Testing the effectiveness of a transdiagnostic treatment approach in reducing violence and alcohol abuse among families in Zambia: study protocol of the Violence and Alcohol Treatment (VATU) trial

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Background. Violence against women and girls (VAWG) is a recognized global health and human rights problem. In 2010, approximately one in three adult women were

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Key words: Alcohol, common elements treatment approach, interventions, intimate partner violence, low- and middle-income country, randomized clinical trial.

Background

Violence against women and girls (VAWG) is a recognized global health and human rights problem. In 2010, approximately one in three adult women were
estimated to have experienced either physical or sexual intimate partner violence (IPV) in their lifetime (Devries et al. 2013). For a substantial proportion of these women, the physical violence experienced is severe, and poly-victimization is common (Garcia-Moreno et al. 2006). A recent systematic review of population-based surveys identified that approximately half of children in Asia, Africa, and North America experienced some form of violence in the past year, with violence in the home the predominant form for children between the ages of 2 and 14 (Hillis et al. 2016). Global prevalence estimates indicate that child sexual abuse victimization occurs in approximately one out of every eight children (Stoltenborgh et al. 2011). In a multi-national study, Zambia, the location of the present study, was found in a multi-national study to have the highest percentage of ever married women reporting IPV (48%) (Kishor & Johnson, 2004), and our own studies indicate that a substantial percentage of youth are exposed to a high number and wide range of violence experiences (Murray et al. 2006, 2015).

Violence has many repercussions. IPV in women is associated with severe injury, gynecological problems, chronic pain, increased risk of sexually transmitted infections (including HIV), poorer overall self-rated health, alcohol use, post-traumatic stress, depression, anxiety, and suicidal ideation, with more severe symptoms linked to poly-victimization (Campbell, 2002; Ellsberg et al. 2008; Trevillion et al. 2012; Dillon et al. 2013; Devries et al. 2014; Lagdon et al. 2014; Li et al. 2014). Experiencing abuse and witnessing violence as a child are associated with a wide range of negative outcomes, including injury, developmental deficits, risk-taking behaviors, poor physical health, mental health problems, and death (Campbell & Lewandowski, 1997; Felitti et al. 1998; Springer et al. 2007; Irish et al. 2010). Further, research shows that witnessing or experiencing violence within the home predicts victimization and perpetration of violence in later life (Abramsky et al. 2011; Fulu et al. 2013; Fonseka et al. 2015).

Partner alcohol abuse is a strong predictor of experiencing IPV (Abrahams et al. 2004; Jewkes et al. 2006; Capaldi et al. 2012). Women whose husbands frequently return home drunk have an increased risk of experiencing abuse (Abramsky et al. 2011; Fulu et al. 2013). The role of alcohol use in IPV perpetration and experience is a particular concern in low- and middle-income countries (LMIC), specifically in sub-Saharan Africa, where rates of problematic alcohol use are increasing (Shield et al. 2013). Mental health problems, particularly depression and post-traumatic stress disorder, have also been associated with experiencing (Iverson et al. 2011; Kuipers et al. 2012) and perpetrating (Fulu et al. 2013; Oram et al. 2014) violence.

Economic and social ‘structural’ interventions have demonstrated effectiveness for addressing some risk factors (e.g. inequitable gender norms) of violence, but findings for actual reductions in its occurrence are mixed (Bouey et al. 2015). Although these structural interventions are essential to broad primary prevention of IPV, the complex inter-relationship between violence, alcohol, and mental health suggests a need for integrated approaches that include treatments targeting high-risk groups (Guedes et al. 2016). Two trials conducted in the USA suggest cognitive–behavioral therapy (CBT) interventions and alcohol treatment combined with violence prevention programs show promise for impacting some types of IPV (Tirado-Muñoz et al. 2014; Wilson et al. 2014). Given the high rate of IPV in LMIC and the dearth of evidence-based interventions in these settings, more studies are needed to evaluate approaches that address high-risk families affected by IPV, alcohol use, and/or mental health problems.

This paper describes: (1) the process of adapting an evidence-based, modular transdiagnostic treatment approach (common elements treatment approach; CETA) (Murray et al. 2014) to address violence and alcohol abuse, and (2) the protocol for testing CETA in an ongoing randomized controlled trial. The trial is part of a larger consortium of studies, the What Works to Prevent Violence Against Women and Girls Programme (http://www.whatworks.co.za/), investigating the underlying causes of VAWG and strategies for prevention in LMIC. The primary aims of the trial are to evaluate the effectiveness of the adapted CETA intervention on (a) reducing and preventing women’s experience of IPV and (b) reducing male partner’s hazardous alcohol use.

