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A Randomised Feasibility Study of a Transdiagnostic Intervention Targeting Alcohol Misuse and Psychological Distress Among Men Affected by War in Ukraine

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Abstract

Background

There is a lack of scalable, community-based interventions addressing alcohol misuse in conflict-affected humanitarian settings. To address this gap, we developed CHANGE, a psychological intervention targeting alcohol misuse and psychological distress among war-affected men in Ukraine. This individually randomised feasibility trial aimed to assess study procedures in preparation for a definitive randomised controlled trial, evaluate implementation outcomes including feasibility and acceptability, and explore preliminary perceptions of the intervention's effectiveness.

Methods

A parallel-arm, single-blind, individually randomised feasibility trial was conducted in Kyiv and Dnipro. Adult men affected by war (≥ 18 years) were randomised (1:1) to either the CHANGE intervention plus enhanced usual care (EUC) or EUC alone. Interventions and assessments were delivered either in person or remotely. Outcomes were assessed at baseline and 3 months post-randomisation. A mixed-methods approach was used to evaluate feasibility indicators (recruitment, retention, randomisation, and data collection), acceptability, feasibility of delivery, safety, and perceived effectiveness.

Results

Of 122 individuals screened, 62 were enrolled over 7 months. Most exclusions (77%) were due to high Alcohol Use Disorders Identification Test scores. Retention at 3 months was 66%. Fourteen participants who discontinued the intervention were not invited to follow-up due to a procedural oversight. Participants and facilitators considered the intervention acceptable and relevant to the war context, with remote delivery enhancing feasibility. No adverse events were reported. Participants and implementation teams perceived the intervention as helpful in reducing alcohol misuse. Recruitment was challenged by low motivation, stigma, and war-related logistical barriers.

Conclusions

The CHANGE intervention and trial procedures were feasible and acceptable, particularly when delivered remotely. Modifications for the definitive trial include expanding recruitment to all government-controlled regions, excluding occupied territories for safety reasons, and refining eligibility criteria (e.g., excluding prior substance use treatment). These findings support progression to a fully powered RCT evaluating an intervention addressing psychological distress and alcohol misuse among war-affected men.

Trial registration

ISRCTN11369479

KEY MESSAGES REGARDING FEASIBILITY

What uncertainties existed regarding the feasibility?
• It was unclear whether war-affected men could be effectively recruited, randomised, and retained in a trial given displacement, psychological distress, and high alcohol use.
• Concerns existed about the practicality of delivering the intervention and collecting data in an active conflict setting.
• The study also examined acceptability of the intervention and explored participants' perceptions of its usefulness.
What are the key feasibility findings?
• Ongoing war-related risks (e.g., safety concerns, mobilisation, limited mobility) necessitated flexible delivery formats, including both remote and in-person options.
• Recruitment was slower than expected due to stigma, normalization of alcohol use, and challenges in identifying eligible participants; targets were reached over 7 months.
• Eligibility criteria were generally appropriate, although 77% of all exclusions were due to high AUDIT scores, suggesting the need for refinement, such as excluding individuals with prior treatment for substance dependence, including not only alcohol dependence but also drug dependence.
• Retention at 3 months was 66%; forteen from fiveteen missed follow-ups were due to procedural issues, which were subsequently addressed.
• Randomisation procedures were largely successful, though minor imbalances (e.g., displacement status) suggest potential stratification in the main trial.
• Data collection was feasible with minimal missing data.
• Overall, the intervention was acceptable to participants and implementers, with qualitative findings indicating perceived benefits.
What are the implications of the feasibility findings for the design of the main study?
• The definitive trial will use fully remote delivery (online/telephone) to improve safety, feasibility, and recruitment.
• Recruitment will be expanded to all government-controlled regions while excluding occupied territories.
• Intervention refinements include enhanced guidance for remote delivery, an optional additional session, and content addressing stigma and war-related context.
• Materials were adapted to improve cultural and contextual relevance.
• These findings support progression to a fully powered RCT with targeted protocol adjustments.

BACKGROUND

Armed conflicts severely undermine public health, leading to widespread displacement and reduced access to essential services such as housing, healthcare, and education, alongside heightened exposure to violence and insecure living conditions (1). These stressors place enormous pressure on health systems and create significant barriers to meeting basic needs. Mental health is disproportionately affected, with heightened risks of trauma and psychological distress, particularly among vulnerable groups such as unaccompanied children and individuals exposed to violence, torture, or prolonged instability. Systematic reviews (2) indicate that exposure to armed conflict is associated with two- to three-fold higher prevalence rates of anxiety, depression, and post-traumatic stress disorder compared to non-exposed populations; moreover, a range of war-related, migratory, and post-migratory stressors further compounds both short- and long-term mental health problems among affected populations.

Cumulative trauma and depression are well-established risk factors for alcohol misuse, which is also associated with the male gender, older age, and exposure to traumatic events (3). Alcohol misuse has long posed a major public health challenge in Ukraine, with a substantial proportion of adult deaths linked to alcohol use and notably high rates of heavy drinking among men and women compared with most European countries and global average (4, 5). Even prior to the full-scale invasion, conflict in eastern Ukraine had already intensified alcohol and substance misuse, with studies among internally displaced persons showing alcohol use disorder (AUD) rates of 14.9% among male drinkers and 1.8% among female drinkers, along with frequent comorbidity with depression and PTSD (6). Recent World Health Organization (WHO) data further underline the widespread use of alcohol, with 77% of Ukrainians reporting alcohol consumption and 24.9% of male drinkers and 8.1% of female drinkers engaging in monthly episodes of heavy drinking (7).

Despite the existence of effective interventions for AUDs, no established community-based interventions currently exist that can be feasibly implemented to address alcohol misuse among conflict-affected populations in humanitarian settings (8). To bridge this gap, the CHANGE research consortium was formed to develop and evaluate a new brief psychological intervention targeting both alcohol misuse and associated psychosocial distress in these contexts'(8, 9). The development of CHANGE was informed by evidence from a global systematic review (10) of brief alcohol interventions combined with qualitative insights into local understandings of alcohol misuse in humanitarian settings (11). The intervention was shaped through a multi-stage, iterative process, including expert workshops, repeated Delphi consultations, and Theory of Change exercises, which are detailed in previous publications(10).

The therapeutic foundation for the CHANGE intervention was Problem Management Plus (PM+), an evidence-based psychological intervention developed by the World Health Organization for populations exposed to adversity (8, 12). PM + has demonstrated effectiveness in reducing symptoms of depression and anxiety (13–15) and has been successfully implemented among violence-affected populations in Ukraine (16). Its flexible structure enabled the integration of alcohol-focused strategies such as drink refusal skills, managing drinking urges, and emotional regulation. Further details on the structure and content of the CHANGE intervention can be found in the intervention manual, available from the CHANGE research consortium upon request.

To understand the external generalizability of the CHANGE intervention in conflict affected settings, the evaluation of CHANGE took place in two settings with different populations, namely with the war-affected population in Ukraine and with South Sudanese refugees in Uganda (17, 18). The current paper reports on the feasibility trial of the CHANGE intervention conducted in Ukraine. Findings from Uganda will be published separately as the intervention and context are distinct from the Ukraine study.

The overall aims of the feasibility trial in Ukraine were threefold: Firstly, to test the methodological trial procedures in advance of a definitive RCT; secondly to assess early implementation outcomes such as acceptability and feasibility of delivery; and thirdly to investigate perceived effectiveness of CHANGE. The specific objectives were:

1. to assess and refine procedures for recruiting, randomisation, and retaining war-affected men in Ukraine, and to determine whether the data-collection procedures were suitable for a future definitive RCT;
2. to examine whether CHANGE plus enhanced usual care (EUC) could be delivered acceptably, feasibly, and safely within the Ukrainian conflict setting;
3. to explore participants' and facilitators' perceptions of whether CHANGE influenced alcohol misuse and psychological distress.

