CHANGE study – Northern Uganda and Ukraine definitive trials

Statistical Analysis Plan

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1. Description of the study

1.1. Overview and research objectives

This study will evaluate the effectiveness and cost-effectiveness of a transdiagnostic intervention addressing alcohol misuse and psychological distress among men in conflictaffected settings. The intervention will be implemented in two locations: Northern Uganda and Ukraine. The CHANGE intervention is delivered in individual face to face sessions in Uganda and delivered remotely (online or via the phone) in Ukraine.

The primary hypothesis of the study in Uganda and Ukraine is that men receiving both the CHANGE intervention and enhanced usual care (EUC) will have a higher proportion of days abstinent from alcohol (PDA) at 3 months following randomization compared with men receiving EUC only.

Secondary hypotheses include for Uganda: (1) the population receiving the CHANGE intervention plus EUC will have higher PDA at 12 months compared with EUC only; and (2) the population receiving the CHANGE intervention plus EUC will have reduced psychological distress, depression, anxiety, PTSD, disability levels, and perpetration of intimate partner violence at 3- and 12- months compared with EUC only (secondary outcomes).

Secondary hypotheses include for Ukraine: (1) the population receiving the CHANGE intervention plus EUC will have lower PDHD, reduced psychological distress, depression, anxiety, PTSD, disability levels, and perpetration of intimate partner violence at 3 months compared with EUC only (secondary outcomes).

The intervention will be evaluated independently in each location, but similar methods will be used in data collection and analysis. Results will be presented in concordance with CONSORT reporting guidelines (1)

This statistical analysis plan (SAP) covers the analysis of health outcomes data only. Costeffectiveness analysis will be covered in a separate document.

1.2. Study design

The CHANGE intervention will be evaluated using two independent, individually randomized parallel arm trials, one in Ukraine and one in Northern Uganda. Participants in each location were randomized 1:1 after baseline assessment to receive the CHANGE intervention plus EUC or EUC only.

1.3. Randomization and allocation concealment

Randomisation will be conducted by a statistician independent of the trial team using Stata 18.0 statistical software (College Station, TX, USA). In Northern Uganda only, randomisation will be stratified by village and blocked in groups of 4, 6, or 8 participants in random order. Within the villages, participants will be individually randomised 1:1 to both arms of the trial after baseline assessment. In Ukraine, randomisation was blocked in groups of 4, 6, or 8 participants in random order, and not stratified.

The trial statisticians and principal investigators will be masked to allocation until the analysis of the primary outcome is completed, and the initial analysis syntax will be written using a randomly generated allocation variable. Additionally, in each location we used the following methods to ensure allocation concealment:

- ***Northern Uganda.*** Allocation concealment will be maximised using sequentially numbered opaque sealed envelopes, which will hold the randomisation code inside (generated by an independent statistician using statistical software). The envelope

seal will be signed over to prevent tampering and will be opened by the village health teams with the participant. Envelopes with evidence of tampering will not be used. All research assistants and members of Village Health Teams will be trained on the importance of maintaining the randomisation sequence and spotting tampering. Data monitoring checks will be used to identify irregularities in the sequence in which envelopes are opened.

- ***Ukraine*.** Concealment of allocation will be ensured using sequentially numbered virtual envelopes. Microsoft Lists will be used to store the randomisation sequence, which will only be accessible to the team members that are unmasked throughout the trial. Virtual envelopes will be assigned to the participant in the order that participants are enrolled into the study. The virtual envelope will display the envelope ID and status (locked/unlocked). The EUC specialist will unlock the respective virtual envelope, after which the envelope status automatically updates to unlocked, the date and time of unlocking is recorded, and the randomisation code and allocation is displayed. All actions related to unlocking the virtual envelopes will be tracked using version control mechanisms. This mechanism improves procedural accuracy by demonstrating compliance to standard operating procedures, ensuring there are no errors in the randomisation process. All EUC specialists will be trained on the importance of maintaining the randomisation sequence and weekly data monitoring checks will be done to identify irregularities in the allocation sequence in which envelopes are opened.

1.4. Selection of participants for fidelity assessment

In both locations, we will evaluate the fidelity of intervention implementation using audio recordings of a random subset of participant sessions. In Northern Uganda, audio recordings of 75 sessions will be reviewed by external evaluations. In Ukraine, audio recordings of 100 sessions will be reviewed by trainers. In both settings, recording contents will be evaluated against checklists of components expected to be covered in each session.

