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Title: Alcohol Use, Partner Violence, and Mental Health Distress among South African Township Mothers from Pregnancy to Three Years Post-birth: A Cluster Randomized Controlled Trial

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Abstract: Background. Pregnant South African women experience multiple risks from HIV and malnutrition, as well as emotional distress, alcohol use, and partner violence. Purpose. This study examines predictors of maternal outcomes over three years in South Africa, based on a maternal history of drinking alcohol during pregnancy, having partners who become violent, depression, or HIV positive status during pregnancy. Methods. All pregnant women in 24 Cape Town neighborhoods were recruited into a cluster randomized controlled trial (RCT) by neighborhood to either: 1) a standard care condition (n= 12 neighborhoods, n=594 mothers); or 2) a home visiting intervention condition (n=12 neighborhoods, n=644 mothers). Mothers were reassessed at 18 and 36 months post-birth: 80.6% of mothers completed all assessments between 2009 and 2013 and were included in these analyses performed in 2014. Longitudinal structural equation modeling examined alcohol use, partner violence, and emotional distress at the baseline and 18 month interviews as predictors of maternal outcomes at 36 months post-birth. Results. Compared to the standard care, intervention mothers were significantly less likely to have mental health symptoms at 36 months. Alcohol use was significantly related to use over time, but was also related to depression and HIV status at each assessment and partner violence at 36 months. Conclusions. Alcohol, partner violence, and emotional distress are significantly related over time; a home visiting intervention improved the emotional health of these township mothers even when depression was not initially targeted.

Cover Letter (Original Submission)

October 24, 2014

American Journal of Preventive Medicine

Dear Editors:

Attached please find the manuscript "Alcohol Use, Partner Violence, and Mental Health Distress among South African Township Mothers from Pregnancy to Three Years Post-birth: A Cluster Randomized Controlled Trial," by Mary Jane Rotheram-Borus, Mark Tomlinson, Ingrid le Roux and Judith A. Stein. Please consider this manuscript as a research article for possible publication in the *American Journal of Preventive Medicine*.

We verify that all authors have contributed substantially to the conception and design or analysis and interpretation of the data, as well as the drafting or revision of the content, and have approved the final version. The protocol for this study was approved by the Institutional Review Board of the University of California, Los Angeles. This paper was completed with the support of funding from the National Institute on Alcohol Abuse and Alcoholism, #R01-AA017104, and NIH grants MH58107, 5P30AI028697, and UL1TR000124.

We confirm that the content has not been published elsewhere and does not overlap or duplicate our published work. All authors also certify that their affiliations with or financial involvement with any organization does not pose a conflict of interest with the publishing of the paper. I have followed the *American Journal of Preventive Medicine*'s manuscript preparation guidelines closely, but please let me know if anything additional is needed.

Correspondence regarding this paper should be directed to me, Mary Jane Rotheram-Borus, Ph.D., at the UCLA-Semel Institute, Global Center for Children and Families, 10920 Wilshire Blvd., Suite #350, Los Angeles, CA, 90024, Tel.: (310) 794-8280; Fax: (310) 794-8297; E-mail: CCHPublications@mednet.ucla.edu. As corresponding author, I confirm that I have full access to all aspects of the research and writing process, and take final responsibility for this paper.

Thank you very much for your consideration.

Sincerely,

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Alcohol Use, Partner Violence, and Mental Health Distress among South African Township Mothers from Pregnancy to Three Years Post-birth: A Cluster Randomized Controlled Trial

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Abstract

Background. Pregnant South African women experience multiple risks from HIV and malnutrition, as well as emotional distress, alcohol use, and partner violence.

Purpose. This study examines predictors of maternal outcomes over three years in South Africa, based on a maternal history of drinking alcohol during pregnancy, having partners who become violent, depression, or HIV positive status during pregnancy.

Methods. All pregnant women in 24 Cape Town neighborhoods were recruited into a cluster randomized controlled trial (RCT) by neighborhood to either: 1) a standard care condition (n= 12 neighborhoods, n=594 mothers); or 2) a home visiting intervention condition (n=12 neighborhoods, n=644 mothers). Mothers were reassessed at 18 and 36 months post-birth: 80.6% of mothers completed all assessments between 2009 and 2013 and were included in these analyses performed in 2014. Longitudinal structural equation modeling examined alcohol use, partner violence, and emotional distress at the baseline and 18 month interviews as predictors of maternal outcomes at 36 months post-birth.

Results. Compared to the standard care, intervention mothers were significantly less likely to have mental health symptoms at 36 months. Alcohol use was significantly related to use over time, but was also related to depression and HIV status at each assessment and partner violence at 36 months.

Conclusions. Alcohol, partner violence, and emotional distress are significantly related over time; a home visiting intervention improved the emotional health of these township mothers even when depression was not initially targeted.

Key Words: alcohol, partner violence, depression, maternal HIV, and emotional health

Introduction

To stem the public health consequences of both infectious and chronic diseases in low and middle income countries (LMIC), task shifting from professionals to community health workers (CHW) is being broadly adopted.[1,2] In Africa, CHW have been primarily engaged in reducing perinatal HIV transmission , low birth weight infants, and malnutrition.[3-8] Yet, there are concurrent challenges that frequently impact families, particularly mothers.[9] This article examines how alcohol, intimate partner violence, and mental health symptoms among pregnant women impact these mothers through the first three years of their children's lives.