METHODS

We followed the CONSORT statement for conducting and reporting pilot and feasibility trials (19). The CONSORT checklist is included in Appendix A. The feasibility trial was registered on the ISRCTN registry (reference: ISRCTN11369479).

Description of feasibility trial

Design

A parallel-arm, single-blind feasibility trial with individual randomisation was carried out in Kyiv and Dnipro. Eligible participants were allocated in a 1:1 ratio to receive either the CHANGE intervention or enhanced usual care (EUC). The CHANGE intervention was delivered flexibly, either in person or remotely, depending on participant preference and contextual constraints.

Sample size

The sample size for the feasibility trial was determined pragmatically, based on anticipated recruitment capacity and the need to assess the feasibility outcomes outlined in Table 1, rather than on formal sample size calculations(19, 20).

Participants and Setting

Participants were adult war-affected men (≥ 18 years) who were recruited from two Ukrainian cities, namely Kyiv and Dnipro. The cities of Kyiv and Dnipro were selected because they house a large number of internally displaced persons (IDPs) as well as local populations that have experienced war. During the pilot RCT, these cities were not under direct threat of military invasion or artillery fire but were targeted regularly by drone and missile attacks. Furthermore, there were mental health services available for referrals if needed.

Men with AUDs were recruited from the community using various methods. We collaborated with recruiters (community-based specialists, healthcare professionals, service providers, etc.), who used their local connections and networks to engage participants. We disseminated information using recruitment flyers including a link to online registration forms, and through various social media platforms and groups (Telegram, Viber). We also developed project pages on Facebook and Instagram to

share information and encourage participation. We regularly reached out to different programs, organizations (community-based, governmental, non-government organizations), and healthcare providers (primarily those trained in the WHO Mental Health Gap Action Programme), who provided different services for war affected individuals(21). Additionally, project facilitators shared information about the trial with beneficiaries of their organizations which included community psychosocial centers, social services, community-based non-governmental organisations. We also developed and disseminated through telegram groups leaflets for family members (wives, mothers), with the aim of reaching and engaging potential male participants indirectly through trusted relatives.

Once the participants completed the study registration form (the link which was provided in leaflets and all other project materials shared with different organizations and stakeholders) or contacted the study team? by phone, a research assistant reached out to confirm interest in the study, after which they were assigned to a data collector for screening and baseline assessment. At this stage, participants were asked whether they consumed alcohol to ensure that the primary eligibility criterion was met. Prior to screening, participants were given a participant information sheet and consent form in their preferred language (Ukrainian or Russian) for written consent. All outcome measures, as well as the intervention and EUC sessions, were offered either in person or remotely in Ukrainian or Russian. At the outset, participants were asked to select their preferred mode of delivery and language. Once chosen, the format remained fixed and could not be changed at later stages of the study.

Consenting participants were screened and included in the study if they scored between 8 and 19 on the Alcohol Use Disorders Identification Test (AUDIT)(22) and were experiencing psychological distress, indicated by a score ≥ 16 on the Kessler Psychological Distress Scale (K-10) (23). Participants were excluded if any of the following criteria were met: Having an AUDIT score of ≥ 20 (indicating possible alcohol dependence) or < 8 (indicating non-hazardous alcohol use); showing observable signs of severe mental disorders such as psychoses or severe cognitive impairment (assessed using a standardized checklist identifying signs such as incoherent speech, lack of comprehension, or extreme agitation); presenting with acute medical conditions (assessed through observations) or imminent risk of suicide or other life-threatening risk (assessed through standardized questions). Eligible participants then proceeded with the baseline assessment. Both the screening and baseline assessments were administered by the same outcome assessor.

Randomisation

After baseline assessment, participants were randomised 1:1 into one of the two arms of the trial by the EUC specialist, who was independent from the outcome assessors and intervention facilitators, and was unmasked. Allocation was concealed using sequentially ordered, opaque sealed envelopes prepared for the Ukraine feasibility trial. Each envelope contained the intervention allocation and randomisation code, was linked to a unique envelope ID, and was stored securely until opened in sequence by the EUC specialist with the participant. The randomisation codes were generated by an independent statistician, using randomly ordered blocks of 20 participants to maintain balance between trial arms. For remote

randomisation, the same procedure was followed, with the envelope opened in front of the camera so that the participant could see the process. Additional details on the allocation procedures, including implementation for remote contacts, are provided in Appendix B.

Intervention

Participants allocated to the intervention arm received the CHANGE intervention alongside EUC. The CHANGE intervention was based on PM+ strategies to treat underlying symptoms of common mental disorders and has additional psychological components that addresses alcohol misuse. It was originally designed as a brief, in-person intervention consisting of six individual sessions, each lasting approximately 90 minutes, delivered face to face by trained providers, including both experienced and lay health care providers (hereafter referred to as facilitators). The intervention was adapted to permit delivery in two formats: in-person and remote (online or by phone). The mode of delivery was chosen by participants according to their individual preferences and their own perceptions of safety.

CHANGE was organised into three linked phases that guided participants from assessment and goal-setting through skills practice and relapse-prevention planning. In phase 1, the first two sessions explored current alcohol-use patterns, provided personalised feedback, introduced the intervention structure, and supported participants to set initial change goals. Phase 2, delivered in sessions 3 and 4, focused on practical skills for recognising and managing situations in which participants were more likely to drink. Depending on each participant's needs, facilitators drew on strategies such as problem solving, emotion regulation, stress management, and techniques for coping with urges to drink. Finally, in phase 3 (sessions 5 and 6), relapse prevention is focused on practicing strategies that were learnt in phase 2 (10). All participants allocated to CHANGE also received EUC materials and referral information. EUC consisted of an information sheet outlining available support resources that participants could access either within their local community or remotely if alcohol consumption became problematic, as well as information on available mental health services. EUC was delivered to participants immediately after randomisation by a trained EUC specialist. Each participant received an information pamphlet electronically or in printed form detailing information on reducing alcohol intake and managing psychological distress as well as contacts of alternative psychological services. Participants allocated to the comparison arm received EUC without the CHANGE sessions.

Facilitator training followed a Training of Trainers model to support implementation quality and sustainability. Initially, four local clinicians with extensive experience in mental health care, treatment of alcohol dependence, and supervision of trauma-focused evidence-based interventions were trained as CHANGE intervention trainers by experienced psychologists. These trained clinicians subsequently delivered a 6-day, in-person training programme for 8 facilitators in Ukraine. Most facilitators had a mental health background and included 5 experienced mental health counsellors, 2 social workers and 1 priest, who was in-training to become a psychologist (Appendix 11). The training covered common mental disorders, basic counselling skills, intervention delivery, self-care, safety protocols, and referral procedures for cases beyond facilitators' scope of practice. Additionally, a one-day training session was

conducted to strengthen facilitators' remote counselling skills, including how to deliver the intervention by phone or online. Facilitators received weekly online group-based supervision from local trainers. In-person supervision was not feasible due to geographical distance, travel constraints, and competing professional commitments. Facilitators were divided into two groups, with two supervisors assigned to each group; supervisors rotated between the two facilitator groups on a weekly basis so that all facilitators could benefit from the expertise of the two supervisors with extensive experience in treating alcohol dependence.