**Methods/design**

**Overview of study design**

The Violence and Alcohol Treatment (VATU) study (vatu means ‘ours’ in Nyanja, a commonly spoken language in Zambia) is a parallel group randomized clinical trial comparing the effectiveness of CETA to treatment as usual (TAU) among family ‘units’ consisting of three individuals: an adult woman, her male husband or partner, and one of her children (male or female, ages 8–17). The study settings are three high-density, low-resource ‘compounds’ (i.e. neighborhoods) in Lusaka. Eligible families are randomized as a unit to CETA or to TAU. All participants are assessed at four time points: (1) baseline; (2) 4–5 months (following CETA completion); (3) 12 months; and (4) 24 months post-baseline. The study flow is illustrated in Fig. 1.
Ethical approval and trials registration

The study has been approved by the Johns Hopkins Bloomberg School of Public Health Institutional Review Board and the University of Zambia Biomedical Research Ethics Committee. The trial is registered at ClinicalTrials.gov (NCT02790827; date of registration 05/24/2016). The study methods described below cover the recommended items to address in a clinical trial protocol according to SPIRIT (Chan et al. 2013).

Recruitment

Initial recruitment, screening, baseline assessment, and randomization for the study were conducted between May and July 2016. Following principles of community-based participatory research, our research
staff met with community leaders in each compound to discuss the purpose and procedures of the trial prior to its initiation and organized larger meetings open to the community where questions and concerns about the study were addressed. We have found in previous studies in Zambia that this type of community involvement is essential to success (Murray et al. 2006; Kane et al. 2016b). This approach also enabled collaboration with local leaders in identifying community members who they felt were suitable candidates for being hired and trained as CETA counselors. Recruitment of study participants was subsequently conducted by these study counselors. This provider-based recruitment strategy was employed because it is the current method for outreach used by our partnering organization in Zambia for similar behavioral interventions and it has been found to be culturally acceptable and feasible for potentially sensitive topics, such as alcohol use.

Counselors received a 1-day training in recruitment procedures before going door-to-door in their communities with a script to assist in explaining the purpose of the study to families. Counselors worked in male/female pairs when visiting families’ homes, so that women could speak alone to a counselor of the same sex. To ensure that participation in the study would not exacerbate or lead to IPV, counselors specifically asked the women about possible risks. If the woman expressed concern for her safety, the counselor offered her information on, or assistance in, accessing services. Women with a child between the ages of 8–17 were asked if they would like to provide permission for the child to participate. Women with more than one child were encouraged to select the child whom they perceived as being most affected by the violence in the home. Families without a child in this age range or those that did not want a child to participate were still able to join the study as a couple.

Eligibility screening

Families who expressed interest in the study were invited to participate in an eligibility screening at a later date, typically within 1 week, at a site in their community (i.e. school, church, or community center). Study assessors met with families privately and provided a brief overview of the purpose and procedures of the study to all family members (i.e. the woman, man, and child). Informed consent was then obtained with each family member separately in a private space. Consent was obtained for all study activities (screening, assessments, and intervention).

Following informed consent, the woman and her male partner separately completed an eligibility screener. For women, this consisted of the Severity of Violence Against Women Scale (SVAWS; Marshall, 1992), for assessing recent IPV; and the Alcohol Use Disorders Identification Test (AUDIT; Saunders et al. 1993), for measuring her report of her partner’s hazardous drinking. Men only completed a self-reported AUDIT. To be eligible, (a) the woman had to report recent (past 12 months) experience of at least a moderate level of violence (SVAWS physical violence subscale score of $\geq 38$) and (b) she or her partner had to report that he has engaged in hazardous alcohol use (AUDIT score of $\geq 8$). Additional eligibility criteria are detailed in Box 1.

The screener was administered using a laptop-based Audio Computer Assisted Self-Interviewing (ACASI) system. ACASI was chosen for use because previous studies have found that it elicits more valid responses to questions on sensitive behaviors than face-to-face interviewing and because it is feasible and acceptable among this study population (Langhaug et al. 2010; Kane et al. 2016a, b). ACASI scored the screener immediately, and if the family was determined to be eligible, the assessor administered the full assessment battery (approximately 2 additional hours total; see Box 1.

Box 1. Inclusion and exclusion criteria for the VATU trial.

