study (See Chapter 4) were assessed in the current study. We operationalized constructs of the transtheoretical model (TTM) (186, 297, 347) (See Chapter 2) in adapting the BIs (See Chapter 4). Although the patient information sheet (Appendix A) was originally designed as a component of the ABI (see Chapter 4), findings from the inpatient pilot study suggested that this itself—independent of subsequent discussion—could activate therapeutic processes and explore contexts of change in TTM. We therefore extended patient information sheet administration to the FOA, and UOA arms in the current study.

The harms of alcohol misuse extend beyond drinkers to family members and others—sometimes termed "second-hand drinking" effects (348, 349). Family members bear substantial physical, psychological, and economic consequences of another's drinking, yet these harms have been largely overlooked in intervention research. While family member perspectives have been used in alcohol research as collateral informants to validate patient-reported drinking, and as outcome measures in interventions delivered to family members themselves (350, 351), family burden has not been used as an outcome measure of interventions delivered to the drinker. If reducing alcohol-related harms is the goal, then reducing harms to family members is equally important. This gap exists across all alcohol intervention research, including BI trials (see Chapter 1). Our inpatient pilot study, as far as we are aware, was the first to include family member-reported burden as an outcome measure of an intervention delivered to the drinker (See Chapter 4) (179); the present study extends this approach to the outpatient setting.

6.1.1 Objectives

1. Assess the feasibility of study procedures, including patient recruitment and retention, family member involvement in outcome assessment, and suitability of the outpatient department setting, for a future parallel three-arm RCT
2. Evaluate the acceptability and feasibility of three intervention intensities—feedback on AUDIT-C screening (FOA), unit of alcohol education (UOA), and the adapted brief intervention (ABI)—when delivered by non-specialist staff in a high-volume outpatient department
3. Assess the added utility of extended AUDIT-C compared with standard AUDIT-C in capturing consumption patterns across the full severity spectrum
4. Assess the responsiveness of outcome measures (Extended AUDIT-C, heavy episodic drinking frequency, Alcohol Problems Questionnaire, and Family Member Questionnaire) to detect within-group changes, as an indicator of their appropriateness for a future definitive trial
5. Assess the feasibility of using the patient information sheet (See Chapter 4) as a tool to explore processes and context of change in the transtheoretical model

6.2 Methods

6.2.1 Study population

All male patients aged 18 years or older presenting to the OPD—the main primary care health provider in Sri Lanka (See Chapter 5)—of Teaching Hospital Peradeniya, Sri Lanka were eligible to participate in the study. The cross-sectional study in the OPD (See Chapter 5) found that 39% (555/1414) of males and 0.8% (19/2286) of females presenting to the OPD within the study month were risky drinkers. Given this marked sex disparity, this pilot study focused exclusively on male patients.

6.2.1.1 Sample selection

Extended AUDIT-C (section 6.2.3.4) was used for screening and selecting appropriate patients for the study.

6.2.1.2 Inclusion criteria

Patients scoring ≥4 on the Extended AUDIT-C—the cut-off used in the cross-sectional study in the OPD (See Chapter 5) were included, which aligns with the definition of risky drinking (See Chapter 1) and improves identification of heavy episodic drinkers compared to higher AUDIT-C thresholds in primar care.(313) .

6.2.1.3 Exclusion criteria

Patients with at least one of the following criteria were excluded from the study.

1. Patients with ongoing serious physical or mental illness, making them incapable of following the directions/ attending for follow-up
2. Patients already accessing therapy/ intervention for alcohol use disorders or electing to access specialized care
3. Patients who could not communicate adequately due to language barriers or severe sensory impairment

6.2.2 Study design and procedure

This parallel group pilot randomised controlled trial included three arms—FOA, UOA and ABI arms. The study employed a mixed methods approach, combining quantitative assessment of outcome measures with qualitative evaluation of intervention acceptability and feasibility through feedback from patients, family members, and research assistants.

6.2.2.1 Recruitment and consent

Eligible males presenting to the OPD were approached consecutively by research assistants and provided study information. As in the cross-sectional study (See Chapter 5), research assistant capacity meant that not all eligible patients could be approached during the study period; however, there was no systematic selection bias in recruitment. Consent was obtained for screening and use their AUDIT-C scores in reporting. Patients with AUDIT-C ≥4 were invited to participate and provided informed consent for participation, follow-up, and contact with a family member (spouse, adult sibling, parent, or adult child). Family members of patients that provided consent for the study team to contact them were provided study information by research assistants. They also provided informed consent for participation.

6.2.2.2 Baseline assessment

Before intervention delivery, research assistants administered AUDIT questions 4–10 to supplement the AUDIT-C screening data, along with the patient information sheet and

Alcohol Problems Questionnaire (166). The Family Member Questionnaire (165) was administered when both patient and family member had consented.

6.2.2.3 Randomization and intervention delivery

Block randomization allocated patients to FOA, UOA, or ABI arms. Two research assistants trained in ABI conducted screening and randomization for all patients, then delivered ABI to those allocated to that arm. The remaining two research assistants delivered FOA and UOA according to standardized printed guides. To prevent contamination, only ABI-allocated research assistants received ABI training, meaning the same-researcher approach for screening and intervention was only feasible for the ABI arm.

6.2.2.4 Sample Size

The target sample size was 50 per arm, and data collection continued until all arms had reached the target. This sample size exceeds Teare et al.'s recommendation of 35 per arm for continuous outcomes to ensure adequate precision in variance estimation for planning a future definitive trial (352). Based on Whitehead et al.'s recommendations calibrated to anticipated effect size, 25 per arm is sufficient for small effect sizes typical of BI research (353). The larger sample of 50 per arm was chosen to increase precision given the absence of prior alcohol intervention trials in Sri Lankan primary care settings from which to derive local variance estimates, and to adequately assess feasibility outcomes including recruitment, retention, and acceptability across three intervention intensities.

6.2.2.5 Follow-up

Patients were followed up at 2 and 6 months; The 2-month follow-up was intended to enhance patient engagement, with extended AUDIT-C administered at this timepoint. Family members were followed-up at 6 months only. Patients were contacted by phone two weeks before their follow-up due date and allowed up to two weeks after to attend, either to the OPD or department of psychiatry, according to their preference. The

principal investigator allocated research assistants for follow-up assessment; hence the research assistants were blind to participant arm allocation.

6.2.3 Outcome measures

The main outcomes measured were: 1) feasibility of the study procedure, 2) acceptability and feasibility of the three intervention intensities (FOA, UOA and ABI) 3) utility of extended AUDIT-C 4) ability of outcome measures to detect change, and 5) utility of the patient information sheet.

6.2.3.1 Feasibility of the study methodology

Feasibility of the methodology was assessed through: patient recruitment (proportion of eligible patients who consented to participate); patient retention (follow-up completion at 6 months); suitability of the OPD setting (ability to complete screening and intervention delivery with minimal disturbance to routine care, assessed through direct observation; and patient and research assistant feedback); and feasibility of family member involvement (proportion of patients with family member participation at baseline and at follow-up).

6.2.3.2 Acceptability of the FOA, UOA and ABI

Patient feedback questionnaire (Appendix C): This questionnaire, retained from the inpatient pilot study (See Chapter 4) (179), assessed satisfaction with content, setting, duration, research assistant qualities, and perceived effectiveness. Feedback was obtained from all patients across all three arms at the 6-month follow-up visit. Patients rated several statements using a 5-point scale (Completely disagree, Disagree, Undecided, Agree, Agree completely), with two open-ended questions for suggestions and comments. There were 11 items common to all arms—'I am satisfied with the study', 'I am satisfied with the content delivered', 'I am satisfied with the location of the study', 'The information received was useful', 'The information received was relevant', 'The leaflet was useful', 'I can manage alcohol-related situations better now', 'The time with the research assistant was adequate', 'I was not kept waiting', 'I am glad that I

participated in the study', and 'I was planning to change my alcohol-related behaviours when I was recruited'. The latter statement was included to retrospectively assess whether patients were in early or late stages of change at recruitment, potentially informing interpretation of intervention effectiveness in a future RCT. In addition, each had different statements specific for the arm.

Research assistant feedback questionnaire (Appendix C): Modified from an intervention facilitator feedback tool (306), and was used in the inpatient pilot study (See Chapter 4), this questionnaire used the same 5-point scale to assess research assistants' perceptions of patient reception, training adequacy, delivery confidence, and intervention duration. Additional items specific to the ABI arm assessed perceptions of ABI components. The questionnaire included two open-ended questions for suggestions and comments.

Time taken to complete the intervention: This was determined by direct research assistant feedback.

6.2.3.3 Adaptation of the Extended AUDIT-C for the Sri Lankan Context (Appendix C)

The standard AUDIT-C exhibits ceiling effects: question 1 caps at "4 or more times a week" and question 2 at "10 or more drinks", limiting detection of changes at higher consumption levels. The Extended AUDIT-C captures more granular consumption data, helping detect subtle but clinically meaningful reductions that would otherwise be obscured—particularly important in a harm reduction context where any reduction matters. Additionally, this limitation in the standard version could discourage patients making genuine progress that remains undetected by the instrument.

To address this, we adopted the Extended AUDIT-C proposed by Dutey-Magni et al. (354), (Appendix C) which modifies questions 1 and 2 to capture higher consumption (Table 6.1). However, Extended AUDIT-C did not modify the responses of question 3, which measures frequency of HED. Considering the importance of measuring it, as accurately as possible (12), we modified it—to provide additional response categories that enable more granular measurement of consumption (Table 6.1), enabling more precise

quantification of change and to give better feedback to the patient (134)—while preserving the Extended AUDIT-C total (0–12), as in the standard AUDIT-C, for comparison with existing literature.

Table 6-1 Comparison of AUDIT-C and Extended AUDIT-C, and adaptation of question 3 of AUDIT-C in the current study

Version	Response Options	Score
AUDIT-1: How often do you have a drink containing alcohol?		
AUDIT-C	Never | Monthly or less | 2-4 times/month | 2-3 times/week | 4+ times/week	0 | 1 | 2 | 3 | 4
Extended AUDIT-C	Never | Monthly or less | 2-4 times/month | 2-3 times/week | 4-5 times/week | 6+ times/week	0 | 1 | 2 | 3 | 4 | 4a
AUDIT-2: How many units of alcohol do you drink on a typical day when you are drinking?		
AUDIT-C	0-2 units | 3-4 units | 5-6 units | 7-9 units | 10+ units	0 | 1 | 2 | 3 | 4
Extended AUDIT-C	0-2 units | 3-4 units | 5-6 units | 7-9 units | 10-12 units | 13-15 units | 16+ units	0 | 1 | 2 | 3 | 4 | 4a | 4b
AUDIT-3: How often have you had 5 or more units on a single occasion in the last year?		
AUDIT-C and Extended AUDIT-C	Never | Less than monthly | Monthly | Weekly | Daily or almost daily	0 | 1 | 2 | 3 | 4
Current study: Categorical-to-numeric conversion for AUDIT-C Question 3		
Category	Conversion Method	Days/Month
Never	—	0
Less than monthly	Interval midpoint	0.5
Monthly	Exact frequency reported (1, 2, or 3 times)	1, 2, or 3
Weekly	(times/week × 30) ÷ 7	4
Daily or almost daily	(2–7 × 30) ÷ 7	8–30

[Note: For participants selecting 'daily or almost daily,' we asked them to specify how many days per week they typically binged, then converted this to days per month: (days per week × 30) ÷ 7. This approach captured variation within the category (range: 8–30 days/month) that would otherwise be obscured by categorical scoring: [e.g.: A patient drinking 6 times per week with 13 units per occasion scores identically on standard AUDIT-C to one drinking 4 times per week with 10 units. Similarly, participants selecting 'monthly' were asked to specify frequency (1, 2, or 3 times per month)]. These represent meaningfully different positions on the risk curve (134). The highlighted items show additional responses of Extended AUDIT-C, compared to AUDIT-C]

Our Extended AUDIT-C incorporated questions 1–3 from a culturally adapted complete AUDIT with visual aids depicting unit equivalents [1 unit = 10 grams of pure ethanol (102, 293)] for commonly consumed local beverages (arrack, beer, wine, kasippu, and toddy) (317). Question 3, which assesses HED, was modified to reflect updated evidence defining HED ≥5 standard drinks per occasion for men, as discussed in Chapter 5.

Extended AUDIT-C was administered at three timepoints: initial assessment (preceding 6 months), 2-month follow-up (0–2 months post-recruitment), and 6-month follow-up (0–6 months post-recruitment).

6.2.3.4 Outcomes: Patient perspective

Extended AUDIT-C total score: (See Section 6.2.3.3)

Estimated HED days per month: HED is a pattern contributing alcohol-related harms, over and above the total weekly consumption (12) and 15-30% socioeconomic inequalities in harm are explained by quantity per drinking occasion or frequency of HED (32). To capture this, we derived estimated HED days per month from AUDIT-C question 3 using categorical-to-numeric conversion (Section 6.2.3.3, Table 6-1)

Alcohol problems questionnaire (APQ) (Appendix C): The APQ assesses alcohol-related problems over the preceding 6 months across nine domains: friendships, partner/spouse, children, work, money, legal, physical, psychological, and spiritual (166, 355). The questionnaire comprises 49 yes/no items, with intervention effectiveness determined by reduced total APQ score. Certain sections in the questionnaire may not apply to individual patients—for example, the children domain for patients without children. Additionally, some sections become inapplicable at follow-up if the patient remained abstinent during the follow-up period. We coded these as 60 (not applicable throughout) and 80 (not applicable due to abstinence) respectively during data entry.

The APQ captures harm reduction from a different angle: a patient may experience fewer alcohol-related problems even without reducing consumption amount or frequency, making this a valuable complementary outcome measure. The questionnaire was translated into Sinhala by the principal investigator and back-translated by a subject expert fluent in both languages. Inconsistencies were identified and corrected.

6.2.3.5 Outcomes: Family member perspective

To our knowledge, this is the first alcohol intervention study in an outpatient setting to include family member-reported burden as an outcome of an intervention delivered to the drinker, following our inpatient pilot which introduced this approach (See Chapter 4) (179). Family burden is an intervention outcome in its own right, not merely a secondary consideration, and warrants recognition as a primary outcome measure.

Family Member Questionnaire (165) *(Appendix C)*: This interviewer-administered 30-item tool measures social, emotional, physical, and financial impacts of patient drinking on family members, along with coping strategies and support. Responses use a 4-point scale (0 = "Never", 1 = "Once or twice", 2 = "Sometimes", 3 = "Often"). Intervention effectiveness is determined by reduced "Total family burden", which combines impact domains, symptoms, emotional coping, and tolerant inactive coping.

Family member feedback questionnaire (Appendix C): Family members were asked four open-ended questions at follow-up: whether they observed any change in the patient's alcohol consumption, whether they noticed any behavioural changes, whether they still faced difficulties related to the patient's drinking, and any suggestions for improving the intervention. These questions were developed for this study rather than drawn from a validated questionnaire. Responses were collected in Sinhala and reviewed descriptively to inform feasibility and acceptability. In addition, there was a section ‘Any other comments’.

6.2.3.6 Outcome measures, and multidimensional harm reduction

We assessed outcomes using four measures (Extended AUDIT-C, HED frequency, Alcohol Problems Questionnaire, and Family Member Questionnaire), capturing alcohol consumption, problems experienced by the drinker, and family burden. This approach reflects a comprehensive view of harm reduction that extends beyond the alcohol consumption per se (See Section 7.4), while also strengthening validity through triangulation—particularly important given the tendency for patients to underreport their consumption.

6.2.4 Baseline characterisation of alcohol problem severity

Extended AUDIT-C does not include questions to detect dependence, and we considered it important to characterise the nature and severity of patients' alcohol problems at baseline to provide context for interpreting changes in AUDIT-C scores, and other outcome measures over the follow-up period. Therefore, we administered the rest of the AUDIT at initial assessment.

AUDIT questions Q4-Q10: AUDIT questions 4–6 assess dependence symptoms (impaired control, increased salience, morning drinking), while questions 7–10 assess harmful use (guilt, blackouts, injuries, others' concern) (236).

Table 6-2 Summary of pilot study objectives, constructs and findings

Objective	Construct	Data source	Key findings
1. Feasibility of the study methodology			
a. Recruitment	Screening consent	Study records	86.8% (765/881)
	Eligibility (AUDIT-C ≥4)	Study records	22.4% (197/881) of approached
	Enrolment	Study records	17.0% (150/ 881) of approached
	Recruitment duration	Study records	~6 weeks
b. Retention	Patient follow-up	Study records	Overall: 88.7% (133/150) FOA: 92% | UOA: 84% | ABI: 90%
	FM follow-up (paired data)	Study records	93.7% (74/79)
c. Setting suitability	Integration with OPD workflow	Direct observation; Patient feedback	Screening and intervention completed without disrupting routine care
d. Obtaining FM-reported outcomes	Patient consent for FM contact	Study records	72.7% (109/150)
	FM participation at baseline	Study records	52.7% (79/150)
	FM participation at any timepoint	Study records	68.7% (103/150) *(An additional 24 FMs came at 6-month time point)*
2. Acceptability of interventions			
a. Feedback on AUDIT-C (FOA)	Delivery time	Direct observation	~3 minutes
	Patient satisfaction	Patient feedback questionnaire (11 items)	See Figure 6.3 (common items)
	Leaflet comprehension	3 arm-specific items	73% indicated they would need RA explanation of leaflet content; opinion divided on simplification
b. Unit of Alcohol education (UOA)	Delivery time	Direct observation	~5 minutes
	Patient satisfaction	Patient feedback questionnaire (11 items)	See Figure 6.3 (common items)
	Perceived helpfulness of advice	2 arm-specific items	88% found advice helpful; 95% rated RA as knowledgeable
c. Adapted Brief Intervention (ABI)	Delivery time	Direct observation	15-30 minutes

Objective	Construct	Data source	Key findings
	Patient satisfaction	Patient feedback questionnaire (11 items)	See Figure 6.3 (common items)
	Overall quality of RA interaction	5 arm-specific items	100% rated discussion as useful; 100% positive ratings for RA skills
3. Acceptability and feasibility of outcome measures			
a. Extended AUDIT-C *(has more response categories in each question than in AUDIT-C)*	Completion proportion	Study records	100% at baseline; 88.7% at follow-up
	Comprehension	RA feedback	The AUDIT questions with calculated number of units were helpful. Exact heavy episodic (HED) days were calculable.
	Time to complete	RA feedback	~2–5 minutes
b. HED days/month *(derived from AUDIT-C Q3)*	Completion proportion	Study records	As above (part of extended AUDIT-C)
c. Alcohol Problems Questionnaire (APQ)	Completion proportion	Study records	96.7% (145/150) at baseline
	Comprehension	Missing data patterns; RA feedback	Low missing data; some N/A responses appropriately handled
	Time to complete	RA feedback	~10–20 minutes
d. Family Member Questionnaire (FMQ)	Completion proportion	Study records	52.7% at baseline; 93.7% retention of those enrolled
	Comprehension	RA feedback	FM understood the questionnaire
	Time to complete	RA feedback	~10–15 minutes
	FM willingness to participate	Qualitative feedback	Family members expressed relief at opportunity to discuss concerns; some reported perceived improvement in the drinker's overall behaviour, some requested further help

6.2.5 The patient information sheet

The patient information sheet explores income, drinking contexts/ companions, reasons for drinking, life goals, alcohol-related myths, alcohol-related problems already experienced, whether they had received information on alcohol previously, and if so, what it was and the outcome (Appendix A). These aspects reflect the context of change in TTM (186), which is critical in relapse prevention (356-358), but hardly explored in research. It was administered to all in the three arms as part of the initial assessment, not as a component of the intervention. However, the patient information sheet may itself activate processes of change (186) through systematic questioning about drinking patterns, contexts, and consequences. These processes may generate cognitive dissonance—the mechanism underlying the question-behaviour effect, where questioning people about a behaviour can influence subsequent performance of that behaviour (167, 359)—potentially triggering positive outcomes even in the less intensive arms when combined with screening feedback.

6.2.6 Incentives

Patients and family members were reimbursed Rs. 2,500 (~USD 7.25) per assessment for transport costs and time (a day worker would draw about Rs. 4000), both at initial assessment and follow-up—a method commonly used to enhance participant engagement in BI studies (235, 281, 360).

6.2.7 Selection, training, allocation and supervision of research assistants

Selection: Of eight research assistants who participated in the inpatient pilot study (See Chapter 4) (179), three were available for the current study. A fourth research assistant was recruited through advertisement; selection focused particularly on communication skills. All research assistants were female as no males applied.

Training: The principal investigator, who is a specialist in the field and has been working with patients having alcohol use disorders and their families for about two decades, trained all research assistants through lectures, role-plays, and hands-on sessions covering study purpose; basic alcohol knowledge; UOA and low-risk drinking concepts;

alcohol-related societal harms and mental illness; research ethics and consent procedures; and administration of study measures. Two research assistants from the previous pilot received additional ABI training, which was restricted to them to minimize contamination risk.

Allocation: The two ABI-trained research assistants conducted screening and randomization for all patients, then delivered ABI to patients allocated to that arm. The other two research assistants delivered FOA and UOA respectively.

Supervision: The principal investigator made regular visits to the OPD to ensure protocol adherence and address difficulties. Weekly meetings were held with all research assistants to discuss emerging issues, and research assistants could contact the principal investigator by phone at any time.

6.2.8 Interventions

FOA: The research assistant informed the patient that his AUDIT-C score indicated that his consumption had already caused problems or was likely to cause problems in the future. Patients received the alcohol leaflet (Appendix A), which contained information on the harms of alcohol, illustrations showing standard drinks for commonly consumed alcoholic beverages in Sri Lanka, and an explanation of low-risk drinking. This involved one-way information provision, with no interactive discussion.

UOA: In addition to all components of FOA, patients received brief education from the research assistant on units of alcohol and low-risk drinking [i.e., maximum 10 units/week, no more than 4 units/day, activities to avoid after drinking, and risks of HED (≥5 units/occasion)]. There was no interactive discussion.

ABI: ABI included all components of UOA plus an interactive discussion. Research assistants used information from the patient information sheet to initiate and tailor the interactive discussion according to the ABI manual (Appendix A).

The three interventions tested represent a continuum of intensity: FOA—~3 minutes, one-way information; UOA—~5 minutes, adds brief education on standard drinks and low-risk limits, one-way information; and the ABI—15–30 minutes, interactive, patient-centred discussion. Each less intensive intervention is nested within the more intensive one (Figure 6.1), enabling direct comparison while controlling for contextual effects.

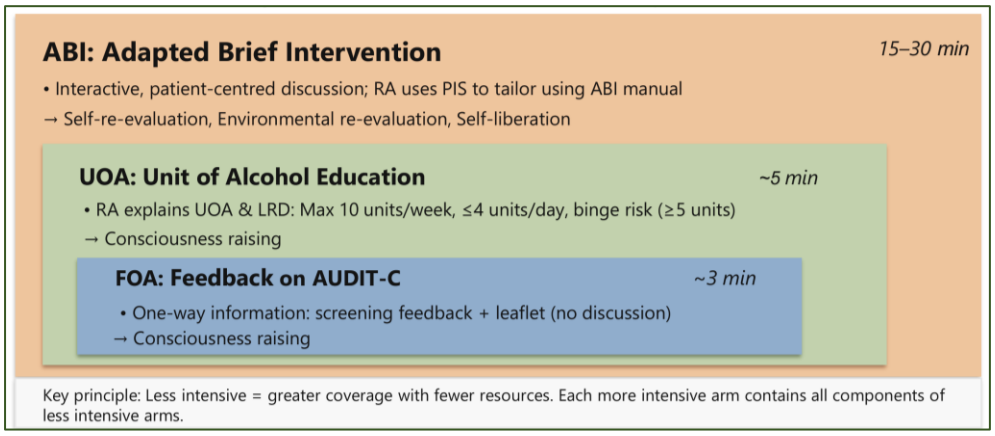

Figure 6-1 Three-arm nested intervention structure

If FOA or UOA prove effective as standalone interventions in future trials, they would require substantially fewer resources than ABI, making widespread implementation feasible in high-volume, low-resource settings.

6.2.9 Ethics and trial registration

Ethics approval was granted by the Ethics Review Committee, Faculty of Medicine, University of Peradeniya (2023/EC/83) and the Australian National University (ANU) Human Research Ethics Committee (H/2024/0656). The trial was registered in the Sri Lanka Clinical Trials Registry (SLCTR/2024/018).

6.2.10 Analysis

Descriptive analysis was conducted using Stata/MP 19.5. Consistent with the CONSORT extension for pilot and feasibility trials (Eldridge et al. 2016), no hypothesis tests were performed, as the study was not powered for between-group comparisons. Within-arm changes in outcome measures are presented as means (SD) to assess responsiveness of the measures and to provide variance estimates for planning a definitive trial, not as

evidence of efficacy. Qualitative feedback was reviewed descriptively and summarised to inform future intervention development.

6.3 Results

6.3.1 Sample characteristics

Each arm had 50 patients. Mean age was 49.6 years (SD 12.8) in FOA, 52.4 years (SD 14.1) in UOA, and 51.1 years (SD 14.7) in ABI. Mean years of education ranged from 10.0 to 11.0 years across arms (FOA: 10.3, SD 3.0; UOA: 11.0, SD 2.8; ABI: 10.0, SD 3.0). Baseline AUDIT-C scores were similar (FOA: 6.06, SD 1.95; UOA: 6.00, SD 2.17; ABI: 6.16, SD 2.00). Type of alcohol commonly consumed and HED frequency at initial assessment are shown in Table 6.3.

AUDIT questions 4–6 revealed that 20 patients (13.3%) scored ≥2 on at least one AUDIT dependence item (Q4, Q5, or Q6) at initial assessment, suggesting that they were probably dependent. Of these, 16 (80%) were retained at follow-up: 7/8 in FOA, 4/5 in UOA, and 5/7 in ABI. Among those retained, FOA showed a reduction in HED days of 4.72 (SD 8.12), UOA 0.25 (SD 0.34), and ABI 3.72 (SD 15.51) (Table 6.3).

6.3.2 Feasibility of methodology

6.3.2.1 Patient recruitment, characteristics and follow-up

Recruitment commenced on 14.06.2024 and was completed on 23.07.2024. The two research assistants who screened the patients invited 881 patients to join the study. Of these, 765 (86.8%) consented to be screened. There were 197 (22.4% of all approached) who had AUDIT-C ≥4—the inclusion criterion—of which 47 declined to participate in the study. A total of 150 male risky drinkers (17% of those invited) were randomised equally to the three arms (n=50 each) (Figure 6.2).

Of the 150 patients, 124 (82.7%) were married, 19 (12.7%) were unmarried, and 7 (4.7%) were separated or divorced.

Follow-up of patients at two months was 96% (48/50), 92% (46/50) and 90% (45/ 50) for FOA, UOA and ABI respectively.

Overall retention at 6-month follow-up was 88.7% (133/150), with FOA achieving 92% (46/50), UOA 84% (42/50), and ABI 90% (45/50) (Figure 6.2 and Table 6.3).

6.3.2.2 Family member recruitment and follow-up

Of 150 patients, 109 (72.7%) consented to family member contact, and 81 family members consented to participate (Figure 6.2). Seventy-nine family members (52.7% of all patients; 72.5% of those contactable) were assessed at the initial assessment—26, 26, and 27 in FOA, UOA, and ABI arms respectively. Of these, 56 (70.9%) were wives or partners, 8 (10.1%) were children, 7 (8.9%) were mothers, 5 (6.3%) were siblings, and 3 (3.8%) were other relatives.

Retention among family members was 93.7% (74/79) at 6-month follow-up—26, 23, and 25 in FOA, UOA, and ABI arms respectively. An additional 24 family members participated only at follow-up, including 14 whose patients had not initially consented to family contact but brought family members when attending their follow-up appointment; and eight family members who did not consent to participate at recruitment.

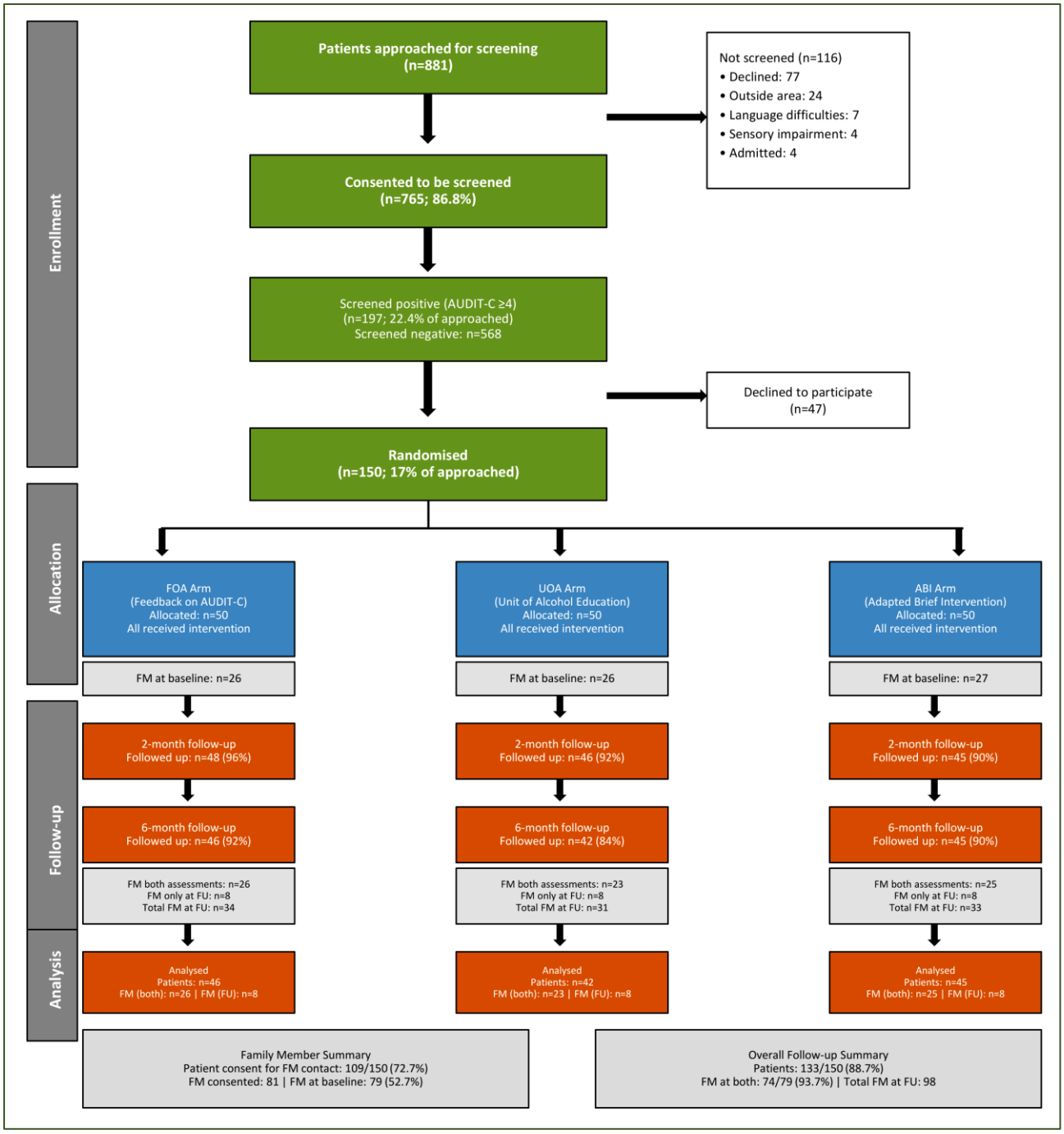

Figure 6-2 The CONSORT flow-chart of patient selection, randomization, and follow-up, and family member recruitment and follow-up

(Notes: FM = Family Member; FOA = Feedback on AUDIT-C; UOA = Unit of Alcohol Education; ABI = Adapted Brief Intervention. Of 24 FM assessed only at follow-up, 14 were from patients who had not initially consented to FM contact, FM at baseline: 56 wives/partners, 7 mothers, 8 children, 8 other relatives.)