Trial Outcomes

Outcome assessments for the trial were conducted at baseline and 3 months after randomisation using Open Data Kit (ODK) on tablets. Baseline assessment included age, education, marital status, employment, information regarding displacement, and city. The primary trial outcome was the percentage of days abstinent (PDA) during the past 14 days at 3 month follow up using the Timeline Followback (TLFB) measure (24). Secondary outcomes included percentage days of heavy drinking (PDHD) using TLFB, alcohol misuse measured with AUDIT(22) and the Alcohol, Smoking and Substance Involvement Screening Tool (ASSIST) (25). Psychological distress was measured using the Kessler Psychological Distress Scale (K-10) (23). Depression, anxiety, PTSD and functional disability were measured using the Mental Health Assessment Inventory (MHAI) (26), and perpetration of intimate partner violence was measured using the United Nations Multi-Country Study instrument(27). Health economic outcomes included health related quality of life (HRQoL) measured using the EuroQol 5-dimension 5-level tool (EQ-5D-5L), and subjective wellbeing (SWB) measured using the OECD SWB tool (28–31). See Appendix C for an overview of the outcomes. The outcome assessors, principal investigators, and statistician were masked to study arm allocation; the local project coordinator, participants, the field team lead, EUC specialists, facilitators and supervisors were unmasked.

Ethics

Ethics approval was obtained from the LSHTM Ethics Committee (ref: 28853) and the National University of "Kyiv-Mohyla Academy" Ethics Committee (ref: FWA00030125).

Methods to assess feasibility trial objectives

A mixed-methods approach was used to address the feasibility trial objectives, including the assessment of trial procedures, early implementation outcomes, and perceived intervention effectiveness. A detailed overview of the feasibility objectives, corresponding assessment criteria, data collection methods, and timing of assessments is provided in Appendix D. Progression criteria for advancing to a definitive trial were informed by Mellor et al.(32) and are presented in Appendix E.

Testing trial procedures

To inform the design of a definitive RCT, we examined key trial procedures, including recruitment, randomisation, and participant retention. Recruitment processes were monitored by recording the

number of participants approached, assessed for eligibility, found eligible, consented, and lost before randomisation. Recruitment feasibility was then summarised using monthly enrolment counts, recruitment rates, and participant flow through each stage of the trial. We also explored barriers to recruitment through qualitative interviews with 5 research assistants after recruitment was completed. To assess the feasibility of randomisation, the process was peer reviewed at the start of the trial, including correct implementation of the allocation sequence and maintenance of allocation concealment. Before envelopes were issued to EUC specialists, the envelope ID, randomisation ID, and envelope order were double-checked by the unmasked field team lead and research coordinator. Retention was assessed descriptively by calculating the overall follow-up rate and recording the timing of dropouts, with subgroup patterns explored by characteristics such as age, displacement status, and education. Data collection quality was assessed by examining the completeness of primary and secondary outcome measures, the extent of missing data, and any errors in data entry.

Early implementation outcomes and safety

To assess acceptability of the intervention (for participants, facilitators and supervisors), and feasibility of delivery of CHANGE (for facilitators and supervisors), we conducted qualitative interviews (n = 5 with participants, n = 4 with facilitators, and n = 2 with supervisors). Acceptability and feasibility were defined according to Proctor (33). Feasibility of delivery was complemented by intervention fidelity checks. For this, 14 randomly selected sessions across 7 facilitators were audio-recorded per phase of treatment and assessed by intervention supervisors using a fidelity checklist (included in Appendix G). Data was also collected on duration of sessions, and serious and adverse events.

Perceived effectiveness

The perceived effectiveness of CHANGE on participant's alcohol misuse and mental well-being was explored through qualitative interviews (n = 5 with participants, and n = 4 with facilitators) in Ukrainian or Russian after the intervention ended. The interview guide explored acceptability, delivery feasibility, perceived benefits, contextual barriers, and adaptations needed for the Ukrainian setting. Thematic analyses according to Braun and Clarke(34) was used to analyse the data. NVivo 12(35) was used to conduct the qualitative analyses. Exploratory quantitative analyses were also conducted to describe the possible direction and size of changes associated with CHANGE. Because the feasibility trial was not designed to test effectiveness, the analytic approach for these exploratory estimates is reported in Appendix G.

RESULTS

Findings are presented in the order of the feasibility objectives: trial procedures, implementation outcomes and safety, and perceived effectiveness. Table 1 summarises the key Ukraine feasibility findings and the implications for the definitive trial.

Table 1
Summary of feasibility results

OBJECTIVES OF FEASABILITY TRIAL	ASSESSMENT CRITERIA	SUMMARY OF RESULTS
1. Piloting trial procedures		
Recruitment: To investigate recruitment and expected recruitment timeline to reach target sample size	Number of participants approached	N = 509
	Number assessed for eligibility	N = 122
	Number eligible	N = 63
	Recruitment rate per month	Seven months of recruitment: n = 62 participants recruited by beginning of April 2024. Recruitment rate varied with minimum 4 participants per month, and maximum 20 participants per month.
	Number consented or enrolled	N = 62
	Number of dropouts before randomization	N = 1
	Barriers and facilitators towards recruitment	Facilitators: social media platforms, partner organizations, community-based recruiters. Barriers: war-related (military conscription, limitations on in-person activities, power outages, etc.), stigma, lack of identification of alcohol misuse by healthcare and community specialists, resulting in lack of referral and low motivation of men to participate.
Randomisation: To investigate if randomization was successful	Baseline characteristics between both groups by using descriptive statistics	Baseline characteristics between both intervention arms were evenly distributed (see Table 2 and Appendix 9)
	Randomization process	without deviations from the protocol
Retention: To investigate how well participants stayed in the trial through follow up	Overall retention rate at 3 months follow up	66%
	Overall drop-outs by sub-group (e.g. age, ethnicity, education, marital status, employment)	Total dropouts n = 21. Drop-outs from intervention arm n = 14. Results show that around 40% of drop-outs from intervention occurred due to a lack of time or changed priorities. Some clients discontinued because of unstable work schedule or needs to relocate. A few others stopped due to health conditions and inability to continue attending sessions. Two clients were discontinued

OBJECTIVES OF FEASABILITY TRIAL	ASSESSMENT CRITERIA	SUMMARY OF RESULTS
1. Piloting trial procedures		
		because of heavy drinking, while another client discontinued because he hadn't been drinking at all for some time. Drop outs from control arm n = 6, can't be reached to follow up.
	Timing of drop out in intervention group (e.g. after specific sessions; at 3 months follow up), and reasons	Drop-outs: before 1st session n = 5, after 1 session n = 5, after 2 session n = 2, after 3 session n = 2, after 4 session n = 0, after 5 session n = 0. n = 1 participant was not answering during 3 attempts to contact at 3 months follow up.
	Dose (number of sessions received per participant)	55% of all participants received all six CHANGE sessions
Data collection: To investigate if data collection was possible and conducted accurately	Completeness (%) for primary and secondary outcomes (i.e. missing values across time points, variables, participants; and data accuracy: out of range checks, wrong entries)	- 100% non-missing at baseline for primary outcome (abstinent days measured using TLFB) (see also Appendix 10) - 100% non-missing at baseline for 8 of 10 secondary outcomes - 98.5% non-missing at baseline for 2 of 10 secondary outcomes (ASSIST, WHO-DAS) - 90.9% non-missing at follow-up for all primary and secondary outcomes (6 participants lost to follow-up) - 100% non-missing for key covariates measured at baseline (age, educational attainment, marital status, ethnic group) - 100% non-missing at baseline for all health economic outcomes (EQ-5D-5L, OxCAP-MH, SWB)