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
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<tbody>
<tr>
<td>1. The family must live in one of the three study compounds in Lusaka (i.e. cannot only be staying temporarily).</td>
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<tr>
<td>2. All family members must speak at least one of the three study languages: English, Bemba, or Nyanja.</td>
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<td>3. The family must consist of an adult (aged 18 years or older) female and adult male in a relationship (i.e. married or dating). In addition, the woman has the choice (if applicable) to identify one of her children between the ages of 8 and 17 for inclusion in the study.</td>
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<tr>
<td>4. Both the adult female and her male partner must provide consent. For one of her children to also participate, the woman’s permission and the child’s assent are required.</td>
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<tr>
<td>5. The adult female must score 38 or more on the Severity of Violence Against Women Scale (SVAWS; physical violence subscale) indicating experience of at least a moderate amount of intimate partner violence.</td>
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<tr>
<td>6. The adult male must have a score of 6 or higher on the Alcohol Use Disorders Identification Test (AUDIT) as reported by himself or his partner, indicating that he drinks alcohol at hazardous levels.</td>
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<tr>
<th>Exclusion criteria</th>
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<tr>
<td>1. No family member can currently be on an unstable (i.e. altered in last 2 months) psychiatric drug regimen.</td>
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<td>2. No family member has had a suicide attempt or suicidal ideation accompanied by intent, a plan, or self-harm in the past month.</td>
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<td>3. No family member has been diagnosed with a current psychotic disorder (identified by the University of Zambia Teaching Hospital Psychiatric Unit).</td>
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<tr>
<td>4. No family member has a serious developmental disorder (e.g. mental retardation, autism) that would preclude participation in a cognitive-behavioral oriented skills intervention or completing the assessment battery.</td>
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</table>
Assessments section below) separately to all participating family members. If the family was ineligible, the assessor discussed services in the community that may be appropriate. Following administration of the full ACASI, any participant who reported suicidal ideation, homicidal ideation, or who was currently experiencing violence, was flagged as ‘high risk’. ACASI automatically alerted the assessor about the high-risk status, and the assessor immediately activated a standardized safety plan (included in full as online Supplementary material and summarized in Box 2).

**Randomization and blinding**

All participants were assigned a unique ID number following informed consent procedures. ID numbers of eligible participants were forwarded from the assessors to the Zambia-based study director at the end of each day, who then sent them to a designated US-based research staff member who was not involved in clinical activities. The US-based staff member maintained a computer-generated (via Microsoft Excel) 1:1 randomization sequence stratified by study compound and in blocks of 20 (i.e. each 20 assignments included 10 CETA and 10 TAU). Each of the three lists contained a sequence of treatment assignments in random order. These lists were not available or viewable to any staff in Zambia. The US-based research staff member would assign a family to the next available slot on the randomization sequence. Eligible families were contacted within a day of randomization to inform them of their status. Study assessors and data analysts were masked to randomization status at the baseline assessment and will remain blinded throughout the duration of the study.

**Interventions**

**CETA**

CETA is a transdiagnostic mental health intervention developed for delivery by non-professionals in LMIC (Murray et al. 2014). The development of CETA (Table 1) was based on research of common elements or transdiagnostic treatment approaches used in the USA (Chorpita & Daleiden, 2009; Farchione et al. 2012; Weisz et al. 2012), but with a focus on being appropriate for training and delivery by non-
professional (i.e. lay providers) in lower resource settings (Murray et al. 2014). CETA is not a ‘new’ treatment but rather an approach that teaches CBT elements common to evidence-based treatments (Chorpita et al. 2005) for trauma, anxiety, depression, and behavioral problems. As a CETA, this approach allows a counselor to flexibly decide on what element(s), order, and dose are needed depending on presentation. CETA was chosen as the intervention due to its evidence base and its modular transdiagnostic design. CETA is currently the only transdiagnostic model with two rigorous clinical trials in LMIC that each show strong effect sizes across a range of symptoms: (a) on the Thailand/Myanmar border with Myanmar refugees (N = 347; ES: 1.19 post-traumatic stress, 1.16 depression, 0.79 anxiety) (Bolton et al. 2014) and (b) in Southern Iraq with survivors of conflict, torture, trauma, and ongoing stressors (N = 149; ES: 2.40 post-traumatic stress, 1.82 depression, 1.60 anxiety) (Weisz et al. 2015). These findings provide some evidence of effectiveness for CETA with adults, as well as ability of lay providers to learn this type of modular, flexible approach. In Ethiopia, results showed significant decreases in symptoms of internalizing (d = 1.37), externalizing (d = 0.85), and post-traumatic stress (d = 1.71) symptoms, and improvements in well-being (d = 0.75) (Murray et al. under review). The modular nature of CETA allowed us to develop and adapt the elements and flows to fit our study population.

For this study, CETA was originally planned and initially implemented as a group treatment. Groups were set up to be specific to one participant type (i.e. men, women, or children) and composed of 5–7 individuals. Group assignment was based on the participants’ language, residence, and age (for youth groups). Each group was run by two trained providers pre-paired based on language fluency and location. Specifically, counselors were not allowed to work in or near the neighborhoods where they reside to reduce counselor