6.3.3 Feasibility and acceptability of the ABI, UOA and FOA

6.3.3.1 Intervention duration

FOA required approximately 3 minutes. UOA required approximately 5 minutes. ABI required 15–30 minutes.

6.3.3.2 Patient feedback

Common statements across all arms: The responses to the first 10 statements—common to all three arms—are shown in Figure 6.3. Almost all responses for all statements across all three arms were either 'completely agree' or 'agree'.

‘Any other comments’ included ‘Come to villages and do it. It would be more helpful than doing it in only a hospital’, ‘Simplify the leaflet and make it available in English and Tamil as well’, ‘I feel I am a different man altogether’, ‘Have it (intervention) in the psychiatry department not in the OPD’, ‘I mix my drinks with soft drinks now’, ‘Knowledge on unit of alcohol was very useful’, ‘I shared what I learned with others’, ‘I need more help to stop drinking’, ‘Have it in groups, so we can share ideas’, 'Knowing about health consequences of drinking was the turning point', 'We have never been told reduction also helps (that we don't have to stop completely)’. In the FOA arm, only one-third of patients found the leaflet alone sufficient for understanding harmful alcohol use, whereas nearly three-quarters indicated they needed explanation from the research assistant.

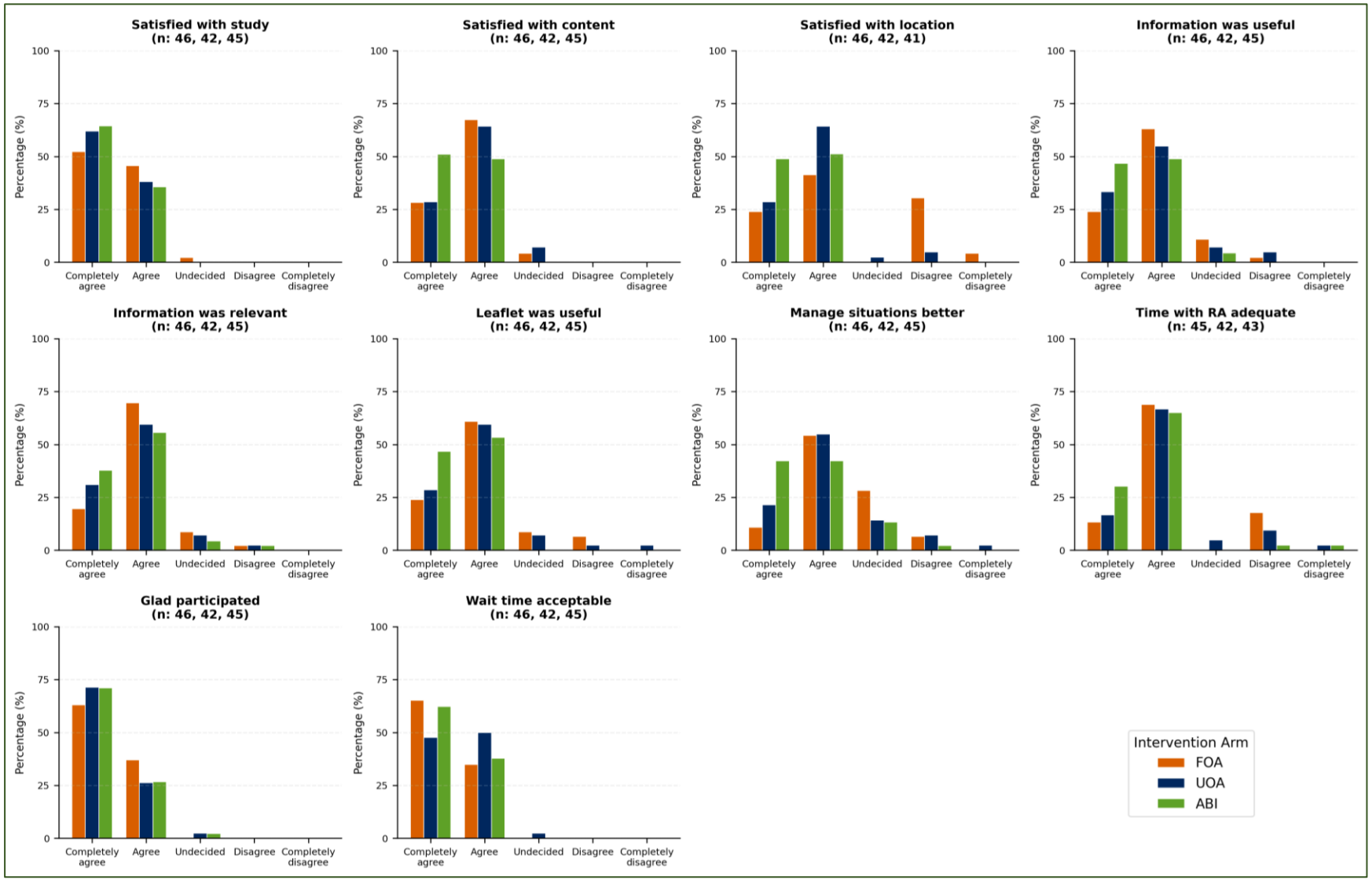

Figure 6-3 Patient acceptability ratings by intervention arm (items common to all arms)

[Notes: Research assistant (RA); Feedback on AUDIT-C (FOA); Unit of Alcohol education (UOA); Adapted Brief Intervention (ABI)]

FOA-specific feedback: The FOA arm included three additional statements relating to the educational leaflet. When asked whether they were clear about harmful alcohol use through the leaflet alone, only 15 (33.3%) agreed or completely agreed, with 22 (48.9%) undecided. However, 33 (73.3%) agreed or completely agreed that they needed an explanation from the research assistant about the leaflet content. Opinion was divided on whether the leaflet needed simplification: 19 (42.2%) agreed it did, while 19 (42.2%) disagreed.

UOA-specific feedback: In the UOA arm, 37 (88.1%) agreed or completely agreed that the research assistant's advice on alcohol was helpful. Regarding research assistant competence, 40 (95.2%) agreed or completely agreed that the research assistant was knowledgeable about alcohol.

ABI-specific feedback: The ABI arm included five additional statements evaluating the overall quality of research assistant interaction. All 45 respondents (100%) agreed or completely agreed that the discussion with the research assistant was useful. Similarly, all respondents rated the research assistant positively on interpersonal skills: All agreed the research assistant was friendly, listened well, was well-trained, and was knowledgeable about alcohol. Of these, approximately two-thirds responded 'completely agree' rather than 'agree' for each statement.

6.3.3.3 Research assistant feedback

The research assistants who administered the interventions agreed or completely agreed that each intervention was useful to patients, that they could empathize with patients experiencing alcohol problems, that they felt comfortable discussing alcohol-related issues, that their training was adequate, and that the alcohol leaflet was useful when providing information. All research assistants noted that the majority of patients were happy that they participated. Research assistants were happy to be involved in the research and were passionate about doing the respective intervention. Some patients had requested the research assistants that similar programmes be conducted in their residential areas and plantation settings, where *'females seem to be suffering due to*

male drinking'. All four research assistants indicated that the leaflet required simplification if it were to be given to patients without explanation. All suggested making the leaflet available in Tamil (the other commonly spoken language in Sri Lanka aside from Sinhalese) and providing a quieter space for conducting the interventions.

The two research assistants who administered the ABI reported that the intervention duration (15-30 minutes) was adequate and that the patient information sheet provided useful information to begin the discussion and tailor it within a shorter timeframe than would otherwise be possible. The research assistant who administered UOA observed: 'In arms FOA and UOA we did not give much information, but many appeared to have benefitted. The questions we asked (i.e., questions in the APQ)—"Have you ever assaulted your children or wife?", "Have there been times when your children stopped giving you money?"—made them think about their behaviours 'again and again.'

6.3.3.4 Family member feedback

The family members suggested to expand the intervention to community settings beyond hospitals, targeting younger drinkers, involving family members earlier in the process, establishing dedicated alcohol counselling services, and providing materials in Tamil as well. A few family members commented favourably on the non-directive approach, noting that education and asking questions rather than instructing patients to stop drinking appeared effective: "Once they are educated about the harmful effects of alcohol, they feel embarrassed, driving them to change" These observations, while not formally analysed, support the acceptability of the interventions and highlight directions for future implementation. Further, a few family members requested healthcare referrals for themselves.

6.3.3.5 Readiness to change of patients at the recruitment

The statement *'I was planning to change my alcohol-related behaviours when I was recruited'* provides an indication of readiness to change at recruitment. There were 43 (93.5%), 35 (83.3%), and 33 (75.6%) patients in FOA, UOA, and ABI arms respectively—i.e. 111/133 (83.4%) of those who came for follow-up—who were not planning to change

(the total of 'undecided', 'disagree', and 'completely disagree' in each arm) suggesting most were in precontemplation stage when recruited (Figure 6.4).

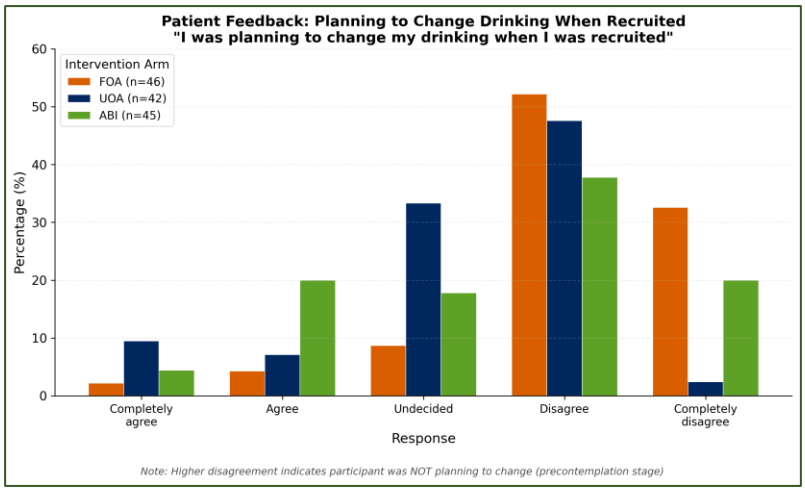

Figure 6-4 : Readiness to change drinking behaviour at baseline, by intervention arm

(Notes: Feedback on AUDIT-C (FOA); Unit of Alcohol education (UOA); Adapted Brief Intervention (ABI). Disagreement indicates possible precontemplation stage)

6.3.4 Extended AUDIT

The extended AUDIT-C response options captured consumption levels beyond standard AUDIT-C thresholds. At initial assessment, 10 participants reported drinking frequency of 6+ times per week (captured by extended Q1 but would have scored identically to 4+ times/week in standard AUDIT-C), and 3 participants reported consuming 13+ units per typical drinking day (captured by extended Q2 options).

Categorical-to-numeric conversion of AUDIT-C Q3 (HED frequency) revealed variation masked by categorical scoring (Table 6.3). Twelve participants and 4 participants, respectively, reported daily HED (30 days/month) at initial assessment and at six-month follow-up. Among those scoring "daily or almost daily" (categorical score 4) at baseline, the numeric measure differentiated those HED 8 days/month from those HED 30 days/month—a distinction invisible to standard AUDIT-C.

6.3.5 Ability of outcome measures to detect change

All four outcome measures (Extended AUDIT-C, HED frequency, Alcohol Problems Questionnaire, and Family Member Questionnaire) showed changes from initial assessment to six-month follow-up across the three intervention arms. These within-group changes are presented (Table 6.3) to demonstrate that each measure changed at 6-month follow-up assessment. However, they do not constitute evidence of intervention efficacy, as the pilot was not powered for between-group comparisons.

6.3.5.1 Patient perspective

Extended AUDIT-C scores: Mean AUDIT-C scores reduced in all three arms. FOA showed a mean reduction of 0.80 (SD 1.94), UOA 1.55 (SD 2.50), and ABI 2.36 (SD 2.81). At follow-up, 2 patients in FOA, 5 in UOA and 12 in ABI had AUDIT-C scores of zero.

Heavy episodic drinking: Estimated HED days per month reduced in all arms. FOA showed a mean reduction of 1.99 days/month (SD 6.20), UOA 1.75 (SD 6.17), and ABI 3.75 (SD 9.52). Median HED days reduced from 2 days/month at baseline to 0.5 days/month at follow-up across all arms.

Alcohol problems: APQ total scores reduced similarly across all three arms (FOA: 2.23, SD 5.84; UOA: 2.24, SD 4.14; ABI: 2.45, SD 4.37).

Type of alcohol beverage: The consumption of spirits reduced in all arms—40 to 29, 40 to 25 and 38 to 19 in FOA, UOA and ABI arms respectively.

Table 6-3 Patient-related outcomes, by study arm

Outcome measure	FOA arm (n=50)	UOA arm (n=50)	ABI arm (n=50)
Retention at FU2, n (%)	46 (92%)	42 (84%)	45 (90%)
AUDIT-C total score			
Initial assessment, Mean (SD)	6.06 (1.95)	6.00 (2.17)	6.16 (2.00)
6-month follow-up, Mean (SD)	5.26 (2.14)	4.48 (2.86)	3.69 (2.89)
Change over 6 months, Mean (SD)	-0.80 (1.94)	-1.55 (2.50)	-2.36 (2.81)
AUDIT-C = 0 at FU2, n	2	5	12
AUDIT scores – for dependence category and harmful effects category (at initial assessment)			
Dependence (Q4-Q6 ≥2 on any), n (%)	8 (16%)	5 (10%)	7 (14%)
Q9 or Q10 = 4 (harm), n (%)	35 (70%)	24 (48%)	27 (54%)
Alcohol Problems Questionnaire (APQ) total score			
Initial assessment, Mean (SD)	10.15 (6.59)	7.10 (3.92)	8.32 (6.31)
6-month follow-up, Mean (SD)	7.91 (5.57)	5.19 (4.19)	5.93 (4.91)
Change over 6 months (Paired), Mean (SD) (Negative mark indicates improvement)	-2.44 (5.73)	-2.24 (4.14)	-2.49 (4.32)
Type of alcohol			
Initial assessment - Spirits, n	40	40	38
6-month follow-up - Spirits, n	29	25	19
HED days per month			
Initial assessment, Mean (SD)	5.19 (8.02)	5.33 (9.06)	5.91 (8.51)
Initial assessment, Median (IQR)	2 (0.5-4)	2 (0.5-4)	2 (0.5-9)
6-month follow-up, Mean (SD)	2.98 (4.71)	3.62 (7.77)	2.05 (4.96)
6-month follow-up, Median (IQR)	0.5 (0.5-3)	0.5 (0.5-3)	0.5 (0-2)
Change over 6 months (Paired), Mean(SD)	-1.99 (6.23)	-1.75 (6.20)	-3.72 (9.58)
Dependence subgroup (scored ≥2 on Q4, Q5, or Q6)			
N at initial assessment	8	5	7
Retained at FU2, n (%)	7 (87.5%)	4 (80%)	5 (71.4%)
HED days/month at IA, Mean (SD)	8.88 (10.45)	13.10 (15.49)	11.21 (10.52)
HED days/month at FU2, Mean (SD)	3.58 (4.24)	15.13 (17.18)	6.70 (13.04)
Change in HED days (Paired), Mean (SD)	-4.75 (8.1)	-0.25 (0.29)	-3.80 (15.58)

[Notes: Feedback on AUDIT-C (FOA); Unit of Alcohol education (UOA); Adapted Brief Intervention (ABI)
Heavy episodic drinking (HED) days per month derived from AUDIT-C Q3 responses. Distribution is right-skewed; both mean (SD) and median (IQR) are reported; Dependence defined as scoring ≥2 (monthly or more frequent) on any of AUDIT Q4, Q5, or Q6, per WHO AUDIT Manual guidance (102); APQ data available for 145/150 at IA and 133 at FU2; change calculated for 128 patients with complete data.; Spirits = Arrack, Brandy, Whiskey, Gin; Non-spirits = Strong Beer, Toddy, Lager Beer; Overall retention: 133/150 (88.67%); Dependence subgroup retention: 16/20 (80%)]

6.3.5.2 Family member perspective

Family burden: Baseline family burden scores were FOA: 11.77; UOA: 11.83; ABI: 13.16 (Table 6.4). Among 74 family members with data at both timepoints, total family burden reduced in all arms. FOA showed a mean reduction of 3.65 (SD 6.37), UOA 1.30 (SD 8.37), and ABI 1.80 (SD 9.39).

Family members assessed only at follow-up: An additional 24 family members participated only at follow-up. Among the corresponding patients, 79.2% showed improvement or stability in AUDIT-C scores and 69.6% showed reduced APQ scores.

Table 6-4 Family member related outcomes, by study arm

Outcome measure	FOA	UOA	ABI
Total family burden (n=74)			
N	26	23	25
Initial assessment, Mean (SD)	11.77 (9.79)	11.83 (6.33)	13.16 (9.78)
Follow-up 2, Mean (SD)	8.12 (7.06)	10.52 (7.00)	11.36 (9.50)
Change over 6 months, Mean (SD)	-3.96 (6.31)	-1.30 (8.37)	-1.80 (9.58)

[Notes: FOA = Feedback on AUDIT-C; UOA = Unit of Alcohol education; ABI = Adapted Brief Intervention
Total family burden- AFI-Net Family Member Questionnaire (165); Analysis restricted to family members with data at both initial assessment and follow-up (matched pairs). Negative change indicates improvement (reduced burden].

Family Member Feedback: this was assessed depending on the feedback on two aspects; amount of drinking of the patient and behavioural improvements.

The changes in drinking amount show a downward trend—65.7% of FOA family members reported a reduction, compared with 57.6% in ABI and 50.0% in UOA. However, the nature of these reports differed across arms. In the FOA arm, family members reported modest or mixed changes in drinking behaviour, with some attributing any reduction to external factors such as economic hardship or health problems rather than the intervention. In the UOA arm, reports of reduced consumption were more consistent, with several family members noting that patients had substantially decreased or nearly stopped drinking. The most emphatic reports of change came from the ABI arm, where family members frequently attributed improvements directly to the study intervention, with some spontaneously mentioning that patients had referenced advice received during sessions.

The behavioural improvements reported were reduced frequency of anger outbursts, fewer quarrels, giving more money to the family, engaging more with the family, coming home early after work—*'I was embarrassed when he shouted. He does not shout at me now*', '*He cares for me and my children now', 'He gives more money to us now', 'I was burning within, not knowing what would happen next. He is 100% better now'*—followed a similar gradient across arms. ABI family members reported the highest proportion of

behavioural improvement (20.7%), compared with UOA (10.7%) and FOA (9.4%). Several ABI-arm respondents expressed gratitude in spiritual terms *("The spirits have sent you to me")*, describing the intervention as a blessing. Family members also reported that educational materials (leaflets) provided in the UOA and ABI arms were shared within households, including with children.

6.3.6 Patient information sheet

The most commonly reported drinking context was at functions (94.0%). Over half reported drinking when feeling tired (61.3%) with friends (53.3%), or with relatives (11.3%). Approximately half drank to feel happy (49.3%). Drinking to socialise (26.7%), due to peer pressure (24.7%), or when experiencing negative emotions—loneliness (22.7%), sadness (22.7%), or anxiety (15.3%)—were also reported.

33.1%, mentioned their children's welfare, 30.2% financial security and 15.4% having a house as their life goals. Out of 54 who commented on problems experienced due to alcohol, 40.7% reported health problems/ injuries, 33.3% interpersonal conflicts, 20.4% financial problems, while 5.6% reported having no problems. 52.8%, 15% and 14.2% have received information on alcohol from TV, internet/ YouTube/ social media and newspapers respectively, while 52%, 22.9% and 22.3% respectively from family, friends and health care workers. In 51.1% of instances where they received information on alcohol, the consequences of drinking mentioned, 32.4% were asked not to drink only, 13.7% information given was inaccurate——such as claims that alcohol aids sleep, relieves tiredness, or benefits health— and 2.8% about cutting down. 53.1% reported that the information received had no effect on their drinking and 46.9% reported to have reduced drinking (Table 6.5).

Table 6-5 Findings from patient information sheet

Domain / Item	n (%)
Drinking context (n=150)	
At functions	141 (94.0)
When feeling tired	92 (61.3)
With friends	80 (53.3)
To feel happy	74 (49.3)

Domain / Item	n (%)
To socialise	40 (26.7)
Due to peer pressure	37 (24.7)
When feeling lonely	34 (22.7)
When feeling sad	34 (22.7)
When feeling anxious	23 (15.3)
With relatives	17 (11.3)
Life goals* (n=169)	
Children's welfare	56 (33.1)
Financial security	51 (30.2)
Housing acquisition	26 (15.4)
Other	36 (21.3)
Reasons for drinking* (n=105)	
Peer-related drinking	28 (26.7)
Fatigue relief	20 (19.0)
Pleasure-seeking	15 (14.3)
Coping with distress	14 (13.3)
Other	28 (26.7)
Problems experienced due to alcohol* (n=54)	
Health problems/ injuries	22 (40.7)
Interpersonal conflicts	18 (33.3)
Financial problems	11 (20.4)
No problems reported	3 (5.6)
Prior alcohol information - Media sources (n=233)	
Television	123 (52.8)
Internet/YouTube/Social media	35 (15.0)
Newspaper	33 (14.2)
Books/ leaflets/ posters	31(13.3)
Radio	11 (4.7)
Prior alcohol information - People (n=179)	
Family	93 (52.0)
Friends	41 (22.9)
Healthcare workers	40 (22.3)
Other	5 (2.8)
Content of prior information* (n=182)	
Consequences of drinking stated	93 (51.1)
'Don't drink' / 'Stop drinking' *(No reason given)*	59 (32.4)
Inaccurate information	25 (13.7)
Instructions to cut down	5 (2.8)
Self-reported effect of prior information (n=130)	
No effect	69 (53.1)
Reduced drinking	61 (46.9)

*(Note: *Open-ended responses categorised thematically; categories not mutually exclusive)*

6.4 Discussion

This pilot study demonstrated that delivering culturally adapted BIs are feasible and acceptable in Sri Lankan primary care settings—where primary and secondary prevention is a core function, making opportunistic interventions, such as BIs, for risky drinkers particularly appropriate. Despite Sri Lanka's substantial burden of alcohol-related harm, BIs have rarely been evaluated in the country. By measuring family member-reported burden, this study addresses a gap in intervention research that has traditionally focused only on self-reported consumption while overlooking harm reduction within families as a valid outcome on its own.

This is the first pilot study of BIs for alcohol use in Sri Lankan outpatient primary care—a setting where risky drinkers routinely present, yet evidence on effective interventions remains limited. The finding that only 22% of patients had previously received alcohol information from healthcare workers—despite regular contact with the health system—underscores both the gap this research programme addresses and the opportunity for systematic screening and intervention. This pilot establishes the feasibility and acceptability of the methodology, laying the foundation for what would be the first adequately powered randomised controlled trial of BIs in this setting.

Approximately 83% of patients were likely in the precontemplation stage at recruitment, yet they returned for follow-up and showed trends toward improvement, underscoring the value of opportunistic interventions that reach individuals not actively seeking help. This supports the feasibility of opportunistic screening and intervention in Sri Lankan primary care—reaching individuals not actively seeking help for alcohol problems (361). Whether these preliminary signals of benefit are confirmed will require an adequately powered trial.

An unanticipated finding was that educational materials provided in the UOA and ABI arms were shared within households, including with children. While not formally measured in this pilot, patients sharing their own educational materials with family members or friends could generate a ripple effect—extending harm-reduction messages

through social networks beyond the index patient. This is plausible given that 52% and 23% of patients had previously received alcohol-related information from family members and friends respectively, suggesting that informal information-sharing is already common in this population. The intervention may therefore channel an existing behaviour towards the dissemination of accurate, evidence-based content. This warrants investigation in future studies and represents a potential additional benefit of providing written materials as part of BIs.

6.4.1 Feasibility of the study methodology

Recruitment of 150 patients within six weeks, with 89% patient retention and 94% family member retention, confirms the feasibility of this methodology in routine OPD settings. Screening and interventions were conducted with minimal disruption or delay to patients attending for the purpose for which they came to the hospital. Although the study setting was rated as acceptable, many patients and research assistants suggested a quieter place within the OPD premises.

The majority of patients with indicators of possible dependence attended follow-up, and data show a trend towards reductions in HED days across all three arms. These may be the patients who requested additional support to reduce their alcohol consumption at follow-up—a response potentially reflecting cognitive dissonance between their drinking behaviour and newly acquired knowledge of its harms, self-efficacy, trust in healthcare, or some combination of these factors—which itself is a positive outcome. In fact, the first use of BI was to encourage those with severe alcohol problems to attend to specialized care (243, 362) (See Chapter 3).

6.4.2 Acceptability of interventions

Patient feedback was overwhelmingly positive across all three arms, with patients agreeing or completely agreeing with statements regarding intervention usefulness, duration, comfortable setting, and research assistant qualities including friendliness and attentiveness. Notably, all ABI patients (100%) agreed that the discussion with the

research assistant was useful and rated the research assistant positively on interpersonal skills including listening, training, and alcohol knowledge.

We did not formally assess stages of change. However, the observation that most patients were likely in precontemplation (83%) stage at recruitment, yet attended follow-up and reported benefit, suggests that all three interventions may facilitate movement through stages of change regardless of initial readiness—consistent with the transtheoretical model's emphasis on consciousness-raising and self-re-evaluation as processes that precede action (347) (See Chapter 2). The arm-specific findings are instructive: majority of FOA arm indicated they needed explanation of the information leaflet from the research assistant—suggesting that written materials require supplementation with brief discussion to achieve their educational purpose or simplification of the leaflet or both. In the UOA arm, nearly 90% found the research assistant's education helpful, and in the ABI arm, unanimous positive ratings for the structured discussion indicate high acceptability of the more intensive intervention.

Research assistant feedback corroborated patient perspectives—they agreed that across all arms the interventions were useful, that patients appeared satisfied, and that their training was adequate. The two research assistants delivering ABI reported that 15-30 minutes was sufficient and that the patient information sheet provided them a point to start the discussion and enabled efficient tailoring of discussion. One research assistant's observation that even assessment questions in the FOA and UOA arms—such as *'Have you ever assaulted your children or wife?'*—prompted patients to reflect on their behaviours *'again and again'* suggests that the assessment process itself may have therapeutic value (238)—a phenomenon consistent with the question-behaviour effect (167, 359) and consciousness-raising within the transtheoretical model (347)

Behavioural improvements reported were reduced anger, fewer quarrels, improved engagement with family. Several family members expressed gratitude for the opportunity to discuss their concerns, and some requested healthcare referrals for themselves. While such requests represent additional service demand, this should be viewed as

uncovering unmet need rather than creating burden. Family members of risky drinkers experience elevated rates of anxiety, depression, and somatic complaints—conditions that generate healthcare utilisation regardless of whether the underlying cause is identified. Addressing family member distress within the same intervention pathway may, ultimately prove more efficient and cost-effective than managing these presentations separately across fragmented services. The bidirectional relationship between drinker behaviour and family member wellbeing is well documented (310): improving one often improves the other. This represents an important context of change—interpersonal relationships (see Chapters 2 and 7)—described in the TTM (347), but rarely addressed in BI research.

6.4.3 Utility of extended AUDIT-C in capturing consumption patterns

The ceiling effect of the standard AUDIT-C (See Section 6.2.3.3) prevents detection of changes at higher consumption levels (See Table 6.1 *Note*). For patients already drinking heavily, genuine reductions remain invisible—potentially discouraging those making real progress.

The extended AUDIT-C (354), with modification to question 3 in the present study, addressed this limitation. The approach proved feasible, requiring only approximately one additional minute to administer. Beyond feasibility, it captured detailed consumption patterns across the full severity spectrum—information obscured by capped response options. A patient drinking 6 times per week with 13 units per occasion scores identically on standard AUDIT-C to one drinking 4 times per week with 10 units—yet these represent meaningfully different positions on the risk curve (Figure 6.5) (134). The extended version captures these distinctions, enabling clinicians to show patients their actual consumption relative to the Nutt's risk curve and reinforce that any reduction yields health benefit. This numeric approach—focusing on units consumed rather than disease categories—parallels successful public health strategies for calories, cholesterol, and blood pressure (134) and represents an achievable treatment goal that could engage more patients in treatment (102, 363). Figure 6.5 illustrates how patients can be encouraged to move along this risk curve.

