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# BMJ Open

## A trauma-informed substance use and sexual risk reduction intervention for young South African women: a mixed-methods feasibility study

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3 **A trauma-informed substance use and sexual risk reduction intervention for young South**  
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5 **African women: a mixed-methods feasibility study**  
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## ABSTRACT

**Objectives:** Sexual and physical trauma and substance use are intersecting risks for HIV among young women. This study assesses the feasibility, acceptability and preliminary effects of a novel trauma-informed substance use and sexual risk reduction intervention for young South African women.

**Design:** A single arm feasibility test and qualitative interviews of participants.

**Participants:** Sixty women, between 18 and 25 years of age who reported trauma exposure, substance use and recent condom-less sex were recruited. Twenty participants were randomly selected for qualitative interviews.

**Intervention:** A six session group-based intervention.

**Main Outcome Measures:** We examined the proportion of women who provided consent, completed counselling, and were retained in the study. Qualitative interviews explored intervention acceptability. Preliminary effects of the intervention on substance use, mental health (depression, psychological distress, trauma symptoms) and sexual risk outcomes (STI symptoms, number of partners, condom-less sex) were explored.

**Results:** Of the 66 eligible women, 91% were enrolled. Rates of intervention completion were low; 35% attended all sessions, although 68% completed at least three sessions. A 93% follow-up rate was achieved at the three-month end-point. Significant reductions in the proportion of participants who tested positive for methamphetamine ( $p < 0.0001$ ), cannabis ( $p < 0.0001$ ), and methaqualone ( $p < 0.0001$ ) were observed at the three-month end-point. Symptoms of depression ( $p < 0.0001$ ), psychological distress ( $p < 0.0001$ ), and trauma ( $p < 0.0001$ ), number of STI symptoms ( $p < 0.0001$ ) and number of sexual partners ( $p = 0.001$ ) also decreased. Participants

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3 thought the intervention was highly beneficial, and proposed modifications to enhance  
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5 acceptability.  
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8 **Conclusions:** This novel intervention seems acceptable and may improve substance use, sexual  
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10 risk and mental health outcomes for trauma-exposed young women who use substances. To  
11  
12 enhance the likelihood of intervention completion and implementation, this intervention should  
13  
14 be truncated and requires testing in a randomised controlled trial to establish efficacy.  
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## 17 18 19 **ARTICLE SUMMARY**

### 20 21 **Strengths and limitations of this study**

- 22  
23 • The first study to compare the feasibility and acceptability of a trauma-informed  
24  
25 substance use and sexual risk reduction intervention for young women  
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- 28  
29 • The use of mixed methods enables triangulation of findings, increasing confidence in the  
30  
31 results.  
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- 33  
34 • Qualitative interviews provide a rich description of young women's experiences of the  
35  
36 intervention and recommendation for intervention enhancement.  
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- 38  
39 • This was a single arm feasibility test so we cannot make inferences about intervention  
40  
41 efficacy.  
42  
43

44  
45 **Keywords:** gender, substance use, mental health, sexual risk, low-and-middle-income country  
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## BACKGROUND

Substance use<sup>1</sup> and exposure to physical and sexual trauma<sup>2</sup> are highly prevalent, intersecting risks for HIV acquisition among young women in South Africa.<sup>3</sup> Substance use is a common coping strategy among trauma-exposed women who use substances to avoid or numb the negative emotions associated with traumatic experiences.<sup>4-5</sup> As substance use impairs decision-making which leads to inconsistent condom use,<sup>6</sup> this coping response may increase young women's risk for HIV. Substance use also places women in high-risk environments and fuels conflict in interpersonal relationships,<sup>7-8</sup> increasing risk of further exposure to physical and sexual trauma<sup>9</sup> and directly contributing to HIV risk.<sup>10</sup> With a high incidence of HIV among young women in emerging adulthood,<sup>11</sup> South Africa needs innovative programmes that address these syndemic, intersecting risks for HIV acquisition amongst this vulnerable population.