OBJECTIVES OF FEASABILITY TRIAL	ASSESSMENT CRITERIA	SUMMARY OF RESULTS
1. Piloting trial procedures		
		- 100% non-missing at follow-up for 2 out of 3 health economic outcomes (EQ-5D-5L, SWB) - No wrong entries spotted
2. **Testing early implementation outcomes, and safety of CHANGE**		
Feasibility of delivery: To investigate if mental health experts and lay health care providers can deliver the intervention and session content as intended, and/or if there are any barriers to service delivery.	*(…)* the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting[2]	In response to safety risks within the war context and the constraints of martial law, participants consistently expressed a preference for remote intervention delivery over face-to-face sessions.
	Intervention fidelity checks (i.e. with regards to session content)	Quite high intervention fidelity; the average indicator of fidelity ratings is 79,79% (see also Appendix 13)
	Session length (in minutes)	79.33 minutes duration of each session (on average); range from 30–150 minutes (see also Appendix 12)
Acceptability of session content: To assess if CHANGE is suitable to the target population, and if participants and lay health care providers find the intervention and its content acceptable	*(…)* the perception that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory.[2]	High acceptability of session content was reported by participants and facilitators.
Serious adverse events (SAEs) / adverse events (AEs): To assess if any safety concerns and risks are linked to the intervention, or the process of delivery	Number of SAEs/AEs (related and unrelated to intervention)	No SAEs/AEs recorded.
3. **Perceived effectiveness of CHANGE**		

OBJECTIVES OF FEASABILITY TRIAL	ASSESSMENT CRITERIA	SUMMARY OF RESULTS
1. Piloting trial procedures		
Perceived effectiveness: To explore qualitatively how participants perceive the intervention and its impact on drinking and well-being	Perceived reduction in alcohol misuse and perceived improvement in mental well-being	Participants suggest that CHANGE improved their psycho-social functioning and patterns of drinking alcohol. This positively engagement in meaningful activities and self-awarness.

- put Table 1 around here -

Feasibility of trial procedures

Recruitment and retention

Participants were recruited between September 2023 and April 2024. This approach was initially productive but led to rapid network saturation, and resulted in rapid decrease of recruited participants. Recruiters also reported challenges in motivating men with alcohol misuse to engage with the study, which slowed down the recruitment over time. Recruitment rates varied with minimum 4 participants per month, and maximum 20 participants per month. The higher recruitment rates at the beginning of the study may have reflected the involvement of recruiters who were outreach workers for internally displaced persons and were able to draw on existing social and professional networks. Once these contacts had been exhausted, recruitment rates declined, and the study team was unable to identify similarly effective recruiters to sustain the initial pace. During this period, 509 individuals were screened prior to formal eligibility assessment. Of these, 387 individuals were excluded at the initial screening stage, primarily due to not meeting basic eligibility criteria or declining further assessment.

A total of 122 individuals proceeded to formal eligibility assessment, of which 60 were excluded. The primary reason for exclusion was an AUDIT score above the eligible range (n = 46), followed by an AUDIT score below the eligible range (n = 10). Additional exclusions were due to low psychological distress (K10 below threshold; n = 1), receipt of any form of alcohol dependance treatment (n = 2), and data integrity concerns (n = 1).

Sixty-two participants met all eligibility criteria and were randomised, with 31 participants assigned to the CHANGE intervention plus EUC (CHANGE/EUC) and 31 participants assigned to EUC alone. In the intervention arm, 14 participants have chosen to receive intervention in-person and 17 remotely.

Attrition occurred in both trial arms during the follow-up period. In the CHANGE/EUC arm, 17 participants completed the intervention. Fourteen participants discontinued treatment and, due to a procedural oversight, were not invited to the follow-up assessment (n = 14). Among the 17 completers one participant could not be reached at the 3-month follow up (n = 1), resulting in 15 participants without

follow-up data in total for treatment arm. In the EUC arm, six participants were lost to follow-up due to inability to establish contact. No participants in either arm formally declined follow-up assessments. Overall, 41 participants completed the 3-month follow-up assessment, corresponding to a retention rate of 66%.

All participants with available outcome data were included in the primary outcome analysis, and no participants were excluded from analysis following randomisation. The study flow diagram is presented in Fig. 1.

Participants lost to follow-up were more likely to be aged 30 years or older, have secondary or technical education, be single, employed, not displaced, and recruited in Dnipro, compared with the overall trial sample, with no losses observed among participants with prior military involvement. (table included in Appendix H).

- Put Fig. 1 around here -

Recruitment of study participants was constrained by several interrelated barriers, including low motivation among male participants, stigma related to alcohol misuse and psychological help-seeking, and logistical challenges associated with the war context. Research assistants frequently reported non-responsiveness following initial registration despite repeated and proactive recruitment efforts, which was interpreted as declining interest:

“That is, three—or even more—we always made, I think, several attempts with [research assistant] not to lose a client. But then… they’re unreachable, not answering, or they read messages on social media and don’t respond. So it becomes clear that the person has probably lost interest.” (research assistant)

In some cases, lack of engagement stemmed from non-consensual registration. Research assistants noted that several potential participants were registered by their wives, and when contacted directly, these men expressed reluctance or refusal to participate:

“I’m really trying to remember refusals—and I can’t, actually. Most of my refusals were from [those participants who were registered by] wives (smiles). Wives registered them [participants], and then they say, ‘Listen, I didn’t register myself,’ and that’s it. Almost all refusals were because of this.” (research assistant)

Low motivation was further characterised by limited interest in psychological support, prioritisation of work or other responsibilities, and expectations of financial incentives. Additionally, some individuals expressed interest in receiving psychological support but declined participation in the study because they did not wish to be randomly assigned to the EUC-only group.. Even among men who initially expressed interest, stigma surrounding alcohol misuse and help-seeking represented a substantial barrier to enrolment:

“Some clients actually said that they were interested, but they were afraid to seek help on their own—psychological help, or even to look in that direction at all.” (research assistant)

Research assistants consistently highlighted shame as a central factor inhibiting engagement, noting that men were often reluctant to discuss alcohol-related problems with anyone, including professionals, family members, or friends:

"This is exactly that painful topic we don't talk about. How do you engage people if they are ashamed to talk about it? They are ashamed to talk about it with strangers. They are ashamed to talk about it with their relatives. People are ashamed of this topic in general." (research assistant)

In addition to motivational and stigma-related barriers, research assistants identified multiple war-related logistical challenges that further impeded recruitment and attendance. These included power outages, unstable internet connectivity, transportation difficulties, and disruptions caused by air raid alerts. Such constraints particularly affected in-person engagement and follow-up communication:

"There were people who didn't make it to face-to-face meetings because it was hard to get there with the air raid sirens and everything else. And I think it just became uncomfortable for them to respond to my fourth or fifth message… even though I kept saying it wasn't a problem to reschedule. But for them it already felt uncomfortable. So this was a purely logistical issue." (research assistant)

Together, these findings highlight key feasibility challenges related to recruitment in a conflict-affected setting and informed subsequent adaptations to recruitment strategies and intervention delivery in the definitive trial.