<table>
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<tr>
<th>Component</th>
<th>Simplified name (used in training)</th>
<th>Description</th>
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| Psychoeducation and engagement         | Introduction                      | • Focus on obstacles to engagement  
• Linking program to assisting with client’s problems  
• Includes family when appropriate  
• Program information (duration, content, expectations)  
• Normalization/validation of current symptoms/problems  
• Strategies to improve physiological stress  
• Examples include: deep breathing, meditation, muscle relaxation, and imagery. Others added by local cultures |
| Anxiety management strategies          | Relaxation                        | • Strategies to improve physiological stress  
• Examples include: deep breathing, meditation, muscle relaxation, and imagery. Others added by local cultures |
| Behavioral activation                  | Getting active (GA)               | • Identifying and engaging in pleasurable, mood-boosting, or efficacy-increasing activities |
| Cognitive coping/restructuring         | Thinking in a different way – part I and part II (TDW1 and TDW2) | • Understand association between thoughts, feelings, and behavior  
• Learn to restructure thinking to be more accurate and/or helpful |
| Imaginal gradual exposure              | Talking about trauma memories (TDM) | • Facing feared and avoided memories in detail  
• Gradual desensitization/exposure |
| In vivo exposure                       | Live exposure                     | • Facing innocuous triggers/reminders in the client’s environment  
• Gradual desensitization/exposure |
| Suicide/homicide/danger assessment and planning | Safety | • Assessing client risk for suicide, homicide, and domestic violence  
• Developing a focused plan with the client and client’s family (when appropriate)  
• Additional referral/reporting when needed |
| CBT for substance use and relapse prevention | Substance use element (SU) | • Utilizes motivation and CBT principles and activities to get client buy-in and alter behavior patterns to change substance use/abuse behavior |
| Safety planning and violence prevention | Safety and violence prevention    | • Walks through detailed safety plans specific to IPV  
• Discusses behavioral or situational modifications that may help prevent violence |
bias and ensure client anonymity. Groups were designed to run for 90–120 min, with each session beginning with a tea time where participants could socialize to promote group cohesion and motivate regular and punctual attendance. Delivery of CETA included varying elements and ‘dose’ of elements (i.e. the number of sessions or time spent on it) depending on clients’ symptoms, with a suggested 6–12 weekly sessions depending on need. Figure 2 shows a common flow for the men’s, women’s, and children’s group with comments on what might be added for flexibility based on need.

CETA was adapted for this trial to include a CBT-based substance use (SU) reduction element. CBT for SU disorders has demonstrated efficacy as both a mono-therapy and as part of combination treatment strategies (McHugh et al. 2010). Evidence from numerous large-scale trials and reviews support the efficacy of CBT for alcohol and drug use disorders (Dutra et al. 2008; Magill & Ray, 2009). Typically, CBT for SU includes any or a combination of the following: (a) motivational enhancement strategies, which target ambivalence to behavior change related to substances (Miller & Rollnick, 2013); (b) contingency management approaches, which work on countering the reinforcing effects of substances and providing positive reinforcemements tied to non-using decisions; (c) relapse prevention, which applies a functional analysis of personalized SU cues (e.g. places, smells, people, etc. that promote urges to use) and implementation of alternative/competing responses to these cues.

Two authors drafted the SU element (LKM and CKD), which was then reviewed by other CETA trainers, SU treatment experts, and local counselors from Zambia who had provided other CBT treatments (i.e. trauma-focused CBT; Murray et al. 2015). Within the CETA SU element, there were motivational statements, including asking participants at multiple time points throughout the session to determine a behaviorally specific goal and rate their motivation to complete that goal. Adapted from other empirically supported SU treatments (Henggeler et al. 2002; Danielson et al. 2012), this component also includes helping participants identify all of the drivers that underlie their drinking behavior (e.g. boredom, passing the bar on their way home, coping with stress). Specific interventions and strategies that counter this list of individualized reasons listed (e.g. behavior replacement, avoidance) are then taught to the participants and practiced. The session is completed with revisiting the individual goals and the motivation to work toward or complete that goal. This component was designed in the context of this study to be delivered to all men, and also any women who also reported substance abuse.

Since our population of interest was the family unit, and our primary outcome is prevention of violence (which commonly co-occurs with SU; Widom & White, 1997) our team also developed a ‘SU support’ element that was delivered to the women when applicable. Utilization of a family support system, including family-based approaches, has been shown to be an efficacious approach to decreasing SU and relapse in other

![Fig. 2.](https://www.cambridge.org/core. IP address: 54.70.40.11, on 22 Jan 2020 at 20:25:27, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/gmh.2017.10)
populations (Waldron & Turner, 2008). In CETA, the
SU support element is designed to: (a) provide psy-
choeduction about the SU to the partner of the sub-
stance abuser, (b) to have the partner help in
identifying the user’s drivers (e.g. why the participant
uses), and (c) to help the partner identify ways in
which she can support the reduction of use (e.g. plan
activities that are not at a bar, offer a favorite dinner
with a beer at home).