At present, there are few programmes that offer an integrated approach to addressing these risks. Although several HIV prevention programmes reach young South African women, these generally do not focus on women who have been trauma-exposed and may be using substances. Further, trauma and substance use services in South Africa are provided by separate systems of care.<sup>12-13</sup> As substance use services do not provide trauma counselling, women with histories of trauma are often reluctant to utilise these services and those that do tend to have poorer substance use outcomes than women without a history of physical or sexual abuse.<sup>9,14</sup>

In high-income countries, trauma-informed substance use interventions have been recommended as a means of overcoming barriers to trauma-exposed women's use of substance use services.<sup>15</sup> Evidence from systematic reviews suggests that this integrated approach leads to significant reductions in substance use and trauma symptoms among women with these multi-morbidities.<sup>16-17</sup> Despite global HIV prevention guidelines for adolescent girls and young women

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3 that recommend the provision of integrated mental health, substance use and HIV prevention  
4 services for young women,<sup>18</sup> trauma-informed substance use interventions have generally not  
5 included HIV prevention components,<sup>16</sup> reflecting a missed opportunity to address sexual safety  
6 among this highly vulnerable population. To address this gap, we developed a trauma-informed  
7 SUD and sexual risk reduction intervention for South African women in emerging adulthood.  
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14 This study aimed to (i) assess the feasibility of recruiting and retaining trauma-exposed  
15 women who use substances in this intervention; (ii) obtain preliminary information on the  
16 intervention's substance use, mental health and sex risk outcomes and (iii) explore participants'  
17 perceptions of the acceptability of the intervention. This information is needed to guide decision  
18 making about the future of the programme and whether it is worth investing in a randomised  
19 controlled trial to establish its efficacy.  
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## 31 **METHODS**

32 This manuscript is in accordance with the "Good reporting of a mixed methods study guidelines"  
33 (GRAMMS).<sup>19</sup> See Supplementary file 1 for the GRAMMS checklist. This Phase I feasibility  
34 study, conducted between July 2016 and February 2017, tested a trauma-informed substance use  
35 and sexual risk reduction intervention combined with post-programme qualitative interviews of  
36 participants.  
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### 47 **Participants and procedures**

48 We recruited 60 young women from two low-income communities in Cape Town, South  
49 Africa characterised by high levels of sexual and physical violence, substance use and HIV.  
50 Fieldworkers used established community-based street outreach techniques<sup>20</sup> to identify potential  
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3 participants to whom they described the study before requesting verbal consent for eligibility  
4 screening. Women were eligible if they were between 18 and 25 years old; lived in the target  
5 communities; and reported lifetime experiences of sexual or physical abuse, using at least one  
6 illicit drug or heavy episodic drinking (defined as four or more alcoholic drinks on one occasion)  
7 weekly for the past three months, and condom-less sex in the past three months. Fieldworkers  
8 gave eligible women more information about the study and invited those who were eligible and  
9 interested to an enrolment appointment (see Fig 1 for participant flow chart).

19 At the enrolment appointment, fieldworkers rescreened women to verify study eligibility  
20 and obtained their informed consent before collecting contact information, administering the  
21 baseline behavioural assessment, and conducting rapid biological testing for recent drug use,  
22 pregnancy and HIV. The Medical Diagnostech drug test and NHMed tests were used to test urine  
23 samples for methamphetamine, cocaine, opiates, THC (cannabis) and methaqualone use in the  
24 past 72 hours. Two rapid finger-prick tests were used to test for HIV (Unigold and Determine  
25 Rapid Tests). If either test was reactive or indeterminate, a confirmatory Tri-line HIV-1/2 Rapid  
26 Test was performed. A participant was considered HIV positive when at least two tests were  
27 reactive. Participants were also breathalysed to assess recent alcohol use. Immediately after this  
28 assessment, participants received information about the intervention programme, they developed  
29 a personalised action plan, and appointments were scheduled for the intervention. Participants  
30 had three weeks to complete the intervention programme. All participants were asked to return  
31 for one-month case management visit and a three-month post-enrolment follow-up appointment  
32 at which time participants were re-consented, the behavioural assessment was re-administered,  
33 and they were re-tested for recent substance use, HIV and pregnancy. In addition, twenty  
34 participants were randomly selected for a qualitative in-depth interview of their perceptions of



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2  
3 the acceptability and utility of the programme. These interviews, conducted by an experienced  
4 qualitative researcher in isiXhosa (the primary language spoken by participants), occurred after  
5 their three-month assessment and lasted approximately 45 minutes. Interviews were audio-  
6 recorded and transcribed verbatim before being translated into English using standard forward-  
7 and back-translation techniques. All project activities occurred in private rooms at a field site.  
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14 After each contact, participants were given referrals to additional substance use and  
15 trauma counselling. Participants received grocery vouchers for completing the baseline and  
16 follow-up appointments and the qualitative interviews as well as transport to these appointments.  
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Participants were not incentivised to attend the intervention sessions, although transport and refreshments were provided.