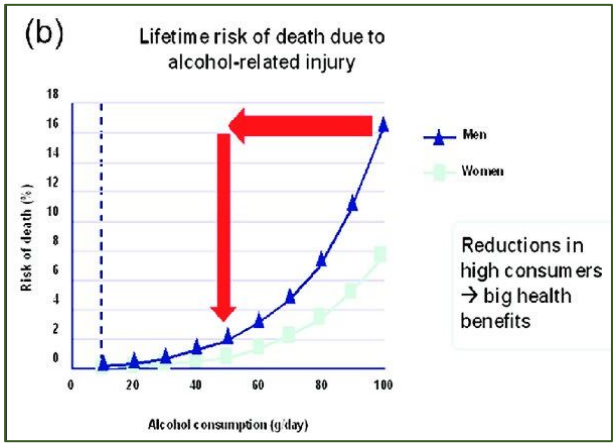

Figure 6-5 Lifetime risk of death due to alcohol-related injury ***(134)***

This approach also has research implications. AUDIT-C is widely used as an outcome measure, but its ceiling effect means that clinically meaningful reductions—in frequency (e.g., from 6 times to 4 per week), quantity (e.g., from 16 units to 10 units per day), or HED episodes (e.g., from 5 times to 3 times per week)—may go undetected among more problematic drinkers. This raises the possibility that effective interventions have been dismissed as ineffective in trials relying solely on standard AUDIT-C scores.

The categorical-to-numerical conversion for HED frequency warrants comment. The usual AUDIT-C reference period is one year—a timeframe during which situational factors such as job loss, bereavement, or relationship breakup may precipitate escalation in someone's alcohol consumption without established dependence. Stress-induced escalation is well-documented (364), and early identification matters before progressive changes in brain structure, gene expression, and neurotransmitter function take place (365, 366), which makes treatment more difficult. These individuals frequently present to primary care with somatic complaints and minor injuries, offering a window for intervention before dependence establishes. The numerical conversion enables this differentiation: within the 'daily or almost daily' category (5th response of Q3 of the AUDIT-C), it distinguishes a patient HED 8 days per month from one HED 30, a clinically meaningful distinction invisible to categorical scoring

6.4.4 Family member perspectives as an outcome measure

The total family burden showed a reducing trend which needs further research to be conclusive. Family member feedback gave a glimpse of the problems they face in day to day life, lived reality of which any questionnaire is unlikely to reveal—*'He used to get angry all the time', 'He is caring towards me and children now', 'He gives more money to us now', 'I was burning within, not knowing what would happen next. He is 100% better now', 'He used to shout. I was quite embarrassed'*. These experiences reflect an aspect of care rarely addressed in primary care. These statements have been translated from Sinhala to English by the PI. A few local studies highlight the outcomes of such experiences by family members—high prevalence of depression among spouses, domestic violence, suicide, self-harm and child abuse (Section 1.5.2).

Not all family members reported improvement, however. Many observed no change in drinking or behaviour, and several attributed reductions to factors other than the intervention—financial constraints ('He drinks less now because he has no money'), illness, or life events such as the birth of a child. Some described concealed drinking ('He doesn't drink in front of me; he drinks secretly'), continuing anger and conflict, unsafe behaviour while intoxicated, or financial hardship ('He gives only a third of what he earns to the family'), and one reported that drinking had increased in the preceding three months. Comments on the study itself were largely appreciative, but one family member observed that 'people don't answer 100% honestly'—a pertinent reminder of the limitations of self-reported consumption and of the value of family member reports for triangulation. Some requested materials in Tamil. These responses directly inform the design of a future trial: retention of family member-reported outcomes alongside patient self-report, designing information leaflets in Tamil.

Although we did not deliver any formal intervention to family members nor hold have lengthy discussion with them, unintended spillover effects emerged. Several expressed being relieved after talking to the research assistant and a few requested further help for themselves—aligning with evidence that voicing concerns can itself be therapeutic, even without formal intervention (367). The act of articulating experiences to an attentive

listener may facilitate emotional processing and reduce psychological burden, suggesting that even brief, structured contact with family members warrants further investigation as a low-cost adjunct to patient-focused interventions. A separate observation hints at bidirectional behaviour change. One family member commented, *'After I talked to you, I also changed—I corrected my mistakes.'* This occurred despite research assistants only administering the Family Member Questionnaire (165), suggesting that family members may independently modify their own behaviours in response to the patient's intervention, even without being directly targeted. This phenomenon warrants further study.

6.4.5 Ability of outcome measure to detect change

A key objective of this pilot was to assess whether the selected outcome measures were responsive enough to detect within-group changes over time—an essential prerequisite for powering a future definitive trial. All four measures demonstrated responsiveness to change.

Extended AUDIT-C total score: demonstrated that it can detect change across all arms (Table 6.3). At follow-up, 12 patients in the ABI arm had AUDIT-C scores of zero—indicating abstinence—compared with 5 in UOA and 2 in FOA. This gradient across intervention intensities, while not constituting evidence of differential effectiveness in this underpowered pilot, demonstrates that the extended AUDIT-C total score can detect the magnitude of change likely to be of interest in a future trial.

HED days per month: derived from AUDIT-C question 3 using the categorical-to-numerical conversion described in Section 6.4.3, captured change better—mean estimated HED days showed a trend towards reduction (Table 6.3).

The Alcohol Problems Questionnaire: captured harm reduction from a different angle than consumption measures alone. Total APQ scores reduced similarly across arms (Table 6.3): This parallel movement in AUDIT-C scores and HED days provides some evidence of convergent validity—patients reporting reduced consumption also reported

fewer alcohol-related problems. The relationship was imperfect, perhaps reflecting that consumption and consequences change through different mechanisms and at different rates.

The Family Member Questionnaire: proved sensitive to detecting change in family burden (Table 6.4). A patient may reduce consumption without immediately alleviating family strain, or family dynamics may improve even before drinking patterns change substantially. This complexity argues for retaining both patient and family member outcomes in a future trial rather than treating family data solely as collateral information.

An exploratory finding warrants attention. Among 24 patients whose family members participated only at follow-up (not at baseline), 79.2% showed improvement or stability in AUDIT-C scores, and 69.6% showed reduced alcohol problems. The direction of causality is unclear: family engagement may have facilitated patient improvement, or patients who improved may have had more willing family members, or family members who observed improvement became hopeful and chose to engage. Regardless of mechanism, this observation, too, supports including family member assessment in future trials.

Family member data serves two purposes. First, it triangulates patient-reported outcomes—particularly valuable where social desirability bias may influence self-report (239). Second, it captures harm beyond the drinker: alcohol affects family members and the broader community (1), and measuring these wider impacts aligns with a harm reduction framework (10).

The observed changes confirm that all measures are responsive to change over time and yield clinically interpretable data, supporting their suitability as outcome measures for a future adequately powered trial.

6.4.6 Patient information sheet—a tool to explore processes and context of change in TTM

The patient information sheet findings revealed important contextual patterns with direct intervention implications. Drinking was predominantly social and occasion-driven — over nine in ten participants drank at functions, and over half when tired or with friends — yet emotional drinking contexts (loneliness, sadness, anxiety) were also prevalent, affecting up to a quarter of participants. The most commonly stated life goal was children's welfare (33.1%), followed by financial security (30.2%)—findings that offer concrete gain-frame anchors for behaviour change conversations. Among those who had previously received alcohol-related information, over half reported it had no effect on their drinking. Critically, a third had been told simply to stop drinking without explanation, 13.7% had received inaccurate information—including claims that alcohol aids sleep or relieves tiredness—and only 2.8% had been advised that cutting down, rather than stopping, was a valid goal. This pattern reflects a functional health literacy gap at the system level: prior information was neither accurate nor actionable.

The patient information sheet represents a methodological innovation that serves multiple purposes—(1) activating experiential processes of change across all three arms; (2) systematically capturing context of change across DiClemente's domains (186); (3) triggering the question-behaviour effect through structured self-reflection (238, 359); (4) providing an 'ice-breaker' and tailoring tool for the ABI discussion; and (5) surfacing cultural norms and myths that must be addressed for effective behaviour change. These aspects are further discussed in Chapter 7.

6.4.7 Interpreting outcome data from a pilot trial.

How much weight should be placed on outcome data from feasibility pilot trials is debated. The CONSORT extension for pilot and feasibility trials, which provides a reporting checklist specific to such studies, advises against formal hypothesis testing, as they are not powered for between-group comparisons (368). Some authors argue that treatment effects calculated from pilot studies should be used neither for sample size calculation nor for progression decisions, as they are imprecise and may be biased where

the pilot is unrepresentative of the main trial; instead, the target difference for a definitive trial should be based on clinical judgement of the minimum important difference rather than on pilot statistics (369).

Both types of error are possible in interpreting these data. The risk of a Type I (false positive) error arises from three arms, four outcome measures and subgroup observations, which together provide many opportunities for chance patterns to appear as signals. The gradient in mean AUDIT-C reduction across arms (FOA −0.80, UOA −1.55, ABI −2.36) illustrates this. The difference between ABI and FOA would reach conventional statistical significance, even allowing for multiple comparisons; however, it was not mirrored in other outcomes—family burden showed the largest mean reduction in the FOA arm (−3.65, compared with −1.30 in UOA and −1.80 in ABI)—and may partly reflect performance bias, as ABI was delivered by the research assistants who also screened participants, and social desirability in self-reported consumption following a more personal interaction. This finding is therefore a signal to be tested in a definitive trial rather than evidence of superiority. Enthusiasm and close protocol adherence at a single pilot site may also inflate effects that are not replicated in a larger trial (370).

Equally, a Type II (false negative) error is likely for most between-arm comparisons: with 23–46 participants per arm and wide variance, particularly for binge drinking days and family burden, clinically meaningful differences between interventions could be neither detected nor excluded. Concluding from these data that the less intensive interventions are ineffective, or that they are equivalent to ABI, would therefore be unwarranted. Further, apparent improvements in all arms, including the minimal FOA arm, are consistent with regression to the mean and assessment reactivity (Section 2.9.1) as well as with intervention effects, which only an adequately powered controlled comparison can distinguish. Accordingly, the sample size for a future definitive trial should be based on a clinically important difference, informed by the variance estimates from this pilot, rather than on the effect sizes observed here (369).

6.4.8 Limitations

Several constraints affected this study. We did not assess for polysubstance use, adverse childhood experiences and psychiatric comorbidity, which are important contextual factors in addressing alcohol related problems (205, 371), to minimize assessment burden on patients, which should be considered in future trials. We did not formally assess intervention fidelity, though positive patient feedback on research assistant qualities provides indirect support for adequate delivery. We didn't evaluate research assistant micro-skills (listening, communication), which may influence outcomes more than content itself (127). The AUDIT-C cut-off we used was not validated, which is a limitation in the study.

Family member recruitment was lower than anticipated (52.7%, 79/150), and strategies to engage more should be explored. Follow-up was limited to 6 months; a future trial should include 12-month follow-up to align with field standards and to differentiate intervention-induced change from spontaneous remission—particularly among those whose heavy drinking may have been precipitated by temporary stressors. Differential dropout may reflect intervention response—participants who improve substantially may perceive follow-up as unnecessary, while those experiencing minimal benefit may disengage. These patterns, though clinically recognised, remain under-researched. Future trials could incorporate brief telephone follow-up to characterise dropout reasons and distinguish between these trajectories. Interventions were conducted only in Sinhala; adaptations will be needed for other Sri Lankan communities and females.

6.4.9 Strengths

This pilot study has several methodological strengths that directly address recognised limitations in already existing alcohol BI research (Table 6.6) and support the feasibility of a future adequately powered trial in the OPD.

Table 6-6 Addressing recognised limitations in brief intervention research

Known limitation	How addressed in this pilot
Focus on efficacy rather than effectiveness	Pragmatic design in routine OPD setting; minimal exclusion criteria
Reliance solely on patient self-report	Family member-reported outcomes demonstrated feasible; can triangulate patient accounts in future trial
Failure to assess harm reduction beyond consumption	Multiple outcome domains proved feasible: AUDIT-C, HED frequency, APQ, family burden
Interventionist anxiety about raising alcohol issues	Patient information sheet facilitated initiation and tailoring of discussions
Heterogeneous, poorly documented interventions	All three interventions protocolised and fully described
Limited evidence from LMICs	Conducted in Sri Lankan outpatient setting; establishes foundation for definitive trial

[Note: OPD-Out-patient Department, APQ- Alcohol problems questionnaire, LMICs- Lower Middle Income Countries (Based on (127), (133, 295)]

High retention rates: Patient retention at six-month follow-up exceeded the 60–80% commonly reported in BI trials (273). Family member retention was even higher at 93.7%. These figures are particularly notable given that all follow-up assessments required in-person attendance. Retention remained high even among patients with indicators of possible dependence (80%), a subgroup often difficult to retain in intervention research. The high retention also reflects practical aspects of study design, including flexible follow-up windows and reimbursement for transport costs—strategies that could be replicated in a future trial.

Family member perspectives as an outcome measure: A distinctive feature of this pilot is the systematic inclusion of family member-reported outcomes. Unlike previous studies that used family reports solely as collateral information to verify patient consumption (351), we measured family burden as an outcome in its own right. This approach recognises that alcohol-related harm extends beyond the drinker (1), and that reduction in family burden represents a meaningful outcome independent of changes in drinking. The pilot demonstrated that this approach is feasible: 53% of patients had family members assessed at baseline, and family members expressed appreciation for the opportunity to discuss their concerns—with some requesting healthcare referrals for themselves. The observation that 24 family members presented only at follow-up, including 14 whose index patients had not initially consented to family contact, suggests

patients were sufficiently satisfied with their experience to subsequently involve their families. This finding supports the inclusion of family member outcomes in a future adequately powered trial. This aspect is further discussed in Chapter 7.

Pragmatic design in a real-world setting: The study employed a pragmatic design with minimal exclusion criteria ((including patients who were possibly dependent—a category typically excluded in BI research (273) in a routine outpatient setting, targeting effectiveness over efficacy (See Chapter 7).

Multiple outcome domains: Rather than relying solely on consumption measures, this pilot assessed multiple outcome domains: AUDIT-C scores, HED frequency, alcohol-related problems, and family burden. This comprehensive approach captures harm reduction more broadly, triangulates outcomes to improve validity, and addresses the criticism that previous research has overlooked improvements in other aspects of patients' lives and family environments.

Comparing intervention intensities within a single trial: BIs vary considerably in content, duration, and intensity—from brief advice through BI to extended BI (102)—making cross-study comparisons almost impossible. All three arms in this pilot represent BIs of varying intensity: FOA (feedback only, ~3 minutes) constitutes brief advice, UOA (education on units and low-risk drinking, ~5 minutes) represents a BI, and ABI (structured discussion, 15–30 minutes) corresponds to an extended BI. By randomising patients to these three intensities within the same setting and study period, contextual factors were eliminated as potential confounders. This design demonstrated the feasibility of comparing BI intensities within a single trial, providing a template for a future adequately powered study to determine whether more intensive interventions confer additional benefit over less resource-intensive alternatives.

Structured, culturally adapted intervention with clear documentation: The ABI was developed through systematic cultural adaptation using Resnicow's framework (168) and WHO framework of BI (102), with input from psychiatric specialists experienced in alcohol-related issues (See Chapter 4) (179). All three interventions were fully

protocolised, addressing the criticism that BI research often involves heterogeneous, poorly documented interventions that cannot be replicated.

Patient information sheet activating processes of change and capturing context of change: The patient information sheet represents a methodological innovation that serves multiple purposes (See Chapter 7).

Task-shifting to non-specialist staff: The research assistants had no prior health sector experience, yet after brief training reported confidence and received overwhelmingly positive patient feedback on their knowledge, friendliness, and listening skills. This demonstrates that task-shifting BIs to trained non-specialists is feasible—an important consideration for scalability in resource-limited settings where specialist alcohol services are scarce.

Mixed methods approach: The pilot combined quantitative outcome measures with qualitative feedback from patients, family members, and research assistants. This approach provided complementary perspectives that together inform the design of a future trial: the quantitative data establish the responsiveness of outcome measures and the feasibility of data collection across arms, while the qualitative feedback illuminates the mechanisms and contextual factors that will shape intervention refinement. Family member narratives, for instance, revealed a gradient across arms in the attribution of improvements to the intervention, with ABI family members most frequently citing advice from sessions as the catalyst for change—a finding that generates hypotheses for investigation in a future adequately powered RCT.

6.5 Conclusions

This was the first pilot study to evaluate adapted BIs for risky drinking in a primary care setting in Sri Lanka, and the first in this setting to assess outcomes from family member perspectives—building on our inpatient pilot which introduced this approach. Although assessing family burden as an outcome measure could add to health cost initially, addressing it will positively affect patient outcomes, leading to reduced health costs in

the long run. The pilot study demonstrated that the methodology, outcome tools, and implementing three intensities of BIs are feasible in primary healthcare settings. All three interventions showed high acceptability among patients and research assistants. Retention was excellent (88.7% for patients, 93.7% for family members), supporting feasibility of this approach. An adequately powered trial is warranted to provide sufficient evidence of the effectiveness of these BIs among Sinhala-speaking male patients presenting to primary healthcare in Sri Lanka. Such a trial should include 12-month follow-up and consider expansion to Tamil-speaking populations. Further, preliminary outcome data showed directional changes across all arms, demonstrating that the selected outcome measures are responsive to change—an essential prerequisite for powering a future definitive trial.

Chapter 7: Discussion

7.1 Introduction

Alcohol-attributable harm remains one of the most significant yet inadequately addressed public health challenges globally, with low- and middle-income countries (LMICs) bearing a disproportionate burden despite lower per capita consumption (20, 23) (See Chapter 1). Comparatively higher alcohol-attributable death rates among males compared to females have been consistently documented across all age categories (20). Although higher prevalence of risky drinking among males is a plausible contributor to lower male life expectancy globally, the direct evidence for this comes primarily from Central and Eastern Europe (372). Sri Lanka's similar gendered drinking pattern—alcohol-attributable deaths among males and females is 24 and 3.4 per 100,000 population, respectively (23)—may contribute to the existing difference in life expectancy between males and females.

In Sri Lanka, where universal free health care is available, public health facilities are well placed to do opportunistic interventions for risky drinkers. The potential for brief interventions (BIs) to reduce alcohol related health and economic burden at population level is substantial—outpatient departments record 55 million visits annually (125) and our findings showed an estimated 39% of adult male attendees met criteria for risky drinking (See Chapter 5),—yet routinely unrealised. This thesis embarked on developing and evaluating culturally appropriate BIs for this context, adopting an iterative research approach. This discussion synthesises findings across these studies, integrates them with established theoretical frameworks—particularly Nutbeam's health literacy (148) model and the modern Transtheoretical Model (186)—and positions harm reduction as the central paradigm for alcohol interventions. The chapter concludes by examining methodological contributions, contextualising findings within Sri Lankan and LMICs evidence, and identifying priorities for future research and policy.

Throughout this discussion, the term 'individuals' is used in preference to 'patients' when referring to people who drink at higher-risk levels, except where the clinical context of healthcare delivery makes 'patient' appropriate. This terminology reflects the harm

reduction paradigm underpinning this thesis: people presenting to health care with risky drinking are not defined by a diagnosis but exist along a continuum of risk—most below any diagnostic threshold.

Similarly, 'higher-risk drinking' and 'lower-risk drinking' are preferred over categorical terms such as 'harmful use' or 'hazardous drinking', consistent with dose-response evidence discussed in Section 7.4, although the term 'risky drinking' is used throughout the thesis as a non-diagnostic descriptor for consumption above low-risk thresholds (See Section 7.4.1).

7.2 Key findings and achievements of the thesis

The thesis involved an iterative research sequence, a process helpful in adapting interventions deemed effective in other settings—BIs have been used to reduce alcohol consumption in high-income countries but there is inadequate evidence from LMICs (373). The Figure 7.1 summarizes the process.

Development and adaptation of WHO's BI → Inpatient Pilot Study → Acceptability and feasibility of ABI; identified setting and outcome limitations; identified FOA and UOA as potential less intensive BIs *(See Chapter 4)* → Cross Sectional Study at the OPD → Identified knowledge deficits, feasibility of the setting, determined an empirically derived AUDIT-C cut-off *(See Chapter 5)* → OPD Pilot Study → Feasibility and acceptability of three BI intensities, responsive outcome measures, trends toward improvement *(See Chapter 6)*

Figure 7-1 From cultural adaptation to pilot testing—study sequence and findings
(Note: BI- Brief Intervention, FOA-Feedback on AUDIT-C, UOA-Unit of Alcohol, OPD-Outpatient Department)

7.2.1 The burden of risky drinking in Sri Lankan primary care

Thirty-nine percent (555) of male attendees to the outpatient department (OPD) were risky drinkers, 84% of male drinkers had engaged in HED—a pattern of drinking which increases alcohol-related risks (23); and over the previous year, 43% of them had done so more than once a month (See Chapter 5). This represents a major missed opportunity for intervention by the Sri Lankan health system, considering the high turnover in OPDs (125), yet education and screening for alcohol-related problems is not routine in the

system. This is not a practice commonly implemented globally either; only 15% of healthcare workers conduct alcohol screening routinely (279).

7.2.2 The failure of existing health education

Data from 150 patients in the OPD pilot study (See Chapter 6) revealed family, friends, television and internet to be the main sources of information regarding alcohol—32% were told 'Don't drink', without any reason given, indicating commonly practised binary framing and paternalistic approach, and likely positioning drinking as a morally bad behaviour. Further, 14% received inaccurate information (e.g., alcohol aids sleep, relieves tiredness). Only 22% had received information from a healthcare worker. Furthermore, 53% reported that the information had no effect on their drinking. These findings suggest failure at the most basic level of health literacy—functional health literacy (See section 7.2.1 below) (148) and need further investigation with a larger sample.

7.2.3 Knowledge deficits as modifiable risk factors

Knowledge of alcohol and related harms among OPD male attendees was alarmingly poor—only 0.9% knew about low-risk drinking thresholds, 3.4% understood unit of alcohol, and only 5% were aware of the increased risk of accidents (See Chapter 5). Many patients in the OPD pilot study acknowledged the education they received from the BI, and this education could have contributed to the observed trend towards reduction in all the outcome scores, indicating possible improvement in alcohol-related problem behaviours (See Chapter 6). The latter finding is encouraging, and provides adequate grounds to plan a future RCT.

Another finding was unintended 'spill-over effect' of patients sharing the leaflet and knowledge with their children and peers/colleagues. Since information sharing seems to be taking place in the population, educating patients who come to health care may initiate a ripple response of sharing accurate knowledge and potentially modifying harmful drinking patterns among recipients. Rogers' diffusion of preventive innovations framework posits that health information transmitted through trusted interpersonal

channels carries greater influence on behaviour than formal health messaging (374, 375), lending theoretical support to this observed spillover. This aspect warrants investigation in future research.

7.2.4 Limitation of inpatient setting in determining effectiveness of BIs

It appeared that 'the harm the patient was admitted to the ward with' itself constituted the 'intervention' in the inpatient setting as many patients remained abstinent—38% at baseline and 76% at follow-up primarily due to health concerns (See Chapter 4). This ceiling effect may have contributed to the modest effectiveness of BIs observed over control conditions demonstrated in a systematic review of BIs in inpatient settings (376).

7.2.5 Acceptability and feasibility of all three BI intensities

Three BIs of varying intensities were explored in the OPD pilot study (See Chapter 6). Trained, non-health research assistants delivered the BIs, and research assistant, patient, and family member feedback—both quantitative and qualitative—were overwhelmingly positive for all arms. The impressive retention proportions of patients (92% in FOA, 84% in UOA—both involving one-way information provision—and 90% in ABI, which included an interactive discussion, with 94% overall for family members) were also highly suggestive of the acceptability of the BIs and feasibility of the methodology.

7.3 Theoretical integration

The thesis started with TTM as the conceptual framework, and the TTM constructs were successfully operationalized into interventions in three BI intensities. While it is beyond the scope of this thesis to determine which constructs of TTM are necessary for effectiveness, the findings clearly support the utility of TTM in identifying potential mechanisms of change in alcohol-related harms.

Although Nutbeam's framework was not used to guide the thesis a priori, the findings reported above (See Section 7.2.3)—particularly the documented deficits in functional health literacy and the observed information-sharing behaviour—provided a post-hoc

rationale for its incorporation as a complementary lens through which to interpret the mechanisms of change.

7.3.1 Nutbeam's health literacy framework

The 1986 Ottawa Charter for Health Promotion established a holistic framework positioning health literacy as the driving force in health promotion—'the process of enabling people to increase control over, and to improve, their health' (377). WHO defined health literacy as the cognitive and social skills determining an individual's motivation and ability to access, understand and use health information—extending beyond reading pamphlets to empowerment through effective use of health information (378).

Nutbeam operationalised WHO's definition of health literacy into a tiered framework. His conceptual model (148) operates at three levels: basic/functional—sufficient reading and writing skills for everyday situations; communicative/interactive—cognitive and social skills enabling extraction and application of information to changing circumstances; and critical—skills for analysing information to exert greater control over life events. This sense of control aligns with broader definition of health as dynamic balance and adaptation to life's challenges (44). Health literacy is thus not merely reading and writing, but what it enables people to do for their health—requiring approaches adapted to individuals with varying abilities. WHO reiterated this in 2021: health literacy represents personal knowledge and competencies accumulated through daily activities and social interactions, mediated by organisational structures and resource availability, enabling people to access, understand, appraise and use information to promote health and well-being (379).

Health education is the primary process used to promote health, with health literacy as its outcome. BIs, through health education, improve health literacy while simultaneously operating therapeutically—the process of engagement, feedback, and dialogue can itself prompt behaviour change beyond simple information transfer.

Each stage of this thesis addressed a specific dimension of Nutbeam's framework. Cultural adaptation of the WHO BI to the Sri Lankan setting, guided by Resnicow's principles of surface and deep structure adaptation (See Chapter 4), was a prerequisite for health education at any literacy level—ensuring that materials, language, and framing were meaningful within the local context rather than merely translated. The OPD cross-sectional study (See Chapter 5) then diagnosed the health literacy deficit itself: very low levels of basic alcohol-related knowledge, with the health system having missed opportunities for even functional-level health education through opportunistic interventions. This diagnostic step—identifying what people do not know before attempting to address it—is precisely what Nutbeam advocates as the foundation for effective health education (148). The inpatient pilot established acceptability of three BI intensities (FOA, UOA, and ABI), each designed to engage patients at progressively higher literacy levels, from basic information provision through to interactive dialogue (See Chapter 4). The OPD pilot (See Chapter 6) then tested whether these graded intensities could address the identified knowledge gaps within routine primary care, targeting functional and interactive health literacy simultaneously.

All three interventions addressed functional literacy by informing patients that their alcohol use is likely to, or already causing, harm, and providing the alcohol information leaflet with illustrations of units of alcohol in commonly consumed local beverages, health hazards, and low-risk drinking guidelines (Appendix A). All three arms also included active self-engaging elements: the patient information sheet facilitated self-reflection through active cognitive engagement, potentially triggering the question-behaviour effect—whereby answering questions about one’s behaviour can itself prompt reflection and change (238, 359), while the screening process itself required patients to engage with their drinking patterns rather than passively receive information. The ABI arm extended this interactive component through structured personalized dialogue. By framing the message around harm reduction rather than the binary 'don't drink' messaging, the interventions laid groundwork for critical literacy—enabling patients to question prevailing abstinence-only norms, and myths on HED—though achieving this

remains a longer-term outcome requiring further research. Table 7.1 summarizes how the current thesis promotes health literacy.

Table 7-1 Promoting health literacy–Thesis approach

ACTION AREAS OF HEALTH PROMOTION	HEALTH EDUCATION	HEALTH LITERACY
(WHO 1986)	*Process (adapted via Resnicow)*	*Outcome (Nutbeam 2000)*
• Policy & Legislation • Supportive • Community Action • **Health Education** →	Components: Content: Units, harms, LRD thresholds By whom: Non-health RAs (task-shifting) To whom: Risky drinkers Three BI Intensities: *(All informational; all require patient reflection)* FOA: Feedback on screening | screening, PIS, leaflet UOA: Didactic education on units and LRD thresholds| screening, PIS, leaflet ABI: Interactive discussion with RA | screening, PIS, leaflet *PIS triggered self-reflection in all arms (question-behaviour effect)*	1. FUNCTIONAL *Basic health knowledge* Problem: 0.9% LRD, 3.4% UOA Target: All 3 arms Evidence: Trends ↑ all arms 2. INTERACTIVE *Derive meaning, engage, apply* Problem: 53% no effect from prior info Target: PIS (all); dialogue (ABI) Evidence: "Never thought this way" 3. CRITICAL *Analyse, challenge norms* Problem: Binary "Don't drink" framing Target: Harm reduction framing Evidence: Future research

(Note: LRD: Low-risk drinking, PIS: Patient Information Sheet)

7.3.2 Transtheoretical model of behavioural change

The Transtheoretical Model (TTM) provided the conceptual framework for intervention design throughout this thesis (See Chapter 2). This section synthesises how the empirical findings illuminate the utility of TTM-informed interventions in resource-limited primary care settings and the thesis's contribution to addressing gaps in TTM based alcohol research.

Figure 7.2 illustrates how the three-arm nested intervention structure operationalised experiential and behavioural processes of change within patients' own contexts of change. Experiential processes—consciousness raising, self-re-evaluation, environmental re-evaluation, and dramatic relief—were activated in the initial phase of

interventions through intervention components of increasing intensity, while behavioural processes (stimulus control, counter-conditioning) were observed at follow-up. The nested design ensures that each more intensive arm contains all components of less intensive arms, enabling greater coverage with fewer resources. Stages of change are not formally assessed; instead, the design targets process activation regardless of stage.