The apprenticeship model of training and supervi-
sion is being used to deliver CETA (Murray et al.
2011). A 10-day in-person CETA training was con-
ducted by study authors (LKM and SSVw), followed
by weekly small group meetings in which lay coun-
selors practiced the treatment elements with a local
supervisor (before providing CETA to clients). Sixty-three lay counselors (20 male, 43 female) and
seven supervisors (3 male, 4 female) between the
ages of 20 and 60 years (average age 33.7 years) were
trained in February and March 2016. Supervisors of
CETA completed one pilot treatment group to
strengthen their skills and understanding of the com-
ponents decision-making process and CETA treatment.
Counselors continue to meet in small groups and
receive supervision on each case throughout the
study. Weekly meetings are also continuously held
between each local supervisor and a CETA trainer
(SSVw in person, LKM via skype) for 2–3 h to either
review group role-plays or discuss CETA cases.

**Treatment as usual**

The control condition is defined as TAU. In Zambia, no
formal services or standard of care exists for IPV or
alcohol use problems. There are some organizations
that provide services such as informal counseling
from parish priests, church officials, or other commu-
unity leaders. At the beginning of the study, all partici-
ants were provided a list of relevant services in
Lusaka. We did not exclude any families based on hav-
ing received these types of services and do not in any
dissuade families from accessing these types of
services or information during the study.

**Assessment of outcomes and follow-up**

Post-assessments were conducted with participants
starting in October 2016 and are ongoing. All post-
assessments (4/5, 12, and 24 months post-baseline)
are conducted in the same format (i.e. ACASI), and
at the same locations as baseline. At baseline and all
follow-up visits, participants are provided with reim-
bursement for travel. The primary outcome in the
study is violence as measured by the SVAWS.
Secondary outcomes include alcohol and other SU,
mental health, psychological violence, and gender
norms. Each participant type (woman, man, child)
completes a specific battery of instruments via
ACASI. The measures included in ACASI were tested with participants sampled from the same source
population as those in the trial to check translation
accuracy and item comprehension. In addition to the
self-report measures administered via ACASI, a hair
sample is collected from participants as a biomarker
of chronic stress (Russell et al. 2012). The full list of out-
come instruments is displayed in **Table 2**.

In addition to the primary assessment time points,
participants are tracked weekly during the interven-
tion phase. For CETA participants, counselors admin-
ister a brief symptom monitoring form and the
Alcohol Timeline Followback (TLFB; Sobell & Sobell,
1992) at each session. Additionally, the Short
Inventory of Problems (SIP; Tonigan & Miller, 2002),
which measures consequences associated with alcohol
misuse, is administered at the first and last CETA ses-
sion. Control participants receive weekly phone calls or
home visits from our research staff to assess safety dur-
ing the intervention period and complete the Alcohol
TLFB and brief symptom monitoring form monthly.
Following the first ACASI post-assessment, both con-
trol and intervention participants receive monthly
safety check-in phone calls from the research team.

**Data and safety monitoring**

The trial is monitored by a four-person Data Safety
Monitoring Board (DSMB). It was mutually deter-
mined between DSMB members and study investiga-
tors that if the CETA intervention displayed
statistically significant effectiveness with at least a
moderate effect size at the 12-month follow-up asses-
ment, it would be ethically appropriate to stop the trial
and offer the intervention to control participants.
Therefore, the DSMB will conduct an effectiveness anal-
ysis following the completion of the 12-month post-
baseline assessments. The trial will be unmasked and
stopped if there is a statistically significant difference
between the change in primary outcome (i.e. SVAWS
score among female participants) by treatment arm,
defined as a Cohen’s d effect size of ≥0.5 and a p
value of <0.05. In that scenario, control participants
would not be assessed at 24 months post-baseline but
would be offered CETA, and CETA participants
would still be assessed at 24 months as planned to
measure whether treatment effects were sustained. If
no significant difference in change in SVAWS score by
treatment arm is found in the 12-month DSMB ana-
lysis, the trial will continue as planned with all partici-
ants assessed at the primary study endpoint of 24
months (see **Fig. 1**).
### Table 2. Primary and secondary outcome measures for VATU trial