## Intervention

We developed a novel trauma-informed substance use and sexual risk reduction intervention for young South African women, known as the trauma-informed Women's Health Coop (WHC). The process of developing this intervention has been described elsewhere.<sup>21</sup> The intervention comprises six group sessions delivered over a two-week period. The intervention provides psychoeducation about substance use, trauma and HIV; cognitive-behavioural strategies for identifying emotional triggers for substance use, emotional regulation, adaptive coping and problem-solving, and managing cravings; conflict resolution and sexual safety skills training; and self-care strategies for sustaining recovery and creating a meaningful life. Participants were given opportunities for skills rehearsal and a handout summarising session content and containing exercises for further skills practice. At the end of the programme, participants review

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3 their personalised action plan, which was re-reviewed during case management activities that  
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5 occurred one and two months after enrolment.  
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### 10 **Counsellor training and supervision**

11 A registered psychological counsellor, fluent in isiXhosa, was trained to deliver the programme.  
12  
13 She received two weeks of training in the intervention which included an assessment of her  
14  
15 competence to deliver the intervention. The training curriculum was manualised. We audio-  
16  
17 recorded the group sessions and reviewed a random sample for fidelity. During weekly  
18  
19 supervision, findings from these fidelity checks were used to provide feedback to the counsellor  
20  
21 on how to improve intervention quality.  
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### 28 **Measures**

#### 30 *Sociodemographic variables*

31  
32 Sociodemographic variables included participants' employment status (employed versus  
33  
34 unemployed), relationship status (single versus in a relationship) and HIV status (positive or  
35  
36 negative). Type of trauma exposure was assessed using items from the Trauma History  
37  
38 questionnaire.<sup>22</sup> A positive response to any of the three items on sexual abuse was classified as  
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40 sexually abused; any of the three physical abuse questions as physically abused; and at least one  
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42 physical *and* one sexual abuse item as both physically and sexually abused.  
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#### 49 *Substance use outcomes*

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51 Change in recent drug use was assessed through results of biological testing (positive versus  
52  
53 negative). Questions on the number of days of heavy episodic drinking (defined as four or more  
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3 drinks on one occasion), methamphetamine, cannabis, and methaqualone use in the past 30 days  
4  
5 assessed change in frequency of substance use.  
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### 10 *Mental health outcomes*

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12 The 20-item Centre for Epidemiologic Studies Depression Scale (CES-D) assessed change in  
13 depressive symptomatology.<sup>23</sup> For this scale, a cut-off score  $\geq 16$  indicates probable depression.<sup>24</sup>  
14  
15 The 10-item Kessler Psychological Distress Scale (K-10) measured change in symptoms of  
16 psychological distress. This scale has been shown to have good psychometric properties in  
17 South African studies, with a cut-off score  $\geq 20$  indicating psychological distress.<sup>25</sup> The 10-item  
18 Drug Abuse Treatment Outcome Study post-traumatic stress disorder (PTSD) scale,<sup>26</sup> adapted  
19 for use in South African populations, assessed changes in trauma symptoms. The 19-item  
20 Medical Outcomes Study Social Support Survey (MOS-SSS) assessed change in perceived social  
21 support. This scale has excellent psychometric properties.<sup>27</sup>  
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### 35 *Sexual risk outcomes*

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37 Change in condom use was assessed through a question on condom use at last sexual encounter.  
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39 Questions on the number of sexual partners and number of symptoms of sexually transmitted  
40 infections (STI) in the past month also assessed change in sexual risk behaviour.  
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### 46 **Analyses**