Participant sessions for fidelity assessments were selected at random using Stata 18.0 statistical software (College Station, TX, USA). The intervention was delivered in 6 sessions, and the random selection was balanced to ensure the same number of recordings were conducted for each of the 6 sessions, and that participants were only recorded one time. In Northern Uganda, 78 participant sessions were selected, with loss to follow-up and refusal assumed to be low based on previous experience. In Ukraine, previous experience has suggested that participants were likely to refuse recording, so 250 participant sessions were randomly selected for possible recording.

1.5. Sample size estimation – Northern Uganda

A sample size of 500 enrolled participants (250 in each arm with 1:1 allocation) will provide 90% power to detect a difference in the PDA from alcohol of 55% in the EUC arm vs 68% in the CHANGE arm (SD = 37%) at 3 months follow-up with alpha = 0.05. The sample size calculation accounts for 20% loss to follow-up at 3 months. The estimated PDA and SD are conservative, based on the CAP trial (54% vs 69%) (Nadkarni et al., 2017).

1.6. Sample size estimation – Ukraine

A sample size of 500 enrolled participants across both arms (250 in each arm with 1:1 allocation) will provide 90% power to detect a difference in the proportion of days abstaining from alcohol of 40% in the EUC arm vs 25% in CHANGE arm (SD=37%) at 3 months followup with alpha = 0.05. Sample size calculation accounts for 20% loss to follow up at 3 months.

The sample size calculation accounts for 20% loss to follow-up at 3 months and is based on Nadkarni et al. 2017 (2).

1.7. Description of intervention and comparison activities

The intervention and EUC procedures were similar in both locations. However, in Ukraine the intervention and EUC activities were conducted remotely, while in Northern Uganda these were in person.

- **Intervention.** Briefly, the CHANGE intervention is a 6-session program based on PM+ (3) with additional focus on addressing alcohol misuse. In Ukraine only, an additional revision session was added for participants with high stress levels.
- **EUC.** EUC consists of a pamphlet detailing information on reducing alcohol intake and managing psychological distress. The material covered in the pamphlet will be explained to participants in both the intervention and control arms by trained EUC specialists. All participants, including those allocated to the intervention, receive EUC.

1.8. Outcome assessment

Outcomes for both trials are detailed in **box 1**.

Box 1. CHANGE trial outcomes

Outcome description	Measures		End point
	Northern Uganda	Ukraine	
Primary outcome			
Percentage of days abstinent (PDA) at 3 months follow-up	Timeline Followback (TLFB) (4)		3 months
Secondary outcomes			
PDA at 12 months follow-up	TLFB	n/a	12 months
Percentage of days of heavy drinking (PDHD)	n/a	TLFB	3 months
Alcohol misuse: AUDIT mean score	Alcohol Use Disorders Identification Test (AUDIT) (5) mean score		3 months, 12 months (N. Uganda only)
Alcohol misuse remission	Alcohol Use Disorders Identification Test (AUDIT) (5) score < 8		
Alcohol misuse: ASSIST	Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) (6), mean score		3 months, 12 months (N. Uganda only)
Psychological distress: K10 mean score	Kessler-10 (K10) (7), mean score		3 months, 12 months (N. Uganda only)
Depression	Patient Health Questionnaire-9 (PHQ9) (8), mean score	Mental Health Assessment Inventory (MHAI), depression sub-scale (9), mean score	3 months, 12 months (N. Uganda only)
Remission from depression	PHQ-9 score <10	MHAI depression full or short score less than established cut point*	3 months, 12 months (N. Uganda only)