Alcohol. South Africa has the highest rates of both alcohol consumption and Fetal Alcohol Spectrum Disorder (FASD) ever observed globally.[10-13] Alcohol use is responsible for 60% of automobile accidents, more than 75% of homicides, 50% of non-natural deaths, and is implicated in 67% ver two-thirds of all intimate partner violence .[14] Alcohol abuse costs South Africa about R9 billion annually.[15] Alcohol use disinhibits sexual behavior, thus, associating it with HIV.[16,17] Alcohol use is also associated with unplanned pregnancies, and is more common among women whose partners also abuse alcohol.[18-20] Mothers who use alcohol in pregnancy have children who often fail to thrive, as the homes are less organized and daily family routines more chaotic (E Davis, MJ Rotheram-Borus, M Tomlinson, in submission, 2014). Alcohol use also reduces maternal adherence to all health regimens, inlcuding HIV medications.[21]

Partner violence. Poverty has been the primary marker associated with intimate partner violence.[22,23] When poverty is the only predictor, it is not feasible to screen and target women in a specified geographic area, as 74.4% of South Africans are considered low-income.[24] Intimate partner violence is a problem that can only then be identified after an initial violent episode or addressed preventively with public health intervention strategies. In this article, we examine if there are other predictors or significant correlates of intimate partner violence over time.

Depression and emotional distress. Post-partum depression in South Africa has been found to exceed 30%.[25,26] Depression impacts children's development, has and impacts on

maternal functioning. Depressed mothers have been found to have lower levels of social support.[27,28] Depressed women are more likely to use alcohol frequently and be more resistant to treatment to reduce alcohol use in other countries but patterns in South Africa are not well-documented over time.[29-31]

HIV. South Africa has 3.5 million women living with HIV (WLH).[32] In 2013, 19.1% of South Africans aged 15-49 years, who are most likely to be women of childbearing age, were infected.[32] Antenatal testing during pregnancy identifies most WLH, with high rates of pregnant women testing for HIV in the Western Cape, a region with a relatively strong health infrastructure. HIV impacts many areas of a woman's life: her relationships with partners and children, her mental health, as well as her physical health.[33,34]

Summary. Given the high prevalence of each of these maternal risk factors for negative long-term outcomes, we examined the Cape Town mothers from pregnancy until 36 months post-birth. We examined how the risk factors interact, as well as how these factors are related to demographic and behavioral contexts that indicate potential avenues for intervention. We hypothesized that participation in a supportive pre-natal and post-natal intervention would have positive long-term consequences for maternal well-being.

Methods

The Institutional Review Boards of University of California Los Angeles (UCLA), Stellenbosch University, and Emory University approved the study, whose methods have previously been published.[35] Three independent teams were involved: assessments (Stellenbosch University), intervention (Philani Project), and data analyses (UCLA).

Neighborhoods and Participants

Six matched sets of four neighborhoods each (N=24 neighborhoods) were identified in the townships outside Cape Town, South Africa, based on similarity in size, number of shebeens (bars), electricity, access to running water, toilets, and clinic care. UCLA randomized each neighborhood to either an intervention condition, in which all pregnant women received

home visitors from CHW, called Mentor Mothers in this project) as well as clinic care; or a standard care condition (regular clinic care).

From May 2009 to September 2010, 12 township women functioned as recruiters and went house-to-house to identify all adult pregnant women (at least 18 years old) and obtained consent for them to be contacted by the assessment team. Only 2% of pregnant women refused participation. We recruited, trained, and certified township women to interview participants by entering responses on mobile phones in an hour long interview. Supervisors monitored and gave feedback on the data quality weekly.

Figure 1 summarizes participant flow through the study. The neighborhoods and pregnant women were highly similar across conditions. The minimum number of pregnant women needed per neighborhood to achieve 80% power to detect a standardized effect size of 0.40 established the sample size. The original sample consisted of 1238 women. There were 117 dyads in which either the mother or infant died who were removed from the study (final n=1121). The current sample of mothers has 904 women (80.6%) participated in all assessments at baseline, 18 months, and 36 months.

Insert Figure 1 about here

Intervention and control conditions

Control condition. Standard clinic care in Cape Town is accessible, provides TB, HIV and CD4 testing, partner testing, dual regimen therapies for people living with HIV, consistent access to milk tins (formula), Co-trimoxazole for infants until HIV testing, HIV polymerase chain reaction (PCR) testing at 6 weeks, and (inconsistent) postnatal visits at one week. Standard antenatal care is typically four visits, with well-baby visits continuing post-birth. HIV care is offered within antenatal visits for pregnant women and then in specialized HIV care clinics post-birth.

Intervention condition. In addition to standard clinic care described above, CHWs made home visits to participants in the 12 intervention neighborhoods. CHWs were trained for one

month in cognitive-behavioral change strategies and role-playing. They also watched videotapes of common situations that a CHW might face. CHWs were selected due to their good social and problem solving skills and for their success in raising their own healthy children. They were trained to provide and apply health information about general maternal and child health, HIV/ TB, alcohol use, and nutrition to township women's lives. CHWs were certified, and supervised bi-weekly with random observations of home visits.