47  
48 We used SPSS version 25.0 to describe the proportion of participants who completed the  
49 intervention and retention at three-month follow-up. We used Chi-square tests (or Fisher exact  
50 tests if cell sizes were small) for categorical and t-tests for continuous variables to explore  
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3 whether participant attributes were associated with intervention and study completion. Chi-  
4 square tests explored change from baseline to three-month follow-up on the categorical outcome  
5 variables. Paired sample t-tests were used to examine whether there was change on the outcomes  
6 from baseline to follow-up. Results are presented as differences in mean scores with 95%  
7 confidence intervals. All testing was two-sided and a significance level of 0.05 was used for all  
8 analyses.  
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12 The framework approach<sup>28</sup> was used for qualitative data analysis. Two people coded the  
13 interview transcripts using NVivo version 11; they met regularly to compare notes and resolved  
14 discrepancies through discussion. A third person was not needed to break coding ties. No new  
15 codes emerged after coding half the transcripts, implying thematic saturation. Inter-coder  
16 reliability was high, with a Kappa score of 0.93.  
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## 31 RESULTS

### 32 *Feasibility of patient recruitment and retention*

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35 Field staff screened 557 young women for potential study eligibility of which 66 met the study's  
36 eligibility criteria. Almost three quarters (72.6%) of women screened reported trauma exposure  
37 and more than half (56.9%) heavy alcohol or drug use. Of the eligible women, 60 (90.7%) were  
38 interested in study participation and were enrolled (see Fig 1). On average, participants were 22  
39 years old (SD = 2.0), mostly unemployed (91.7%) and most were in a romantic relationship  
40 (91.7%). In terms of trauma, 91.7% reported lifetime physical abuse, 68.3% reported sexual  
41 abuse, and 56.7% reported experiences of physical and sexual abuse. Most (93.3%) had never  
42 received substance use or trauma care, and 85.0% reported not knowing where to go for these  
43 services. At baseline, 50.0% tested positive for cannabis, 48.3% for methaqualone, 45.0% for  
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3 methamphetamine, and four tested positive for opiates (6.7%). On average, participants reported  
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5 11.4 days of heavy episodic drinking (SD = 11.8) in the past month. At baseline, 46.7% of  
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7 participants tested positive for HIV. Most (83.1%) participants reported no condom use during  
8  
9 their last sexual encounter. In addition, 40.7% reported having multiple sexual partners in the  
10  
11 past 30 days. Most (86.7%) participants had K-10 scores  $\geq 20$  indicating psychological distress.  
12  
13 Similarly, most (85.0%) participants had CES-D scores  $\geq 16$  indicating probable depression.  
14  
15 Table 1 depicts participants' demographic and clinical characteristics.  
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19  
20 Of the 60 enrolled participants, 35.0% completed the intervention. On average,  
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22 participants completed four of the six group sessions (M= 3.8; SD = 2.2), 68.0% of the sample  
23  
24 attended 3 or more of these groups. Fig. 1 provides reasons for missed sessions. We found no  
25  
26 baseline differences on socio-demographic characteristics, patterns of substance use, mental  
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28 health outcomes, type of trauma exposure or HIV status between intervention completers and  
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30 non-completers (see Table 1). Forty-five (75.0%) participants completed the one-month and 56  
31  
32 participants (93.3%) completed the three-month follow-up assessment. Fig. 1 provides reasons  
33  
34 for attrition. There were no baseline differences on socio-demographic characteristics, patterns of  
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36 substance use, mental health outcomes, type of trauma exposure or HIV status between  
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38 participants who completed the one- and three-month appointments and those who did not.  
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#### 44 *Outcomes*

45  
46 Participants significantly reduced the frequency of past-month heavy episodic drinking (t =2.9  
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48 (df= 47), p = 0.006), methamphetamine use (t =2.7 (df= 25), p = 0.012) and cannabis use (t =3.4  
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50 (df= 43), p = 0.001) from the baseline to three-month assessment (Table 2). The proportion of  
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52 participants who tested positive for methamphetamine (p < 0.0001), cannabis (p < 0.0001), and  
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3 methaqualone ( $p < 0.0001$ ) decreased significantly from baseline to three-month follow up  
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5 (Table 2).  
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8 Participants significantly reduced their CES-D ( $t = 5.3$  ( $df = 55$ ),  $p < 0.0001$ ) and K-10 ( $t$   
9  
10  $= 6.8$  ( $df = 55$ ),  $p < 0.0001$ ) scores over time as well as their trauma symptom scores ( $t = 9.4$  ( $df =$   
11  
12  $55$ ),  $p < 0.0001$ ). Social support did not improve from baseline to three-month time point (Table  
13  
14 2). For sexual risk outcomes, participants reported significant reductions in the number of past-  
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16 month STI symptoms ( $t = 5.7$  ( $df = 55$ ),  $p < 0.0001$ ) and the number of past-month sexual partners  
17  
18 ( $t = 3.5$  ( $df = 55$ ),  $p < 0.001$ ; Table 2). The proportion of participants who reported condom use at  
19  
20 last sexual encounter increased from baseline to three-month follow up, although this increase  
21  
22 was not statistically significant ( $p = 0.069$ ).  
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### 26 27 28 *Participants' perceptions of the intervention*