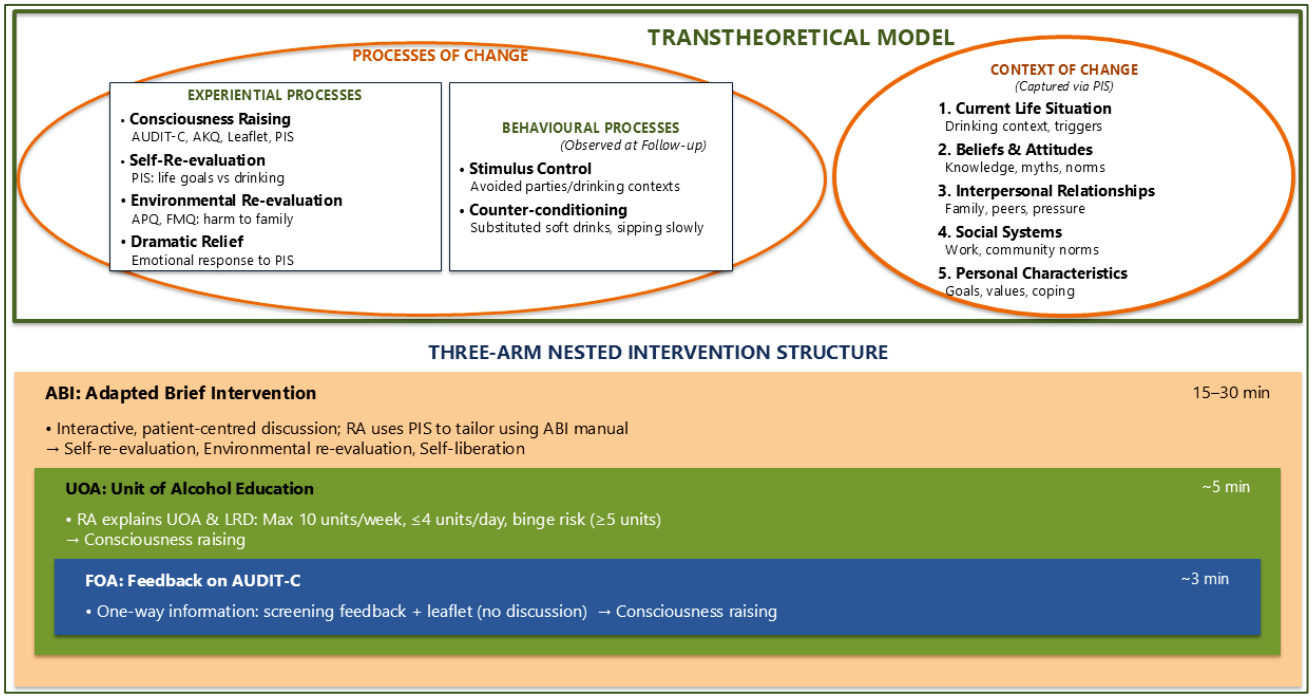

Figure 7-2 Integration of TTM constructs into the intervention design – OPD pilot study

(Note: 1. BI - brief intervention; AUDIT-C- Alcohol Use Disorders Identification Test- Consumption, AKQ - Alcohol Knowledge Questionnaire, PIS - Patient Information Sheet, APQ - Alcohol Problems Questionnaire, FMQ - Family Member Questionnaire, LRD - low-risk drinking; UOA - unit of alcohol
2.Stages of change- not formally assessed)

7.3.2.1 Addressing the Gap: Processes beyond stages

TTM-informed alcohol intervention research has overwhelmingly focused on a single construct—stages of change—as discussed in Chapter 2, while neglecting the processes through which change actually occurs. The proponents of the model themselves (196) and others (218) also have reiterated this fact, and encourage to move away from this. The current thesis addressed this imbalance by designing interventions that systematically operationalize processes of change.

The research tools and interventions were designed to activate multiple experiential processes simultaneously across early stages of change. Screening using AUDIT-C serves as a consciousness-raising 'wake-up call' to those who believe they are drinking at low-risk levels or socially. The Alcohol Knowledge Questionnaire extends consciousness raising by addressing alcohol-related health problems and low-risk drinking thresholds—information that was virtually unknown to participants (Section 7.2.3). The Alcohol Problems Questionnaire activates self and environmental re-evaluation by making patients aware of harms caused to themselves and to family members. The ABI arm extended these processes further, incorporating self-liberation (committing to change), helping relationships (through research assistant discussion), counter-conditioning (identifying alternative behaviours), and stimulus control (strategies to avoid triggers).

This process-focused design reflects TTM's theoretical specification that experiential processes are most effective for individuals in precontemplation and contemplation (196). In the OPD pilot study, 83% of participants were not planning to change at recruitment—consistent with the broader evidence that most patients presenting to primary care are in early stages of change. This finding questions the need for formal stage assessment in such settings: if the majority are in precontemplation, the clinical priority is simply to activate consciousness raising, dramatic relief, and self and environmental re-evaluation—precisely what the nested intervention design achieved. The observed trends toward improved outcomes across all three arms support this proposition.

The three intervention arms represent a hierarchy of process intensity, each targeting the continuum of change, rather than discrete stage-matched interventions. The FOA arm provides consciousness raising through personalised feedback and written educational material. The UOA arm extends consciousness raising by adding verbal explanation to enhance comprehension and personal relevance. The ABI arm incorporates a range of TTM processes—consciousness raising, dramatic relief, self-re-evaluation, environmental re-evaluation, and self-liberation—within a structured conversation that

also addresses decisional balance and self-efficacy. Crucially, all three arms included the patient information sheet—an instrument whose multiple functions as both a process-activating and context-capturing tool are discussed in Section 7.5.3.

7.3.2.2 Addressing the Gap: Context of Change

As discussed in depth in Chapters 1 and 2, context of change is a core construct of TTM, but rarely addressed in alcohol research. Understanding context is essential to minimizing risky drinking, and relapse prevention—to understand why they drink, in what context, with whom, their income, their knowledge of alcohol-related harms, myths, problems faced due to alcohol and their life goals (186, 380). The patient information sheet captures contextual factors across multiple domains (see Section 7.5.3).

The cross-sectional study on knowledge of alcohol related harms revealed a substantial gap in knowledge (See Chapter 5)—a major barrier for attitudinal change (381). Resnicow's principles (168) of cultural sensitivity, are important determinants of acceptability, feasibility and salience of an intervention. The patient information sheet was designed to capture contextual information across these domains, enabling the ABI to address deep structure requirements. Feedback from patients suggests that the intervention components resonated with their personal circumstances (See Chapter 6): *'Unit of alcohol illustration in alcoholic beverage was very helpful'*, *'I now add more soft drinks into my glass and sip it', 'Knowing about health consequences of drinking was the turning point', 'We have never been told reduction also helps (that we don't have to stop completely)*'.

Interpersonal relationships, whether they are between family members, with friends or any other close relationships, are a very important context of change in initiating, continuing and modifying/cessation of drinking. Actions of individual family members affect all other members of the family, and their typical and repetitive ways of interactions maintain behaviour patterns of the family as a whole (382); and McCrady in a review has reiterated the importance of addressing family issues to achieve better results in alcohol intervention programmes (310). Attitudes of peers/workmates towards substance use is

a known risk factor for initiating and maintaining alcohol use (383-385). The OPD pilot study revealed information on how especially friends and peers impact the patients' drinking (See Chapter 6).

It also revealed that the commonest goal was children's welfare—a finding with particular significance in the Sri Lankan context, where family-centred values are deeply embedded; but where alcohol-related harms to children, including domestic violence and economic deprivation, are quite prevalent (See Chapter 1). This suggests that framing reduced drinking in terms of tangible benefits to children—one patient indicating that he spends his savings from alcohol on food for children—may be a culturally resonant motivational lever, aligning the intervention with what matters most to the individual, and exemplifying the 'intimacy'—where content that resonates personally is prized because it taps into what matters to the individual (45).

Another principle of cultural adaptation, cultural competence, which describes the qualities of interventionists, was assessed through patient feedback. Although, this was mainly relevant to the research assistants in the ABI arm, many in FOA and UOA arms commented positively on them, too. In the ABI arm, almost everyone rated 'the discussion with research assistant' as the most helpful. Several commented on how kind, trustworthy, respectful and non-judgmental they were, *'No need to resist them, when they treat us with so much love and kindness'*. One ABI arm patient, when asked 'Any part of the discussion that stuck in your mind?', responded simply —hearing *'You are a good person'* —implying that no one had previously conveyed this to him, and revealing how drinkers may internalise the stigma they encounter in everyday interactions. This demonstrates that context of change extends beyond patient characteristics to encompass the interpersonal qualities of those delivering interventions (386)—a factor rarely assessed in BI research.

The patient information sheet captured drinking patterns within social systems: drinking at functions, drinking to socialize, and work-related drinking contexts. The thesis's use of non-health research assistants (task-shifting) itself represents engagement with the

social system of healthcare delivery—demonstrating that BIs can be delivered outside traditional clinical hierarchies in LMICs.

Another important aspect of interpersonal relationships, leading to increased alcohol use is having been subjected to childhood adversities (384, 387, 388)—a factor with implications for both understanding drinking behaviour and designing interventions, discussed further in Section 7.5.

The above findings suggest that integrating context of change in BI is acceptable to patients, and that systematic assessment of contextual factors, can inform tailored intervention delivery (See Section 7.5.3)

7.3.2.3 Synthesis: The Patient Information Sheet as an integrative tool

The patient information sheet emerged as an integrative tool that bridges TTM's processes of change and context of change constructs. By activating experiential processes while simultaneously capturing contextual factors across DiClemente's domains (380), it serves both theoretical and practical functions within the intervention design. In the ABI arm, the contextual information elicited through the patient information sheet was used to tailor the discussion—research assistants reported that it helped them empower patients and design behaviours to resist temptations (e.g., role-playing how to decline a drink). Its dual role as both an assessment instrument and an intervention component—and the methodological implications of this integration—are discussed in Section 7.5.3.

7.3.3 Health literacy and TTM

Both Nutbeam's health literacy framework and TTM converge on a critical point: effective behaviour change requires not merely imparting information (functional literacy, consciousness raising) but engaging individuals in meaning-making about their own circumstances (interactive literacy, self-re-evaluation). Table 7.2 summarizes how Nutbeam's health literacy levels (148) and TTM processes of change (186, 196) were operationalized in the study design, with both educational and interventional goals.

Although, functional and interactive health literacy have been targeted, critical literacy requires further research.

Table 7-2 Integration of Nutbeam's health literacy framework with TTM processes of change in the study design

Health Literacy Level	TTM Processes of Change	Intervention Components	Status
Functional *Basic health knowledge*	-Consciousness raising	-AUDIT-C feedback -Alcohol Information Leaflet -Alcohol Knowledge Questionnaire	✓ Targeted
Interactive *Derive meaning, engage, apply*	-Self-re-evaluation -Environmental re-evaluation -Dramatic relief -Counter-conditioning -Stimulus control	-Patient Information Sheet (all arms) -Discussion component (ABI)	✓ Targeted
Critical *Analyse, challenge norms*	-Social liberation -Self-liberation	-Harm reduction framing (vs binary "Don't drink")	Groundwork laid *(future research)*

(Note: All three BI intensities (FOA, UOA, ABI) addressed functional and interactive literacy levels simultaneously through their respective components.)

In summary, this thesis demonstrates that brief alcohol interventions can be designed to systematically operationalize both Nutbeam's health literacy framework (targeting functional, interactive, and critical levels) and TTM constructs (activating processes of change within the patient's own context of change). These frameworks are complementary: their integration strengthens intervention design without requiring additional delivery resources. The three BI intensities targeted functional and interactive health literacy while activating multiple processes of change, across the precontemplation–contemplation spectrum. The patient information sheet enabled systematic capture of contextual factors that shape drinking behaviour. Health education—delivered through the three BI intensities—serves as the mechanism for improving health literacy, while TTM's experiential and behavioural processes provide the theoretical specification for how that education translates into behaviour change. These theoretical foundations underpin the harm reduction paradigm discussed in Section 7.4.

7.3.4 Synthesis: Conceptual foundations of the thesis

Figure 1.4 (See Chapter 1) outlined the conceptual framework underpinning this thesis: the interaction of individual and social risk factors generating alcohol-related harms, the policy and individual-level responses available to reduce them, and the barriers to implementation in Sri Lanka. Figure 7.3 illustrates how this thesis addressed those barriers through its three sequential studies.

Figure 1.4 identified six implementation barriers: stigma surrounding alcohol problems; limited resources and trained workforce; absence of a proper screening tool; lack of a culturally adapted BI; no identified suitable setting for implementation; and binary paternalistic approach towards alcohol interventions in clinical practice. The inpatient pilot study (See Chapter 4) culturally adapted the WHO BI for Sri Lanka and established its acceptability and feasibility, while the finding that illness-induced abstinence limited effectiveness assessment pointed to the need for an outpatient setting. The OPD cross-sectional study (See Chapter 5) addressed four barriers simultaneously: determined an empirical AUDIT-C cut-off to capture more risky drinkers (See Chapter 1) for Sri Lankan primary care; confirmed the high prevalence of risky drinking among male OPD attendees, establishing the scale of the problem; identified critical knowledge gaps regarding alcohol-related harms, low-risk drinking, and units of alcohol; and demonstrated the feasibility of the OPD as a setting for screening. The OPD pilot study (See Chapter 6) then tested three BI intensities that proved acceptable to patients, research assistants, and family members, and demonstrated that BI delivery is feasible despite high patient turnover, while incorporating responsive outcome measures capturing both patient and family member perspectives. The use of trained non-specialist staff addressed the resource barrier by demonstrating that BIs need not depend on scarce health professionals. Sri Lanka's high patient turnover at OPDs—55 million visits annually (125)—represents a substantial opportunity for opportunistic BIs at population level. The outcomes were focused on harm reduction, not merely abstinence. These achievements position the research for a future fully powered RCT, to determine the effectiveness of the three BI intensities, backed with the most up to date evidence of the alcohol field. These aspects are further discussed in Section 7.8 below.

Furthermore, the thesis findings have important policy implications, which are discussed in Section 7.9.2

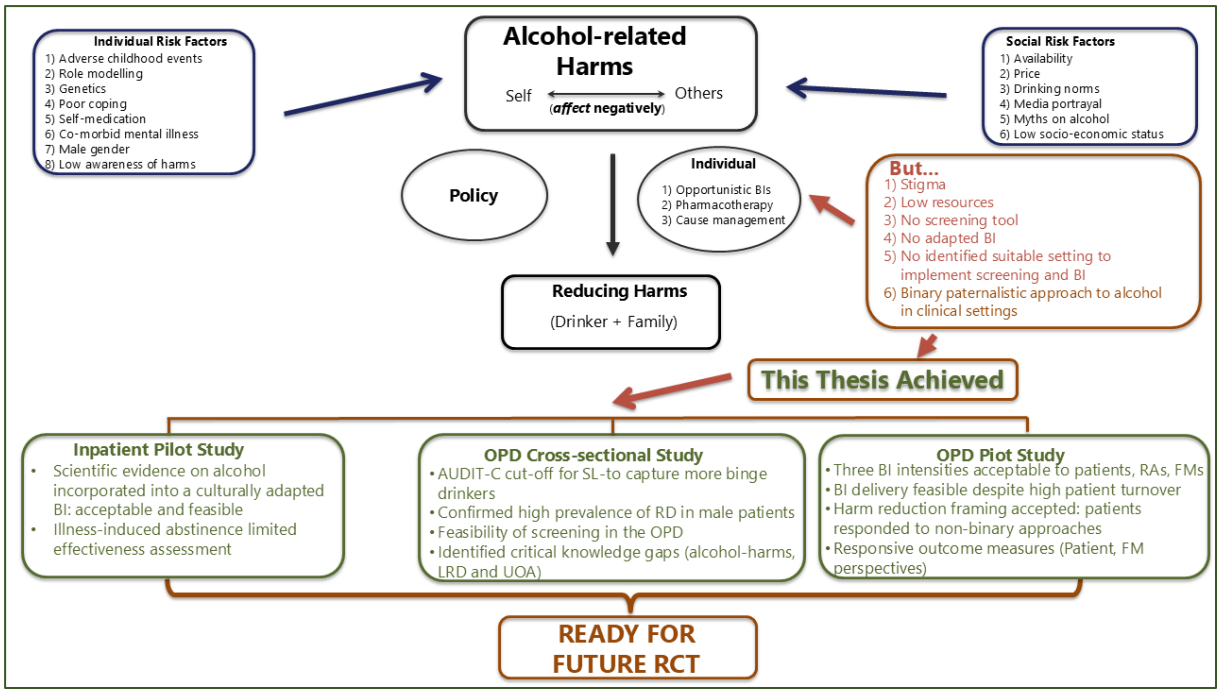

Figure 7-3 Conceptual framework of the thesis

(Note 1. BI - brief intervention; AUDIT-C- Alcohol Use Disorders Identification Test - Consumption; RD - risky drinking; LRD - low-risk drinking; UOA- unit of alcohol; OPD - outpatient department; FM - family member; RA - research assistant; RCT- randomised controlled trial; SL - Sri Lanka
Note 2. This figure illustrates how the three sequential studies addressed the barriers to BI implementation identified in Figure 1.4)

7.4 Harm reduction as the central paradigm

The preceding sections examined theoretical contributions to TTM operationalisation and alignment with emerging directions in BI research. This section addresses a more fundamental issue: the conceptual paradigm underpinning the current thesis.

Our approach reflects the prevention paradox (105), as discussed in Chapter 1: the larger population of moderate-risk drinkers generates greater cumulative harm than the smaller dependent minority, making the OPD with high turnover as discussed in 7.1—a uniquely cost-effective platform for opportunistic BIs in a resource-limited LMIC.

As established in Chapter 1, consumption reduction, adopting less harmful patterns of drinking, improving other aspects of drinkers' lives and improvement of family members'

lives have been considered as clinically meaningful outcomes—a typical harm reduction approach. This is particularly appropriate for primary care populations where the majority of patients are in precontemplation or contemplation stages and would disengage from abstinence-only messaging that fails to meet them where they are. The patient information sheet data from this thesis illustrates this directly: 32% of patients had previously received only 'don't drink' messaging with no reason given—binary framing that ignores the dose-response relationship between alcohol and harm and provides no pathway for those unwilling to abstain completely.

Within this harm reduction framework, the OPD pilot study results can be interpreted as illustrating how each outcome measure captures a different dimension of harm reduction. All outcome measures showed a trend towards improvement. Although not considered as an outcome measure by itself, many patients in all arms had shifted consumption from spirits to non-spirits, which is an effective first step to reduce alcohol-related harms—'Cutting consumption without diluting the experience' (389). Viewed through the harm reduction lens, this beverage switching strategy is consistent with harm reduction principles: reducing alcohol concentration per serving lowers HED. HED is a factor contributing to the discrepancy observed in harm per gram of alcohol consumed, between high-income and LMICs (23) and acute harm risk even when overall drinking frequency remains unchanged (38, 390, 391). Further, 83% of the OPD pilot study patients were not prepared to change their alcohol consumption on recruitment, but many adopted less harmful patterns; and some requested referrals for further care (See Chapter 6). These observations are described here to illustrate how a harm reduction conceptualisation frames the interpretation of outcomes; they do not constitute evidence for the framework itself. This broader conceptualisation extends beyond consumption to encompass the pattern of drinking and its wider effects—health consequences, family burden, and economic impacts—and positions harm reduction not as a compromise but as the approach most consistent with epidemiological evidence. The significant impact on family members further warrants consideration as an outcome measure on its own, an approach elaborated in Section 7.5.2.

In 2024, Stewart et al (45) called for a reappraisal that moves beyond the traditional focus on individual self-regulation of drinking—advocating instead for broader conversations about alcohol's role in life, health inequalities, and the social determinants of drinking. The present thesis was designed around this harm reduction perspective, treating any reduction in alcohol-related risk as clinically meaningful regardless of whether abstinence is achieved or a diagnostic threshold is crossed—an approach that Stewart and colleagues' subsequent call for reappraisal has since validated. This independent convergence on similar principles—the thesis conceived in 2021; Stewart et al. published in 2024—suggests the field is reaching consensus on the need to move beyond abstinence-focused paradigms.

7.4.1 Need for terminology reform

The terminology used to describe alcohol consumption patterns warrants scrutiny within a harm reduction framework. Terms such as 'harmful use', 'alcohol abuse', and 'hazardous drinking' implicitly suggest corresponding categories of 'non-harmful use' or 'safe drinking'—a framing that aligns with alcohol industry messaging about the 'responsible drinker' but conflicts with epidemiological evidence, leading to misunderstanding among the public. Current evidence demonstrates dose-response relationships between alcohol consumption and health harms with no entirely safe threshold (19, 20, 134). This linguistic framing may contribute to individuals self-categorising as 'not having a problem' and thus not requiring intervention—precisely the barrier encountered in the 83% of this thesis's sample who appeared to be precontemplators. The present thesis uses 'risky drinking' as a descriptive term reflecting AUDIT-C threshold scores rather than a diagnostic category, while acknowledging the limitation that such language may inadvertently imply a corresponding 'safe' category that the evidence does not support. A shift toward terminology emphasising continuous risk—such as 'higher-risk drinking' and 'lower-risk drinking' describing dose-response relationships rather than absolute safety—may better support both clinical communication and public health messaging. The primary concern is with industry-promoted language such as 'responsible drinking' which obscures the inherent risks of any alcohol consumption.

7.5 Methodological Contributions

The thesis addressed several deficits in BI research, the implications of which need confirmation through a future trial.

7.5.1 Inclusive design vs exclusionary trials

In both pilot studies we did not exclude patients with possible dependence, an exclusion criterion in many BI trials (273, 392, 393). This tendency promotes an unhealthy dichotomy, stigma associated with alcohol interventions, and disregards the holistic approach of harm reduction—a concern reiterated by Stewart et al. (45) in their call for reappraising BI paradigms. Thirteen percent of the OPD pilot sample had features suggestive of dependence: according to AUDIT questions 4-6, and their retention at six months was 80%. Some showed reduced frequency of HED. And a few requested further help, which itself is indicative of BIs directing them along the desired direction—this was what BI was initially used for—to engage patients in therapy (243) (See Chapter 2). As explained in Chapter 6, even patients screened as possibly dependent may respond to BI—dependence itself exists on a spectrum, and those presenting to primary care are most likely in early stages where neuroadaptation is not yet sufficiently marked to require pharmacotherapy, meaning behavioural approaches such as BI may still be effective. Such patients may reduce harms through BI and may even be motivated to seek stepped-up care. The methodological implications of this inclusive design for generalisability are discussed in Section 7.8.

7.5.2 Family member perspectives as an outcome measure

The bidirectional influence of the individual and the family on the individual's alcohol use and overall health, and family members' overall health is well established (310). Research has addressed how family member interventions improve patient outcomes (310). However, the effect of an intervention to the patient on a family member as an outcome measure has never been assessed before. Alcohol being the most harmful substance of abuse to others (1), using family member perspectives as an outcome measure supports the case that alcohol interventions should address harm reduction in

a broader perspective, extending beyond the individual patient to encompass family and societal wellbeing (45).

Family member feedback from the study revealed the lived reality of alcohol's impact on the household—accounts of anger, financial deprivation, fear, and shame that no standardised questionnaire is likely to capture fully (See Chapter 6). Such accounts paint vivid pictures of the family environment of an individual, and how this environment compounds problems, and potentially promotes intergenerational transfer of risky drinking. The latter is supported by evidence operating through various mechanisms—genetic vulnerability; constant exposure to adverse childhood experiences and resultant neurobiological changes from chronic stress, which make them vulnerable to alcohol problems later in life; self-medicating distress; social learning (learning mal-adaptive coping strategies from their drinking family members); emotional dysregulation from disrupted attachment; and cumulative social disadvantage (177, 178). Evidence from gene-by-intervention studies suggest that improving the family environment can attenuate genetic susceptibility to alcohol problems in offspring. Further, this evidence supports the finding that individuals with genetic vulnerability are more vulnerable to negative aspects of the environment and more responsive to positive aspects of the environment (387, 394). Even without genetic vulnerability, the adverse childhood experiences (which are prevalent in a household with a drinker) increase the risk of alcohol problems in the offspring (178). One of the common goals in the study participants' life as revealed in patient information sheet was 'children's welfare', and BIs can easily incorporate this as a gain-frame message.

By measuring family burden as an outcome of patient-focused intervention, this thesis captures potential intergenerational harm reduction—a longer-term public health benefit extending beyond the immediate patient-level outcomes. However, it must be acknowledged that the existing gene-by-intervention evidence derives from prevention programmes delivered directly to families with children, whereas the current thesis targeted BIs to adult drinkers themselves presenting to healthcare settings. Whether these BI-induced changes are of sufficient magnitude and duration to attenuate genetic

risk in offspring—as supportive family environments have been shown to do—remains an empirical question for longitudinal research.

Engaging family members in BIs to the patient can modify this 'toxic environment', minimizing harm across generations (388). This itself is another line of future research in Sri Lanka. Although the sample was only 48 patients in the inpatient pilot study (See Chapter 4), 96% reported experiencing at least one adverse childhood event—majority in the home environment—which gives a snapshot of this burden. It is challenging to address childhood trauma in primary care, but a simple screening questionnaire like the Adverse Childhood Experiences International Questionnaire 10 item version (ACE-IQ-10) (395), could help recognize—the first step to take proper action—those who need more support, and direct them accordingly.

Although the family context is an important domain of context of change within the TTM framework, it remains under-researched as a modifiable factor in BI studies—a gap that McCrady and Flanagan (310) have also highlighted in their review of family involvement in alcohol interventions.

7.5.3 Patient information sheet as a multi-purpose assessment and intervention tool

The patient information sheet was designed as a component of the ABI (See Chapter 4). However, based on ABI-arm patient responses to the questions in the inpatient pilot study, we hypothesised that the patient information sheet would raise awareness of their problem (consciousness raising), arouse emotions and encourage self and environmental re-evaluation'—processes important in early stages of change in TTM—even in those who were randomised to FOA and UOA arms. The OPD pilot findings support this hypothesis: *'the questions asked about my children made me think of my alcohol use over and over again', 'I buy milk and meat for my kids from my savings now'* (See Chapter 6).

Crucially, all three intervention arms included the patient information sheet, meaning that all participants received an instrument designed to activate multiple processes of

change. This may explain, in part, why all arms showed trends in outcome measures towards positivity (See Chapter 6)—the patient information sheet functioned as a process-activating intervention component across all three arms, not merely as a data collection tool.

Beyond process activation, the patient information sheet systematically captures contextual factors that shape drinking behaviour. It elicits current life situations—health problems, the context in which patients consume alcohol, financial difficulties, family conflicts, and personal goals (children's welfare, financial security, housing acquisition). This information maps onto DiClemente's five context of change domains (186), capturing not only intrapersonal factors but also interpersonal relationships, societal influences, and physical environment—dimensions often overlooked in standardised screening approaches.

This dual capture of processes and context may trigger the question-behaviour effect—a phenomenon whereby questioning people about a behaviour, whether through intention measures, self-predictions, or satisfaction ratings, can influence subsequent performance of that behaviour (167, 359) . Patient feedback from the OPD pilot study supports this (See Chapter 6 and Section 7.3.2.2).

The information elicited in the patient information sheet, served as an 'ice breaker' in the ABI arm, helping to initiate this very sensitive and anxiety-provoking discussion, both to the patient as well as to the interventionists (396). Further, it was very helpful to tailor the discussion within a relatively shorter time than would otherwise be possible. The research assistants mentioned that the information was helpful to empower the patients according to the exact background information revealed—'intimacy' in the sense described by Stewart et al. (45). This enabled delivery of messages in a 'gain-frame' manner (e.g.: '*You will be able to save money to spend on your child's tuition class', 'Your body aches will reduce if you reduce your drinking')*. This approach also helped to inculcate behaviours to resist temptations (e.g.: role-playing how to decline a drink),

which are likely to help in preventing relapses—an area requiring confirmation in a future RCT.

Further, the patient information sheet reveals the myths people hold and inaccurate information being circulated (See Chapter 6), which need to be addressed as a priority in any alcohol-related discussion, creating cognitive dissonance, if we are to counter the increased positioning of alcohol as 'essential for socializing', the notion that 'it is the responsibility of the drinker to keep to the limit', and framing alcohol consumption as a 'way of life' by the alcohol industry (397). As discussed in Section 7.4, Stewart et al. (45) note that the power of alcohol industry marketing and the persistence of stigmatising stereotypes obstruct meaningful conversations about alcohol harms—the patient information sheet provides a structured means to surface and address these influences at the individual level.

What distinguishes the patient information sheet from routine clinical history-taking is its structured positioning before screening results are revealed, its specific focus on alcohol-relevant contextual factors, and its dual purpose as both assessment and intervention. Unlike standard history-taking that follows diagnosis, the patient information sheet creates a foundation for therapeutic conversation before any 'problem' label is applied, potentially reducing defensiveness and enhancing engagement.

The patient information sheet also captured drinking patterns within social systems: drinking at functions, drinking to socialize, and work-related drinking contexts—enabling the ABI to address deep structure requirements of cultural adaptation, following Resnicow’s principles (168) of cultural sensitivity.

It should be acknowledged that the effectiveness of the patient information sheet in activating processes of change is inferred from qualitative feedback from patients, family members and research assistants rather than directly measured through validated instruments. Future research should incorporate systematic assessment of whether the patient information sheet activates processes of change.

In summary, the patient information sheet serves at least five distinct functions within the intervention design: (1) activating experiential processes of change across all three arms (Section 7.3.2.1); (2) systematically capturing context of change across DiClemente's domains (Section 7.3.2.2); (3) triggering the question-behaviour effect through structured self-reflection; (4) providing an 'ice-breaker' and tailoring tool for the ABI discussion; and (5) surfacing cultural norms and myths that must be addressed for effective behaviour change. This combination of assessment and intervention functions within a single instrument represents a methodological contribution that warrants further development and testing.

7.5.4 Testing three protocolized BI intensities in the same context

The WHO depiction of BIs demonstrates how wide and varied they are (102). A major challenge in comparing BI effectiveness is this heterogeneity—variation in content, duration, and number of sessions (284). What constitutes BIs actually delivered in most studies remains unclear due to poor intervention documentation (238). When different contexts are added to the equation, the comparison becomes even more problematic. Understanding these variations is essential for determining which type of BI is effective for which patient populations—knowledge critical for improving delivery efficiency and resource allocation. Most BI research has compared a particular BI with a control, and depending on the context the latter is also not homogeneous—some constitute 'usual care' which varies considerably by setting (398) and others include assessment-only conditions which may themselves trigger behaviour change through reactivity effects (238).

The current thesis laid the foundation for addressing this methodological dilemma by testing three protocolized intensities—FOA, UOA and ABI—in a nested design, in the same setting, thereby minimizing the effects of contextual confounders such as variations in healthcare system characteristics, population demographics, heterogeneity of the control arm, and cultural factors that typically complicate cross-study comparisons.