Key facilitators of successful recruitment included the responsiveness and cooperativeness of registered participants, the proactive and flexible efforts of research assistants, and strong support from the broader research team aimed at identifying and overcoming recruitment barriers. In particular, the willingness of some participants to remain engaged after initial contact enabled continued recruitment despite contextual challenges. Participants with higher self-motivation were less likely to raise war-related logistical difficulties as barriers to participation and were more willing to proceed despite challenges such as travel disruption, air raid alerts, or unstable connectivity. Flexibility and persistence on the part of research assistants were consistently identified as critical. This included making repeated attempts to contact registered participants at different time points, adapting communication to participants' availability, and approaching potential participants in a respectful and non-pressuring manner. Research assistants described making multiple follow-up attempts to maintain engagement, especially when initial contact did not lead to immediate enrolment:

"You really had to find the right time and approach the person very gently, so that they would agree—or find a moment when it was convenient for them to talk… Three—or even more—we [the research assistant] always made, I think, several attempts with [clients] so as not to lose a client." *(Research assistant)*

Establishing transparency about trial procedures was another important facilitator, particularly for participants who initially expressed concerns or hesitations. In addition to providing the participant information sheet and consent form, research assistants took time to discuss the study procedures in

detail, answer participants' questions, clarify what would happen during counselling sessions, and address concerns about confidentiality, camera use, online communication, and randomisation. This additional verbal explanation helped participants feel more informed and reassured before deciding whether to take part:

"There were some who had serious concerns before starting. They asked: 'What is this? What will happen there? Do I have to turn on the camera? What if I don't want to?' So, this was more about explaining the work with the counsellor" (Research assistant)

Ongoing support from the research team was therefore essential to sustain motivation and problem-solving capacity, particularly in the adverse and unpredictable war context. Team-level coordination and encouragement helped research assistants maintain persistence, adapt recruitment strategies, and continue seeking effective solutions to emerging barriers.

"It took place weekly. We discussed the cases that were of greatest concern, decided how to act in similar situations, and developed an overall understanding of the client landscape—where participants were coming from and through which channels. This helped us build a general strategy for identifying where it was most effective to disseminate information, how it was received by different humanitarian groups, and which populations were being reached." (Research assistant)

Randomisation and data collection

A total of 62 participants were enrolled in the pilot trial, with 31 allocated to the CHANGE + EUC group and 31 to the EUC group. Overall, participants were predominantly aged 30–49 years (67.7%), with the largest proportion in the 40–49 age group (35.5%); the age distribution was broadly similar across treatment arms, although a higher proportion of younger participants aged 18–29 years was observed in the EUC group. Nearly two thirds of participants (64.5%) had completed university-level education, while the remainder had secondary or technical–professional education. Just over half of participants were single, separated, or widowed (53.2%), and 46.8% were currently married, with comparable distributions between groups. Most participants were engaged in formal, casual, or self-employment (77.4%), while 21.0% were unemployed. More than half of the sample (58.1%) reported being displaced, with displacement more common in the EUC group than in the CHANGE + EUC group. None of the participants reported prior involvement in military action. Participants were evenly recruited from Dnipro and Kyiv, with approximately half of the sample drawn from each location (Table 2, Appendix I).

Table 2
Baseline characteristics

	CHANGE + EUC		EUC		Total	
	n	%	n	%	n	%
Total	31	100	31	100	62	100
Age (years)						
18–29	2	6,5	7	22,6	9	14,5
30–39	10	32,3	10	32,3	20	32,3
40–49	13	41,9	9	29	22	35,5
50+	6	19,4	5	16,1	11	17,7
Educational attainment						
Secondary/technic-professional	13	41,9	9	29	22	35,5
University (undergraduate or postgraduate)	18	58,1	22	71	40	64,5
Marital status						
Single/divorced/widowed	17	54,8	16	51,6	33	53,2
Currently married	14	45,2	15	48,4	29	46,8
Employment status*						
Unemployed	7	22,6	6	20	13	21,3
Formal/casual/self-employed	24	77,4	24	80	48	78,7
Displaced from home because of war**						
No	17	54,8	8	26,7	25	41
Yes	14	45,2	22	73,3	36	59
Site						

* 1 respondent missing employent status (in EUC arm)

**1 respondent missing displacement (in EUC arm)

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1. Eldridge, S.M., et al., *CONSORT 2010 statement: extension to randomised pilot and feasibility trials.* BMJ, 2016. **355**: p. i5239.

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	CHANGE + EUC		EUC		Total	
	n	%	n	%	n	%
Kyiv	15	48,4	15	48,4	30	48,4
Dnipro	16	51,6	16	51,6	32	51,6
* 1 respondent missing employent status (in EUC arm)						
**1 respondent missing displacement (in EUC arm)						
References						
1. Eldridge, S.M., et al., *CONSORT 2010 statement: extension to randomised pilot and feasibility trials.* BMJ, 2016. **355**: p. i5239.						
2. Proctor, E., et al., *Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda.* Adm Policy Ment Health, 2011. **38**(2): p. 65–76.						

- Put Table 2 around here -

There was minimal missing data for key covariates and outcomes in the trial. At baseline, there was no missing data for the primary outcomes, and completeness was high across secondary outcomes, with only small amounts of missing data for selected mental health and functional measures. At follow-up, non-missing data were available for the primary outcomes for all participants who completed follow-up, corresponding to an overall follow-up rate of 66%. No errors in data entry were detected. Further details on missing data for the primary and secondary outcomes are presented in Appendix J.

Early implementation outcomes and safety

Feasibility of delivery

Eight intervention facilitators delivered CHANGE, resulting in a caseload from two to eight (in average five) participants per facilitator. One facilitator was male, while seven were female. Four facilitators were from Kyiv region and other four were from Dnipro regions. Five facilitators had prior professional experience in mental health, one was in-training to become psychologist and two facilitators were employed as social workers. Additional information on facilitator backgrounds, roles, and regions is provided in Appendix K. On average, each intervention session lasted 80 minutes (see Appendix L for detailed session durations). Intervention fidelity with regards to session content was relatively high with an average of 81% fidelity (see Appendix M for further detail).

Interviewees identified practical, contextual, and therapeutic factors that shaped the feasibility of session delivery in Ukraine. A key facilitator was the flexibility demonstrated by facilitators in adjusting session schedules when participants' circumstances changed. Facilitators' ability to continually and

supportively adapt to participants' needs helped participants balance intervention attendance with work and family responsibilities. One participant noted that both the facilitators and the programme were designed to minimize inconvenience, with session timing negotiated collaboratively and tailored to individual availability, leaving little perceived need for improvement:

"I don't know how it could be improved. Both the counsellors and the whole programme were set up to remove different inconveniences for me; the timing was adjusted to my possibilities, and everything was discussed" (participant).

The option to deliver sessions remotely was also highly valued by both participants and facilitators, as it made scheduling easier and increased accessibility. At the same time, a clear intervention structure and adherence to the treatment protocol provided consistency and predictability, which participants found reassuring. While schedules could be adjusted when necessary, having a routine remained important:

"If circumstances change, it gets adjusted. But usually, it's still easier for people this way. It's easier for me too… At the end of each meeting, we just agree—'Does next Wednesday at 7 pm work for you?' He [client] says yes, and that's it" (facilitator).

Several adaptations to the intervention content were required to better align it with contextual realities and local attitudes regarding alcohol use and mental health. Facilitators identified their own need for more detailed and concrete information on the physiological and psychological effects of alcohol, which was addressed during supervision. One facilitator reflected that although this information initially seemed overly technical, it later proved practically useful in client interactions:

"I never thought that I would remember how this works at a chemical level or that I would need it—but later it turned out to be useful, and I could answer people's questions" (facilitator).

Additional emphasis was placed on supporting facilitators to help participants identify and understand emotions, including brief explanations of the functions different emotions may serve. The war context also necessitated adaptations to examples used in behavioral activation, as many commonly suggested pleasurable activities mentioned in the manual were no longer feasible or safe. Facilitators worked collaboratively with participants to identify alternative, contextually appropriate activities, often shifting focus from previously valued but inaccessible activities to smaller, achievable sources of behavioral activation that did not expose individuals to additional risk.