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30 Three broad themes emerged from the qualitative data that reflect participants' perceptions of the  
31  
32 intervention's acceptability. The first, *A moment to pause*, describes how the programme offered  
33  
34 participants an opportunity to reflect on changes they wished to make. The second theme, *Salient*  
35  
36 *programme content*, describes the intervention components that participants found most salient  
37  
38 and how they used this content for behavioural change. The third theme, *Areas for programme*  
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40 *strengthening*, reflects participants' recommendations for how to modify the intervention for  
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42 greater acceptability.  
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### 46 47 48 *A moment to pause*

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50 Almost all participants described how the programme offered them respite from their daily  
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52 struggles. For many, this was their first opportunity to "share their problems with someone" and  
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3 reflect on their past experiences, current needs, and future goals. Many participants felt that the  
4 intervention gave them “a different perspective on life” and helped them regain hope for their  
5 future despite their troubled past:  
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10 This programme opened my eyes that I am still young, I still have a future ahead of me  
11 despite everything that has happened to me. Now I can move on and still achieve big  
12 things. [Participant 12]  
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17 The intervention’s person-centred approach helped participants speak freely about their  
18 lives. Several participants described seeking trauma counselling in the past, but not following  
19 through because they felt judged and stigmatized. In contrast, participants were “thankful for  
20 how we were treated” in this intervention. For many participants, the “respectful” staff made  
21 them feel “valued” and “not alone with my problems.” Participants described how this made  
22 them feel safe enough to engage in the intervention:  
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30 You feel comfortable here. Things become less stressful when you get here.  
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33 [Participant 18]  
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35 I felt free [to talk], there was no-one who was judging me, telling me how wrong I was,  
36 or saying “you are doing such bad things” and judging my past. [Participant 15]  
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### 42 *Salient programme content* 43

44 Despite some initial concerns that the intervention would be “boring”, all participants seemed to  
45 gain new “knowledge and skills of how to live life positively.” Information about emotion-  
46 focused coping responses to trauma (such as substance use and risky sexual behaviour) together  
47 with strategies for managing emotion-related triggers for substance use was highly salient for  
48 participants:  
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3 It's these triggers that I need to overcome and through the program I've learned to  
4 overcome them and handle abuse. [Participant 12]  
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7 For most participants, anger towards others and self-loathing were common emotional  
8 triggers for substance use. Many participants reflected how they were now aware how a build-up  
9 of these negative emotions led to "explosions" that created conflict in their intimate and family  
10 relationships, social isolation, and triggered substance use:  
11  
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15 I was an angry person. Sometimes I would look at myself in the mirror and hate myself  
16 and end up crying. I was always sitting alone. [Participant 3]  
17  
18

19 I used to blame others or myself if bad things were happening. Sometimes I would be so  
20 angry out of the blue ... then you want to use drugs and then end up doing bad things and  
21 being hurt. [Participant 6]  
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28 Through the intervention, participants not only became aware of how these negative  
29 emotions were a response to unresolved trauma but also learned how to manage these negative  
30 emotions (and substance-related cravings) through exercise and mindfulness practice:  
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34 That mindfulness exercise we did with breathing. It helps me when I feel sad and lonely  
35 ... and to stop the cravings. [Participant 7]  
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38 I would be feeling tired, I would wake up feeling down. Now with this exercise, I wake  
39 up feeling fine. [Participant 10]  
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44 Participants also reported that the communication and conflict resolution strategies taught  
45 in the programme helped them better manage relationship conflict that triggered substance use  
46 and violence:  
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50 My boyfriend used to hit me when he is angry. Now he speaks to me. I also know how to  
51 speak to him. We get along and do not fight anymore. [Participant 2]  
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3 Almost all participants reflected how these new skills and strategies for coping with  
4 emotional and other triggers for substance use helped them take steps towards change:  
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6  
7 I can see change in my life. Ever since I came here I have become someone else, the  
8 person I want to become. It is happening step by step but there is some change.’  
9