Anxiety*	Hopkins Symptom Checklist Anxiety (HSCL-A) (10), mean score	Mental Health Assessment Inventory (MHAI), anxiety subscale (9), mean score	3 months, 12 months (N. Uganda only)
Outcome description	**Measures**		**End point**
	Northern Uganda	**Ukraine**	
PTSD	PTSD Checklist for DSM-5 (PCL-6) (11), mean score	Mental Health Assessment Inventory (MHAI), PTSD subscale (9), mean score	3 months, 12 months (N. Uganda only)
Remission from PTSD	n/a	MHAI depression full or short score less than established cut point*	
Mental health	n/a	Mental Health Assessment Inventory (MHAI) (9), mean score	3 months
Functional disability	WHO Disability Assessment Schedule (WHODAS 2.0) (12), mean score	MHAI Impaired Function Measure (13), mean score	3 months, 12 months (N. Uganda only)
Perpetration of intimate partner violence: physical violence	United Nations Multi-Country Study on Men and Violence (14), percentage perpetrating physical violence in last 3 months		3 months, 12 months (N. Uganda only)
Perpetration of intimate partner violence: sexual violence	United Nations Multi-Country Study on Men and Violence (14), percentage perpetrating sexual violence in last 3 months		3 months, 12 months (N. Uganda only)
Health economics indicators**	• EuroQol 5 dimensions 5 Levels (EQ-5D-5L) (15) • Subjective wellbeing (16) • Oxford Capabilities Mental Health questionnaire (OxCAP-MH) (17) • User cost questionnaire		3 months, 12 months (N. Uganda only)

* Cut points for full and short measures are listed in table 5, (9). Cut points for MHAI anxiety measure are not listed, and dichotomized anxiety will not be included as a secondary outcome. If additional unpublished cut points are made available after the SAP is finalized, we will analyse dichotomized anxiety as a post-hoc analysis. ** Not covered in this SAP

1.9. Visit windows

We will follow up with participants up to 3 times; if they are not available after 3 attempts, they will be considered lost to follow-up. Procedures for tracing and reaching participants who miss a scheduled assessment are detailed in various Standard operating Procedures. The median and interquartile range of the timing of the 3 month and 12 month visits relative to the randomisation date will be reported, along with the number and proportion of participants who were visited outside of the acceptable window. Depending on the numbers recorded we will carry out sensitivity analyses comparing those who completed within $\leq$4 weeks of the expected visit date with those beyond >4 weeks.

1.10. Data management

While data management tools and procedures have been planned to ensure consistency across trials, each location has developed a data management plan that is specific to the location.

Three data collection instruments were used to collect data from participants: a screening tool, a baseline data collection tool, and 3- and 12-month follow-up tools (12-month follow up in N. Uganda only). Range checks and skip patterns were developed and programmed into

data collection tools to ensure consistency of responses. Additional queries and checks will be completed by the trial statistician before analysis begins.

In both locations, data are collected on tablets programmed using ODK and uploaded at the end of the workday to servers located at LSHTM. The local monitoring and evaluation lead will check the number of records uploaded each day to ensure data are not lost. Additional copies of the data are kept locally.

2. Data collected

2.1. Screening

Participants are asked the following items in screening:

- Socio-demographic questions, including:
    - ***General***: age, marital status, educational attainment, employment status
    - ***Northern Uganda-specific***: ethnic affiliation, duration of stay in current settlement, previous settlements lived in, duration of refugee status.
    - ***Ukraine-specific***: region of residence; experience with psychological support services, substance use treatment, and/or psychotropic medications; whether displaced as a result of ongoing conflict; duration of displacement; number of times displaced; involvement in military action; trauma exposure
- K10 psychological distress scale
- AUDIT alcohol use scale
- Assessment of thoughts of suicide
- Assessment of homicidal ideation (Ukraine only)
- Assessment of severe mental disorder

2.2. Baseline

Participants are asked the following items in baseline:

- TLFB
- WHO ASSIST
- PHQ-9 (Northern Uganda only)
- HSCL (Northern Uganda only)
- PCL (Northern Uganda only)
- WHODAS 2.0 (Northern Uganda only)
- MHAI (Ukraine only)
- Intimate partner violence perpetration (UN multi-country study on men and violence)
- EQ-5D-L
- OECD subjective well-being
- OxCAP-MH
- User costs

2.3. Follow-up

At follow-up, participants are asked the K10 and AUDIT tools and the tools listed at baseline.

2.4. Contamination measure

A contamination measure developed for this trial will be completed at 3 months in both locations. The contamination measure will be completed by participants in both conditions and contains questions on sharing or receiving information regarding the CHANGE intervention, including specific strategies.