This design also carries practical and theoretical significance. From a practical standpoint, testing three intensities within the same population allows exploration of whether resource allocation in primary care can be optimised by beginning with lower-intensity interventions—a consideration particularly relevant for settings with limited specialist capacity. Theoretically, as discussed in Section 7.3.2, all three intensities target similar processes of change (consciousness raising, self-re-evaluation, environmental re-evaluation) but with varying depth of engagement. The three-arm design enables comparison of whether fuller process activation through ABI yields incremental benefit over the process activation inherent in assessment and feedback alone (through FOA) or with brief low-risk drinking education (through UOA)—testing a dose-response relationship in therapeutic process intensity rather than discrete stage-matching.

As discussed in Section 7.5.3, the patient information sheet functioned as an active ingredient across all three arms; rather than treating assessment reactivity as a methodological nuisance, the design incorporates it as a shared baseline component, with the three arms representing incremental additions to this foundation.

While the nested design controls for contextual confounders, the pilot nature of this study means that sample sizes within each arm limit statistical power to detect differences between intensities. The primary purpose at this stage was to establish feasibility and acceptability; a fully powered RCT is required to determine definitive effectiveness differences between the three intensity levels.

7.5.5 Multiple outcome measures: Triangulation and therapeutic functions

The Hawthorne effect, social desirability bias, recall bias, false reporting and assessment reactivity are inherent methodological challenges in planning and interpreting findings of BI research (254). To address these challenges through cross-validation, we used multiple outcome measures—total extended AUDIT-C score, number of HED days per month (calculated from the former) (See Chapter 6), Alcohol Problems Questionnaire and Family Member Questionnaire—a strategy rarely used in BI research, where most

trials rely primarily on single self-reported consumption measures (273). Triangulation (399)—the use of multiple measures to cross-validate findings—does not eliminate response biases inherent in self-report but allows detection of inconsistencies and strengthens confidence when measures converge. The OPD pilot study revealed that all measures used were able to capture changes of outcomes over time.

Beyond methodological triangulation, this approach aligns with the main theme of the thesis: 'harm reduction' (not mere abstinence). Harm reduction is not a unitary construct; it manifests differently across domains. Our multiple measures capture this multidimensionality: from the patient perspective (across three domains—consumption reduction or abstinence, less risky patterns of drinking, both captured through extended AUDIT-C; and reduction of alcohol-related harms as captured by the Alcohol Problems Questionnaire) and from the family member perspectives (burden and relationship quality as captured by the Family Member Questionnaire).

A further consideration is that outcome measures may not be passive assessment tools but may themselves have therapeutic properties. The questions themselves—informing a person who believed he was 'drinking within limits' that his level of consumption is high risk; questions about a wider range of alcohol-related issues in the Alcohol Problems Questionnaire reminding them of problems they might have already faced but overlooked—may have challenged their core belief system, creating cognitive dissonance. This aligns with Stewart et al.'s (45) call for materials that 'prompt thinking' and enhance readiness to consider alcohol's role in one's life. Whether outcome measures function therapeutically in this manner remains a question for future research.

However, if the BIs are proven effective in a future RCT, the Alcohol Problems Questionnaire and Family Member Questionnaires are unlikely to be administered routinely in clinical practice, although the extended AUDIT-C score and number of HED days derived from the latter would likely remain as standard screening and monitoring tools. Therefore, in routine clinical implementation, the question-behaviour effect, if it occurs through the fuller measurement battery, may not be as marked. This distinction

between comprehensive research measurement and streamlined clinical application is important when interpreting trial findings and planning implementation.

As discussed in Section 7.5.2, family member responses suggested effects beyond simple burden measurement—including harm reduction without consumption change and bidirectional spillover where family members reflected on their own behaviours—representing an important area for future investigation.

7.5.6 Within-arm pre-post analysis: A neglected, but clinically useful, analytic approach

The dominant analytic paradigm in alcohol BI research—shaped by CONSORT guidelines—compares intervention and control arms at follow-up, yielding between-group effect sizes that form the basis of meta-analytic syntheses (273, 281). This between-group focus is appropriate when control conditions are truly inert, as in placebo-controlled drug trials or drug trials with active comparators. However, in BI trials, control conditions are rarely inert—they typically involve screening, assessment, sometimes feedback on screening results, written information, or variably-defined 'usual care.' These components may themselves activate psychological processes: a patient who completes a screening tool, receives their score, and is handed a leaflet about alcohol, has *experienced something*—not nothing. Yet BI trials have adopted the placebo-comparison mindset even when their control conditions contain demonstrably active elements, and neither CONSORT (400) nor standard practice in BI research requires within-arm reporting that would reveal whether these control conditions are themselves producing clinically meaningful improvement.

A small number of trials have reported within-arm change in both arms, and their findings challenge the assumption that control conditions are therapeutically inert. Owens and colleagues (401), in the Alcohol-Dependent Patients in an Acute Care (ADPAC) trial of extended BIs for those who scored =>15 for AUDIT (n=267), reported that "all secondary outcome measures improved, on average, in both arms" despite no between-group difference. The Booze-buster trial (402), testing a mobile application against an educational website in young adults (n=503), found "both groups showed medium to high

within-group effect sizes for drinking-related measures" with no intervention effects compared to the control group.

Several mechanisms are suggested in underlying control arm improvement—including assessment reactivity (See 7.5.4), regression to the mean—where patients recruited for alcohol clinical trial during a peak period of alcohol consumption often improve naturally over time (403), and the question-behaviour effect (See Section 7.5.3).

The clinical implication is significant: if control arm participants show clinically meaningful improvement, then the components they received may constitute an effective minimal intervention in their own right. This reframes the policy question from 'whether to implement BI' to 'what is the minimal effective intervention?' This threshold could be remarkably low—perhaps no more than engaging patients with a personally relevant questionnaire that activates self-reflection [the 'intimacy' of assessment; (45)], with or without screening and formal feedback. More intensive interventions could then be reserved for non-responders.

The present thesis contributes to addressing this gap. Unlike most BI trials comparing a single intervention against variably-defined usual care, this thesis tests three protocolised intervention intensities—FOA, UOA, and ABI—each with explicitly documented components (see Section 7.5.4). Crucially, all three arms receive the patient information sheet, meaning even the minimal arm (FOA) includes a self-reflective component rather than an undefined control condition. This design enables within-arm analysis at each intensity level, allowing examination of whether the minimal intervention produces clinically meaningful improvement from baseline—a question conventional between-group analyses cannot answer. Pre-specifying such analyses in the planned fully-powered RCT would allow systematic examination of whether each intensity produces improvement from the baseline and whether more intensive interventions provide incremental benefit sufficient to justify additional resource investment.

7.6 Contextualizing Findings: Sri Lanka and LMICs

The findings of this thesis must be interpreted within the distinctive context in which they were generated. LMICs account for more than 85% of all alcohol-attributable deaths globally yet the evidence base for alcohol BIs derives overwhelmingly from high-income settings (138). The most comprehensive Cochrane review of BIs in primary care drew 34 of its 69 studies from the United States, 10 from the United Kingdom, with the remainder predominantly from Western Europe and Australia; only a small number originated from LMICs (273). A systematic review specifically examining patient-level alcohol interventions in LMICs found that while BIs showed the most consistent positive effects, all six included studies were conducted in a single country—South Africa (133). This geographical concentration of evidence creates what Stewart and colleagues (45) term a fundamental mismatch: the BI paradigm forged in the 1980s was developed for, and tested within, healthcare systems and drinking cultures substantially different from those where alcohol harm is now expanding most rapidly.

Sri Lanka exemplifies this contextual gap. The country faces rising alcohol-related harm amid multiple compounding crises—pandemic, economic collapse, recurrent flooding—yet operates a very few dedicated alcohol treatment centres. The WHO data revealed rising alcohol use among adolescents (See Chapter 1). This research therefore contributes evidence from a setting where BIs have been called for but rarely tested, where contextual adaptation is essential rather than optional, and where success must be measured against realistic rather than idealised implementation conditions.

7.6.1 LMIC burden

Although Europe accounts for highest levels of alcohol consumption, alcohol attributable burden is highest in Africa (138). This disparity is compounded by the alcohol-harm paradox (31) (See Chapter 1). Compounding this burden, there is an increasing trend of alcohol use among youth and females in some of these countries, while it is going down in the West. The alcohol market is expanding in LMICs, with media

portrayals of alcohol as a way of life and a coping strategy increasing over the last few decades (404).

7.6.2 Sri Lanka's specific challenges and opportunities

7.6.2.1 The evolving drinking landscape

As established in Chapter 1, Sri Lanka faces rising alcohol use among both youth and women, compounded by transnational media portrayals that normalise drinking and circumvent existing regulatory frameworks. The findings of this thesis sharpen the urgency of these trends. The cross-sectional study reported in this thesis revealed that only 0.9% of primary care attendees could correctly identify low-risk drinking limits and knowledge of alcohol-related harms was alarmingly poor across all drinking categories—including that of abstainers, whose low knowledge suggests their abstinence is maintained by cultural norms rather than informed choice (See Chapter 5). If these cultural protections erode—as the trends show (See Chapter 1)—a population with almost no understanding of alcohol-related risk will be exposed to increasing consumption without the health literacy foundations needed to moderate it. The finding that only 22% had ever received any alcohol-related information from healthcare workers, suggests a failure at system level (See Chapter 6).

However, some evidence offers grounds for cautious optimism. An ADIC survey found that among youth who had quit alcohol, reasons included perceiving alcohol use as 'purposeless behaviour', health concerns, and financial constraints (405)—suggesting that interventions emphasising health literacy and reframing drinking behaviour may resonate with Sri Lankan populations. This aligns with the present thesis' findings: those with better awareness of harms of alcohol seem to be adopting less-risky patterns of drinking (See Chapter 5). The fact that patients who received education on units of alcohol and low-risk drinking reporting that this knowledge was 'the turning point' (See Chapter 6), and the observed trend towards reduced consumption across all three intervention arms may support the proposition that addressing knowledge deficits can contribute to behaviour change even among those not actively seeking help, and even those seem to be dependent on alcohol on recruitment.

Knowledge was analysed only among men in this thesis. However, the poor understanding observed even among male abstainers raises concern for groups whose consumption is increasing, particularly women. Between 2016 and 2019, past-12-month drinking among adult women rose from 17.9% to 27.0%, and heavy episodic drinking among adolescent females rose from 1.6% to 7.0%, while it declined slightly among adolescent males [see Table 1.4; (23, 50)]). Although risky drinking in this thesis was more prevalent among middle-aged men, and adolescent male drinking mirrors the global decline, these trends indicate that women and adolescent girls warrant targeted attention (See Chapter 1), and the need to develop culturally adapted BIs for this demographic—an adaptation that may require different approaches to engagement given the stigma barriers that make female drinking less visible to the healthcare system.

7.6.2.2 Implementation context: gaps and assets

Sri Lanka lacks a single published RCT of BIs in primary care—a striking evidence gap given the scale of the problem established in Chapter 1 and the OPD prevalence findings of this thesis (See Chapter 5). This thesis provides the formative evidence necessary to design such a trial, addressing both the feasibility question and the contextual adaptation requirement that existing LMIC evidence cannot supply (See Section 7.5.1).

A critical gap exists in Sri Lanka's current healthcare response: alcohol screening and BIs—one strategy of SAFER (2) (See Chapter 1)—have not been systematically implemented in primary care. This report by the United Nations Development Programme, suggests that lack of awareness of alcohol use disorders and limited knowledge about community prevalence, result in under-diagnosis by physicians. This gap represents both a challenge and an opportunity. The challenge lies in the absence of systematic screening infrastructure, limited physician awareness of alcohol use disorders, and under-recognition of community prevalence. The opportunity is that this thesis demonstrates BIs can be feasibly delivered by trained non-healthcare workers, bypassing this physician-level barrier while reaching risky drinkers presenting in high volumes to primary care.

Several Sri Lankan assets support implementation at scale. The OPD system—with over 55 million visits annually—creates a high-volume, low-barrier point of access for opportunistic screening, requiring no specialist referral pathway. The country's high literacy rate—93%; (147)—supports health education delivery and underpins the functional-to-critical health literacy progression (148) that the thesis interventions were designed to activate (See Section 7.2.1). Perhaps most importantly, the collectivist cultural orientation observed in this study—whereby participants spontaneously shared intervention materials with family members and social contacts—suggests that well-designed BIs may reach well beyond the individual patient, extending the public health impact of each clinical encounter.

7.6.2.3 Resource allocation mismatch

As was discussed in Chapter 1, there is a substantial deficit in number of rehabilitation centres for those with alcohol use disorders. However, this apparent gap may warrant reframing rather than simple expansion. The proportion of drinkers meeting criteria for alcohol dependence—who would benefit from intensive rehabilitation—is relatively small (2.6% among both sexes (50) compared to the larger population of risky drinkers whose cumulative harm to themselves, families, and society exceeds that of dependent drinkers. This aligns with the prevention paradox (105), as mentioned in Section 7.4. If BIs prove effective in Sri Lankan primary care settings, the strategic priority may not be expanding rehabilitation capacity but rather integrating screening and BI into existing healthcare touchpoints—OPDs, non-communicable disease clinics, and Health Lifestyle Clinics already addressing diabetes, hypertension, and cardiovascular risk (3). Such integration and using trained non-health staff to implement would reach the majority of risky drinkers where they already present, potentially achieving greater population-level harm reduction than facility-based treatment expansion alone.

7.7 Limitations

The thesis has several limitations, discussed below.

The principal limitation is that, as a series of pilot studies, it was not designed or powered to determine the effectiveness of the interventions. The follow-up duration was only six months, failing to capture longer term drinking patterns. However, the 6-month retention rates achieved (88.7% for patients, 93.7% for family members) substantially exceeded the 60–80% commonly reported in BI trials (273), suggesting that 12-month follow-up is feasible in this population. Both limitations will be addressed in the future RCT.

The AUDIT-C ≥4 cut-off used in this thesis was determined against frequency of HED (AUDIT-C Question 3) as the internal criterion (See Chapter 5). While this threshold was responsive to prevailing Sri Lankan drinking patterns and captured 23.3% more heavy episodic drinkers than the WHO-recommended ≥5 cut-off, formal validation against an external diagnostic gold standard was not undertaken and is essential in future research.

A design constraint arose from the need to minimise contamination—only the ABI arm had the advantage of utilizing rapport developed during screening, which may have given the ABI arm an additional advantage. It should be noted, however, that the ABI arm design reflects intended real-world implementation more accurately than the FOA and UOA arms, where the artificial separation of screening and intervention would not occur in routine practice. This limitation will persist in the future RCT unless an additional research assistant is employed to screen and randomize, which would increase costs.

Mental illness and adverse childhood experiences—contextual factors central to alcohol-related harms—were not assessed due to time constraints, representing a limitation that future trials should address. While randomization will minimize their effect on outcome comparisons between arms, screening for these using appropriate tools would strengthen the future RCT. This limitation is particularly relevant given emerging calls for BIs to address the broader context of people's lives, including psychological comorbidities, rather than focusing narrowly on consumption self-regulation (45).

Intervention fidelity was not formally assessed, though positive patient feedback on research assistant qualities provides indirect support for adequate delivery. We did not evaluate research assistant micro-skills (listening, communication), which may influence outcomes more than content itself (127).

All three studies were conducted at a single site. In the Sri Lankan healthcare system, government-run OPDs—whether attached to tertiary, base, or district hospitals—function as the primary point of contact for non-emergency care, serving populations comparable to primary care settings internationally. Nevertheless, the prevalence of risky drinking and the knowledge gaps identified in the cross-sectional study (See Chapter 5) may not be generalisable to other regions of the country. Similarly, the acceptability and feasibility of the three BI intensities require confirmation across different healthcare settings and regions in future RCTs. The studies recruited only males, reflecting the marked gender disparity in alcohol use in Sri Lanka (5.9% prevalence in males versus 0.7% in females); while this was an appropriate design choice for feasibility in the pilot phase, adaptations for female risky drinkers, and for Tamil speaking risky drinkers will be needed.

Although only 0.8% of female OPD attendees were risky drinkers (Chapter 5), this may represent a substantial number of women nationally and is likely an underestimate. Social disapproval of female drinking may encourage concealment, under-reporting during face-to-face screening, and drinking in private settings, reducing visibility to health services. Women may also be affected as victims of harm from alcohol-using male family members, an aspect partly explored in this thesis through family member outcomes (Section 7.5.2) and one that warrants further study.

7.8 Strengths of the thesis

This thesis has several strengths, discussed in detail throughout this chapter and summarized here.

Real-world inclusive design: All consenting participants were included except those with communication difficulties or those already receiving specialised alcohol treatment. Critically, patients who were likely dependent (i.e., those who scored ≥2 for either questions 4, 5 or 6 of AUDIT—See Chapter 6) were retained if they did not wish to be directed to specialised care—precisely the population encountered in primary care, yet one that international BI trials have systematically excluded (273, 393), greatly impacting generalizability of their findings. This inclusive approach revealed an unanticipated spillover effect: several patients with possible dependence indicators requested referral to specialised care at follow-up—itself a positive outcome within a harm reduction framework, and consistent with the original purpose for which BIs were designed (243) (See Section 7.5.1).

Inclusiveness, however, extends beyond dependence. Although only 0.8% of female OPD attendees screened as risky drinkers (Chapter 5), this small proportion may represent a substantial number of women nationally and is likely an underestimate. In Sri Lanka, strong social disapproval of female drinking may encourage concealment, under-reporting during face-to-face screening, and drinking in private settings, making women's alcohol problems less visible to health services (see Chapter 1). Women are additionally affected as partners and family members of male drinkers, a perspective this thesis captured through family member outcomes (Section 7.5.2). Tamil-speaking drinkers and patients with communication difficulties were also excluded by design (Section 6.2). Future adaptations should address these groups, using gender-sensitive screening and engagement approaches (Section 7.9.1).

Family member perspectives as a formal outcome measure: To our knowledge, this was the first instance in alcohol BI research that family member perspective was considered as a formal outcome measure, producing its own spillover effects: family members

reported that voicing their concerns helped relieve distress, some corrected their own behaviours, and some requested further help (See Section 7.5.2). This area needs further investigation.

Focus of harm reduction as outcome measures: The main focus was to pilot a design which targets harm reduction across multiple dimensions of alcohol-related harms, rather than focusing only on consumption (See Section 7.4). Therefore, we used four outcome measures—a strategy hardly used in BI research, which also enabled triangulation (See Section 7.5.5). It also guarded against single-measure bias.

An empirical AUDIT-C cut-off responsive to Sri Lankan drinking patterns: This thesis adopted a lower AUDIT-C cut-off of ≥4, responsive to the prevalent HED pattern in Sri Lankan primary care—84% of male drinkers reported such episodes and approximately 90% of recorded consumption is spirits (See Chapter 1). Several authors have emphasised the need to use locally appropriate thresholds (151, 323) (See Chapter 1), yet no locally determined cut-off exists. AUDIT-C ≥4 captured 23.3% more heavy episodic drinkers than the WHO-recommended ≥5 cut-off, prioritising sensitivity to identify those who would benefit from BI in a population where HED carries the highest acute harm risk (23). The three BIs tested in this thesis were feasible and acceptable when delivered to patients identified using this lower threshold in the primary care (See Chapter 6).

Extended AUDIT-C with modification of Question 3: Given that 84% of male drinkers in the study sample engaged in HED, accurate measurement of this frequency is critical when giving feedback. However, the standard AUDIT-C Question 3 uses categorical responses that mask clinically meaningful variation—a patient HED 30 days per month scores identically to one HED 8 days per month (See Chapter 6). Further, using the extended AUDIT-C (354) with modification of Question 3 (See Chapter 6) could enable more granular tracking of changes in HED frequency—which matters in a harm reduction paradigm where any reduction is clinically meaningful (See Section 7.4)

Three protocolized BI intensities in the same setting: Testing three intensities within the same setting controls for contextual confounders and will help determine whether even

the least resource-intensive BI (FOA) leads to significant improvements in outcomes—potentially allowing more intensive BIs to be reserved for those who do not respond, thereby optimising cost-effectiveness for large-scale implementation. All three are protocolized, reproducible, and include materials for easy delivery—a frequently reported barrier in primary care BI implementation (309) (See Section 7.5.4).

Comprehensive stakeholder feedback: We obtained feedback from all stakeholders—patients, family members, and research assistants—including both structured ratings and open comments. The latter revealed several important aspects which align with Stewart et al.'s (45) reconceptualization of BIs as addressing broader life contexts beyond consumption alone—aspects that warrant further investigation in separate studies, while others could be easily incorporated into the future RCT (e.g.: simplifying the alcohol information leaflet). The feedback from all stakeholders was overwhelmingly positive, supporting the pilot design.

Documentation of critical knowledge gaps: only 0.9% understood low-risk drinking, 3.4% knew what a unit of alcohol is, and only about 5% recognised accident risk, and 84% engaging in HED. The fact that only 22% received information from health care workers, despite the huge patient turnover in the OPD, is a stark realization of a missed opportunity to incorporate reflective self-assessment, and likely spillover of accurate knowledge (See Chapter 6 and Section 7.2.3).

Iterative research design: Each study informed the next—the inpatient pilot confirmed ABI acceptability and feasibility of non-specialist delivery; the cross-sectional study determined the prevalence of risky drinking and empirical AUDIT-C cutoff to detect risky drinking; the OPD pilot tested three BI intensities and new outcome measures. (See Figure 7.1)

Exceptional retention rates: Six-month retention was 88.7% for patients and 93.7% for family members—comparatively higher than most BI research (typically 60–80%)—and especially notable given physical attendance in a resource-constrained LMIC setting.

Systematic operationalisation of TTM constructs beyond stages of change: Prior BI research informed by TTM has over-focused on stage-matching while neglecting processes of change and context of change. We incorporated both through specific intervention components nested within successively more intensive interventions. This approach is also likely to facilitate non-judgmental attitudes towards those not ready to change or those who relapse (216) (See Section 7.3.2 and Figure 7.2).

The patient information sheet as a multi-purpose innovation: A single tool serving multiple functions: activating processes of change, capturing context of change, potentially triggering the question-behaviour effect, providing an icebreaker for the ABI discussion, and surfacing cultural norms and myths (See Section 7.5.3).

Successful non-specialist delivery: Three BI intensities—FOA, UOA and ABI—were successfully delivered by trained research assistants with no prior health sector experience. This demonstrates that with appropriate training, non-specialist personnel can deliver culturally adapted BIs—particularly significant for resource-constrained healthcare systems where specialist availability is limited. This approach may also help reduce stigma in patients seeking help (308).

7.9 Future directions

7.9.1 Research priorities

The most important next step is to plan an adequately powered RCT in an OPD setting. This must be conducted at a different hospital or in a community setting, since many OPD patients presenting to Teaching Hospital Peradeniya are likely to have already been exposed to content in this study. This will provide definitive findings about the effectiveness of the three BI intensities. Simplification of the alcohol information leaflet is required and modification of trial design to explore question behaviour effect will be necessary. Further, a future definitive trial could adopt a hybrid effectiveness-implementation design (406), since both effectiveness and implementation outcomes are needed to translate these findings into routine clinical care. It is also important that health care professionals/ workers are engaged in such trials to get their point of view, at

least in designing stage, as they may be too busy with clinical work to participate as delivery personnel. Considering the changing demographics of female alcohol consumption, it is important to devise appropriate strategies to avert this future risk. This emerging pattern, potentially influenced by transnational media portrayals of women and alcohol (See Chapter 1), warrants targeted research attention.

More research is needed to explore the most cost-effective ways of educating the public about how alcohol affects the health of the user and people living around them, as well as the economy and development of the country. Digital media for health education and delivering interventions should also be researched as a matter of priority.

Validating the AUDIT-C cut-off for Sri Lankan primary care is a further research priority. The ≥4 cut-off for males adopted in this thesis was determined against HED as an internal criterion (See Chapter 5); formal validation against an external diagnostic gold standard across multiple sites is essential. Additionally, a female-specific cut-off for Sri Lanka has not been determined. Given the emerging trend of increasing alcohol consumption among women (See Section 7.6.2), establishing an evidence-based female threshold is becoming increasingly important as the population at risk expands.

Globally, all future BI research—and alcohol intervention research more broadly—should adopt outcome measures that capture overall harm reduction, not merely consumption, incorporating tools such as the Alcohol Problems Questionnaire and Family Member Questionnaire, and recognising that cutting down on alcohol is itself a clinically meaningful treatment outcome. Equally important is clear documentation of both the intervention and control conditions, which is essential for meaningful comparison across studies and for determining the settings and patient characteristics for which each intervention is most effective.

7.9.2 Policy implications

The evidence supports that alcohol unit information labelling reduces risky drinking (407). The WHO (408) strongly advocates labelling alcoholic beverages—number of units in the can, nutrition information, ingredient lists (like most other food and drinks), and specific health warnings; some member states in Europe had taken steps towards it with positive results. The evidence from the current thesis (See Chapter 6) suggests that when people are made aware of unit of alcohol and low-risk drinking guidelines they tend to reduce their harmful patterns of drinking and tend to request referral to specialised treatment. The National Authority on Alcohol and Tobacco (NATA) and the Ministry of Health in Sri Lanka should urge the government to implement such labelling as a matter of urgency.

It is well known that as people's alcohol consumption increases, they shift to beverages with higher alcohol percentage that costs them less (409). Pricing is an important determinant of alcohol consumption and related harms, and therefore a key strategy in minimizing alcohol related harms (23, 38). A UK parliamentary report (410) summarizes success stories—reduced consumption and related harms—of countries which implement 'minimum unit price' for alcohol. It is important that policy makers focus on this, as a matter of urgency.

It is also important to make the policy-makers, and the administrators aware of the already available scientific evidence and the findings of the current thesis. Although scientific evidence clearly mentions that paternalistic approach to alcohol harms could be counterproductive (See Chapter 1) and cutting down on alcohol (without abstinence) clearly is beneficial, the most recent (2025) 'Manual for the Management of Primary Medical Care Units' (3), recommends screening for 'Alcohol consumption', and all who have used alcohol in the previous 12 months will be marked red, and will be 'counselled for cessation of alcohol'. This approach might in fact promote stigma and deter these people attending these 'Healthy Lifestyle Centres' altogether. Furthermore, the Personal Medical Record (3) issued to patients at these centres records alcohol use as a simple binary—user or non-user—with no assessment of quantity, pattern, or level of risk,

precluding any possibility of harm reduction messaging at the point of care. Findings of the current thesis support that the scientific evidence could be translated into practice successfully in a culturally acceptable manner in the local context.

Translating these findings into practice will require engaging key stakeholders—policymakers, health administrators, and allied healthcare workers—well before a future RCT. Since the BIs are designed as opportunistic interventions, allied and healthcare workers who encounter risky drinkers in routine care should be included in BI training programmes from the outset. Moreover, the current policy framework, as reflected in the Primary Medical Care Unit Manual and the Personal Medical Record, would itself need to shift from a cessation-only approach to one informed by harm reduction principles, for BIs to be implemented effectively within the existing system.

7.9.3 Need for terminology reform

Terminology confusion between motivational interviewing (MI) and BI has become a genuine issue in comparing research and implementing findings. BI and MI are distinct constructs: BI refers to a time-limited, opportunistic intervention defined by its brevity, setting, and target population, while MI (207, 267) is a specific counselling style characterised by particular techniques and a spirit (partnership, acceptance, compassion, evocation), addressing those with severe alcohol related issues. The former can be delivered following brief training but MI needs longer training. However, interchangeable use (139, 269, 411) and the WHO definition of BI itself (102) adds to this confusion. Clear documentation of the intervention—such as in Hettema et al.'s (2018) (311) 'three BIs for risky alcohol use that include varying doses of MI'—is of utmost importance to minimize this dilemma. BI uses communication skills of MI, but it is not equal to MI: this distinction should be very well understood to use both these constructs appropriately in clinical practice, as was discussed in Chapter 3.

7.10 Conclusions

Alcohol exerts substantial harm on individuals, families, communities, and the economy. Despite approximately 20,000 alcohol-attributable deaths annually and economic costs reaching 2.18% of the annual GDP, Sri Lanka has no systematic screening and BI programme in primary care. The burden falls disproportionately on risky drinkers—those exceeding low-risk guidelines but not meeting criteria for alcohol dependence—who, while individually at lower risk than dependent drinkers, generate greater cumulative harm at the population level. This prevention paradox underscores the public health opportunity: reaching the larger population of risky drinkers where they present, in primary care settings.

The thesis demonstrated profound knowledge gap in a representative sample of OPD attendees, which needs to be addressed as a matter of priority through policy.

The thesis confirmed the acceptability of three intensities of BIs for delivery by trained non-health staff—a pragmatic first step toward addressing this gap in a resource-limited setting. The OPD prevalence study revealed the scale of the opportunity: 39.3% (of 1414) of male attendees within a single month were drinking above low-risk guidelines.

A harm reduction paradigm guided the thesis from its inception: treating any reduction in alcohol-related harm as clinically meaningful, regardless of whether abstinence is achieved. The pilot studies were designed around processes and context of change—two TTM constructs critical for this population yet largely overlooked in BI research. Family member perspectives were incorporated as an outcome measure—a methodology not previously reported in BI research—alongside patient-reported outcomes extending beyond consumption alone.

The thesis demonstrated that the patient information sheet is a useful tool in BI research; simultaneously capturing contextual factors shaping drinking behaviour, activating processes of change through reflective self-assessment, and enabling the 'intimacy' of intervention. The inclusive design—not excluding patients with possible dependence

indicators—tested interventions under real-world health care settings; and several patients requested referral to specialised care at follow-up. All outcome measures except Timeline Follow Back proved appropriate for a future trial. Trends toward reduced consumption, shifting from spirits to non-spirits, reduced HED frequency, reduced family burden, and improved knowledge were observed, although no finding was conclusive given the pilot nature of the study.

The three BI intensities—brief, culturally adapted, and deliverable by trained non-specialist staff—proved acceptable and feasible in routine outpatient care, and the theoretical and methodological framework developed in this thesis is directly transferable to a future trial. However, translating evidence into practice will also require aligning the current policy framework—which remains oriented toward cessation—with the harm reduction principles that this research supports.