Supervisors identified overwhelming emotional distress among study participants related to ongoing war exposure as a key challenge that required additional time and attention from facilitators. Rather than necessitating changes to the core intervention structure, this was addressed by allowing greater flexibility within sessions to prioritise the sharing and processing of acute, emotionally intense experiences before transitioning to more structured skills-based components. This flexibility was feasible partly because most facilitators had prior experience in the mental health sector; implementing the same approach with truly lay health workers may have required more intensive training, supervision,

and support. One supervisor described the ethical and clinical importance of allowing space for disclosure, particularly when facilitators were the first or only individuals with whom participants felt able to speak about their trauma:

"The level of traumatisation is extremely high, and the need to talk about these experiences is very strong… we cannot interrupt someone just to follow the protocol. We give the person space to speak, because people are traumatised, and sometimes we are the only people they have started talking to. This must be held" (Supervisor).

In terms of training and supervision, facilitators consistently described the training as highly beneficial, highlighting the substantial amount of new information, opportunities for skills practice, and the development of a detailed and in-depth understanding of the intervention manual. Although some facilitators noted that the training was long and intensive and could be physically and emotionally tiring, they emphasized that the skills and knowledge gained proved valuable and applicable to real-world practice. This perception should be understood in the context of the ongoing war, where attending a six-day training could be particularly demanding for facilitators, especially for those who had to leave children or other family responsibilities during a period of heightened insecurity:

"I understood how to work with people as a community first responders—I could identify the problem and refer it well. But I didn't know how to work with the problem itself. Everything I was learning was new to me… I was starting from the very beginning, and it was interesting" (facilitator).

The same facilitator reflected that the training revealed gaps in their knowledge and motivated further professional development, including pursuing additional psychological education and multiple supplementary trainings. One supervisor reflected on in-person training sessions as particularly meaningful, describing them as warm, supportive, and deeply engaging, and noting a strong sense of gratitude and mutual respect within the group, especially given the challenging cases facilitators were managing:

"It felt like just a little more and we would all start crying… there was so much gratitude and respect. We knew the work involved real cases and that it was difficult, and this training was truly supportive."(supervisor)

Facilitators consistently described supervision as highly supportive and instrumental to intervention delivery, emphasizing the value of peer learning and guidance from experienced supervisors. Supervisors' expertise in alcohol misuse and alcohol-related problems, often informed by substantial prior experience working with alcohol dependence, was particularly valued. Supervision also enabled collective problem-solving, both for clinical challenges with facilitators and supervisors and for addressing logistical issues in collaboration with the research team. Supervisors' availability and responsiveness fostered a strong, trusting supervisory relationship. One facilitator highlighted the emotional safety and reliability of the supervision space:

"It's very comfortable… you feel the support—you know that the supervision will take place, that you can ask questions and receive a qualified answer and advice" (Facilitator).

Facilitators reported satisfaction with the format and frequency of supervision, which strengthened team cohesion and partially mitigated the lack of regular in-person supervision. Observing tangible positive changes in study participants further reinforced facilitators' sense of success and, in turn, strengthened their motivation and commitment to the intervention.

Acceptability of CHANGE

Overall, facilitators reported high acceptance of the intervention and strong satisfaction with its content, structure, and delivery approach. The programme was perceived as well-structured, coherent, and proportionate, with components that logically built on one another and were neither overly complex nor burdensome for clients, requiring no special preparation or material resources. Facilitators emphasized that the six-session format was well balanced and appropriately paced:

"Everything is well thought through, proportional, and aligned with the programme… not too difficult or complicated" (Facilitator).

The intervention was also viewed as broadly applicable. Facilitators consistently highlighted the usefulness and relevance of individual components, including understanding alcohol use, weighing pros and cons of reducing drinking, goal setting, identifying high-risk situations, managing stress and emotions, problem-solving, strengthening social support, and staying well over time. Central to acceptance was the intervention's client-centered orientation, which allowed participants to work directly with their own experiences and challenges rather than abstract strategies:

"Clients work with their own material, their own problems—everything is connected to their real life" (Facilitator).

The interviews suggest that the program was acceptable overall, although participants did not respond to all strategies in the same way. Some components were experienced as too simple, too abstract, or insufficiently aligned with clients' ways of understanding and explaining alcohol misuse. Clients sometimes questioned the relevance of particular exercises, such as the readiness ladder, goal-setting metaphors, urge surfing, or breathing techniques. However, this did not appear to reflect rejection of the program as a whole. Rather, acceptability appeared to be component-specific, as a strategy that felt unhelpful for one client could still be useful for another:

"For me, it definitely does not fit, because I don't have any steps. For me, either there is a problem or there isn't. Either I can overcome it or I can't. I don't see this kind of method — whether I can drink more or drink less. Either I drink, or I don't drink." (Participant)

Facilitators valued the non-judgmental, non-directive stance of the programme, describing it as respectful without use of fear, pressure, or moralizing. Flexibility in applying techniques was also considered essential; clients were encouraged to try and select strategies that worked best for them, rather than being required to follow all elements rigidly.

Facilitators and participants perceived the handout materials as highly useful in supporting comprehension and reinforcing learning. Visual and written materials helped concretize abstract concepts, supported different learning styles, and enabled participants to revisit content between sessions, particularly in online delivery. Facilitators also noted that working with handouts increased the likelihood of practice outside sessions and helped participants articulate emotions and plans that might otherwise have been difficult to express, thereby enhancing the practical application of intervention strategies.

Safety of participants

There were no adverse events reported during the trial period.

Preliminary effectiveness of CHANGE

Qualitative interviews

Qualitative interviews with participants and facilitators indicated strong perceived effectiveness of the intervention in reducing alcohol misuse and improving well-being. Both groups consistently described meaningful reductions in alcohol consumption, often exceeding participants' initial goals. Facilitators noted that even when participants did not fully achieve their original intentions, all of them reported reduced frequency and quantity of drinking and increased awareness of their alcohol use. As one facilitator explained:

"Each of them told me that they felt positive changes. Because regardless of whether everything worked out or not, people still reduced the amount of alcohol they consumed. And when they did drink, they drank more consciously and were better able to analyse why it happened. And I think that's a very positive outcome, because the main goal of the programme is not just to talk, but for a person to improve their relationship with alcohol" (facilitator).

In several cases, participants who initially aimed only to reduce consumption ultimately reported complete abstinence by the end of the intervention:

"Everyone I worked with ended up stopping completely… even though at the beginning *none of them set that goal"* (Facilitator).

Beyond changes in alcohol use, participants described substantial psychosocial benefits associated with the intervention, including increased self-awareness, emotional literacy, confidence, and overall

quality of life. Facilitators observed that many participants began to reflect more deeply on their internal experiences, particularly emotions, often for the first time. Some participants reported overcoming restrictive emotional norms. This included learning to access and tolerate emotions that had previously felt prohibited. Improved self-awareness was frequently accompanied by enhanced confidence and a more positive self-concept. One participant described a shift from longstanding self-doubt to greater assertiveness and ease in professional interactions:

"When I removed that self-doubt—and your project helped me a lot with that—it became much easier for me to talk to people, to achieve what I want. The main thing that changed was my attitude toward myself" (participant).

Improvements in emotional functioning and reduced alcohol use were closely linked to broader gains in quality of life and relationships. Facilitators shared examples of meaningful changes in family dynamics and values, noting how participants re-invested time, care, and resources into relationships. Participants also described increased engagement in meaningful activities, personal development, and a renewed sense of purpose:

"Thanks to the support and the methods, and especially the structure, I reached a new stage of self-improvement" (Participant).

Finally, facilitators observed that participation in the intervention often increased readiness for continued psychological work. Experiencing tangible improvements motivated some participants to seek further support beyond the programme, while others described discovering what it feels like to "live differently" and wanting to sustain these changes.