10  
11  
12 [Participant 17]  
13

14 ‘I now know who I am and what I want from life. I learned how to control myself as I  
15 know what I want. I have learned to put the triggers away.’ [Participant 14]  
16  
17

18  
19 Mostly participants described reducing (rather than stopping) their substance use while  
20 acknowledging that these reductions led to improvements in the quality of their family and  
21 romantic relationships and impacted positively on their sexual risk behaviour:  
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23

24  
25 I have taken time off using drugs. Even at home there is some change. When I used  
26 drugs, I was always fighting at home ... we do not fight anymore because using drugs  
27 made us fight. [Participant 9]  
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31 I was using drugs and it [the program] helped me to reduce. I wasn’t using the condom  
32 but now I am using the condom when I am having sex. [Participant 5]  
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36 The self-care components of the intervention (including nutrition, budgeting and  
37 parenting) were less salient for participants and were rarely mentioned in the interviews.  
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#### 40 41 42 43 44 *Areas for programme strengthening*

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46 While participants seemed to benefit from the intervention, they highlighted two opportunities  
47 for programme strengthening. The first relates to sustainability and duration of counsellor  
48 contact, with participants remarking that they “felt bad” when the programme came to an end  
49 and “wished it to continue.” Instead of proposing additional intervention sessions, they  
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3 recommended reducing the intensity of the programme by spreading the sessions over six rather  
4 than two weeks. They thought this would not only enhance support for change but would also  
5 address some of the barriers that prevent women from fully engaging in intensive programmes:  
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10 The two weeks was very short, and I wish we could come back. It must be extended ... I  
11 wish it could be expanded so we were here for longer. [Participant 13]  
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14 A second concern was limited post-intervention support for change. Participants  
15 generally felt supported by others during the group sessions, describing the group as “supporting  
16 each other in the right way.” However, this support did not always extend into the community.  
17 While there were one or two exceptions, most participants did not develop emotionally  
18 supportive relationships with other group members beyond the confines of the programme.  
19 Several participants expressed the need for this community-based support but did not feel they  
20 could establish these support networks themselves:  
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30 We were supporting each other but the support was not like on point ... usually when we  
31 exit here we separate and never visit each other to see how they are doing. We never saw  
32 each other after the sessions. [Participant 3]  
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## 40 **DISCUSSION**