The Philani Program implemented the intervention. Eight health messages were delivered on HIV/TB, PMTCT, alcohol, mental health, breastfeeding, and malnutrition. The intervention dose (i.e., the number and length of home visits) delivered by CHWs was monitored on mobile phones that included a time stamp and brief summary report of visits. On average, CHWs made 6 antenatal visits (SD=3.8), 5 postnatal visits between birth and 2 months post-birth (SD=1.9), and afterwards about 1.4 visits/month until the children were about 18 months old; at that point visits only occurred once every six months. Sessions lasted on average 31 minutes each.

Measures

Baseline measures:

1) The demographic variable of maternal age in years was included in the analyses. Other demographics such as having a current partner, education, and income were not significantly associated with the other variables of interest and were not included in the models.

2) Alcohol Use during Pregnancy: single item dichotomous measure (yes = 1 /no = 0) derived from responses to items indicating that she had used alcohol at any time during her pregnancy.

3) Depressive affect was assessed with two scales which were used as indicators of a latent variable representing depression. The 10-item Edinburgh Postnatal Depression Scale (EPDS asks how a mother has felt in the past 7 days on a 4-point scale ranging from "No, not at all," to "Yes, quite a lot").[36] The EPDS was developed to identify women at risk for post-partum

depression. Items of the scale correspond to various clinical depression symptoms, such as guilt feelings, sleep disturbance, low energy, anhedonia, and suicidal ideation. Overall assessment is done by the total score, which is determined by adding together the scores for each of the 10 items. Higher scores indicate more depressive symptoms. The EPDS has been used during the postpartum period, as well as during pregnancy.[37,38]

The second scale was the GHQ-12, described as a quick, which is a reliable and sensitive short form of the longer General Health Questionnaire which assesses the inability to carry out normal functions and the appearance of new and distressing life events.[39] It has a 4-point scale ranging from "Not at all" to "Much more than usual" and refers to the past few weeks. Scores were summed and higher scores indicated greater psychological distress.

4) HIV-positive serostatus was a dichotomous variable (yes = 1 /no = 0).

5) Intimate Partner Violence (IPV) was assessed with four items that ranged from 1-4. Women were asked if they were slapped, pushed or shoved, punched with a fist or another object, or threatened with a weapon by their partner within the past 6 months. Responses ranged from never (1), once (2), few (3), to many (4).

18-month variables

6) Alcohol Use was a latent variable indicated by three items: 1) The frequency of drinking alcohol (0-9 scale ranging from 0 = never to 9 = every day). 2) Amount of alcohol on days when she drank (0-5 scale ranging from 0 = none to 5 = 10 or more drinks). 3) Frequency of 3 or more drinks per day (0-9 scale ranging from 0 = never to 9 = every day).[40]

7) Depression was measured exactly the same way as described above at baseline.

8) IPV was assessed the same manner as at baseline.

3-year Outcomes

9) Alcohol Use was assessed in the same manner as it was assessed at 18-months.

10) Positive Emotional Health was assessed with four scales that were scored to indicate greater emotional health and less depression. A summary score was used for each subscale.

Scales 1 and 2 are subscales derived from the 36-item Short Form Health Survey (SF-36).[41] The first was the Emotional Health subscale and the second was the Mental Health scale. These scale items are scored from 1-5 and refer to the past four weeks. The third scale we used was the Hopkins Symptom Checklist Depression Scale, also known as the Brief Symptom Inventory.[42] The fourth scale was the EPDS which was described above.

11) IPV was assessed in the same manner as it was assessed at baseline and at 18-months.

Intervention group status

12) A dichotomous variable (yes = 1 /no = 0) indicated if the participant was in the intervention group.

Analysis

The EQS structural equations program was used to assess an initial confirmatory factor model and a predictive path model.[43] The initial confirmatory factor analysis (CFA) assessed the adequacy of the hypothesized measurement model and the associations among the latent variables and the single item variables without imputing any directionality. Then a directional latent variable path model positioned the baseline variables of age, Alcohol Use during Pregnancy, Depression, HIV-positive status, and IPV as predictors of the 18-month intermediate measures of Alcohol Use, Depression, and IPV. These in turn predicted the 36 month outcomes of Alcohol Use, Positive Emotional Health, and IPV. Intervention Condition status initially predicted the 18-month intervening variables and the outcome variables. Non-significant paths and co-variances were gradually dropped until only significant paths and co-variances remained. Paths were added from the baseline variables to the outcome variables based on suggestions from the Lagrange Multiplier test for fit improvement.[44]

These analyses compare a proposed hypothetical model with a set of actual data. The closeness of the hypothetical model to the empirical data is evaluated statistically through various goodness-of-fit indexes. Goodness-of-fit was assessed with both maximum likelihood

χ2 and the robust Satorra-Bentler χ2 (S-B χ2) values, the Comparative Fit Index, Robust Comparative Fit Index (RCFI), and the root mean squared error of approximation (RMSEA).[43,45] The Robust S-B χ2 was used in addition to normal maximum likelihood methods because it is appropriate when the data depart from multivariate normality. The multivariate kurtosis estimate was high in the data set (normalized Mardia z-statistic = 333.88). The CFI and RCFI range from 0 to 1 and reflect the improvement in fit of a hypothesized model over a model of complete independence among the measured variables. RCFI values at .95 or greater are desirable, indicating that the hypothesized model reproduces 95% or more of the covariation in the data. The RMSEA is a measure of lack of fit per degrees of freedom, controlling for sample size, and values less than .06 indicate a relatively good fit between the hypothesized model and the observed data.