2.5. SAEs

The study team in each location maintains a list of serious adverse events (SAEs). SAEs include all those reported by the participant or observed by the outcome assessors or the intervention facilitators, during any of the outcome assessment or intervention sessions. Specific examples of SAEs include:

- Victimization
- IPV perpetration or experience
- Suicide attempt
- Stigmatization
- Serious lack of food or unsatisfied basic needs
- Death of participant due to suicide
- Death of participant due to other causes
- Hospital admission of participant due to psychiatric problems
- Hospital admission of participant due to other causes
- Homicidal ideation (Ukraine only)

3. Data analysis plan

Analyses will follow CONSORT guidelines for parallel-group randomised trials (1). Analyses will be conducted in Stata version 18.0 (College Station, TX, USA). Do-files will be prepared based on masked data, and we will use a randomly generated allocation variable to generate syntax for models testing the effectiveness of the intervention on changing primary and secondary outcomes. Data will not be unmasked until the dataset is finalised and locked. The DSMB will be notified if additional problems with the data requiring database modification are identified after unmasking.

3.1. Recruitment and representativeness

Initial analyses will compare baseline characteristics of individuals who consented and did not consent and participants who did and did not complete outcome assessments respectively. A CONSORT flow chart will be constructed for each trial (Figure 1 and 2). This will include the number of eligible participants, number of participants agreeing to enter the trial, number of participants refusing and reasons for refusal, then by intervention arm: the number of participants allocated to each arm, the number seen at 3 months and 12 months (Uganda only) respectively.

3.2. Baseline comparability of randomised groups

Baseline characteristics of enrolled participants will be compared between treatment arms and overall, summarised using mean and standard deviation, median and interquartile range or numbers and proportions as appropriate. No significance testing will be done as any baseline differences are due to chance if randomisation was correctly applied. For continuous outcomes, histograms will also be plotted within each arm to assess normality, and whether any transformation is required. The variables that will be summarised are as follows:

- Age
- Educational attainment
- Marital status
- Working status
- Ethnicity (Uganda only)
- Displacement status (Ukraine only)
- Involvement with military action in the past (Ukraine only)

- Location/region within Ukraine (Ukraine only)
- Settlement type – urban v. rural (Ukraine only)
- K10 score
- TLFB – PDA, PDHD
- AUDIT

The trial statisticians and investigators will review the distribution of covariates by arm and determine whether outcome modelling should be adjusted for imbalances in the above variables. This decision will be completed before analysis and unmasking.

3.3. Adherence to interventions and fidelity

Uptake and dose of intervention, including number of sessions attended and the duration of each session, will be tracked by the research team in each setting. Fidelity will be assessed by reviewing recordings of randomly selected participant sessions, and assessing the content of sessions against a pre-specified checklist of required items.

3.4. Loss to follow-up and missing data

The numbers and proportions actively withdrawing from the trial and passively lost to followup will be reported overall and within intervention arm at 3m and 12m. The data for those lost to follow-up will be used in the CONSORT flow chart. The reasons for withdrawal from the trial will be summarised.

3.5. Adverse event reporting

SAEs will be summarised (proportion of individuals with each type of SAE, and total number of SAEs) by arm. If there are a sufficient number of these, the risks and 95% CIs will be reported and the risks will be compared between intervention arms.

4. Outcome analysis

Stata will be used for data description and the main inferential analysis. The primary analyses will be intention-to-treat (modified to adjust for baseline values of the outcome measure).

In Northern Uganda, randomization was stratified by village (N=18). For this reason, all analyses of data from this trial will be adjusted for village using a fixed effect. **4.1. Intention-to-treat analysis of intervention differences in primary and secondary outcomes**

The primary outcome of both trials is the percentage days abstinent from alcohol use as measured using the TLFB. Data on substance use is likely to have overdispersion and a high number of zeros, and zeros can result from multiple processes: for example, habitual non-users and users who did not use alcohol during the follow-up period would both have zero drinks measured during follow-up. Depending on the distribution of the data, beta binomial, negative binomial (NB) or zero-inflated NB or Poisson distributions may provide the best fit to the primary outcome data (18). To identify the most appropriate distribution to use to model TLFB, we will run NB, zero-inflated NB, and zero-inflated Poisson models on the TLFB outcome adjusted for a randomly generated allocation variable, baseline outcome value, village fixed effect in N. Uganda only, and baseline imbalances as described above (3.2). The AIC will be used to choose the model with the best fit. Percent days heavy drinking (PDHD) will be analysed using similar methods as PDA.