This thesis provides a methodological and theoretical foundation for a fully powered randomised controlled trial of culturally adapted brief alcohol interventions in Sri Lankan primary care—an essential next step toward addressing the substantial burden of alcohol-related harm in this setting. More broadly, it demonstrates that brief, harm reduction-oriented interventions are acceptable, feasible, and show promising trends in a setting where the burden is substantial, the opportunity is clear, and the response is long overdue.

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Appendix A: Three Components of the Adapted Brief Intervention

1. Alcohol Information Leaflet

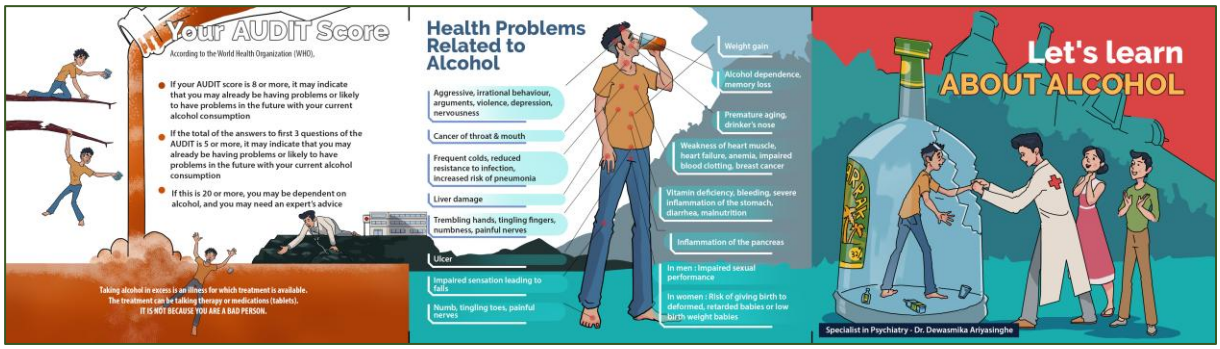

Figure 1: Alcohol information leaflet – Side 1



Figure 2: Alcohol information leaflet – Side 2

2. Patient personal Information sheet

(The information will be collected by the research assistant by direct questioning of the patient.**)**

1. Name: …….
2. Age: ……
3. Address: ……..
4. Level of Education: ……
5. Contact Number/s: ……..
6. The unique identification code of the patient (UIC):

   …….
7. Occupation: ……
8. What is your approximate income?
   a. Daily (If you are paid daily): Rs……..
   b. Monthly (If you are paid monthly): Rs. ……..

9. When was your last alcohol consumption: …….
10. Who do you consume alcohol with?
    a. By yourself mostly
    b. With friends
    c. With relations

11. What is the occasion you usually take alcohol?
    a. When I feel lonely
    b. To enjoy
    c. Due to peer pressure
    d. ‘Social drinking’
    e. When I feel down
    f. When I feel tired
    g. when I feel anxious
    h. When at a party/ funeral
    i. Any other (Write it down): ……

12. Relationship status:
    a. Single
    b. Married
    c. Divorced/ separated
    d. In a relationship
    e. Widower
    f. Not willing to disclose
13. Do you have children? If so, how many?

    .....
14. 'We all have goals in our lives' 'What are yours? Ask for at least two goals for his future
    a. .....
    b. .....
    c. ……
15. 'People have various reasons to like alcohol. It is very individual' 'What do you like most about alcohol?
    a. ……
    b. ……
    c. ……
16. 'Some people, even though they like taking alcohol, experience certain issues which can be disturbing to them. Is there anything you don't like about alcohol? (Tell him if there is none, that is fine)
    a. ……
    b. ……
    c. ……
17. Has there been any information you have received/ gained regarding your alcohol consumption before? (Yes/ No)
    a. If 'Yes', what was it (book, leaflet, TV, paper, internet, others- specify)?
       ……
    b. If it was a person who gave you information, who gave you the information (health care workers, a relative, a friend, others- specify)?
       ……
    c. What was the result of this information (State in 2/3 sentences)?

…….

18. The name of the family member who we can contact (if the patient consents to do so):
    a. His/ her name: ……
    b. His/ her contact number: ……....
    c. The relationship of the family member to the patient:……
    d. His/ her occupation if employed:……

3. Manual for research assistants to deliver adapted brief intervention

Preamble

Sri Lanka has one of the highest rates of deaths due to cirrhosis in the world, an indicator of one of a country's alcohol related problems. Domestic violence, suicide, self-harm, family disharmony, poverty, mental and physical illnesses and overall poor quality of life are some of the adverse outcomes of using alcohol. These outcomes are directly related to levels and patterns of drinking in a population.

The goal of the ABI is to identify real or potential alcohol problems and reduce harmful drinking of a person, by motivating him to reconsider his drinking and change it. This is an intervention used around the world with significant benefit. Since change of behaviour is a process, not just a single event, a patient's reluctance to change his alcohol taking behaviour does not mean that the intervention has failed. The patient may decide later, to change his behaviour. Further, there could be positive outcomes (like avoiding risky behaviours after taking alcohol), which we have not measured.

This is done through a collaborative approach and non-directive and non-confrontational way of conversation. At the end, it is the patient's decision to change/ not to change his drinking behaviour, and we are not there to force/ make decision for him. We should not be judgmental, and we should respect his decision.

3.1 Important points to remember when you talk to patients

1. The interaction is more collaborative, so there is no power difference

2. It is the patient's decision to stop/cut down or continue alcohol; we can't force him to make decisions. Respect the patient's decision

3. Don't be judgemental

4. The idea is to work with the patient's own ideas, concerns and goals (we have to know him first) and then to work with them (dance) not to confront them (wrestle)

5. We are there to help the patient make an informed decision by giving knowledge of alcohol and encouraging him to reflect and think (motivation to change should come from the patient himself)

6. Understand the patient's point of view (e.g., He may really believe that alcohol eases his tiredness, being with friends is the only thing which matters to him)

7. Listen, do not rush the patient

8. Non-verbal communication is quite effective (and can be detrimental as well if done wrong)

9. If the patient is not willing to change that is not your fault/ failure. This encounter could be just the beginning of a change, 'since change is a process not an event'

10. Use terms like 'not so good things of alcohol' instead of 'bad things of alcohol/ disadvantages of alcohol'

11. The central aspect is active listening; using open ended questions (prompt them to think before answering), statements of appreciation and understanding, reflecting on what is being told has been understood and inviting him to expand further, and combing key points to gauge the whole picture which will show that we have been listening and help him to clarify his thoughts.

12. The ABI encourages the patient to take responsibility for their decision (which is shown to be more effective than when someone else makes the decision for him)

13. The outcome of ABI could be that he thinks about changing his drinking behaviour, planning to change his behaviour, successfully stops/ reduces alcohol or even if the patient is not going to change his alcohol consumption, he may change his life in a positive way, (e.g. Refrain from driving after taking alcohol) which improves his (and his loved ones') quality of life.

14. More change talk (the patient's reasons to change or benefits of change) and less sustain talk (the patient's reasons not to change or barriers to change) = increased chance of change

3.2 Introduction to adapted brief intervention

This will be based on the following structure stated in the 'WHO alcohol brief intervention training manual for primary care'

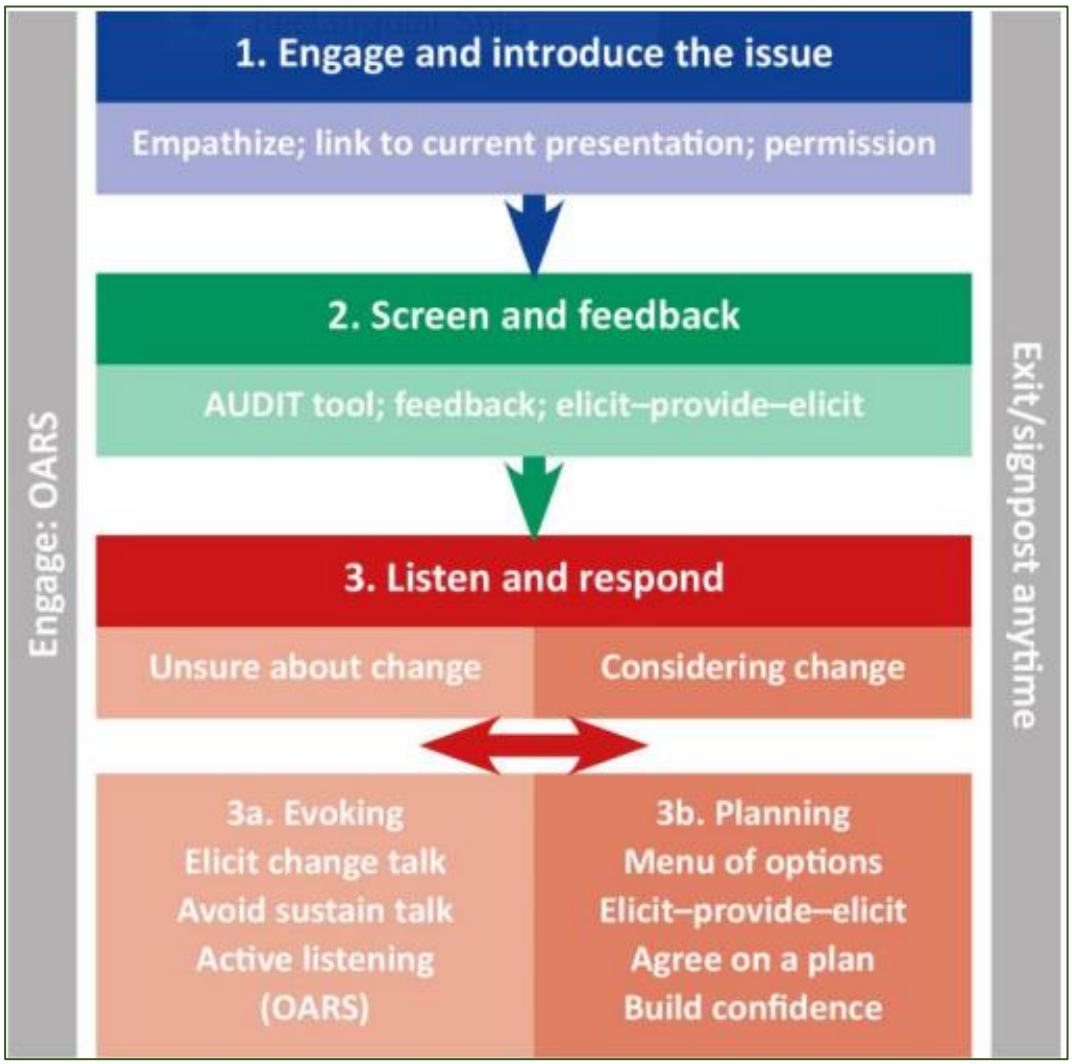

Figure 3 Stages of a brief intervention in primary care (Source: WHO 2017 Alcohol brief intervention training manual for primary care)

- Before going to the patient, be familiar with the patient's responses in the patient information sheet and his AUDIT score.

E.g.

- The patient's income
- Who the patient consumes alcohol with
- The occasion/s the patient usually takes alcohol
- The relationship status
- Whether the patient has any children and if so, how many
- Two future goals of the patient
- What the patient likes most about alcohol (In other words, what he is going to miss if he were to reduce or stop alcohol)
- If there is anything the patient does not like about alcohol (In other words, what he gains by reducing/ stopping alcohol)

This will help you to have a natural conversation with the patient rather than looking at your papers frequently. But do feel free to take a glance if you are not certain of some information. If you make a mistake apologize and correct yourself. DO NOT ask directive/ close ended questions using this information. This information will help in starting the conversation in those who are unsure of what to do (e.g.: 'One of your life goals is to do (Take an example from the Patient information sheet)....., Is it OK if I ask how you are going to achieve this?') or evoke talk.

3.3 Introducing each other and entering the conversation

- Introduce yourself (With your name, the purpose of this discussion and what your role is)

- ‘How would you like me to address you?’ (Use this preferred name by patient to address him throughout the discussion)
- ‘Is it OK if I write down some of what you say? It will be kept confidential.
- If he consents only, you can take your notes, so that you do not forget/ mix up information
- ‘How do you feel now (asking about the current admission)?’
- ‘What brought you to the hospital?’
- Let the patient answer (Remember this to be used later in the discussion)
- ‘How would you rate your ill-being/ well-being over the last 2 weeks?
- ‘What are your worries?’, ‘How would you like things to change’, ‘How would you like your life to be in a year?’,
- ‘What do you think of your current alcohol intake?’

Desire ✔ How would you like things to change? ✔ What do you hope you can change? ✔ Tell me what you do not like about how things are now. ✔ What would you like to be different?	*Reasons* ✔ What concerns you? ✔ Why would you want to cut down? ✔ What might be the benefits of drinking less? ✔ What are the reasons to change as you see them?
Looking forward ✔ How would you like your life to be in a year? ✔ What do you hope for over the next five years? ✔ In what way do you want to feel better?	*Looking back* ✔ Can you remember a time before you were drinking like you've described? What was different? ✔ How did you cope before?
Querying extremes: no change ✔ What most concerns you about your drinking in the long run?	*Querying extremes: change* ✔ If you cut down today, how would you hope to feel different?
Whenever you hear change talk, you can ask open questions that encourage elaboration. ✔ In what way? ✔ Tell me more? ✔ What else?	
Avoid questions that will lead to sustain talk. X Why do you drink in the way you've described? X What's stopping you from cutting down? X What worries you about drinking less?	

Figure 4 Questions for change talk (Source: WHO 2017 alcohol brief intervention training manual for primary care)

If he seems undecided move, to 3.8 directly and start from there.

3.4 A patient who seems to think of changing his alcohol intake

'Maybe it is too much'

3.4.1 'Why do you think so?

(Give him some time to think)

3.4.2 Reflect on what your understanding of what the patient told you 'Is that correct to say that you have had these issues when you took a drink?

3.4.3 If he agrees;

'In fact, this is what we have got from your questionnaire and the other information you have already provided'

3.4.4 If does not agree ‘Can you please explain further?

Once he explains it start from 3.4.2.

3.4.5 ‘We have got the score of your screening test. Would you like to see?

If so, show it and explain what it means and

‘It is great that you yourself have thought so. We can work together to look for a solution’

3.4.6 ‘Would you like to receive more information about alcohol?’

If yes, take the alcohol information leaflet and explain what it means.

3.5 Information on alcohol

3.5.1 What alcohol does to our body?

(Use the diagram)

3.5.2 ‘Have you ever experienced any of these?’

‘The patient may or may not realize the relationship between the current presentation and alcohol’. Even if there does not seem to have a relationship with the current presentation, if he has already experienced features shown in the diagram, help him to make the connection between alcohol and these aspects.

3.5.3 ‘Unit of alcohol’

Use the pictures to indicate what is meant by this in the patient’s favourite liquor type/s (Make sure that you do not change your way of talking if the patient takes ‘illicit liquor’)

3.5.4 ‘Low risk drinking’

- ‘It is best not to take any alcohol at all. But there are people who do not stop it completely. So, the WHO has recommended ‘low risk drinking’
- ‘One should not take more than 4 units of alcohol a day’
- Explain this by taking the patient’s favourite alcoholic beverage/s
- ‘It is recommended that one should not exceed’ weekly alcohol consumption more than 10 units’
- Explain this by taking the patient’s favourite alcoholic beverage/s
- ‘I will next mention the activities that one should avoid doing after taking alcohol and occasions where it is not advisable to consume alcohol at all’
- Explain what is there in the leaflet

3.6 Eliciting the problem:

3.6.1 ‘What would you like to do about this issue?’. Let him express himself

The patient may answer ‘I will cut down on alcohol’.

Acknowledge/ affirm ‘It is really good you have decided. If we can talk about it a little, we may be able to come up with a plan’

‘We can help you with your decision and the plan, if you are ok with that’

3.6.2 ‘What are you going to miss if you were to cut down/ stop taking alcohol?’

After the patient answers, empathize ‘Yes, I understand. It can take some time to adjust. And you are not alone in that, that is the case with almost everyone initially, who tries to cut down’.

3.6.3 ‘I think you mentioned earlier that (e.g.: You do not like forgetting things which happened on the previous night after taking alcohol). Am I correct to say that?

3.6.4 ‘What do you think when you compare what you gain and lose after stopping or cutting down on alcohol?’

(Listen to him and reflect on what he said)

3.7 Working out a plan:

3.7.1 Asking about the difficulties he might encounter

‘Could I ask you what difficulties you would come across when trying to cut down/ stop?’

(Give him some time to think and listen to him)

Depending on the answers, you can make a reflective statement (E.g. ‘Is it correct if I say you take alcohol when you are partying with your friends over the weekend and you lose count of the drinks?’, or ‘You don’t feel like refusing an offer of a drink or ‘When you feel lonely you don’t know what else to do’ or ‘When the mood comes, you really can’t resist it’ or ‘When I you see things which reminds you of the time you took alcohol, you can’t resist it’ .)

3.7.2 Getting patient’s suggestions to face difficulties

‘What can you do to minimize this happening?’

3.7.2.1. Let the patient come out with answers first and if he struggles offer options with his permission.

E.g.:

- .' How about, reducing the frequency of going to parties?'
- 'Taking a drink slowly while talking/ eating?'
- 'Not to take alcohol when you are hungry/ thirsty'
- 'Leaving early?'
- 'Not keeping alcohol at home?
- 'Taking a beer instead of arrack?'

3.7.2.2. 'It is said that these moods are like waves, they come and go. How would you use this in your plan?

Let him come with suggestions. If no suggestions

'How about taking something else like a cup of tea/ coffee or listening to a song or having a chat with your family members or doing some exercises? This will help you to pass the wave'

Drink on fewer occasions, for example, find alternative activities.	On each occasion drink fewer alcoholic drinks, have a soft drink or drink more slowly.	Drink less alcohol in each drink, for example, switch drinks to a lower strength or a different kind of drink with less alcohol in it.

Figure 5 (Source: Options for change (Source: WHO alcohol brief intervention training manual for primary care)

3.7.2.3. If the patient has difficulty passing time after work/ on weekends/ public holidays

- ‘What would you like to do instead of having a drink?’
- ‘What do/ did you enjoy as a child/ enjoy now other than taking alcohol?’
- ‘Would you like to start any of this now?’
- (Show the pictures provided by saying ‘These are some examples for alternative activities if you are interested)
- DO NOT talk about reasons why he does not want to change
- DO NOT ask about what he has lost due to alcohol use/ disadvantages of alcohol use; EMPHASIZE only on what he gains from cutting down/ stopping

3.7.2.4. ‘If he finds it difficult to say ‘no’ when a drink is offered:

- ‘What do you think would happen if you say ‘no’?’
- Let him express himself
- Then rephrase it and reflect on what he said
- ‘You think others will look down on you’
- ‘You are worried that you will lose company’
- Offer any statement which suits the patient’s background.

3.7.2.5. Would you like to role play it with me?’

Simulate that you and the patient are on the occasion that patient finds it difficult to refuse a drink (E.g.: At a party);

You take the role of the patient and ask the patient to offer you a drink/ or more drinks after having 1 or 2 like his friend/s do.

Patient (Friend): ‘Mate, have a drink with us/me’ OR ‘Have one more’

You (Patient): ‘The doctor asked me to reduce my drinking’, ‘I will have a soft drink and hang out with you’ ‘I think I already had enough drinks for today’

OR ‘Enough for today, maybe next time’

Patient (Friend): ‘Have one/ one more just for today’

You (Patient): ‘Mate, please I can’t lie to my doctor. He was very serious about me cutting down. I want to give it a try this time’/ ‘I am serious about my health this time. Appreciate your support to do this’

Repeat this three times with the patient

Then swap the roles and re-do the role-play. DO NOT dictate/ direct patient (e.g., Do it like this’), instead try to re-word it ‘How about trying this way and rephrase’

3.7.3 Maintaining a record of consumption

‘Sometimes it is helpful to keep a record of drinking. Would you like to try it?

‘We have designed this calendar for the purpose’

Offer them the calendar and suggest them to hang it somewhere he can see (he can hide it from others and mark if he prefers it that way).

‘What you can do is to just mark the number of drinks you had on a particular day’. ‘If you are ok with taking this to the next meeting in 4 weeks, please take it with you, or else you can leave it at home’

3.7.4 Building confidence

‘What do you think of the plan you have made for yourself?’

If the patient appears confident, ‘I am positive that you can do this. We can talk if you come across any problem’

The patient appears ‘not that confident’

‘Thinking of doing something about alcohol itself is a step forward. You know what is best for you and what steps would help you to be happy while trying to cut down or stop alcohol’

‘What else has he changed in his life in the past (It may be that he has stopped/ cut down alcohol on his own for a few months/ other day-today problems he has overcome) ‘Is it correct if I say you can achieve things when you commit to something?’

Ask him what helped him doing this. Ask him what support he can get and from whom.

‘Most people do not succeed in the first attempt. But taking small steps can help, to make a big change later’.

3.7.5 Managing craving

If the patient has craving, equip him with strategies to deal with it.

Use the example of the ‘wave’ above in 3.7.2.2.

Delay - ‘May be, you can try to postpone taking/ buying alcohol’

Distract – ‘What can you do to distract yourself for a brief period?’. Let him think. And encourage to decide for himself

Decide – 'You can think of the reason why you decided what you have decided.' 'This may help you to let the craving pass'

3.7.6 Managing cues'

Once you know of his cues, you can talk about them

'When you see ...../ remember .....you are not able to resist the urge to take alcohol. Am I correct to say that?'

'What can you do to stop this from happening?'

Get suggestions from him and with his permission suggest him some possible alternatives to take (E.g. To take a different path back home, have fixed days of the week to go out with friends, so even he meets them on another day he can tell them that it is not his day to take alcohol, distract himself by listening to a song, helping with children/ wife)

Make sure that he has one option to each cue.

3.7.7.Summarizing

Suggest the patient that it is better to go through what has been discussed briefly, so that he can get a better idea of his plan and how to go about it.

'If you would like to summarize what we have discussed so far, we can go through it together. It will help you to remember things'

'You have decided to reduce alcohol/ stop alcohol because you think you have issues (give examples of the patient's problems gathered in the discussion). This is how you have decided to implement the plan (go through the agreed plan). I will send a text message in 2 weeks 'How are you going with your plan?' and you do not have to respond to it and it is just to remind you of the plan. Please see me in 4 weeks with your (family member – wife/

brother/ sister/ father/ mother/ son/ daughter/ mother-in-law, father-in-law, sister-in-law, brother-in-law) at ..... of Teaching Hospital, Peradeniya'

Give him the alcohol information leaflet before he leaves.

3.8. If the patient seems undecided on what to do about his alcohol use

'It is ok. I can understand, making a decision can be harder and you can decide later'

'We have got the score of your screening test. You can see it first and see what is good for you. Would that be ok with you?'

3.8.1 If the patient does not want to hear about it, then give the patient information leaflet only. Do not force him to participate in the ABI, but tell him that we are here to give him support if he changes his decision

3.8.2 If he wants to know the score.

Inform the score to him.

'If you would like to know what it means, I can explain'

If he does not want to know go to 3.8.1.

If he wants to know 'This score means that your alcohol intake is likely to put you in trouble (Do not use 'too much' as this could sound like a judgemental statement).

'Would you like to talk about this?

If ‘Yes’

Start from Information on alcohol and proceed as in 3.4.5.

If ‘No’ proceed as in 3.8.1.

3.9 The patient is in denial and does not want to talk about it

‘That is ok. Could we then talk about how you are doing these days?’

3.9.1.1 If the patient says ‘Yes’,

Ask the patient ‘How are the things with you these days?’

Depending on the response

‘What don’t you like about how things are now?

‘What would you like to be different?’

‘What do you think you can do to change how things are now?

DO NOT push the patient to accept, persuade, advice without permission and avoid argument.

See whether you can find an opening to alcohol conversation. ‘If it is ok for me to say that I would like to point out that your current way of alcohol consumption may be contributing to some of the ‘not so good things’ happening in your life’. ‘If you are willing to talk about it, I am ready to listen to’.

If the patient is not willing,

Go to 3 8.1.

3.9.1.2 For patients who are willing to talk,

‘Shall we start with the questionnaire you filled with me? Your score is ..... and it means your current pattern of consumption of alcohol is likely to put you in trouble in the future’

‘What do you think? (Listen to what he wants to say.)

‘Would you like to know about alcohol?

If ‘Yes’ ‘We have prepared an information sheet’

Start from Information on alcohol from Section 3.5.

3.9.2 If he says ‘No’

Do not proceed.

Go to 3.8.1.

Appendix B: Consent Forms

1. **Patient consent form for participating in the study: 'A pilot study to inform a 3-arm parallel-group RCT of an adapted brief intervention for alcohol use disorders in Sri Lanka, and assess potential correlates of effectiveness, such as early childhood trauma'**

I am *Dr. Dewasmika Ariyasinghe* working in the *Department of Psychiatry, Faculty of Medicine, University of Peradeniya as a senior lecturer*. We are doing research on alcohol abuse which is a common medical/health problem in Sri Lanka. A research assistant on my behalf will give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. There may be some words that you do not understand. Please ask the research assistant to stop as he/she will go through the information and will take time to explain. If you have questions later, you can ask the research assistant or me.

This is done as part of my PhD. I am a PhD student at the Australian National University.

PART I

Information sheet:

Title of the research: A pilot study to inform a 3-arm parallel-group RCT of an adapted brief intervention for alcohol use disorders in Sri Lanka, and assess potential correlates of effectiveness, such as early childhood trauma

Purpose of the research

Alcohol related harms have become a serious issue in Sri Lanka. One of the main reasons for this could be lack of understanding about alcohol related harms and patterns of alcohol consumption which can put them at risks, among who take alcohol. So, the idea of this study is to introduce a simple non-drug treatment (by adapting an already widely used intervention internationally, to suit the culture in Sri Lanka) to reduce this harm and see whether it works.

Type of Research and how the participants are selected:

All male patients getting admitted to wards 1,8,12,16 and 17 of Teaching Hospital Peradeniya, Sri Lanka who will be chosen to administer the questionnaire by the research assistant.

A research assistant will talk to you to get a questionnaire (AUDIT - C) filled, which is about your drinking habits, if you are willing to do so, and you will get the opportunity to participate in the study depending on the score for the questionnaire.

If you are selected and you consent to participate in the study, you will be allocated randomly to one of the three groups depending on the order of recruitment. A research assistant will talk to you, get some important personal information from you, fill out questionnaires of your alcohol consumption, your

childhood experiences, your knowledge on alcohol and do the intervention allocated to that group. At the end you will receive a leaflet on alcohol.

If you consent for the research assistant to talk to a family member, he/she will talk to him/her, who visits you at the hospital to get information about your alcohol use.

Depending on the group you belong to, you will have to spend between 30-60 minutes.

If you are having a severe physical or mental illness, already on treatment to reduce alcohol consumption, if you have features of addiction to alcohol and willing to get specialized care for this, you are not suitable to take part in this study.

Voluntary participation:

Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

Whether you choose to participate or not, all the services you receive in this ward will continue and nothing will change.

You may change your mind later and stop participating even if you agreed earlier.

The pilot study will take place from September 2022 to November 2022.

Depending on the group you belong to you will spend 30-60 minutes at the initial contact and 15-20 minutes in the subsequent visit.

The family member will spend about 20-30 minutes at both contacts.

Information of the procedures and interventions:

The proposed study is a trial but does not include giving medications to the participants. However, this study does not include giving any medications to you, it is about a 'talking therapy'. If you are eligible and consenting, you are allocated randomly to one of the three groups of the study and will receive the particular 'intervention' of that group.

There are three groups named 'FOA', 'UOA' and 'ABI'. You will be randomly allocated to one of the three groups.

If you are allocated to the arm named as 'FOA' you will be told about your score for the questionnaire, and that your consumption is likely to have caused you problems already or is likely to cause you problems in the future. A leaflet on alcohol will be given to you. You are requested to present to Teaching Hospital Peradeniya 4 weeks after the initial contact.

If you are allocated to the arm named as 'UOA', you will be you will be told about your score for the questionnaire, and that your consumption is likely to have caused you problems already or is likely to cause you problems in the future. Then the research assistant will explain you what is meant by 'unit of alcohol' and 'low risk drinking'. A leaflet on alcohol will be given to you. You are requested to present to Teaching Hospital Peradeniya 4 weeks after the initial contact.

If you are allocated to the arm named as 'ABI', you will be you will be told about your score for the questionnaire, and that your consumption is likely to have caused you problems already or is likely to cause you problems in the future. Then the research assistant will have a discussion for about 30 minutes with you about how to change your current drinking pattern with your consent and also explain you what is meant by 'unit of alcohol' and 'low risk drinking'. A leaflet on alcohol will be given to you. You will receive a text message on your phone, 'How are you going with your plan?', after 2 weeks of your initial contact. You do not have to respond to this; it is only to remind you of your plan. You are requested to present to Teaching Hospital Peradeniya 4 weeks after the initial contact.

Ethics Approval no: 2022/EC/56- Ethics Review Committee, Faculty of Medicine, University of Peradeniya, Sri Lanka and 2022/779—Australian National University Australia

Trial is registered in Sri Lanka Clinical Trials Registry: SLCTR/2022/027

Side effects:

You will not experience any side effects by participating in this trial

Risks:

There are no major risks involved in this study.

However, you may need to talk on sensitive issues like describing traumatic/ bad experiences, health issues, but you can avoid discussing about these things if you wish to do so.

Let us know if you have any difficulty, and we can direct you to the on-call doctor of the psychiatry unit of Teaching Hospital, Peradeniya.

Place where the trial is conducted:

At the same ward, in a quiet area where you are currently being treated

The research assistants will inform you of the place you and your family member should come for the follow-up visit.

Audio recording of the interview:

If you belong to ABI arm, and if you give your consent, your conversation with the research assistant will be audio taped. This is to be used only by me and a graduate in psychology to listen and transcribe. This is to ensure the quality of the intervention and also to see important and not-so-important components of the interview. The interview will be transcribed, and the deidentified transcripts will be stored in the PIs personal laptop computer for 7 years for future use if needed.

Benefits:

If you participate in this research, you will have the following benefits:

By participating in this research, you will get a chance to talk about your alcohol use openly and get some basic knowledge of alcohol and its harms. This may help you to think of your current drinking habits and whether you think of changing it.

And the society may also benefit by your participation in this study

The results of this study may help to introduce new strategies to reduce harms related to alcohol in Sri Lanka.