Because of random assignment, we did not expect intervention condition membership to be correlated significantly with any baseline predictors although we examined in the CFA whether by chance any of the baseline measures were associated significantly with intervention status. If so, we controlled for these pre-existing associations. We also report whether there were significant indirect effects on the 36 month outcomes of any baseline predictor or of intervention status mediated through the 18-month variables. Data was collected between 2009 and 2013 for these analyses, which were performed in 2014.

Results

Demographics: The average age of the women was 26.5 years (SD = 5.6) and they ranged in age from 18 to 42 years. Regarding marital status, 43% were single, 20% were living with someone, and 37% were married. Tenth grade was the average education level; 75% had less than a high school education; 79% were not employed; 14% were employed part or full time. Others had temporary jobs or were self-employed. Fifty percent had incomes equal to or under ZAR 2000/month (about $200).

Confirmatory Factor Analysis: Table 1 reports the means, standard deviations, ranges, and standardized factor loadings for the measured variables. All measured variables loaded significantly ($p < .001$) on their hypothesized latent factors. The fit indexes were highly acceptable (ML $\chi 2$ (343, N = 904) = 955.83; CFI = .96; RMSEA = 0.05; S-B $\chi 2$ (343, N = 904) = 551.43; RCFI = .97, RMSEA = .03). No modifications were necessary in this model.

Correlations among all of the latent and single-item variables are reported in Table 2. Of note, intervention membership was not significantly associated with any baseline variables except for an unexpected significant association with the intervention mothers reporting more depression. This relationship was not significant in the original overall sample (only 80.6% of participants were in these current analyses). Focusing only on the most highly significant correlations ($p \leq .001$), having used alcohol during pregnancy was most associated with Intimate Partner Violence at baseline (.26) and then again at 36 months (.21) as well as continued Alcohol Use at 18-months and 36 months (.38, .40 respectively). depression at baseline was most associated with concurrent partner violence (.24), continued depression at 18 months (.17), and more partner violence (.12) and less positive emotional health at 36 months (-.29). HIV-positive status had a significant relationship with more depression at baseline (.11) and was associated with higher age (.10).

Baseline IPV was associated with numerous maladaptive behaviors such as alcohol use at 18 months and 36 months (.19, .20) and more depression at 18 months (.13) and less emotional health at 36 months (-.14). It also was stable over time (.50 at 18 months, and .22 at 36 months post-birth). Older women reported more depression (.15) at 18 months. At 18 months, alcohol use was associated with more intimate partner violence concurrently (.19) and at 36 months (.19). It was also highly associated with continued use at 36 months (.51). Depression at 18 months was associated concurrently with more intimate partner violence and with less Positive Emotional Health at 36 months (-.23). IPV was associated with continued partner violence at 36 months (.21). The cluster of 36 month behaviors were correlated

significantly among themselves as can be seen in Table 2. Being in the intervention group was significantly associated with more positive emotional health (.07, $p \leq .05$).

Path model: The final path model has excellent fit statistics (ML $\chi 2$ (380, N = 904) = 1007.04; CFI = .96; RMSEA = 0.04; S-B $\chi 2$ (380, N = 904) = 601.28; RCFI = .97, RMSEA = .03). Results of the analysis with all significant paths included are depicted in Figure 2. Non-significant paths were dropped gradually. Latent variables are represented by circles; measured variables are depicted in rectangles. Only significant direct effects are shown in the figure. The substantial associations among the residuals of the outcome variables are also depicted.

Direct effects: Focusing on the 36 month outcome variables, alcohol use was significantly predicted by prior alcohol use at baseline and at 18 months as well as younger age. IPV was predicted by Alcohol Use at 18 months, IPV at 18 months, alcohol use during pregnancy, and IPV at baseline. Positive emotional health was predicted by less alcohol Use, less depression and less IPV at 18 months, less depression at baseline, and by being in the intervention. Controlling for the prior association between intervention status and baseline depression significantly enhanced the relationship between better emotional health and intervention participation. The intervention reduced depression even though initially the mothers in this group were more depressed than those in the control group.

Indirect effects: There also were significant indirect effects of baseline variables on the 36 month outcome variables mediated through the 18-month variables. In addition to its direct effect, alcohol during pregnancy had an indirect effect on alcohol use at 36 months through its effect on alcohol use at 18-months ($p < .001$); HIV-positive status and IPV also exerted significant indirect effects on greater alcohol Use at 36 months ($p < .05$, $p < .01$ respectively) also mediated through Alcohol Use at 18 months. Positive emotional health was impacted indirectly by baseline variables of less alcohol during pregnancy ($p < .05$), less depression ($p < .01$), less IPVer Violence ($p < .01$), and younger age ($p < .001$). IPV was impacted indirectly by baseline variables of alcohol during pregnancy ($p < .01$), and more IPV ($p < .001$).

Discussion

The Philani home visiting intervention significantly reduces mental health symptoms at 36 months post-birth. It is noteworthy that the benefits of the intervention were broader than only a measure of perinatal depression. There were four measures of emotional health included in the latent variable reflecting emotional distress: the EPDS measure (the only depression measure used at baseline in pregnancy), The Hopkins measure of depression, and the two scales from the Medical Outcomes Quality of Life measure. The significant intervention impact affects the latent variable reflecting a much broader measure of well-being compared to only being a depression measure.