Preliminary effectiveness appeared to depend less on whether every strategy resonated with a client and more on whether clients engaged with the program sufficiently to identify and practise the components that were useful for them. Several clients who benefited from the program also described particular techniques as irrelevant, difficult, or not personally useful. Instead, the program seemed to function as a flexible set of tools, with different components working for different people. Lower perceived effectiveness was more clearly linked to limited engagement with the program as a whole, especially when clients practised little or nothing between sessions or after the intervention:

"I tried to do it, but specifically for me it does not really help. I would say yes — definitely not. Most likely, my personality type is different. It is not suited to this. I need to look for other options; this does not work for me."(Participant)

Explanatory quantitative assessment of trial outcomes

Although assessing effectiveness was not a primary objective of this feasibility study, we explored the potential direction and magnitude of intervention effects on primary and secondary outcomes. For the primary outcome, PDA, participants in the CHANGE + EUC group showed higher abstinence at follow-up compared with the EUC group (mean 75.4% vs 68.3%). After adjustment for baseline values and

covariates, there was a trend towards increased abstinence in the CHANGE + EUC group, although confidence intervals included the null value (fully adjusted IRR = 0.57, 95% CI 0.30 to 1.11). A similar pattern was observed for percentage of days with heavy drinking, with reductions in both groups and no clear between-group difference. For secondary alcohol outcomes, AUDIT and ASSIST scores decreased in both arms, although adjusted estimates did not indicate clear between-group differences. For psychological distress (K10), participants receiving CHANGE + EUC showed greater reductions than those receiving EUC alone in the fully adjusted model (β = − 4.12, 95% CI − 7.55 to − 0.69). A similar pattern was observed for PTSD symptoms (MHAI), with reductions favouring the intervention group in fully adjusted models (β = − 0.27, 95% CI − 0.54 to − 0.00). Trends towards improvement were observed for depression, anxiety, overall mental health, and functional disability, although estimates were imprecise. Reports of intimate partner violence decreased in the intervention group at follow-up, but these outcomes were not formally modelled due to low event counts. Overall, these exploratory findings suggest a favorable direction of effect for the intervention, particularly for psychological distress and trauma-related symptoms, supporting further evaluation in a fully powered trial. Tables of the outcomes are included in Appendix N and O.

DISCUSSION

This individually randomised feasibility trial evaluated the methodological procedures required for a definitive RCT of the CHANGE intervention in Ukraine, while also examining early implementation outcomes and perceived effectiveness using a mixed-methods approach. Conducted in the context of ongoing war, the study assessed feasibility across multiple domains, including recruitment, retention, randomisation, data collection, acceptability, feasibility of delivery, safety, and preliminary outcome trends. Overall, prespecified feasibility criteria for progression to a definitive RCT were met, indicating that both the trial procedures and the intervention itself are sufficiently robust to warrant further evaluation with targeted refinements.

The pattern of findings is broadly consistent with previous PM+ studies, in which improvements have been observed across several domains of distress and functioning (8, 36, 37). Similar patterns have also been reported in PM+ studies conducted in humanitarian and conflict-affected settings (13, 36). Although this feasibility trial was not designed to estimate effectiveness, the observed direction of change suggests that CHANGE may have potential to address co-occurring psychological distress and alcohol misuse among war-affected men. This is also consistent with evidence from brief alcohol-focused interventions, including pilot trials of text-message and behavioural interventions, which have shown potential to reduce hazardous drinking in low-resource settings (38, 39) Given the high burden of psychological distress and alcohol-related harm in Ukraine, these findings support further evaluation of CHANGE in a definitive trial.

Recruitment of war-affected men experiencing alcohol misuse and psychological distress was feasible, although slower than initially anticipated. Recruitment targets were met over a seven-month period, reflecting both the challenges of engaging men in psychological interventions and the additional

constraints imposed by the war context. Qualitative findings highlighted stigma surrounding alcohol misuse and psychological help-seeking, low intrinsic motivation, competing work and family responsibilities, and war-related logistical barriers (e.g. air raid alerts, electricity outages, unstable internet connectivity) as key obstacles to recruitment and sustained engagement. These findings are consistent with existing literature documenting barriers to male help-seeking and underscore the importance of flexible, context-sensitive recruitment strategies in conflict-affected settings (40). At the same time, the study demonstrated that with persistence, transparency, and adaptive communication strategies, men can be successfully engaged in research and intervention delivery.

Retention at the 3-month follow-up was acceptable, with two-thirds of participants completing outcome assessments. Attrition occurred in both trial arms and was primarily due to loss of contact rather than active refusal, suggesting that disengagement was more closely linked to contextual instability than dissatisfaction with the study. Missing data were minimal across primary and secondary outcomes, supporting the feasibility and reliability of the data collection procedures and indicating that no major modifications are required for outcome assessment in the definitive RCT.

The CHANGE intervention was highly acceptable to both participants and facilitators. Qualitative data indicated strong satisfaction with the intervention's structure, content, and delivery approach. The six-session format was perceived as coherent, proportionate, and manageable, with components that logically built on one another without placing excessive burden on participants. The client-centred and non-judgmental orientation of the intervention was particularly valued, as it allowed participants to work directly with their own experiences and goals rather than abstract strategies. Flexibility in session scheduling and delivery, especially the option for remote sessions, emerged as a critical enabler of feasibility, enabling participants to balance intervention participation with work, family responsibilities, and safety concerns related to the war.

Facilitator training and supervision were consistently identified as key implementation strengths. Training was described as intensive but highly beneficial, equipping facilitators with new knowledge, practical skills, and a deeper understanding of the intervention manual. Supervision provided both clinical guidance and emotional support, fostering confidence, reflective practice, and team cohesion. Supervisors' expertise in alcohol misuse and trauma-related problems was particularly valued, and supervision created a safe space for collective problem-solving. Observing positive changes among participants further reinforced facilitators' motivation and commitment to delivering the intervention with fidelity.

Several contextual adaptations were required to optimise intervention delivery. These included providing more detailed information on the effects of alcohol to address participants' questions, placing greater emphasis on emotion identification and regulation, and adapting behavioral activation examples to reflect the realities of living in a war context. Supervisors also identified overwhelming war-related emotional distress as a key challenge. Rather than necessitating changes to the core intervention

structure, this was addressed by allowing greater flexibility within sessions and, where clinically indicated.

Safety considerations and recruitment challenges identified in the feasibility trial indicate that the definitive RCT should prioritise remote-only delivery of the intervention. Slower recruitment among men appeared to be strongly influenced by fear related to conscription risks, with some potential participants expressing concerns about travelling to fixed locations or being visibly present at organised activities. These safety concerns are specific to the current wartime context and represent a substantial barrier to in-person participation. Findings from the pilot trial demonstrate that remote delivery of the intervention is both acceptable and feasible for participants and facilitators, despite intermittent challenges related to internet connectivity and electricity outages. Importantly, remote delivery increased participants' sense of safety, reduced logistical and time-related barriers, and allowed for greater flexibility in scheduling sessions around work, family, and security constraints. Adopting a remote-only format for the definitive trial would therefore not only mitigate safety risks and improve recruitment but also enable the trial to be extended to men residing across all government-controlled areas of Ukraine, substantially enhancing reach, equity of access, and scalability under ongoing war conditions.

Qualitative findings suggested perceived effectiveness of the CHANGE intervention. Participants and facilitators reported meaningful reductions in alcohol consumption, often exceeding participants' initial goals. In several cases, participants who initially aimed to reduce drinking achieved complete abstinence by the end of the intervention. Beyond alcohol use, participants described increased self-awareness, emotional literacy, confidence, improved mood, enhanced family relationships, and greater engagement in meaningful activities. These psychosocial changes were often described as transformative, contributing to a renewed sense of purpose and readiness to continue psychological work beyond the intervention.