Reimbursements:

In recognition of your time and effort we will give you and your family member Rs. 2500 each, for each visit.

Confidentiality:

Your personal details will be accessible to me and the research assistants, and these will be kept under lock and key and in a password protected folder. This information will be used only to get your phone number to remind you of the follow up appointment.

Other information collected from you will be used under the unique identification number given to you at the recruitment for the study.

The information we collect from you will be stored in password protected folders in my laptop which is given by the Australian National University and a backup password protected folder in my personal desktop computer in the Department of Psychiatry, Faculty of Medicine, University of Peradeniya, Sri Lanka.

The audio tapes once transcribed will be destroyed. The transcripts will be saved but they will not have your personal identification details.

Who to Contact:

If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact me:

Name: - Dr. Dewasmika Ariyasinghe

Address: - Senior Lecturer, Department of Psychiatry, Faculty of Medicine, University of Peradeniya

Telephone number/email:u7087000@anu.au.edu

If you are distressed, you can call 0812388001 and get the extension 309. Then you will be able to talk to a nursing officer of the psychiatry unit of Teaching Hospital, Peradeniya and she will direct you appropriately

PART II

Certificate of Consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked to have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

I agree to participate in the project. YES ☐ NO ☐

I agree to this interview being audio-recorded YES ☐ NO ☐

I agree to a research assistant talking to my family member of my alcohol use YES ☐ NO ☐

Name of Participant_____

Signature of Participant _____ Date _____

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumbprint as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____ Date _____

2. Family member consent form to participate in the study: 'A pilot study to inform a 3-arm parallel-group RCT of an adapted brief intervention for alcohol use disorders in Sri Lanka, and assess potential correlates of effectiveness, such as early childhood trauma'

I am *Dr. Dewasmika Ariyasinghe* working in the *Department of Psychiatry, Faculty of Medicine, University of Peradeniya as a senior lecturer*. We are doing research on alcohol abuse which is a common medical/health problem in Sri Lanka. A research assistant on my behalf will give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. There may be some words that you do not understand. Please ask the research assistant to stop as he/she will go through the information and will take time to explain. If you have questions later, you can ask the research assistant or me.

This is done as part of my PhD. I am a PhD student at the Australian National University.

PART I

Information sheet:

Type of Research

Alcohol related harms have become a serious issue in Sri Lanka. One of the main reasons for this could be lack of understanding about alcohol related harms and patterns of alcohol consumption which can put them at risks, among who take alcohol. So, the idea of this study is to introduce a simple non-drug treatment (by adapting an already widely used intervention internationally, to suit the culture in Sri Lanka) to reduce this harm and see whether it works

A research assistant will talk to you to get some information of alcohol consumption of your family member, who is admitted in the ward.

He/ she will get a questionnaire (Family Member Questionnaire) filled, which is about the problems you may be having due to your family member's drinking habits.

Voluntary participation:

Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

Whether you choose to participate or not, it does not affect the care your family member receives in the hospital

You may change your mind later and stop participating even if you agreed earlier.

Duration:

The pilot study will take place from September 2022 to November 2022.

You will spend about 20-30 minutes in each contact.

Side effects/ risks:

There are no major risks involved in this study.

However, you may need to talk on sensitive issues like describing traumatic/ bad experiences, health issues, but you can avoid discussing about these things if you wish to do so.

Let us know if you have any difficulty, and we can direct you to the on-call doctor of the psychiatry unit of Teaching Hospital, Peradeniya.

Place where the trial is conducted:

At the same ward, in a quiet area where your family member is currently being treated

The research assistants will inform you of the place you and your family member should come for the follow-up visit.

Benefits:

If you participate in this research, you will have the following benefits:

By participating in this research, you will get a chance to talk about your distress if any due to the alcohol use of your family member

And the society may also benefit by your participation in this study

The results of this study may help to introduce new strategies to reduce harms related to alcohol in Sri Lanka.

Reimbursements:

In recognition of your time and effort we will give you and your family member Rs. 2500 each, for each visit.

Confidentiality:

Your personal details will be accessible to me and the research assistants, and these will be kept under lock and key and in a password protected folder. This information will be used only to get your phone number to remind you of the follow up appointment.

Other information collected from you will be used under the unique identification number given to you at the recruitment for the study.

The information we collect from you will be stored in password protected folders in my laptop which is given by the Australian National University and a backup password protected folder in my personal desktop computer in the Department of Psychiatry, Faculty of Medicine, University of Peradeniya, Sri Lanka.

Who to Contact:

If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact me:

Name: - Dr. Dewasmika Ariyasinghe

Address: - Senior Lecturer, Department of Psychiatry, Faculty of Medicine, University of Peradeniya

Telephone number/email:u7087000@anu.au.edu

If you are distressed, you can call 0812388001 and get the extension 309. Then you will be able to talk to a nursing officer of the psychiatry unit of Teaching Hospital, Peradeniya and she will direct you appropriately

PART II

Certificate of Consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked to have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

I agree to participate in the project. YES ☐ NO ☐ Name of Participant_____

Signature of Participant _____ Date _____

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumbprint as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of the participant: .....

Thumb print of participant: Print name of witness: .....

3. **Patient consent form to participate in the study: The relationship between the presence of risky drinking and knowledge on alcohol harms among patients presenting to the outpatient department of Teaching Hospital Peradeniya, Sri Lanka: A cross-sectional study'**

I am ***Dr. Dewasmika Ariyasinghe*** working in the ***Department of Psychiatry, Faculty of Medicine, University of Peradeniya as a senior lecturer***. We are doing research on alcohol abuse which is a common medical/health problem in Sri Lanka. A research assistant on my behalf will give you information and invite you to be part of this research. Before you decide, you can talk to anyone you feel comfortable with about the research. There may be some words that you do not understand. Please ask the research assistant to stop as he/she will go through the information and will take time to explain. If you have questions later, you can ask the research assistant or me.

This is done as part of my PhD. I am a PhD student at the Australian National University**.**

PART I

Purpose of the research

Alcohol related harms have become a serious issue in Sri Lanka. One of the main reasons for this could be lack of understanding about alcohol related harms and patterns of alcohol consumption which can put them at risks, among who take alcohol. So, the idea of this study is to see whether there is a relationship between knowledge on alcohol related harms and engaging in risky drinking. The study may be useful in designing preventative strategies for risky drinking.

Type of Research and how the participants are selected:

A research assistants will talk to all male and female patients who are 18 years or above and who can understand and speak Sinhala well, who present to the OPD at Teaching Hospital Peradeniya and explain the nature of the study. You will also be given the information sheet. The research assistant will talk to you if you are willing to participate, in a place where confidentiality and your privacy could be ensured. You will be requested to sign this document to say that you have understood about the nature of this study and consent to participate. Your name, age and level of education, what age you had your first drink will also be collected. The AUDIT-C and 'Alcohol knowledge questionnaire' will be administered by the research assistants.

It will take 15-20 minutes for you to answer the two short questionnaires.

Voluntary participation:

Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

Whether you choose to participate or not, does not affect the services you receive in the hospital.

You may change your mind later and stop participating even if you agreed earlier.

Duration:

This will take place from mid-March to end of April 2023.

Ethics approval:

Ethics Approval no: 2023/EC/13- Ethics Review Committee, Faculty of Medicine, University of Peradeniya, Sri Lanka and 2022/779—Australian National University Australia

Risks:

There are no major risks involved in this study.

However, you may need to talk on sensitive issues like describing health issues, but you can avoid discussing about these things if you wish to do so.

Let us know if you have any difficulty, and we can direct you to the on-call doctor of the psychiatry unit of Teaching Hospital, Peradeniya.

Place where the study is conducted:

The research assistant will talk to you in an area in the OPD, where confidentiality and your privacy will be assured.

Benefits:

If you participate in this research, you will have the following benefits:

By participating in this research, you will get a chance to talk about your alcohol use openly and get some basic knowledge of alcohol and its harms. This may help you to think of your current drinking habits and whether you think of changing it. And the society may also benefit by your participation in this study. The results of this study may help to introduce new strategies to reduce harms related to alcohol in Sri Lanka.

Confidentiality:

Your personal details will be accessible to me and the research assistants only and these will be kept under lock and key and in a password protected folder.

Other information collected from you will be used under the unique identification number given to you at the recruitment for the study.

The information we collect from you will be stored in password protected folders in my laptop which is given by the Australian National University and a backup password protected folder in my personal desktop computer in the Department of Psychiatry, Faculty of Medicine, University of Peradeniya, Sri Lanka.

Who to Contact:

If you have any questions, you may ask your research assistant at the time of the interview or later, even after the study has started. If you wish to ask questions later, you may contact me:

Name: - Dr. Dewasmika Ariyasinghe

Address: - Senior Lecturer, Department of Psychiatry, Faculty of Medicine, University of Peradeniya

Telephone number/email:u7087000@anu.au.edu

If you are distressed, you can call 0812388001 and get the extension 309. Then you will be able to talk to a nursing officer of the psychiatry unit of Teaching Hospital, Peradeniya and she will direct you appropriately.

PART II

Certificate of Consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked to have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

I agree to participate in the project. YES ☐ NO ☐ Name of Participant_____

Signature of Participant _____ Date _____

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumbprint as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____

4. **Patient consent form for participating in the study: 'A pilot study to assess the feasibility and acceptability of culturally adapted brief intervention to outpatient setting in Sri Lankan context and the assessment tools to inform a future randomized control trial'**

I am ***Prof. Dewasmika Ariyasinghe*** working in the ***Department of Psychiatry, Faculty of Medicine, University of Peradeniya***. We are doing research on alcohol abuse which is a common medical/health problem in Sri Lanka. A research assistant on my behalf will give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. There may be some words that you do not understand. Please ask the research assistant to stop as he/she will go through the information and will take time to explain. If you have questions later, you can ask the research assistant or me.

This is done as part of my PhD. I am a PhD student at the Australian National University**.**

PART I

Purpose of the research

Alcohol related harms have become a serious issue in Sri Lanka. One of the main reasons for this could be lack of understanding about alcohol related harms and patterns of alcohol consumption which can put them at risks, among those who take alcohol and paternalistic approach towards managing those who have alcohol related problems. Therefore, the idea of this study is to trial a simple non-drug treatment, brief intervention, which has been adapted and trialled among males in inpatient units of Teaching Hospital, Peradeniya, to reduce this harm in the outpatient department.

Type of Research and how the participants are selected:

All adult male patients seeking treatment from the outpatient department of Teaching Hospital Peradeniya, Sri Lanka will be eligible to participate in the study. A trained research assistant will administer the questionnaire. Depending on your score for the questionnaire and your willingness to participate in the study you will be/ will not be chosen to participate in the study. If you consent to your family member to being contacted, we would like to talk to them with their consent.

A research assistant will talk to you to get a questionnaire (Extended AUDIT-C) filled, which is about your drinking habits, if you are willing to do so, and you will get the opportunity to participate in the study depending on the score for the questionnaire.

If you are selected and you consent to participate in the study, you will be allocated randomly to one of the three groups depending on the order of recruitment. A research assistant will talk to you, get some important personal information from you, fill out questionnaires of your alcohol consumption, and do the intervention allocated to that group. At the end you will receive a leaflet on alcohol.

If you consent for the research assistant to talk to a family member, he/she will talk to him/her, who visits you at the hospital to get information about your alcohol use.

Depending on the group you belong to, you will have to spend between 30-50 minutes.

If you are having a severe physical or mental illness, already on treatment to reduce alcohol consumption, if you have features of addiction to alcohol and willing to get specialized care for this, you are not suitable to take part in this study.

Voluntary participation and withdrawal:

Your participation in this study is entirely voluntary, and you can withdraw from this study at any time, without giving any reason and your information collected will be removed from the data set, if that is your wish. You can contact me on +94812389445, if you want to withdraw from the study. Further, you can refrain from answering some questions if you decide to do so. We will not contact your family member, if you do not want it. Further, your willingness to participate or not to participate in this study is not going to affect the care you receive for your illness you present to Teaching Hospital Peradeniya with.

You may change your mind later and stop participating even if you agreed earlier.

Duration:

The pilot study will take place from February 2024 to December 2024.

Depending on the group you belong to you will spend 30-50 minutes at the initial contact and 15-20 minutes in the subsequent visit, which will be at 4, 12 and 26 weeks after the initial contact.

The family member will spend about 15-20 minutes at both contacts.

Information of the procedures and interventions:

The proposed study is a trial but does not include giving medications to the participants, and it is about a 'talking therapy'. If you are eligible and consenting, you are allocated randomly to one of the three groups of the study and will receive the particular 'intervention' of that group.

There are three groups named 'FOA', 'UOA' and 'ABI'. You will be randomly allocated to one of the three groups.

If you are allocated to the arm named as 'FOA' you will be told about your score for the questionnaire, and that your consumption is likely to have caused you problems already or is likely to cause you problems in the future. A leaflet on alcohol will be given to you. You are requested to present to Teaching Hospital Peradeniya 4 weeks after the initial contact.

If you are allocated to the arm named as 'UOA', you will be you will be told about your score for the questionnaire, and that your consumption is likely to have caused you problems already or is likely to cause you problems in the future. Then the research assistant will explain you what is meant by 'unit of alcohol' and 'low risk drinking'. A leaflet on alcohol will be given to you. You are requested to present to Teaching Hospital Peradeniya 4 weeks after the initial contact.

If you are allocated to the arm named as 'ABI', you will be you will be told about your score for the questionnaire, and that your consumption is likely to have caused you problems already or is likely to cause you problems in the future. Then the research assistant will have a discussion for about 30 minutes with you about how to change your current drinking pattern with your consent and also explain you what is meant by 'unit of alcohol' and 'low risk drinking'. A leaflet on alcohol will be given to you. You will receive a text message on your phone, 'How are you going with your plan?', after 2 weeks of your initial contact. You do not have to respond to this; it is only to remind you of your plan. You are requested to present to Teaching Hospital Peradeniya 4 weeks after the initial contact.

Ethics Approval no: 2023/EC/83- Ethics Review Committee, Faculty of Medicine, University of Peradeniya, Sri Lanka and H/2024/0656—Australian National University Australia

Trial is registered in Sri Lanka Clinical Trials Registry: SLCTR/2024/018

Side effects:

You will not experience any side effects by participating in this trial

Risks:

There are no major risks involved in this study.

However, you may need to talk on sensitive issues like describing traumatic/ bad experiences, health issues, but you can avoid discussing about these things if you wish to do so.

Let us know if you have any difficulty, and we can direct you to the on-call doctor of the psychiatry unit of Teaching Hospital, Peradeniya.

Place where the trial is conducted:

In a quiet area at the outpatient department of Teaching Hospital Peradeniya.

The research assistants will inform you of the place you and your family member should come for the follow-up visit.

*Audio recording of the interview**:***

If you belong to ABI arm, and if you give your consent, your conversation with the research assistant will be audio taped. This is to be used only by me and a graduate in psychology to listen and transcribe. This is to ensure the quality of the intervention and also to see important and not-so-important components of the interview. The interview will be transcribed, and the deidentified transcripts will be stored in the PIs personal laptop computer for 7 years for future use if needed.

Benefits:

If you participate in this research, you will have the following benefits:

By participating in this research, you will get a chance to talk about your alcohol use openly and get some basic knowledge of alcohol and its harms. This may help you to think of your current drinking habits and whether you think of changing it.

And the society may also benefit by your participation in this study

The results of this study may help to introduce new strategies to reduce harms related to alcohol in Sri Lanka.

Reimbursements:

In recognition of your time and effort we will give you and your family member Rs. 2500 each, for each visit.

Confidentiality:

Your personal details will be accessible to me and the research assistants, and these will be kept under lock and key and in a password protected folder. This information will be used only to get your phone number to remind you of the follow-up appointment.

Other information collected from you will be used under the unique identification number given to you at the recruitment for the study.

The information we collect from you will be stored in password protected folders in my laptop which is given by the Australian National University and a backup password protected folder in my personal desktop computer in the Department of Psychiatry, Faculty of Medicine, University of Peradeniya, Sri Lanka.

The audio tapes once transcribed will be destroyed. The transcripts will be saved but they will not have your personal identification details.

Who to Contact:

If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact me:

Name: - Prof. Dewasmika Ariyasinghe

Address: - Department of Psychiatry, Faculty of Medicine, University of Peradeniya

Telephone number/email:u7087000@anu.au.edu

If you are distressed, you can call 0812388001 and get extension 309. Then you will be able to talk to a nursing officer of the psychiatry unit of Teaching Hospital, Peradeniya and she will direct you appropriately.

PART II

Certificate of Consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked to have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

I agree to participate in the project. YES ☐ NO ☐

I agree to this interview being audio-recorded YES ☐ NO ☐

I agree to a research assistant talking to my family member of my alcohol use YES ☐ NO ☐

Name of Participant_____

Signature of Participant _____

Date _____

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumbprint as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____

5. **Family member consent form for participating in the study: A pilot study to assess the feasibility and acceptability of culturally adapted brief intervention to outpatient setting in Sri Lankan context and the assessment tools to inform a future randomized control trial**

I am ***Prof. Dewasmika Ariyasinghe*** working in the ***Department of Psychiatry, Faculty of Medicine, University of Peradeniya as professor in psychiatry***. We are doing research on alcohol abuse which is a common medical/health problem in Sri Lanka. A research assistant on my behalf will give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. There may be some words that you do not understand. Please ask the research assistant to stop as he/she will go through the information and will take time to explain. If you have questions later, you can ask the research assistant or me.

This is done as part of my PhD. I am a PhD student at the Australian National University**.**

PART I

Type of Research

Alcohol related harms have become a serious issue in Sri Lanka. One of the main reasons for this could be lack of understanding about alcohol related harms and patterns of alcohol consumption which can put them at risks, among who take alcohol. Therefore, the idea of this study is to trial a simple non-drug treatment, brief intervention, which has been adapted and trialled among males in inpatient units of Teaching Hospital, Peradeniya, to reduce this harm in the outpatient department.

A research assistant will talk to you to get some information of alcohol consumption of your family member.

He/ she will get a questionnaire (Family Members Questionnaire) filled, which is about the problems you may be having due to your family member's drinking habits.

Voluntary participation:

Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

Whether you choose to participate or not, it does not affect the care your family member receives in the hospital

You may change your mind later and stop participating even if you agreed earlier.

Ethics Approval:

No: 2023/EC/83- Ethics Review Committee, Faculty of Medicine, University of Peradeniya, Sri Lanka and H/2024/0656—Australian National University Australia

This trial is registered in Sri Lanka Clinical Trials Registry: SLCTR/2024/018

Duration:

The pilot study will take place from February 2024 to December 2024. You will be contacted twice, first day and after 24 weeks from the first contact.

You will spend about 20-30 minutes in each contact.

Side effects/ risks:

There are no major risks involved in this study.

However, you may need to talk on sensitive issues like describing traumatic/ bad experiences, health issues, but you can avoid discussing about these things if you wish to do so.

Let us know if you have any difficulty, and we can direct you to the on-call doctor of the psychiatry unit of Teaching Hospital, Peradeniya.

Place where the trial is conducted:

At outpatient department, in a quiet area.

The research assistants will inform you of the place you and your family member should come for the follow-up visit.

Benefits:

If you participate in this research, you will have the following benefits:

By participating in this research, you will get a chance to talk about your distress if any, due to the alcohol use of your family member

And the society may also benefit by your participation in this study

The results of this study may help to introduce new strategies to reduce harms related to alcohol in Sri Lanka.

Reimbursements:

In recognition of your time and effort we will give you and your family member Rs. 2500 each, for each visit.

Confidentiality:

Your personal details will be accessible to me and the research assistants, and these will be kept under lock and key and in a password protected folder. This information will be used only to get your phone number to remind you of the follow up appointment.

Other information collected from you will be used under the unique identification number given to you at the recruitment for the study.

The information we collect from you will be stored in password protected folders in my laptop which is given by the Australian National University and a backup password protected folder in my personal desktop computer in the Department of Psychiatry, Faculty of Medicine, University of Peradeniya, Sri Lanka.

Who to Contact:

If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact me:

Name: - Prof. Dewasmika Ariyasinghe

Address: - Professor in Psychiatry, Department of Psychiatry, Faculty of Medicine, University of Peradeniya

Telephone number/email: u7087000@anu.au.edu

If you are distressed, you can call 0812388001 and get the extension 309. Then you will be able to talk to a nursing officer of the psychiatry unit of Teaching Hospital, Peradeniya and she will direct you appropriately

Appendix-C: Study tools

The following study tools are included in this appendix:

C.1 AUDIT-C

C.2 Extended AUDIT-C

C.3 Timeline Follow Back Method

C.4 Alcohol Knowledge Questionnaire

C.5 Adverse Childhood Experiences International Questionnaire (ACE-IQ)

C.6 Alcohol Problems Questionnaire (APQ)

C.7 Family Member Questionnaire (FMQ)

C.8 Patient Feedback Questionnaire – FOA Arm

C.9 Patient Feedback Questionnaire – UOA Arm

C.10 Patient Feedback Questionnaire – ABI Arm

C.11 Family Member Feedback Questionnaire

C.12 Research Assistant Feedback Questionnaire

C.1 AUDIT-C

Q1: How often did you have a drink containing alcohol in the past year?		
	Never	0
	Monthly or less	1
	Two to four times a month	2
	Two to three times a week	3
	Four or more times a week	4

Q2: How many drinks did you have on a typical day when you were drinking in the past year?		
	None, I do not drink	0
	1 or 2	0
	3 or 4	1
	5 or 6	2
	7 to 9	3
	10 or more	4
Q3: How often did you have five or more drinks on one occasion in the past year?		
	Never	0
	Less than monthly	1
	Monthly	2
	Weekly	3
	Daily or almost daily	4

C.2 Extended AUDIT-C

The Extended AUDIT-C expands the response options for AUDIT-C Questions 1 and 2 to capture higher levels of consumption. The table below compares the standard AUDIT-C and Extended AUDIT-C response items and scoring.

Response items

AUDIT-1 'How often do you have a drink containing alcohol?'

AUDIT-C	Never	Monthly or less	2–4 times per month	2–3 times per week	4+ times per week	–
Extended AUDIT-C	Never	Monthly or less	2–4 times per month	2–3 times per week	4-5 times a week	≥ 6 times per week
Score	0	1	2	3	4	4a

AUDIT-2 'How many units of alcohol do you drink on a typical day when you are drinking?'

AUDIT-C	0–2 UK units	3–4 UK units	5–6 UK units	7–9 UK units	10+ UK units	–	–
Extended AUDIT-C	0–2 UK units	3–4 UK units	5–6 UK units	7–9 UK units	10–12 UK units	13–15 UK units	16+ UK units
Score	0	1	2	3	4	4a	4b

AUDIT-3 'How often have you had 6 or more units on a single occasion in the last year?'

AUDIT-C	Never	Monthly or less	Monthly	Weekly	Daily or almost daily
Extended AUDIT-C					
Score	0	1	2	3	4

C.3 Timeline Follow Back Method

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

C.4 Alcohol Knowledge Questionnaire

1. What is the type of liquor you commonly use?

.....

2. Have you heard of 'unit of alcohol'? Yes No

3. If the answer to Q2 is 'Yes', how many units do you use on a single day when you use alcohol? .....

4. Have you heard about 'low risk drinking'? Yes No

5. If the answer to Q4 is 'Yes', how many units can you consume within a day to consider it 'low risk drinking'?

.....

6. Which of the following illnesses/features are linked with alcohol? Please tick the box (Yes or No).

Health problem	Yes	No	Do not know
Impaired memory			
Increased weight			
Numbness of hands and feet			
Premature aging			
Sexual problems			
Cancers			
Depression			
Nutritional deficiencies			
Frequent infections			
Accidents (road traffic and industrial)			
Heart problems			
Deformities of the foetus			
Increased risk of dementia			

C.5 Adverse Childhood Experiences International Questionnaire (ACE-IQ)

Source: World Health Organization (WHO). The full questionnaire (Section B) is reproduced below.

Section 0: Demographic Information

0.1 [C1]	Sex (Record Male / Female as observed)	Male / Female
0.2 [C2]	What is your date of birth?	Day [ ][ ] Month [ ][ ] Year [ ][ ][ ][ ] Unknown (Go to Q.C3)
0.3 [C3]	How old are you?	[ ][ ]
0.4 [C4]	What is your ethnic/racial/cultural group background?	[Locally defined] Refused
0.5 [C5]	What is the highest level of education you have completed?	No formal schooling / Less than primary school / Primary school completed / Secondary/High school completed / College/University completed / Post graduate degree / Refused
0.6 [C6]	Which of the following best describes your main work status over the last 12 months?	Government employee / Non-government employee / Self-employed / Non-paid / Student / Homemaker / Retired / Unemployed (able to work) / Unemployed (unable to work) / Refused
0.7 [C7]	What is your civic status?	Married (Go to Q.M2) / Living as couple / Divorced or separated / Single / Widowed (Go to Q.M2) / Other / Refused

Section 1: Marriage

1.1 [M1]	Have you ever been married?	Yes / No (Go to Q.M5) / Refused
1.2 [M2]	At what age were you first married?	Age [ ][ ] / Refused
1.3 [M3]	At the time of your first marriage did you yourself choose your husband/wife?	Yes (Go to Q.M5) / No / Don't know / Not sure / Refused
1.4 [M4]	At the time of your first marriage if you did not choose your husband/wife yourself, did you give your consent to the choice?	Yes / No / Refused
1.5 [M5]	If you are a mother or father what was your age when your first child was born?	Age [ ][ ] / Not applicable / Refused

Section 2: Relationship with Parents/Guardians

When you were growing up, during the first 18 years of your life…

2.1 [P1]	Did your parents/guardians understand your problems and worries?	Always / Most of the time / Sometimes / Rarely / Never / Refused

2.2 [P2]	Did your parents/guardians really know what you were doing with your free time when you were not at school or work?	Always / Most of the time / Sometimes / Rarely / Never / Refused

Section 3: Neglect

When you were growing up, during the first 18 years of your life…

3.1 [P3]	How often did your parents/guardians do not give you enough food even when they could easily have done so?	Many times / A few times / Once / Never / Refused
3.2 [P4]	Were your parents/guardians too drunk or intoxicated by drugs to take care of you?	Many times / A few times / Once / Never / Refused
3.3 [P5]	How often did your parents/guardians do not send you to school even when it was available?	Many times / A few times / Once / Never / Refused

Section 4: Family Environment

When you were growing up, during the first 18 years of your life…

4.1 [F1]	Did you live with a household member who was a problem drinker or alcoholic, or misused street or prescription drugs?	Yes / No / Refused
4.2 [F2]	Did you live with a household member who was depressed, mentally ill or suicidal?	Yes / No / Refused
4.3 [F3]	Did you live with a household member who was ever sent to jail or prison?	Yes / No / Refused
4.4 [F4]	Were your parents ever separated or divorced?	Yes / No / Not applicable / Refused
4.5 [F5]	Did your mother, father or guardian die?	Yes / No / Don't know / Not sure / Refused

These next questions are about certain things you may actually have heard or seen IN YOUR HOME. These are things that may have been done to another household member but not necessarily to you.

4.6 [F6]	Did you see or hear a parent or household member in your home being yelled at, screamed at, sworn at, insulted or humiliated?	Many times / A few times / Once / Never / Refused
4.7 [F7]	Did you see or hear a parent or household member in your home being slapped, kicked, punched or beaten up?	Many times / A few times / Once / Never / Refused
4.8 [F8]	Did you see or hear a parent or household member in your home being hit or cut with an object, such as a stick (or cane), bottle, club, knife, whip etc.?	Many times / A few times / Once / Never / Refused

Section 5: Abuse

These next questions are about certain things YOU may have experienced.

When you were growing up, during the first 18 years of your life…

5.1 [A1]	Did a parent, guardian or other household member yell, scream or swear at you, insult or humiliate you?	Many times / A few times / Once / Never / Refused
5.2 [A2]	Did a parent, guardian or other household member threaten to, or actually, abandon you or throw you out of the house?	Many times / A few times / Once / Never / Refused
5.3 [A3]	Did a parent, guardian or other household member spank, slap, kick, punch or beat you up?	Many times / A few times / Once / Never / Refused
5.4 [A4]	Did a parent, guardian or other household member hit or cut you with an object, such as a stick (or cane), bottle, club, knife, whip etc.?	Many times / A few times / Once / Never / Refused
5.5 [A5]	Did someone touch or fondle you in a sexual way when you did not want them to?	Many times / A few times / Once / Never / Refused
5.6 [A6]	Did someone make you touch their body in a sexual way when you did not want them to?	Many times / A few times / Once / Never / Refused
5.7 [A7]	Did someone attempt oral, anal, or vaginal intercourse with you when you did not want them to?	Many times / A few times / Once / Never / Refused
5.8 [A8]	Did someone actually have oral, anal, or vaginal intercourse with you when you did not want them to?	Many times / A few times / Once / Never / Refused

Section 6: Peer Violence

When you were growing up, during the first 18 years of your life…

6.1 [V1]	How often were you bullied?	Many times / A few times / Once / Never (Go to Q.V3) / Refused
6.2 [V2]	How were you bullied most often?	I was hit, kicked, pushed, shoved around, or locked indoors / I was made fun of because of my race, nationality or colour / I was made fun of because of my religion / I was made fun of with sexual jokes, comments, or gestures / I was left out of activities on purpose or completely ignored / I was made fun of because of how my body or face looked / I was bullied in some other way / Refused
6.3 [V3]	How often were you in a physical fight?	Many times / A few times / Once / Never / Refused

Section 7: Witnessing Community Violence

When you were growing up, during the first 18 years of your life…

7.1 [V4]	Did you see or hear someone being beaten up in real life?	Many times / A few times / Once / Never / Refused
7.2 [V5]	Did you see or hear someone being stabbed or shot in real life?	Many times / A few times / Once / Never / Refused
7.3 [V6]	Did you see or hear someone being threatened with a knife or gun in real life?	Many times / A few times / Once / Never / Refused

Section 8: Exposure to War/Collective Violence

When you were growing up, during the first 18 years of your life…

8.1 [V7]	Were you forced to go and live in another place due to any of these events?	Many times / A few times / Once / Never / Refused
8.2 [V8]	Did you experience the deliberate destruction of your home due to any of these events?	Many times / A few times / Once / Never / Refused
8.3 [V9]	Were you beaten up by soldiers, police, militia, or gangs?	Many times / A few times / Once / Never / Refused
8.4 [V10]	Was a family member or friend killed or beaten up by soldiers, police, militia, or gangs?	Many times / A few times / Once / Never / Refused

C.6 Alcohol Problems Questionnaire (APQ)

(Modified: Q47–49 added to original)

Below you will find a list of problems related to alcohol. The total score should decrease with successful treatment. Not all of the questions may apply to you but try to answer the ones that do.