This outcome was quite encouraging given that within this sample, by chance, the intervention group mothers were more depressed at baseline. This result was also surprising, given that we did not train the CHWs to intervene to reduce depression; having a supportive individual in their lives may have had unanticipated and positive consequences. CHWs did encourage and train mothers to care for their infants, regardless of their mothers' feelings or stress. In prior analyses, we found that mothers' depression did not remit post-birth, or at 6 or 18 months.[4,46] However, we did find that children of depressed mothers maintained a healthier growth pattern, being both heavier and longer than infants of control mothers.[4,46]. We do not know the mechanism by which maternal depression remits significantly more at 36 months among intervention mothers. However, healthier children are easier to care for, and it is possible that the long term benefits of the intervention (which basically stopped at about 6 months post-birth) accrued over time. This effect is even more impressive in that one of the few baseline differences is that the intervention mothers were significantly more depressed at the baseline assessment, compared to the mothers in the control condition.

There is a persistent negative impact associated with partner violence over 36 months post birth. Partner violence is the best predictor of previous partner violence and the effect is maintained across both the 18 month and the 36 month assessments. It is not clear from our

data whether mothers are staying with the same partner or whether new partners continue to engage in this negative behavior.

A similar strong and persistent relationship is found in alcohol use and abuse over time. Mothers who were using alcohol while pregnant continue to be those using and abusing alcohol over time. In previous analyses, we found that mothers in the control condition who drank alcohol prior to knowing that they were pregnant (25%), in fact, increased their use threefold during pregnancy.[4] The intervention reduces alcohol use in pregnancy. However, drinking resumed after the baby was born. These analyses suggest that drinking is a very stable behavior. A more intensive or group-focused intervention is going to be needed for these mothers to be successful in reducing alcohol use over time. This is a disturbing finding given the pervasive and long-term negative outcomes of alcohol use and abuse. Partner violence at baseline also predicted more alcohol use, depression and continued violence at 18 months. It also had significant indirect effects on all three outcomes. This constellation of depression, partner violence, and alcohol behaviors must be addressed with a comprehensive approach when designing an intervention.

Alcohol use and partner violence were highly stable over time. Depression is also relatively stable, even though the emotional health variable at outcome was composed of multiple constructs reflecting mental health status. These behaviors are likely to have lifelong effects on the children of these mothers who have multiple risks over time. The CHWs were only trained to reduce alcohol use – not depression or partner violence. The integrated and persistent risk pattern over time indicates the need for CHWs to extend the length of their interactions and expand beyond HIV, nutrition and alcohol. Existing intervention models are almost all categorical funding streams, with CHWs addressing a single outcome. Families' lives are characterized by embedded risk "routines" of drinking and IPV. Generalist models of interventions with CHWs helping families slowly change their routines and risky behaviours with

practice and small steps over time. Training CHWs as problem-solving coaches is likely to be a more viable, long-term intervention strategy.

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Figure Captions

Figure 1. Movement of participants through the RCT at assessment points comparing mothers in a control condition and a home visiting intervention.

Figure 2. Significant regression paths predicting 3 year outcomes among 904 mothers in Cape Town. Large circles represent latent variables, rectangles represent single-item indicators. For readability, correlations among the predictors are not shown. Regression coefficients are standardized (a = $p < .05$, b = $p < .01$, c = $p < .001$).

Table 1. Summary Statistics, Ranges and Factor Loadings in the Confirmatory Factor Analysis (N = 904 Cape Town mothers).

Variables (range)	Mean (or %)	SD	Factor Loading*
Baseline			
Age (years) (18-42)	26.53	5.63	———
Alcohol Use during Pregnancy (yes = 1, no = 0)	27%		———
Depression			
GHQ (1-36)	14.69	8.62	.95
EPDS (0-30)	10.72	6.91	.85
HIV-Positive (yes = 1, no = 0)	28%		———
Intimate partner violence (1-4)			
Slap	1.51	0.85	.78
Shove	1.32	0.70	.74
Punch	1.19	0.57	.75
Weapons	1.07	0.36	.42
18-months			
Alcohol Use			
Alcohol frequency (1-8)	1.34	1.00	.95
Number of drinks (0-5)	0.19	0.60	.86
Freq. 3 or more drinks (0-7)	0.38	1.03	.97
Depression			
GHQ (1-36)	9.28	8.08	.85
EPDS (0-30)	6.77	7.34	.89
Intimate partner violence (1-4)			
Slap	1.19	0.57	.86
Shove	1.17	0.54	.84
Punch	1.11	0.47	.89
Weapons	1.05	0.29	.55
Year 3 outcomes			
Alcohol Use			
Alcohol frequency (1-8)	1.57	1.35	.97
Number of drinks (0-3)	0.22	0.54	.88
Freq. 3 or more drinks (1-8)	1.42	1.18	.88
Positive Emotional Health**			
SF-36 EH (6-20)	18.54	2.80	.76
SF-36 Depression (9-30)	33.79	6.83	.87
Hopkins (25-100)	89.97	15.98	.94
EPDS (0-30)	23.60	7.61	.88
Intimate partner violence (1-4)			
Slap	1.20	0.58	.88

Shove	1.16	0.53	.81
Punch	1.12	0.49	.86
Weapons	1.05	0.32	.50
Group Membership			
Intervention member (yes = 1, no = 0)	52%		———

* All factor loadings significant, $p \leq .001$. **Higher scores indicate better emotional health. Scales reversed where necessary.