<table>
<thead>
<tr>
<th>Measure</th>
<th>Construct</th>
<th>Reference</th>
<th>Description</th>
<th>Cronbach’s α&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcome</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Severity of Violence against Women Scale</strong></td>
<td>Violence</td>
<td>Marshall (1992)</td>
<td>46 items assessing how often (never, once, a few times, many times) a current partner perpetrated acts of violence against the participant in the past year. Subscales include: (a) threats of violence; (b) physical violence; and (c) sexual violence. Previously used in a study of IPV among women with partners who have alcohol abuse in South Africa (Peltzer &amp; Pengpid, 2013)</td>
<td>0.95</td>
</tr>
<tr>
<td><strong>Secondary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>World Health Organization IPV measure (WHO-IPV)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Violence</td>
<td>World Health Organization (2005)</td>
<td>Nine items assessing how many times a current or previous partner ever and recently perpetrated acts of violence (never, once, a few, many). Previously used in the WHO multi-country study on Women’s Health, including in Tanzania and Namibia</td>
<td>0.95 0.96 –</td>
</tr>
<tr>
<td>Youth Victimization Scale (YVS)</td>
<td>Violence</td>
<td>Nadel et al. (1996)</td>
<td>135 items assessing how often (never, once, sometimes, often) youth have experienced various types of recent violence at school, in the neighborhood, and at home</td>
<td>– – 0.98</td>
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<tr>
<td>Alcohol Use Disorders Identification Test (AUDIT)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Alcohol</td>
<td>Saunders et al. (1993)</td>
<td>10 items assessing hazardous alcohol use. Scores of ≥3 for women and ≥4 for men are considered hazardous. Previously validated in Zambia (Chishinga et al. 2011)</td>
<td>0.88 0.85 –</td>
</tr>
<tr>
<td>Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST)</td>
<td>Drug use</td>
<td>Humeniuk et al. (2008)</td>
<td>Seven items assessing frequency and consequences of use for a range of substance types. Previously validated in Zambia (Kane et al. 2016a)</td>
<td>0.97 0.97 0.98</td>
</tr>
<tr>
<td>Center for Epidemiological Studies-Depression Scale (CES-D)</td>
<td>Depression</td>
<td>Radloff (1977)</td>
<td>20 items assessing frequency of depression symptoms over the past week (never, 1–2, 3–4, 5–7 days). Previously validated in Zambia (Chishinga et al. 2011)</td>
<td>0.92 0.90 –</td>
</tr>
<tr>
<td>Youth Self Report</td>
<td>Mental/behavioral health</td>
<td>Achenbach (1991)</td>
<td>112 items assessing occurrence of child mental health symptoms and behaviors in the past 4 weeks. Response options are: not true, sometimes true, very true. Subscales assess internalizing symptoms and externalizing behaviors. Validation study among adolescents in Zambia currently underway as part of an ongoing study (clinicaltrials.gov # NCT02054780)</td>
<td>– – 0.98</td>
</tr>
<tr>
<td>Harvard Trauma Questionnaire (HTQ)</td>
<td>Trauma/post-traumatic stress disorder (PTSD)</td>
<td>Mollica et al. (1992)</td>
<td>17 items assessing lifetime experience of a range of traumatic events. 39 items assessing symptoms of post-traumatic stress in the past week (not at all, a little, quite a bit, extremely)</td>
<td>0.96 0.95 –</td>
</tr>
<tr>
<td>Child PTSD Symptom Scale (CPSS)</td>
<td>Trauma/PTSD</td>
<td>Foa et al. (2001)</td>
<td>14 items assessing lifetime experience of a range of traumatic events. 17 items assessing symptoms of post-traumatic stress in youth in the past 2 weeks (never, once in a while, more than half the time, almost always). Validation study among adolescents in Zambia currently underway as part of an ongoing study (clinicaltrials.gov # NCT02054780)</td>
<td>– – 0.93</td>
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</table>

(Continued)
Sample size calculations were informed by a study conducted in South Africa that used the SVAWS physical violence subscale to measure violence among women who had been abused by a partner with an alcohol use problem (Peltzer & Pengpid, 2013). We calculated the sample size needed to obtain a 20% reduction in SVAWS physical violence subscale score among intervention participants at a 24-month follow-up, assuming no change among control participants, using a two-sample independent means \( t \) test. For 80% power at an \( \alpha \) level of 0.05, we calculated that we would need to enroll a minimum of 50 families in each study arm to detect this difference in change in means, which we inflated to 84 per arm to account for loss to follow-up and the possibility of small clustering effects at the provider level.

All primary analyses will be based on an intent-to-treat approach with all participants who were randomized included in the final analysis. Loss to follow-up and missing data will be addressed by using multiple imputation (Azur et al., 2011). We will estimate linear (continuous outcomes) and generalized linear (binary outcomes) mixed-effects models that will incorporate a random intercept term to account for within-subject correlation on repeated measures. The outcome scores at the three follow-up times will be modeled separately using treatment arm, baseline symptom score (if there is a meaningful difference between the study arms at baseline), time, and an interaction between the study arms at each visit to detect this difference in change in means, which we inflated to \$1 per arm to account for loss to follow-up and the possibility of small clustering effects at the provider level.