For binary outcomes, the intervention effect will be reported as the prevalence ratio estimated using the marginal standardisation technique with 95%CI for the prevalence ratios

estimated using the delta method following logistic regression (19). Differences in prevalence and 95%CI will also be reported.

For continuous outcomes, the intervention effect will be reported as the difference in mean outcomes between arm, adjusted for baseline values, village (N. Uganda only) and covariates with baseline imbalance. While the outcomes will be modelled initially using ordinary least squares regression, we will investigate the distribution of residuals and consider transforming the outcome if this is appropriate. (This is also discussed in 4.4., model assumption checks.)
As we have only 2 follow-up time points (3 and 12 months) in Northern Uganda and 1 followup point in Ukraine, the analyses will be conducted and interpreted separately for each of these time points.

No interim analyses of outcomes are planned.

4.2. Planned subgroup analyses

For both trials, we will assess the differential effect of the intervention on the primary outcome (percent days abstinent) and at least 1 mental health measure, by severity at baseline and key characteristics related to alcohol misuse and mental health. These are summarized in **box 2** below. In cases where sub-groups will be defined using the distribution of data, these groups will be defined before the data are unmasked.

Box 2. Summary of planned subgroup analyses

Setting	Outcome	Subgroup analysis
N. Uganda	PDA	• Severity of alcohol use at baseline, measured using AUDIT (AUDIT≥13) • 3 age categories: 30 years and younger, 31-60 years, 61 years and older. Age categories to be confirmed after reviewing distribution of data • Ethnic background • Number of years displaced, grouped into higher and lower numbers based on distribution in data
N. Uganda	K10	• Severity of mental distress at baseline, measured using K10 (K10>30) • 3 age categories: 30 years and younger, 31-60 years, 61 years and older. Age categories to be confirmed after reviewing distribution of data • Ethnic background • Number of years displaced, grouped into higher and lower numbers based on distribution in data
Ukraine	PDA	• Severity of alcohol use at baseline, measured using AUDIT (AUDIT≥13) • 3 age categories: 30 years and younger, 31-60 years, 61 years and older. Age categories to be confirmed after reviewing distribution of data • Number of times displaced, grouped into higher and lower numbers based on distribution of data • Rural v. urban place of residence • Married v. not currently married

Ukraine	• MHAI PTSD measure • MHAI anxiety measure • MHAI depression measure	• Severity of mental distress at baseline, measured using MHAI combined score (MHAI combined score >50) • 3 age categories: 30 years and younger, 31-60 years, 61 years and older. Age categories to be confirmed after reviewing distribution of data • Number of times displaced, grouped into higher and lower numbers based on distribution of data • Rural v. urban place of residence • Married v. not currently married

4.3. Additional statistical considerations

Missing baseline data

The number of participants with complete data will be reported and missing values will be imputed using an appropriate method as per the recommendations of White and Thompson (20), such as mean imputation.

Missing outcome data

We will investigate patterns of missing data by sociodemographic and clinical characteristics. Where missing outcome data are substantial, we will use multiple imputation to impute outcome data using multiple imputation. Results estimated using multiple imputation will be considered the primary results, but we will report complete case results as a sensitivity analysis (21). Where missing outcome data are rare and do not appear to be patterned by participant characteristics, we will use complete case analysis.

Model assumption checks

We will investigate models of continuous outcomes to confirm that the assumptions of ordinary least squared regression are met by the data. We will plot model residuals to check for normality and inspected for outliers. If substantial departures from normality occur, transformations will be considered. If a suitable transformation cannot be found, a nonparametric analysis will be considered.

A sensitivity analysis that assesses the effect of deviations from the missing at random assumption on the intention to treat treatment differences for the primary outcomes may be considered if there are considerable amounts of missing data (7). Sensitivity analysis will be conducted to allow for the comparison of results with imputation and results estimated using complete case analysis only.