Table 2. Correlations among Measured and Latent Variables in Model (N = 904) (* $p \leq .05$; ** $p \leq .01$; *** $p \leq .001$).

Variables												
Baseline	1	2	3	4	5	6	7	8	9	10	11	12
1. Age	—											
2. Alcohol during pregnancy	**-.11*****	—										
3. Depression	.01	**.12**** *	—									
4. HIV-Positive	**.10*****	.06	**.11*****	—								
5. Intimate partner violence	-.05	**.26**** *	**.24*****	.01	—							
18-months												
6. Alcohol Use	.04	**.38**** *	.04	**.09****	**.19*****	—						
7. Depression	**.15*****	.00	**.17*****	**.08***	**.13*****	.04	—					
8. Intimate partner violence	-.02	**.10****	.06	.03	**.50*****	**.19*****	**.16*****	—				
3-Year Outcomes												
9. Alcohol Use	**-.10****	**.40**** *	.06	.04	**.20*****	**.51*****	.02	**.11****	—			
10. Positive Emotional Health	-.05	**-.13**** *	**-.19*****	-.06	**-.14*****	**-.11*****	**-.23*****	**-.11****	**-.21*****	—		
11. Intimate partner violence	-.02	**.21**** *	**.12*****	.04	**.22*****	**.19*****	.05	**.21*****	**.29*****	**-.39*****	—	
Group Membership												