Please circle YES or NO depending on whether you have had similar problems. The questions apply to the last SIX MONTHS.

A. Friendships

A1	Have you tended to drink on your own more than you used to?	YES / NO
A2	Have you worried about meeting your friends again the day after a drinking session?	YES / NO
A3	Have you spent more time with drinking friends than other kinds of friends?	YES / NO
A4	Have your friends criticised you for drinking too much?	YES / NO

B. Partner/Spouse

B5	Has your partner complained about your drinking?	YES / NO
B6	Has your partner tried to stop you from having a drink?	YES / NO
B7	Has he/she refused to talk to you because you have been drinking?	YES / NO
B8	Has he/she threatened to leave you because of your drinking?	YES / NO
B9	Has he/she had to put you to bed after you have been drinking?	YES / NO
B10	Have you shouted at him/her when you have been drinking?	YES / NO
B11	Have you injured him/her after you have been drinking?	YES / NO
B12	Have you been legally separated from your spouse?	YES / NO
B13	Has he/she refused to have sex with you?	YES / NO

C. Children

C14	Have your children criticised your drinking?	YES / NO
C15	Have you had rows with your children about your behaviour?	YES / NO
C16	Do your children tend to avoid you when you have been drinking?	YES / NO
C17	Have you hit any of your children after you have been drinking?	YES / NO
C18	Have your children tried to stop you from having a drink?	YES / NO
C19	Have your children refused to lend you money?	YES / NO

D. Work

D20	Have you found your work less interesting than you used to?	YES / NO
D21	Have you been unable to arrive on time for work?	YES / NO
D22	Have you missed a whole day at work after a drinking session?	YES / NO
D23	Have you been less able to do your job because of your drinking?	YES / NO
D24	Has anyone at work complained about you being late or absent?	YES / NO
D25	Have you had any formal warnings from your employers?	YES / NO
D26	Have you been suspended or dismissed from work?	YES / NO
D27	Have you had any accidents at work after drinking?	YES / NO

E. Money

E28	Have you had any debts?	YES / NO
E29	Have you pawned any of your belongings?	YES / NO
E30	Do you find yourself making excuses about money?	YES / NO
E31	Have you been caught out lying about money?	YES / NO

F. Legal

F32	Have you been in trouble with the police due to your drinking?	YES / NO
F33	Have you lost your driving licence for drinking and driving?	YES / NO
F34	Have you been in prison?	YES / NO

G. Physical

G35	Have you been physically sick after drinking?	YES / NO
G36	Have you had any diarrhoea after a drinking session?	YES / NO
G37	Have you had pains in your stomach after a drinking session?	YES / NO
G38	Have you had “pins and needles” in your fingers or toes?	YES / NO
G39	Have you had any accidents needing hospital treatment after drinking?	YES / NO
G40	Have you lost any weight?	YES / NO

H. Psychological

H41	Have you been neglecting yourself physically?	YES / NO
H42	Have you failed to wash for several days at a time?	YES / NO
H43	Have you felt depressed for more than a week?	YES / NO
H44	Have you felt so depressed that you have felt like doing away with yourself?	YES / NO
H45	Have you given up any hobbies you once enjoyed because of your drinking?	YES / NO
H46	Do you find it hard to get the same enjoyment from your usual interests?	YES / NO

J. Spiritual (not included in original APQ)

J47	Have you ever felt in need of forgiveness because of the things your drinking has led you to do?	YES / NO
J48	Have you ever felt that only a great outside power, like God, could help you regain some of the things drinking has caused you to lose?	YES / NO
J49	Have you ever worried that your behaviour under the influence of alcohol might affect what happens to you after you have died?	YES / NO

Please list any other problems you have had due to alcohol which are not included in the questionnaire:

1. .....

2. .....

3. .....

Total APQ Score = _____

APQ Sub-scores

APQ Subscale	Score Range
A. Friendships	(0–4)
B. Partner/Spouse	(0–9)
C. Children	(0–6)
D. Work	(0–8)
E. Money	(0–4)
F. Legal	(0–3)
G. Physical	(0–6)
H. Psychological	(0–6)
J. Spiritual	(0–3) – not included in original APQ

C.7 Family Member Questionnaire (FMQ)

*Short Questionnaire for Family Members (Affected by Addiction) [SQFM(AA)]**

To your knowledge, have any of the following happened in the last 3 months, as a result of your relative's drinking/drug use/gambling? Please tick one answer to each question.

	Never	Once or Twice	Sometimes	Often
1. Have the family's finances been affected?	0	1	2	3
2. Does your relative's drinking/drug use/gambling get in the way of your social life?	0	1	2	3
3. Are you worried that your relative has neglected his/her appearance or self-care?	0	1	2	3
4. Has your relative picked quarrels with you?	0	1	2	3
5. Has your relative sometimes threatened you?	0	1	2	3
6. Has your relative upset family occasions?	0	1	2	3

In the last 6 months, how frequently have you experienced each of the following symptoms? Please tick one answer to each question.

	Never	Sometimes	Often
7. Worrying	0	1	2
8. Being irritable	0	1	2
9. Had thoughts that you cannot push out of your mind	0	1	2
10. Had parts of the body feel weak	0	1	2
11. Cannot concentrate	0	1	2
12. Awakening early and not being able to fall asleep again	0	1	2

With respect to your relative's alcohol or drug use or gambling, in the last 6 months have you...

	Never	Once or Twice	Sometimes	Often
13. Started an argument with him/her about his/her drinking/drug use/gambling?	0	1	2	3
14. Got moody or emotional with him/her?	0	1	2	3
15. Watched his/her every move or checked up on him/her or kept a close eye on him/her?	0	1	2	3
16. Sat down together with him/her and talked frankly about what could be done about his/her drinking/drug use/gambling?	0	1	2	3
17. Made it clear that you won't accept his/her reasons for drinking/taking drugs/gambling, or cover up for him/her?	0	1	2	3
18. Made clear to him/her your expectations of what he/she should do to contribute to the family?	0	1	2	3

19. Put yourself out for him/her, for example by getting him/her to bed or by clearing up mess after him/her after he/she had been drinking/taking drugs/gambling?	0	1	2	3
20. Given him/her money even when you thought it would be spent on drink/drugs/gambling?	0	1	2	3
21. When things have happened as a result of his/her drinking/drug use/gambling, made excuses for him/her, covered up for him/her, or taken the blame yourself?	0	1	2	3
22. Pursued your own interests or looked for new interests or occupation for yourself, or got more involved in a political, church, sports or other organisation?	0	1	2	3
23. Got on with your own things or acted as if he/she wasn't there?	0	1	2	3
24. Sometimes put yourself first by looking after yourself or giving yourself treats?	0	1	2	3

In the last 6 months, have these things happened when you have been concerned about your relative's alcohol or drug use or gambling:

	Never	**Once or Twice**	**Sometimes**	**Often**
25. Friends/relations have listened to me when I have talked about my feelings	0	1	2	3
26. Friends/relations have been there for me	0	1	2	3
27. Friends/relations have talked to me about my relative and listened to what I have to say	0	1	2	3
28. Health/social care workers have given me helpful information about problem drinking or drug taking or gambling	0	1	2	3
29. Health/social care workers have made themselves available for me	0	1	2	3
30. I have confided in my health/social care worker about my situation	0	1	2	3
31. Friends/relations have said things about my relative that I do NOT agree with	0	1	2	3
32. Friends/relations have said that my relative does NOT deserve help	0	1	2	3
33. Friends/relations have said nasty things about my relative	0	1	2	3

Scoring Table

Scale / Sub-scale	Score Before intervention	Score After intervention
Impact		
TOTAL Impact (sum of Q1–6) ↓		
Worrying behaviour (sum of Q1–3) ↓		
Active disturbance (sum of Q4–6) ↓		
Symptoms		
TOTAL Symptoms (sum of Q7–12) ↓		
Psychological symptoms (sum of Q7–9) ↓		
Physical symptoms (sum of Q10–12) ↓		
Coping		
Engaged coping emotional (sum of Q13–15) ↓		
Engaged coping assertive (sum of Q16–18) ↓		
Tolerant inactive coping (sum of Q19–21) ↓		
Withdrawal coping (sum of Q22–24) ↑		
Support		
Helpful informal support (sum of Q25–27) ↑		
Helpful formal support (sum of Q28–30) ↑		
Unhelpful informal support (sum of Q31–33) ↓		
TOTAL FAMILY BURDEN		
Sum the 4 shaded boxes above ↓		

** The SQFM(AA) has been developed by AFINet-UK and should not be altered, used or copied in ways other than those agreed with AFINet-UK.*

C.8 Patient Feedback Questionnaire – FOA Arm

Date: _____

	Completely Agree	Agree	Undecided	Disagree	Completely Disagree
1. I am satisfied with the study.					
2. Satisfied with the quality of the content of the study.					
3. I am satisfied with the location of the study.					
4. The information was useful in helping me think about my alcohol use.					
5. The information provided was relevant to me.					
6. The information about drinking and its consequences in the leaflet was useful.					
7. I feel better able to deal with alcohol-related situations now than before.					
8. The time spent with the research assistant is sufficient.					
9. I was given the opportunity to participate in the study when I expected information about it.					
10. I am happy to have the opportunity to participate in the study.					
11. Time was not spent in vain when I came to participate in the study.					

Additional items:

	Completely Agree	Agree	Undecided	Disagree	Completely Disagree
12. I was very clear about the units of alcohol given in the leaflet.					
13. I need an explanation from the research assistant to get a better understanding of the leaflet.					
14. I need the brochure to be further simplified so that it is easy to understand.					

15. If 'Agree' to question 14 above, which part(s) should be simplified and how do you think it should be?

.....

16. Any comments:

.....

C.9 Patient Feedback Questionnaire – UOA Arm

Date: _____

	Completely Agree	Agree	Undecided	Disagree	Completely Disagree
1. I am satisfied with the study.					
2. Satisfied with the quality of the content of the study.					
3. I am satisfied with the location of the study.					
4. The information was useful in helping me think about my alcohol use.					
5. The information provided was relevant to me.					
6. The information about drinking and its consequences in the leaflet was useful.					
7. The research assistant's advice on alcohol use and its consequences was helpful for me.					
8. I feel better able to deal with alcohol-related situations now than before.					
9. The time spent with the research assistant is sufficient.					
10. I was given the opportunity to participate in the study when I expected information about it.					
11. I am happy to have the opportunity to participate in the study.					
12. The research assistant was knowledgeable about alcohol and its problems.					
13. Time was not spent in vain when I came to participate in the study.					

14. Any comments:

.....

C.10 Patient Feedback Questionnaire – ABI Arm

Date: _____

	Completely Agree	Agree	Undecided	Disagree	Completely Disagree
1. I am satisfied with the study.					
2. Satisfied with the quality of the content of the study.					
3. I am satisfied with the location of the study.					
4. The information was useful in helping me think about my alcohol use.					
5. The information provided was relevant to me.					
6. The information about drinking and its consequences in the leaflet was useful.					
7. The information obtained about drinking and its consequences in the discussion with the research assistant was useful.					
8. I feel better able to deal with alcohol-related situations now than before.					
9. The time spent with the research assistant is sufficient.					
10. I was given the opportunity to participate in the study when I expected information about it.					
11. I am happy to have the opportunity to participate in the study.					
12. Time was not spent in vain when I came to participate in the study.					

Feedback on the Research Assistant

	Completely Agree	Agree	Undecided	Disagree	Completely Disagree
13. Friendly.					
14. Listened well.					
15. Well trained.					
16. Was knowledgeable about alcohol and its problems.					

17. What part of the intervention was most helpful to you (select one)?

a) Alcohol information leaflet

b) Discussion with the research assistant

c) The text message reminding me of my plan

18. Was there any part(s) in the whole discussion which stick in your mind?

.....

19. If “Yes”, which part(s)?

.....

20. Anything you would like to let us know (this will help us to improve the intervention)?

Points to improve:

.....

21. Points to reconsider/you did not like:

.....

C.11 Family Member Feedback Questionnaire

(These were mostly prompts – the family members were encouraged to share whatever they felt.)

1. Have you noticed any change in your family member's drinking behaviour after he joined the study?

.....

2. Have you noticed any change in your family member's behaviours in general after he joined the study?

.....

3. If you had ever faced any problem due to his drinking, do you still face the same (even after he joined the study)?

.....

4. Give us your opinions on the study (weaknesses/strengths/suggestions to improve, etc.).

.....

C.12 Research Assistant Feedback Questionnaire

	Completely Disagree	Disagree	Undecided	Agree	Agree Completely
1. The intervention was useful for patients.					
2. The patients seemed to be happy with the intervention.					
3. The instructions in the manual were clear enough.					
4. I learned new information about drinking and its consequences.					
5. I found the alcohol information leaflet was useful when giving information to patients about alcohol.					
6. I can empathise with a patient who has alcohol-related problems.					
7. The timing of the intervention was ideal.					
8. I felt anxious and nervous before and during the interview.					
9. The length of the session was too long.					
10. I was exhausted after one session.					
11. The training I received was adequate.					

(Please give your honest opinion; your ideas are very important to improve the intervention in the future.)

12. If the time of the intervention was not ideal, what time would you suggest making it more practical and effective?

.....

13. What did you think of the setting of the interview? If you think it was not good enough, please give your suggestions to improve it.

.....

14. What are the areas to improve about the training?

.....

15. What did you like most about the intervention?

.....

16. Was there anything you did not like about the intervention? Please describe.

.....

17. How could we improve it?

.....

18. Any other comments (if you have any).

.....

Appendix D: Training Manual for Research Assistants

Abbreviations

ABI – Adapted Brief Intervention

ACE-IQ – Adverse Childhood Experiences International Questionnaire

AIL – Alcohol Information Leaflet

ARPs – Alcohol Related Problems

AUDs - Alcohol use disorders

AUDIT – Alcohol Use Disorders Identification Test

BI – Brief Intervention

CA – Childhood Adversities

CAU – Care As Usual

FM - Family Member

PI – Principal Investigator

PIS – Patient Information Sheet

RA – Research Assistant

SQFM – Short Questionnaire for Family Members

THP – Teaching Hospital Peradeniya

TLFB – Timeline Follow Back

UOA – Unit Of Alcohol

WHO – World Health Organization

Training of research assistants:

Objectives:

- To understand what alcohol is and how it acts on the brain: reward pathway, cerebral depressant
- To understand the health impact of alcohol to the person

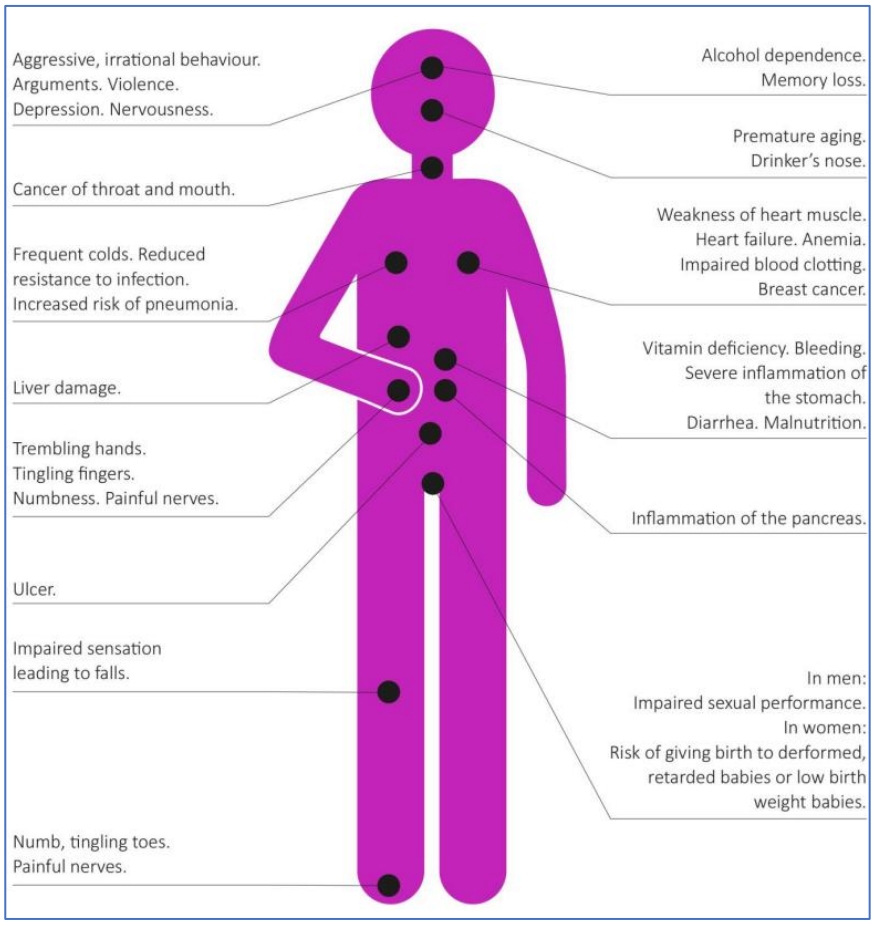

Figure 1: Alcohol induced harms (Source: WHO alcohol brief intervention training manual for primary care)

- To understand the health impact of alcohol on family members, workmates, public
- To get an overall understanding of the impact of alcohol in other aspects like economy, culture etc to broaden the scope of alcohol related harms
- To understand various cultural aspects of 'drinking'
- 'Myths around drinking' (a few case scenarios will be used); to relax after work, to forget problems
- 'What it means to take alcohol in the patient's perspective'

- Possible difficulties faced by the patient when trying to cut down/ give up

- To emphasize that these are treatable illnesses and 'not bad morals'

- To emphasize that the patient is the one to decide what to do about his drinking and when he wants to change it, if he decides to do so (Autonomy and patient-centred collaborative approach). That ABI is not so much about advising the patient to change his alcohol related behaviours but presenting that as an option. Then if the patient choses to change how to work through it. This makes it 'his plan', to which he is likely to adhere to.

- To help them realize that 'change' could be even spreading out of alcohol over several days as opposed to HED, giving some extra money to the family without reducing the individual consumption.

- To introduce useful terminology: hazardous drinking, harmful drinking, and dependent drinking

- To understand the meaning of 'unit of alcohol (UOA)', 'low risk drinking' and 'binge drinking' (102, 293)

- To familiarize the research assistants (RAs) with the commonly used alcoholic beverages and what equals to a UOA and HED

- To be aware of 'Not-good-to-do-things after drinking': driving, operating machinery, swimming

- To be aware of 'Not-good-to-drink-instances'; when under 21 years of age, when on medicine which can interact with alcohol, when ill

- To introduce AUDIT questionnaire, AUDIT-C, Family Member Questionnaire' (FMQ), Adverse Childhood Experiences International Questionnaire (ACE-IQ), and Timeline Follow Back (TLFB) method.

- To develop skills in introducing oneself to the client and explaining the purpose and getting consent (These will be role-played) and to emphasize that 'this is the first step to show that you care'

- To emphasize the importance of confidentiality and RAs are not supposed to divulge information revealed by the patient to the family member or vice versa or to anyone else. If there are issues regarding the safety of any person, to contact the PI as soon as possible

- To develop skills: not to panic, not to be judgemental when the patient is/ becomes uncooperative during the intervention and to acquire skills on appropriate responses on such occasions (These will be role-played)

- To emphasize that if the patient is not willing to divulge information, not to push him

- To familiarize RAs with the material, so that they will not have to look into the paper frequently. This approach will help to simulate the intervention as a conversation, not a 'Q and A session'. This will improve the rapport with the patient

- ‘Understanding his point of view and feelings’ (Empathy)

- To encourage the RAs to be familiarize with the information acquired through the ‘Patient Information Sheet (PIS)’ before commencing the intervention, but not to ask directive/ close ended questions from the patient based on this.

Training Sessions

Trainer:

The trainer is the PI, who is a specialist in psychiatry (MBBS, MD-Psychiatry) and a senior lecturer who has both academic and clinical expertise on the subject and has a decade of experience in teaching medical students and post-graduate trainees in psychiatry.

A researcher who has lot of experience in field work in research on alcohol studies in Sri Lanka will assist the PI in these training sessions.

Outline of the training programme

There will be seven training sessions

First session:

9 a.m. – 10.15 a.m. - Introducing each other and why he/she is interested in the project. Explore what their existing knowledge of alcohol is; ‘What alcohol is? ‘What effect does it have on one’s thinking, behaviour and feelings?’, ‘What their own experiences with alcohol are?’, ‘Any event which has stuck in their lives related to alcohol?’, ‘What effects do they know of, of alcohol other than health effects?’.

This approach may encourage them think actively and may also help to think of their own perceptions of alcohol.

10.15 a.m. - 10.45 a.m. - Tea break

10.45 a.m. – 11.30 a.m. – Lecture; The PI will do a power point presentation which includes answers to above questions, how alcohol affects our body, why people behave as they are when under the influence, ‘concept of unit of alcohol’, ‘low risk drinking’ and ‘instances where drinking is not at all good’.

A handout of the lecture will be given to them before the lecture is done.

The Alcohol Information Leaflet (AIL) will also be introduced.

11.30 a.m. - 12. 00 noon. - Question and answer session

Second session:

9.00 a.m. - 9.10 a.m. - Clarifications of the previous session

9.10 a.m. – 9.50 a.m. - Introducing 'confidentiality' 'empathy', 'being non-judgemental', listening to the patient and 'not to react' (difference between reacting and responding), and why these aspects are especially important in clinical setting. This will be discussed further, giving case scenarios and role-playing.

9.50 a.m.-10.15 a.m. - Introducing the Patient Information Sheet (PIS) and how to make sure the correct coding is done, and it is filled accurately.

10.15 a.m. - 10.45 a.m. - Tea break

10.45 a.m. - 12.00 noon. - Introducing the AUDIT. This will include going through each question of the AUDIT, what each means and revising the 'unit of alcohol' as per commonly used liquor types, AUDIT-C followed by a question-answer session.

Third Session:

9.00 a.m. - 9.15 a.m. - Clarifications of the previous sessions

9.15 a.m. - 10.15 a.m. - Talking with the family members: Reiterate what is said in the first part of the second session are applicable in this instance as well.

Understanding their point of view.

Role playing in pairs, changing roles.

10.15 a.m. - 10.45 a.m. - Tea break

10.45 a.m. – 1 p.m. - Introducing the 'FMQ, ACE-IQ, TLFB for the previous 28 days, Likert Scale to assess quality of life and go through each question separately of each questionnaire.

Role playing in pairs to administer the questionnaire while the PI observes them.

Fourth Session:

9.00 a.m. - 9.15 a.m. - Clarifications of the previous sessions

9.15 a.m. - 10.15 a.m. - Informed written consent and informing the patient of the AUDIT score:

Introducing the meaning of informed written consent

Importance of letting the patient clarifying the doubt

Informing that not participating in the study will not adversely affect their routine management in the ward.

Go through the process of obtaining informed written consent for the study using the prepared consent form; reiterate the need to get informed written consent from the participants initially for screening and data use after informing the purpose of screening and the study.

Informing the patient why/ why not he is included/ not included in the study.

Informing also that it is expected that he and his family member are expected to see us in the hospital in four weeks to get some more information.

Obtaining informed-written consent from the eligible participant for individual participation and then to obtain information from a family member.

10.15 a.m. - 10.45 a.m. - Tea break

10.45 a.m. - 12.00 noon. - Introducing inclusion and exclusion criteria and what they mean.

Inclusion Criteria: The patients who score

≥5 for AUDIT-C will be eligible to participate in the study

Exclusion criteria: If a patient has at least one of the following criteria will be excluded from the study.

The patients who have ongoing serious physical or mental illness, making them incapable of following the directions given

The patients who are already on therapy/ intervention to reduce alcohol related harms

The patients who chose to go for specialized psychiatry care due to the severity of their ARPs (Others in this category will be chosen since BI could be helpful in some such patients (102)

If the patient has been recruited in the current study in a previous admission

Patients who are not able to communicate adequately in Sinhala

Fifth Session:

9.00 a.m. - 9.15 a.m. - Clarifications of the previous sessions

9.15 a.m. – 10.15 a.m. - Role plays by PI with a RA; first with a patient and RA and then with a family member and RA. In both instances the PI will first play the role of the RA and then the role will be reversed. The feedback will be given.

The RAs will get into pairs and do the exact and the PI will observe them and will give feedback

10.15 a.m. - 10.45 a.m. - Tea break

10.45 a.m. - 12.00 noon - A willing patient and a family member will be invited to participate in the training programme, after explaining the purpose. An RA will talk to the patient, and another will talk to the family member.

The RA talking to the patient is supposed to explain the purpose of the interview and go through the verbal consent, screening, informing of the score and that he is selected/ not selected and to explain why/ why not the patient is selected/ not selected. The RA should listen to the patient and clarify his doubts about the study.

The RA talking to the family member is supposed to explain the purpose of the interview and that his/her patient has given the consent to talk to him/her and that the information he/she divulges will remain confidential.

The RA is also supposed to say that his/her family member seems to be having an alcohol related issue and that we would like to get some information on how this has affected him/her.

Once the patient and the family member leave the room, difficulties which have come up during the interviews will be discussed further in the group, exploring practical solutions.

Handing over of inducement to the patient 'This is a small payment for your time spent in support of this study. We really appreciate your participation'. 'Could you please sign this paper after counting the money inside the envelop, it has

Rs.2500.00'

Sixth session:

This will include training session for the RAs of each arm separately, which include role playing case scenarios with each other while the PI observes and gives feedback

2.2.1. For the RAs of the adapted brief intervention (ABI) arm:

To familiarize them with the calendar to mark the number of drinks the patient took

This group will screen all the male patients who have presented to wards 1, 8, 12 (excluding psychiatry side patients in ward 12), 16 and 17 of Teaching Hospital, Peradeniya.

To understand the 'Cycle of change' and importance of considering the changing behaviours related to drinking as a process not as an event. So even if the patient is not willing to change now, he may consider it later (Therefore, it does not mean that we have failed in our care/ intervention).

To empathize with the patient, how he feels in difficult situations. And to role play to enhance assertiveness, initially the PI taking the RA role, RA taking the patient's role and then to reverse the roles and go through the points to improve

To emphasize the importance of non-confrontative, non-directive but guiding approach (Role plays will be used to illustrate these)

To emphasize the importance of 'change talk' (the patient's reasons to change or benefits of doing so) by using open ended questions and reflections and discourage 'sustain talk' (the patient's reasons not to change or barriers to change) (so RAs should avoid persuasion, giving advice without permission and argument)

To understand that outcomes of ABI could be that the patient thinks of or plans (this could be deciding to go to a professional to get help) to reduce alcohol or cuts down/ stops alcohol or thinks of or plans to reduce or stops harmful behaviours to himself or others. It could be a combination of improvement of quantity of alcohol consumed and related harms (Role plays will be used to illustrate differences of these outcomes)

To inform that the patient will receive a message 'How are you going with your plan?' and that he does not have to respond to it, and it is just to remind them of the plan. Emphasize that it is very helpful for us if they keep the contact number, they have already given us.

To explain what his AUDIT score means and do the ABI as in the manual.

If the patient has given the consent to talk to a family member, to talk to the family member to get the FMQ filled.

To remind the patient and the family member of the need to visit us in 4 weeks to get some additional information.

Hand the patient over the inducement in an envelope and get the signature from him.

Hand over the AIL to the patient

Appreciate his willingness to participate in the study.

2.2.2. For the RAs in the 'Feedback on AUDIDT-C' (FOA)' arm:

Appreciate his willingness to participate in the study

And inform that he is likely to already have or is likely to cause him problems in the future

Hand over the AIL to the patient.

If the patient has given the consent to talk to a family member, to talk to the family member to get the FMQ filled.

To remind the patient and the family member of the need to visit us in 4 weeks to get some additional information.

Hand over the inducement to the patient in an envelope and get the signature from him.

2.2.3. For the RAs in the 'Unit of alcohol (UOA)' arm:

Explain what UOA means using the pictures depicting what amount of liquor equals to a UOA in the patient's preferred type/s of liquor

Also mention what is meant by 'low risk drinking', using pictures which show what two units of alcohol means

Go through the AIL with the patient about ‘binge drinking’, ‘what not to do after even taking two UOA’ and ‘better-not-to-take-alcohol-occasions’.

Hand over the AIL to the patient.

If the patient has given the consent to talk to a family member, to talk to the family member to get the FMQ filled.

To remind the patient and the family member of the need to visit us in 4 weeks to get some additional information.

Hand over the inducement to the patient in an envelope and get the signature from him.

The same RAs will do the FOA and UOA arms

2.2.4. For the RAs who will assess the outcome:

Administer TLFB for the previous 28 days to the patient and the FMQ to the family member.

Ensure that the coding is done correctly so that the patient and the family member get the same numbers allocated to them at the recruitment to the study.

The structure given by the WHO in its manual will be used (Figure 2)

Stages of a brief intervention	Notes on what went well/not so well Write examples of the words used for good phrases or missed opportunities to enable you to report back
1. *Beginning the conversation* ☐ Nonjudgemental and linking to the presenting issues.	
2. *Screening and feedback* ☐ Was screening accurately done? ☐ Collaboration with patient? ☐ Feedback using elicit – provide – elicit? ☐ Not making decision for patient (you must/should/need).	
3a. *Evoking* ☐ Open questions for change talk. *Write example.* ☐ Reflections for change talk? *Write example* (advanced only) ☐ Less/little focus on sustain talk. ☐ Summaries. ☐ Personal responsibility. ☐ Correct use of importance ruler?	
3b. *Planning* ☐ Elicit options for change from the patient. *Write example.* ☐ Provide options with permission. ☐ Elicit patient reactions. ☐ Explore commitment to the plan. ☐ Build confidence using past successes, role models or supports. ☐ Correct use of confidence ruler (advanced only)	
4. *Close the discussion* – ensure the patient knows that he/she can return at any time.	

Figure 2: Giving feedback to the patient