Exploratory quantitative analyses, while not powered to detect effectiveness, showed a consistent favorable direction of effect across primary and secondary outcomes. Participants in the CHANGE + EUC group demonstrated higher levels of abstinence at follow-up compared with EUC alone, alongside statistically significant reductions in psychological distress and improvements in PTSD symptoms. Trends towards improvement were also observed for other mental health and functioning outcomes, although estimates were imprecise. The convergence of qualitative and quantitative findings strengthens confidence that the intervention may produce clinically meaningful benefits and supports further evaluation in a fully powered trial.

Several limitations should be acknowledged. The small sample size and short follow-up period limit conclusions about effectiveness and long-term sustainability of outcomes. In addition, a procedural oversight resulted in participants who discontinued treatment not being invited to complete the 3-month follow-up assessment, which may have contributed to higher attrition and limits interpretation of retention rates. The war context introduced unavoidable challenges to recruitment, retention, and delivery, which may limit generalisability to more stable settings. Nevertheless, these constraints also

enhance the ecological validity of the findings and provide critical insights for conducting trials in active conflict settings.

In conclusion, this feasibility trial demonstrates that it is possible to recruit, retain, and deliver a structured psychological intervention addressing alcohol misuse and psychological distress among war-affected men in Ukraine. The CHANGE intervention was acceptable, feasible to deliver, and perceived as effective by participants and facilitators, with promising preliminary outcome trends. With targeted refinements to trial procedures and intervention delivery, these findings support progression to a definitive RCT to rigorously evaluate the effectiveness and scalability of CHANGE in humanitarian contexts.

ABBREVIATIONS

ASSIST
Alcohol, Smoking and Substance Involvement Screening Tool
AUDIT
Alcohol Use Disorder Identification Test
EUC
Enhanced Usual Care
HRQoL
Health related quality of life
HSCL-A
Hopkins Symptom Checklist - Anxiety
K-10
Kessler Psychological Distress Scale
MhGAP
Mental Health Gap Action Programme
ODK
Open Data Kit
OxCAP-MH
Oxford CAPabilities Questionnaire for Mental Health
PHQ-9
Patient Health Questionnaire-9
PM+
Problem Management Plus
PTSD
Posttraumatic Stress Disorder
RCT
Randomised Controlled Trial
SAE
Serious Adverse Event

SWB
Subjective wellbeing
TLFB
Timeline Followback
WHO-DAS
WHO Disability Assessment Schedule
WHO
World Health Organization

DECLARATIONS

Ethics approval and consent to participate:

Ethics approval and consent to participate: All study procedures were approved by the Ethics Committees of the London School of Hygiene and Tropical Medicine (LSHTM; ref: 28853) and the National University of Kyiv-Mohyla Academy (ref: FWA00030125). All participants provided informed consent in Ukrainian or Russian before screening, baseline assessment, or any other research procedures were undertaken.

Consent for publication:

Not applicable.

Competing interests:

The authors report no competing interests relevant to this Ukraine feasibility trial.

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Author Contribution

DCF, BR, SB, AN and HAW conceptualized the study; SB, VK, KH and AP collected data; MN, HAW, KH, GG and KD conducted formal analysis of the data; DCF, BR, AN, HAW and SB acquired the funding; DCF, SB, VK, BR, AP, KH, AN, MN, VR, CB, HAW and KD contributed to the writing, review and editing of the paper. All authors reviewed and approved the submitted manuscript.

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Data Availability

The analysed datasets generated during the current study are available from the corresponding author on reasonable request. Raw data are not publicly available due to ethical and safety considerations, including participant concerns regarding potential misuse of even anonymised data in the context of ongoing conflict. These restrictions were necessary to ensure participant safety and informed consent.

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Figures

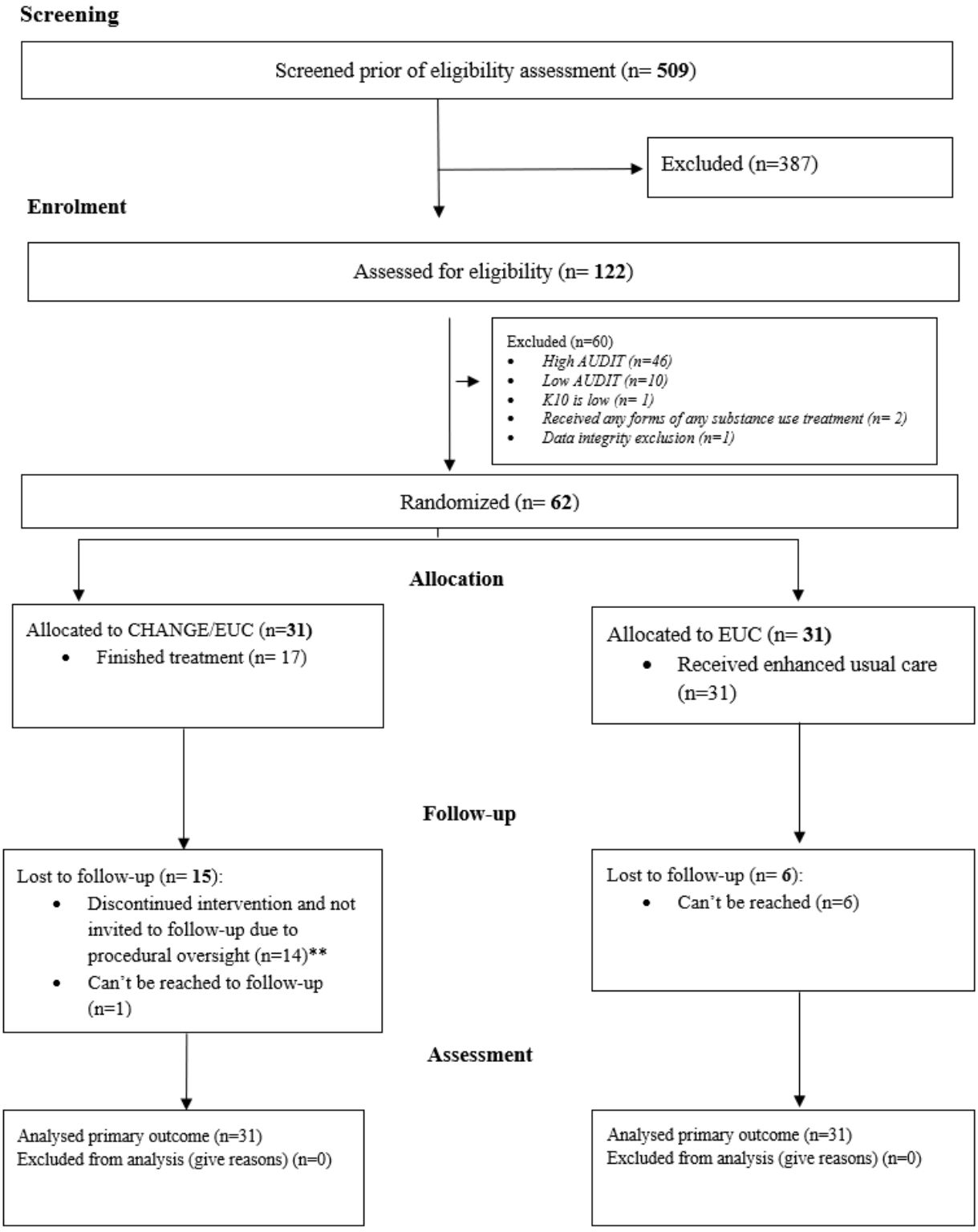


Figure 1

Flow diagram*

*adapted from CONSORT 2010 statement: extension to randomised pilot and feasibility trials[1]

** Participants who discontinued the intervention (n = 14) were not invited to complete the 3-month follow-up assessment due to a procedural oversight.

Supplementary Files

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- AppendixUkrainefeasibilitypaperjune2026final.docx