12. Intervention member	.04	.00	**.07***	-.02	-.02	-.03	.03	.04	-.02	**.07***	.02	—

Figure 1

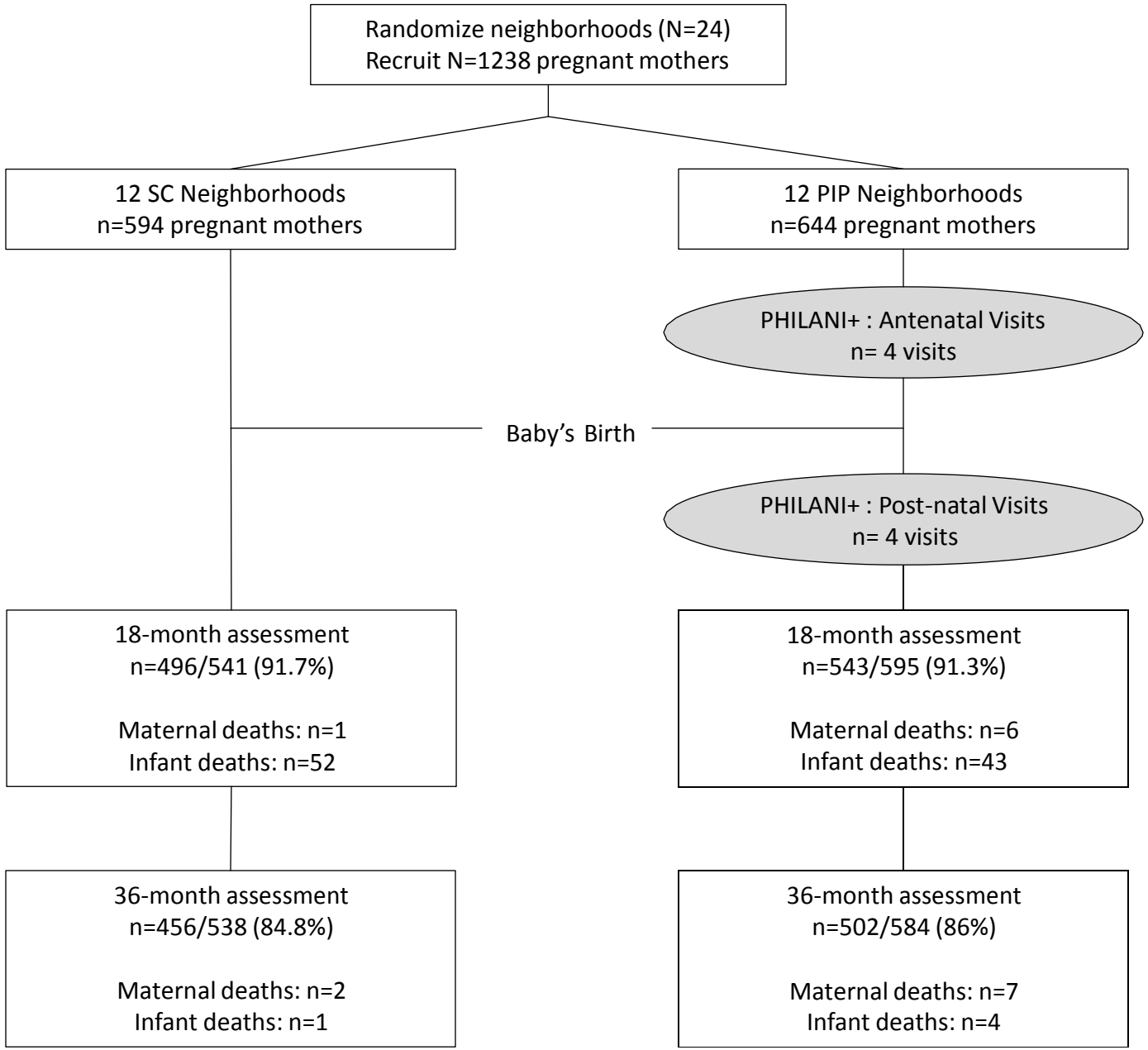
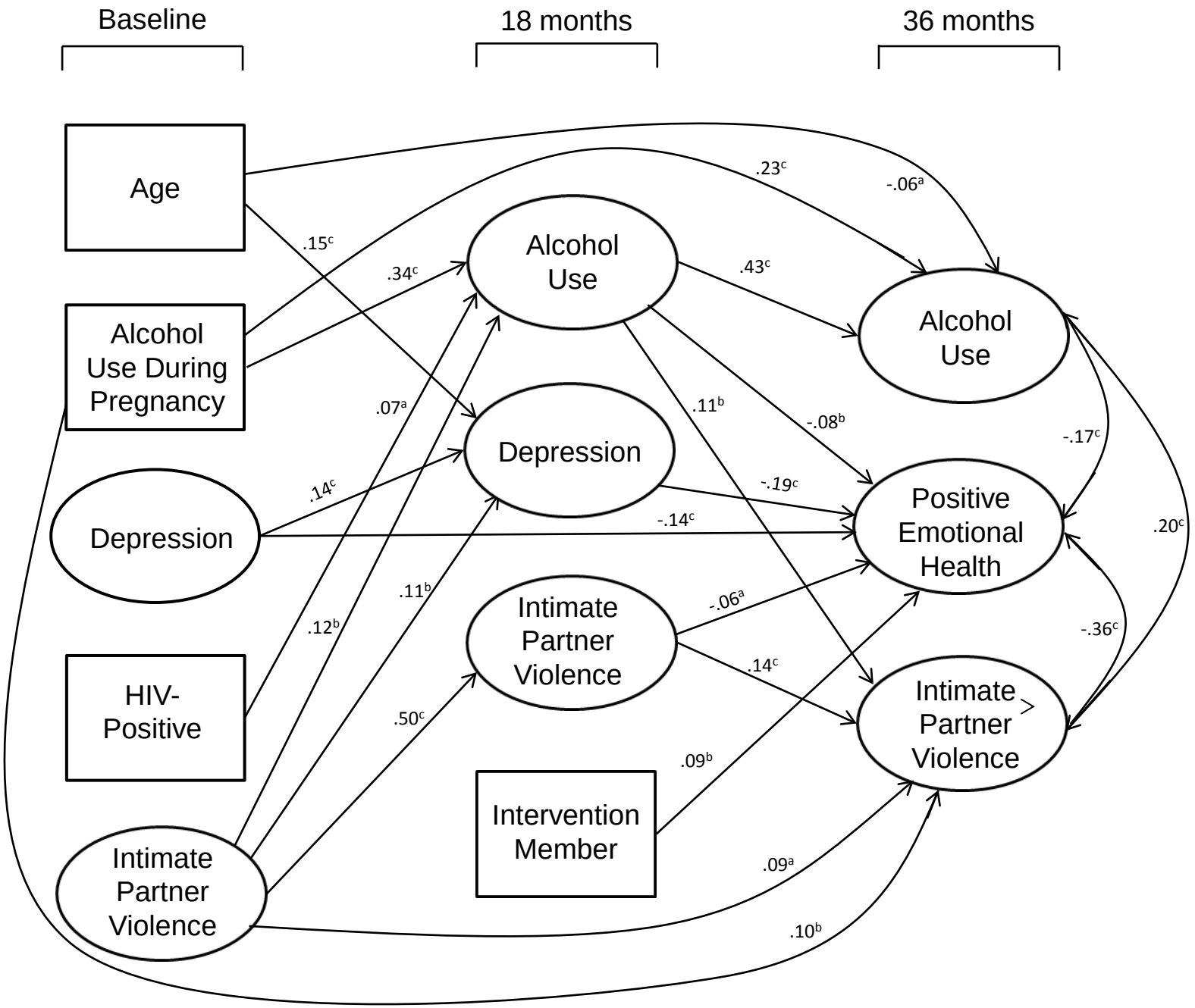

Randomize neighborhoods (N=24)
Recruit N=1238 pregnant mothers
12 SC Neighborhoods
n=594 pregnant mothers
12 PIP Neighborhoods
n=644 pregnant mothers
PHILANI+ : Antenatal Visits
n= 4 visits
Baby's Birth
PHILANI+ : Post-natal Visits
n= 4 visits
18-month assessment
n=496/541 (91.7%)
Maternal deaths: n=1
Infant deaths: n=52
18-month assessment
n=543/595 (91.3%)
Maternal deaths: n=6
Infant deaths: n=43
36-month assessment
n=456/538 (84.8%)
Maternal deaths: n=2
Infant deaths: n=1
36-month assessment
n=502/584 (86%)
Maternal deaths: n=7
Infant deaths: n=4

Figure 2


Baseline
18 months
36 months
Age
Alcohol Use During Pregnancy
Depression
HIV-Positive
Intimate Partner Violence
Alcohol Use
Depression
Intimate Partner Violence
Intervention Member
Alcohol Use
Positive Emotional Health
Intimate Partner Violence
.23c
-.06a
.15c
.34c
.43c
.07a
.11b
-.08b
-.17c
.14c
-.19c
-.14c
.20c
.11b
-.06a
.12b
-.36c
.14c
.50c
.09b
.09a
.10b