We modified the delivery of CETA from group to individual. After the first few weeks of intervention delivery, multiple participants were missing group sessions due to logistical challenges (e.g., work, childcare), which necessitated CETA providers to conduct separate individual sessions for participants who were absent. It became challenging for providers to keep up with the many in-between group sessions they had to conduct, and then also had to repeat material in groups if an individual missed and was not available in between group sessions. Participants also reported frustration in that they did not want to participate but there was no flexibility for tardiness (in Zambia, this may be defined as an hour or more late) or work/family scheduling within groups. The challenges were substantial enough that we would not recommend group CETA in Lusaka, Zambia (urban area), even if it was found to be clinically effective. We therefore modified CETA to be individually delivered. Participants initiating CETA before this change could switch to receiving individually delivered CETA before the trial.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Construct</th>
<th>Reference</th>
<th>Description</th>
<th>Cronbach’s ( \alpha )a</th>
<th>Woman</th>
<th>Man</th>
<th>Child</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aggression Scale</td>
<td>Aggression</td>
<td>Orpinas &amp; Frankowski (2001)</td>
<td>11 items assessing frequency (range of 0 times to 6+ times) of youth aggressive behaviors over the past week</td>
<td>–</td>
<td>–</td>
<td></td>
<td>0.87</td>
</tr>
<tr>
<td>Gender Equitable Men’s Scale (GEMS)</td>
<td>Gender norms</td>
<td>Pulerwitz &amp; Barker (2007)</td>
<td>24 items assessing the degree to which adult participants agree (agree, partially agree, do not agree) with statements on gender norms</td>
<td>0.88</td>
<td>0.89</td>
<td></td>
<td>–</td>
</tr>
<tr>
<td>Index of Psychological Abuse (IPA)</td>
<td>Psychological violence</td>
<td>Sullivan &amp; Bybee (1999)</td>
<td>33 items assessing how often a partner perpetrated psychological abuse over the past 3 months (never, rarely, sometimes, often)</td>
<td>0.94</td>
<td>–</td>
<td></td>
<td>–</td>
</tr>
<tr>
<td>Hair sample for cortisol biomarker</td>
<td>Chronic stress</td>
<td>Henley et al. (2013)</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td></td>
<td>–</td>
</tr>
</tbody>
</table>

a Cronbach’s \( \alpha \) calculated from all available baseline data
b The woman reports experiencing violence and the man reports perpetration of violence on the WHO-IPV measure
c Participants complete two versions of the AUDIT; one in reference to their own alcohol use and one in reference to their partner’s alcohol use
delivered CETA or continue to attend group sessions based on their preference and the counselor’s assessment of feasibility.

We increased our sample size because of this modification to the delivery of CETA. We plan to conduct a subgroup analysis of only those study participants who received individual (and not group) CETA to test whether this individual delivery mode is effective compared with the TAU control group. Of the 83 families originally randomized to CETA, 33 men and 40 women did not receive a group session (only individual session or sessions). Our original sample size calculation for the CETA arm was \( n = 50 \). To have at least \( n = 50 \) CETA participants who received individually delivered therapy, and taking into account potential for up to 30% loss to follow-up, we recruited and randomized an additional 80 families (again randomizing using 1:1 allocation). The final sample size for the study is thus \( n = 248 \). All the families recruited in this second cohort that were randomized to the CETA arm are receiving individually delivered CETA.

**Discussion**

To our knowledge, this is the first trial to test the effectiveness of a modular transdiagnostic treatment

### Table 3. Baseline participant characteristics

<table>
<thead>
<tr>
<th></th>
<th>Adult female ( (n = 248) )</th>
<th>Adult male ( (n = 248) )</th>
<th>Child ( (n = 130) )</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–25</td>
<td>65 (26.2)</td>
<td>27 (10.9)</td>
<td></td>
</tr>
<tr>
<td>26–35</td>
<td>99 (39.9)</td>
<td>94 (37.9)</td>
<td></td>
</tr>
<tr>
<td>36–45</td>
<td>49 (20)</td>
<td>74 (29.8)</td>
<td>8–9 28 (21.5)</td>
</tr>
<tr>
<td>46–55</td>
<td>25 (10.1)</td>
<td>37 (14.9)</td>
<td>10–11 33 (25.4)</td>
</tr>
<tr>
<td>56–65</td>
<td>7 (2.8)</td>
<td>11 (4.4)</td>
<td>12–13 30 (23.1)</td>
</tr>
<tr>
<td>66+</td>
<td>2 (0.8)</td>
<td>5 (2.0)</td>
<td>14–15 20 (15.4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>16–17 19 (14.6)</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>–</td>
<td>–</td>
<td>70 (53.9)</td>
</tr>
<tr>
<td><strong>HIV positive</strong></td>
<td>101 (40.7)</td>
<td>66 (26.6)</td>
<td>12 (9.2)</td>
</tr>
<tr>
<td><strong>SVAWS physical violence subscale, mean (S.D.)</strong></td>
<td>60.7 (16.8)</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td><strong>Child abuse (physical)</strong></td>
<td>–</td>
<td>–</td>
<td>54 (41.5)</td>
</tr>
<tr>
<td><strong>Child abuse (verbal/emotional)</strong></td>
<td>–</td>
<td>–</td>
<td>49 (37.7)</td>
</tr>
<tr>
<td><strong>AUDIT (self-report), mean (S.D.)</strong></td>
<td>10.7 (11.0)</td>
<td>15.8 (10.4)</td>
<td>–</td>
</tr>
<tr>
<td><strong>Lifetime substance use</strong></td>
<td>116 (47.0)</td>
<td>159 (64.4)</td>
<td>–</td>
</tr>
<tr>
<td><strong>Harvard Trauma Questionnaire (HTQ), mean (S.D.)</strong></td>
<td>1.5 (0.7)</td>
<td>1.3 (0.7)</td>
<td>–</td>
</tr>
<tr>
<td><strong>Child PTSD Symptom Scale (CPSS), mean (S.D.)</strong></td>
<td>–</td>
<td>–</td>
<td>0.7 (0.7)</td>
</tr>
<tr>
<td><strong>Center for Epidemiological Studies-Depression (CES-D), mean (S.D.)</strong></td>
<td>2.2 (0.7)</td>
<td>2.0 (0.6)</td>
<td>–</td>
</tr>
</tbody>
</table>