5. References

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6. Figures and tables

Figure 1. Consort diagram, CHANGE trial Northern Uganda

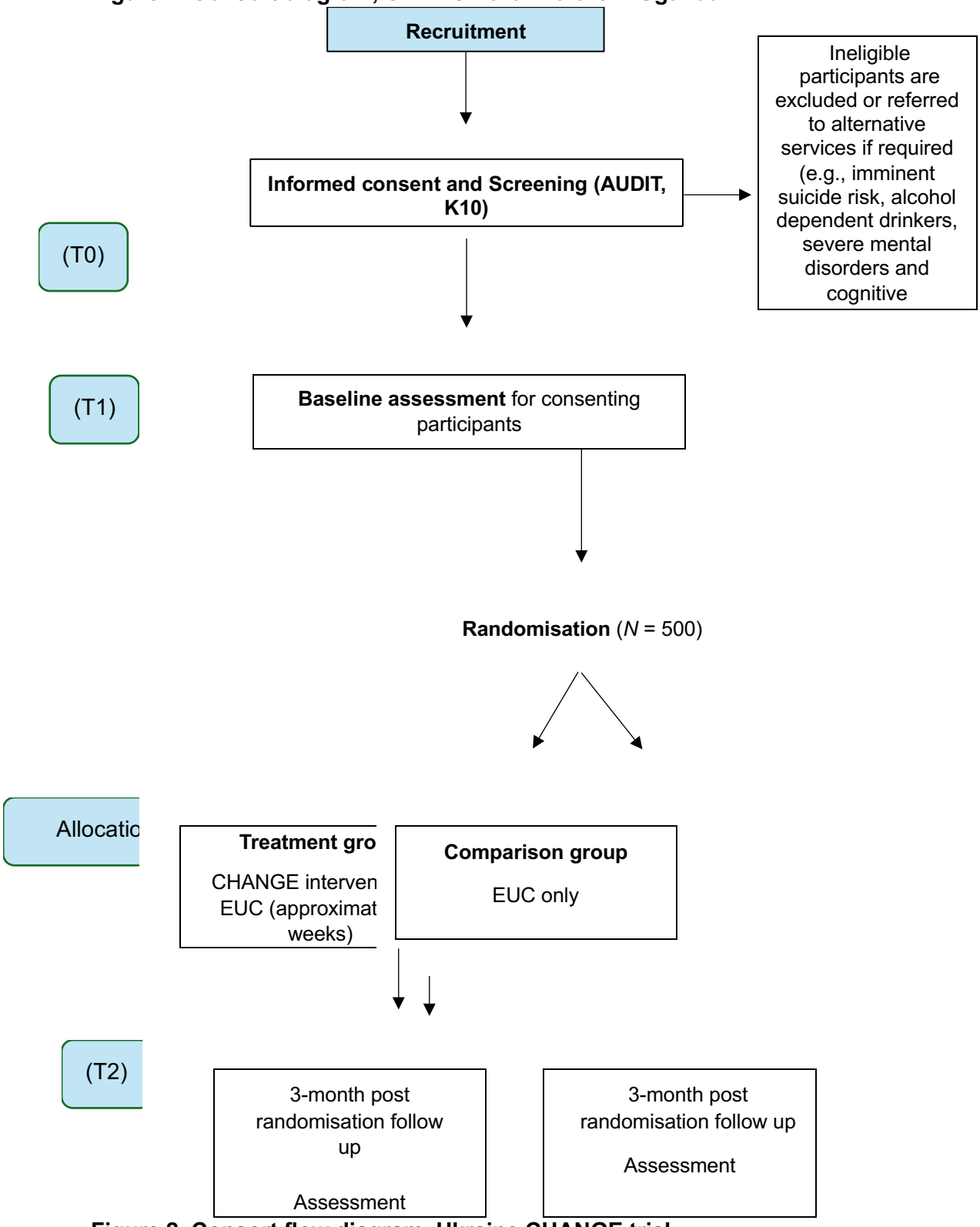
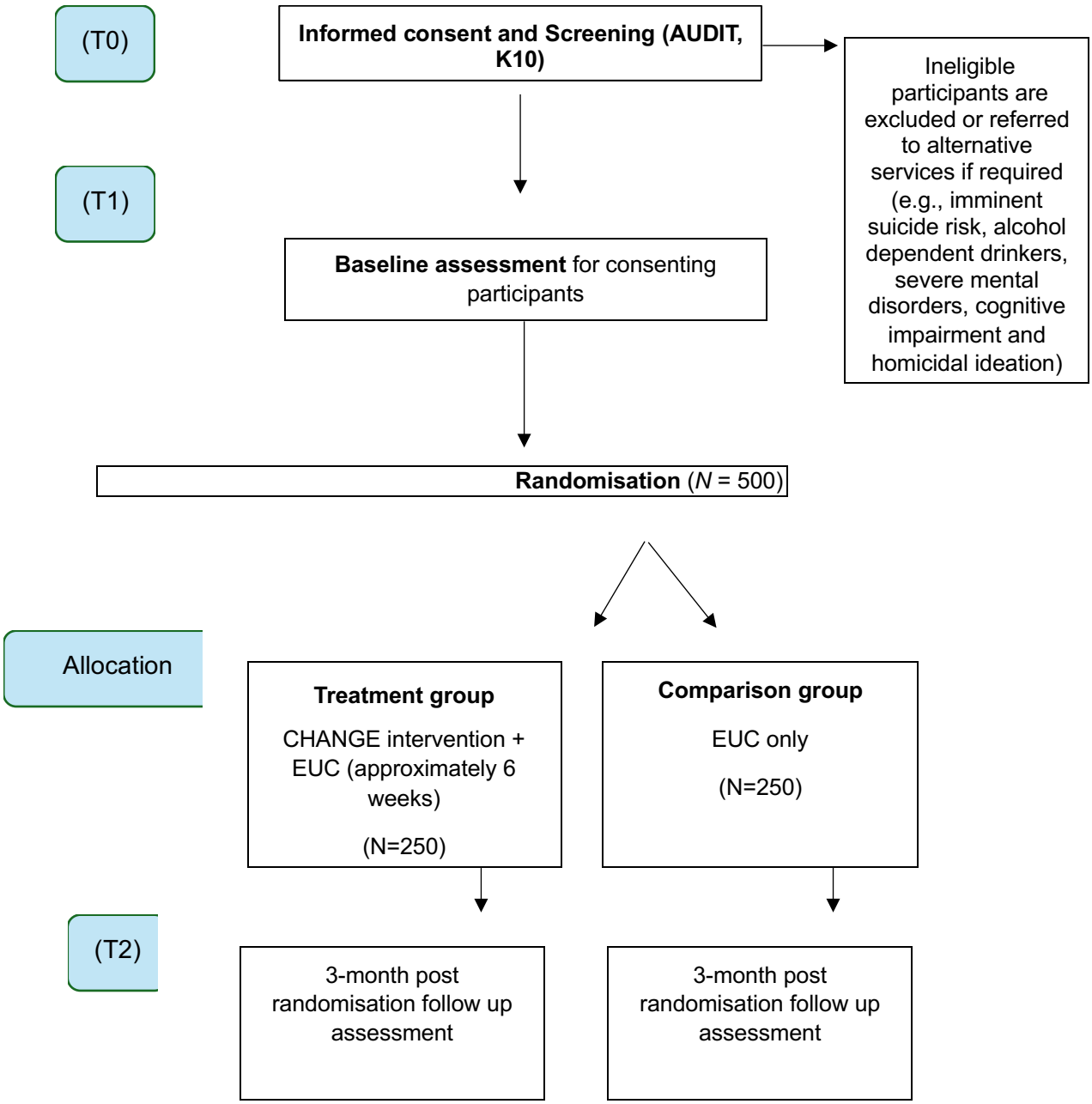


Figure 2. Consort flow diagram, Ukraine CHANGE trial



List of planned tables Table 1. Sociodemographic characteristics of respondents

- Will include all sociodemographic items listed in participant balance checks above, measured at baseline (outcomes will be listed in table 2)

Table 2. Effect of CHANGE intervention on primary and secondary outcomes

- Will include baseline and follow-up summary values (i.e., mean/SD or frequency)
- Model results, CIs, and p-values
- Main effects only – subgroup analyses and interaction in table 3 **Table 3.**

Subgroup analyses

- Subgroup analyses and interaction p-values

Table 4. Dose and fidelity analysis

- Will include summary of dose received and fidelity measures **Additional sensitivity analyses…**

- Complete case analysis if MI used
- Additional sensitivity analyses if substantial missing data (delta adjustment?)
- Exclude participants with data collected well before or after expected follow-up date