Reporting Flow Diagram (same as Figure 1)

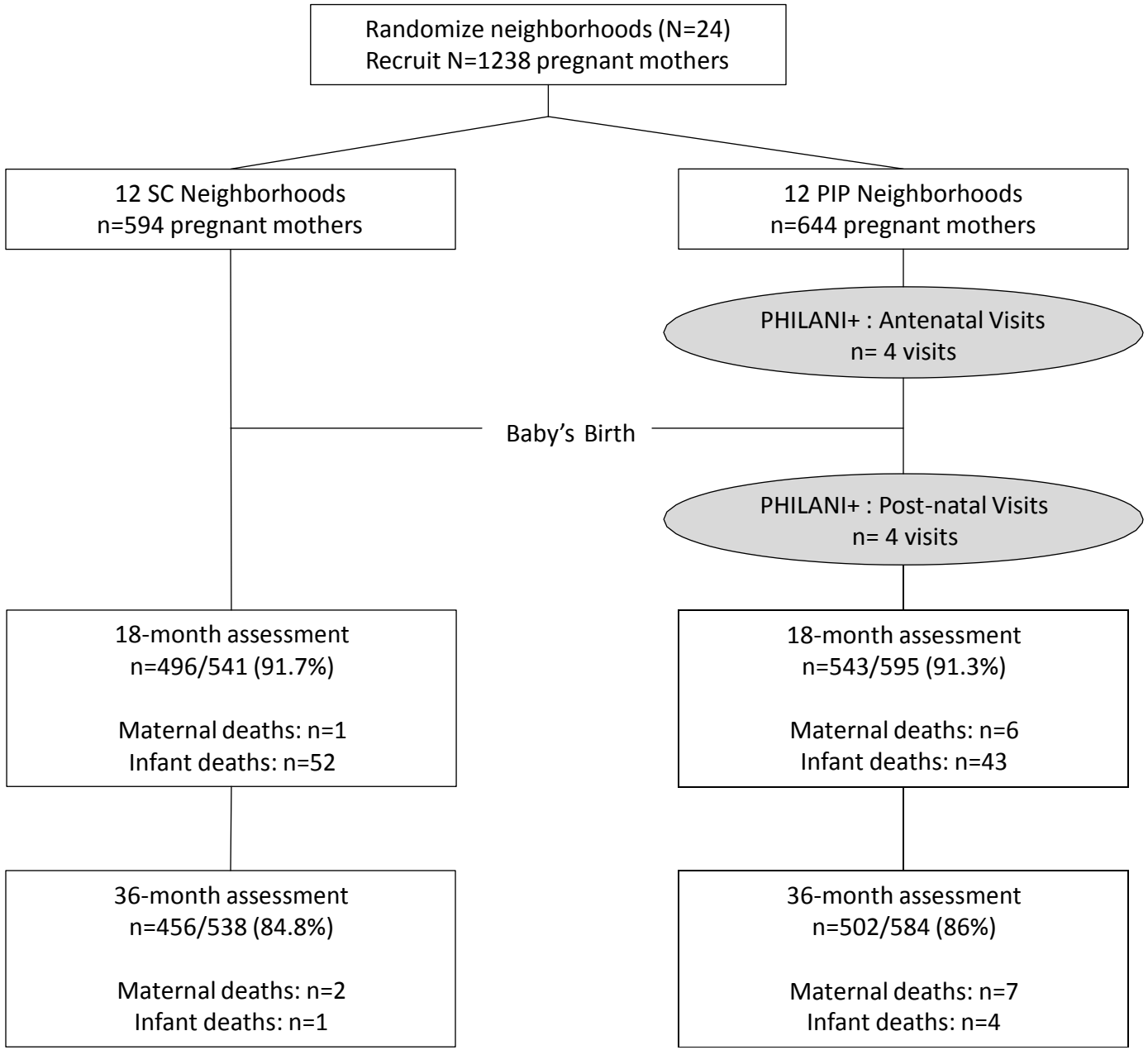


Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	p. 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	p. 2
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	p. 3-5
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	p. 4
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	p. 4-5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		p. 5
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	p. 4-6
	4b	Settings and locations where the data were collected		p. 4-6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	p. 5-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	p. 6-8

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		N/A
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	p. 5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Interim analyses completed at 6 months and 18 months.	References #6, #46
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	UCLA randomized in simple randomization process.	p. 4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used; blocks were two neighborhoods per block.	p. 4-5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	p. 4-5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	p. 4
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	p. 4-5

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	p. 5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Assessment interviewers were blinded, but there was potential to have a participant disclose their status.	p. 4-6
	11b	If relevant, description of the similarity of interventions		p. 5-6
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	p. 8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		N/A
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up		p. 5
	14b	Why the trial ended or was stopped		N/A
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	Table 1

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	p. 9-11, Table 2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		Figure 2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		p. 10
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		p. 12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	p. 10, 12-14
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		p. 12-14
Other information				
Registration	23	Registration number and		p. 1

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	Reference #35
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	p. 1

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	**Abstract**
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	Completed
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	**None**
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	**ClinicalTrials.gov, registration # NCT00972699**
Funding	Source of funding	**NIAAA, Grant # 1R01AA017104; NIH, Grants MH58107, 5P30AI028697, 1R24AA022919 and UL1TR000124**

[1] Relevant to Conference Abstracts

REFERENCES

[1] Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

[2] Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

[3] Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.