Values are \( n \) (%) unless otherwise specified and based on all available data at baseline.

\( ^a \) Response of once, sometimes, or often, to item ‘how often have you been beaten at home in the past 12 months’

\( ^b \) Response of once, sometimes, or often to item ‘how often have you been verbally or emotionally abused at home in the past 12 months’

\( ^c \) Any lifetime substance use reported not including alcohol or tobacco on the Alcohol, Smoking, and Substance Involvement Screening Test.
approach on VAWG among families in LMIC by address-
ing risk factors for experiencing violence (among women and children) and perpetrating violence (among men). Given that many of the violence preven-
tion strategies assessed in LMIC are community-based structural approaches (Bourey et al. 2015), the findings of this trial will enhance understanding of the utility of a targeted treatment approach among high-risk populations (i.e. those with recent severe IPV and hazardous alcohol use), and thus inform policy decisions. Effective combinations of structural (e.g. microfinance, legislation, social empowerment community programs) and clinical (e.g. CBT, CETA) strategies warrant future research. The study has already yielded important information about the clinical challenges associated with group-based therapy in urban LMIC settings.

The study design is not without limitation. Child outcomes from this trial will be considered exploratory. For ethical reasons, we did not exclude families without children, those with children who were infants or grown adults, or those that did not want a child to participate in the study. This resulted in a relatively small number of youth ($n = 130$; 52.4% of recruited families) being enrolled and the study not being pow-
ered to assess change in child outcomes. If the results of these exploratory analyses are promising, future trials should include a larger sample of children, when possible, to better ascertain the effectiveness on family members.

Despite this limitation, our study design is character-
ized by several important strengths. This trial uses the most robust design feasible in Zambia to measure the effectiveness of CETA: randomization with masking at the assessor level, ACASI-administered assessments, a TAU comparator, and multiple outcome time points with an extended follow-up period relative to many previous investigations of violence interventions in LMIC (Bourey et al. 2015). The primary violence outcome is based on an indicator of violence severity (SVAWS), which enhances the statistical power of the study and provides a more nuanced measure of violence experiences than more commonly used binary indicators. Finally, we have instituted an intensive safety plan for study participants, which may be useful for future research with similarly high-risk populations.

We believe that this study has the potential to be generalizable to other low resource settings with popu-
lations affected by violence and/or SU. Similar to most other LMIC, Zambia does not have a mental health infrastructure where providers are trained in evidence-

services available to address these problems. Further, violence and alcohol abuse cut across all cultures and socioeconomic levels – and are very commonly comorbid. In fact, estimates of alcohol use and violence have been reported at high levels across the sub-Saharan Africa region (UNODC, 2012; World Health Organization, 2013). Finally, the trial has few exclusion criteria, which will increase the generalizabil-
ity of findings.

In closing, we believe that the VATU trial will fill a critical gap in current knowledge on the effectiveness of interventions for VAWG in resource-limited settings. Given the significant morbidity and mortality associated with VAWG, rigorously designed effectiveness studies of prevention and reduction strategies are urgently needed. The VATU trial is part of the What Works consortium of studies that currently includes eight impact evaluations across Africa, Asia, and the Middle East. In addition to executing the research, a significant effort of the program is to build capacity of local partners in research design and intervention delivery. Taken together, the capacity building efforts and findings from these ongoing investigations have the potential to inform programming, policy, and research on impactful and cost-effective intervention approaches to reducing VAWG among families in LMIC.

**Supplementary material**

The supplementary material for this article can be found at [https://doi.org/10.1017/gmh.2017.10](https://doi.org/10.1017/gmh.2017.10).

**Acknowledgement**

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**Declaration of Interest**

None.

**Ethical Standard**

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.
References