41  
42 Despite global HIV prevention guidelines that call for the provision of integrated substance use,  
43 trauma and sexual risk reduction services,<sup>18</sup> there are no interventions that address these  
44 intersecting risks for HIV among young women. During this Phase I study, we found high levels  
45 of unmet need for trauma-informed substance use interventions among women from poor  
46 communities in the Western Cape. Almost three-quarters of women screened disclosed physical  
47 or sexual trauma exposure, and more than half reported heavy alcohol or drug use. Women who  
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3 were eligible for our intervention demonstrated a strong desire for change, with more than 90%  
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5 accepting an offer of counselling.  
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7         As with other studies,<sup>12-13</sup> most of our participants had never initiated trauma or mental  
8  
9 health counselling. Along with concerns about stigma and discrimination, limited awareness of  
10  
11 services likely contributed to low rates of counselling initiation. Through continuous  
12  
13 community-based outreach and a person-centred approach, this study was able to overcome  
14  
15 many of these barriers to service initiation to reach and recruit a vulnerable group of trauma-  
16  
17 exposed young women with serious unmet substance use and mental health needs. This confirms  
18  
19 the feasibility of recruiting this vulnerable group of young women for a larger study.  
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24         In addition, findings provide preliminary evidence that this intervention may lead to  
25  
26 reductions in substance use, mental ill-health and sexual risk behaviour. Participants reported  
27  
28 reducing the frequency of heavy drinking, cannabis and methamphetamine use at the three-  
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30 month assessment, with biological evidence of significant reductions in the proportion of  
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32 participants testing positive for methamphetamine, cannabis, and methaqualone supporting self-  
33  
34 report data. Depression, psychological distress and trauma severity also diminished  
35  
36 significantly. Significant reductions in sexual risk behaviour were also noted with participants  
37  
38 reporting fewer sexual partners and STI symptoms at follow-up. Qualitative findings support  
39  
40 these results and suggest possible mechanisms of action. Women reflected how the intervention  
41  
42 helped them make positive changes to their substance use and sexual risk behaviour by  
43  
44 enhancing their understanding of substance use as a coping response to trauma and providing  
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46 them with practical tools for regulating negative emotions related to trauma and other stressors.  
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51         Despite these positive findings, participants reflected that the programme might have  
52  
53 greater success if it provided extended support for change. We had initially hoped that the groups  
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3 would naturally evolve into peer support networks, however these groups dissolved after the  
4 programme was completed. Quantitative findings support these observations: perceptions of  
5 social support did not improve because of the intervention. Future studies should consider  
6 explicitly training programme participants in group facilitation skills and supporting them to  
7 develop peer support networks. This modification may help support sustained behaviour change.  
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12 In addition, while we collected detailed contact information and actively tracked  
13 participants for intervention sessions, just over a third completed the programme. As the contact  
14 information for this mobile and marginalised population changed frequently, multiple tracking  
15 attempts were needed to locate participants for appointments. Given the short three-week  
16 window that participants had to complete the intervention, there were limited opportunities to  
17 make up missed sessions. Other South African studies using lengthy interventions ( $\geq$  five  
18 sessions) with vulnerable populations have also reported low completion rates, with participants  
19 expressing a preference for shorter interventions of three to four sessions.<sup>29-30</sup> As more than two-  
20 thirds of women in this study completed at least three group sessions, it may be more efficient to  
21 offer three rather than six sessions. Participants found the content on substance use, coping with  
22 trauma, and sexual risk most helpful. As this content was concentrated in three sessions, it seems  
23 possible to reduce the number of sessions without affecting programme acceptability. Trimming  
24 the intervention will allow for better spacing of intervention sessions (which participants  
25 explicitly requested as a means of extending contact with the programme) which also could  
26 provide more opportunities for rescheduling missed sessions. This could improve rates of  
27 programme completion. We plan to use these findings to abridge the intervention to three  
28 sessions, each spaced one week apart, with a six-week window within which to complete the  
29 programme.  
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3           These findings should be considered in the light of some limitations. The main limitation  
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5 is that this is a single arm, uncontrolled feasibility study. Findings should therefore be considered  
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7 preliminary and the efficacy of the intervention must still be established in a randomised trial.  
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9 However, our use of mixed methods allowed us to triangulate findings, thereby increasing our  
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11 confidence in the potential benefits of this intervention. Second, as recruitment was limited to  
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13 two low-income communities in the Western Cape, findings may not be generalizable to other  
14  
15 communities or parts of the country. Nonetheless, this study begins to establish the feasibility,  
16  
17 acceptability and preliminary effects of a novel, trauma-informed substance use and sexual risk  
18  
19 reduction intervention for young South African women. Findings are being used to modify and  
20  
21 truncate the intervention for greater efficiency and impact. We plan to assess the acceptability  
22  
23 and initial efficacy of this modified trauma-informed substance use and sexual risk intervention  
24  
25 in a Phase II pilot randomised trial.  
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### 33 **Author Contributions**

34  
35 BM and WMW jointly conceived the project, BM performed the analyses and drafted the  
36  
37 manuscript. FAB and TC played major roles in developing and organizing the project, data  
38  
39 collection and analyses, and revised draft versions of the manuscript critically. All authors read  
40  
41 and approved the final manuscript.  
42  
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46

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3 **Competing Interests:** None declared.  
4  
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7  
8 **Patient Consent:** Not required  
9

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11  
12 **Ethics approval:** The South African Medical Research Council (EC 003-2/2015) and RTI  
13  
14 International provided ethical approval for this study.  
15

16  
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18  
19 **Data sharing:** Quantitative data are available on reasonable request from the corresponding  
20  
21 author.  
22

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27  
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29  
30

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Legend: **Figure 1. Participant flow diagram**

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**Table 1. Baseline demographic and clinical characteristics of the overall sample (n= 60) and by treatment completion status**

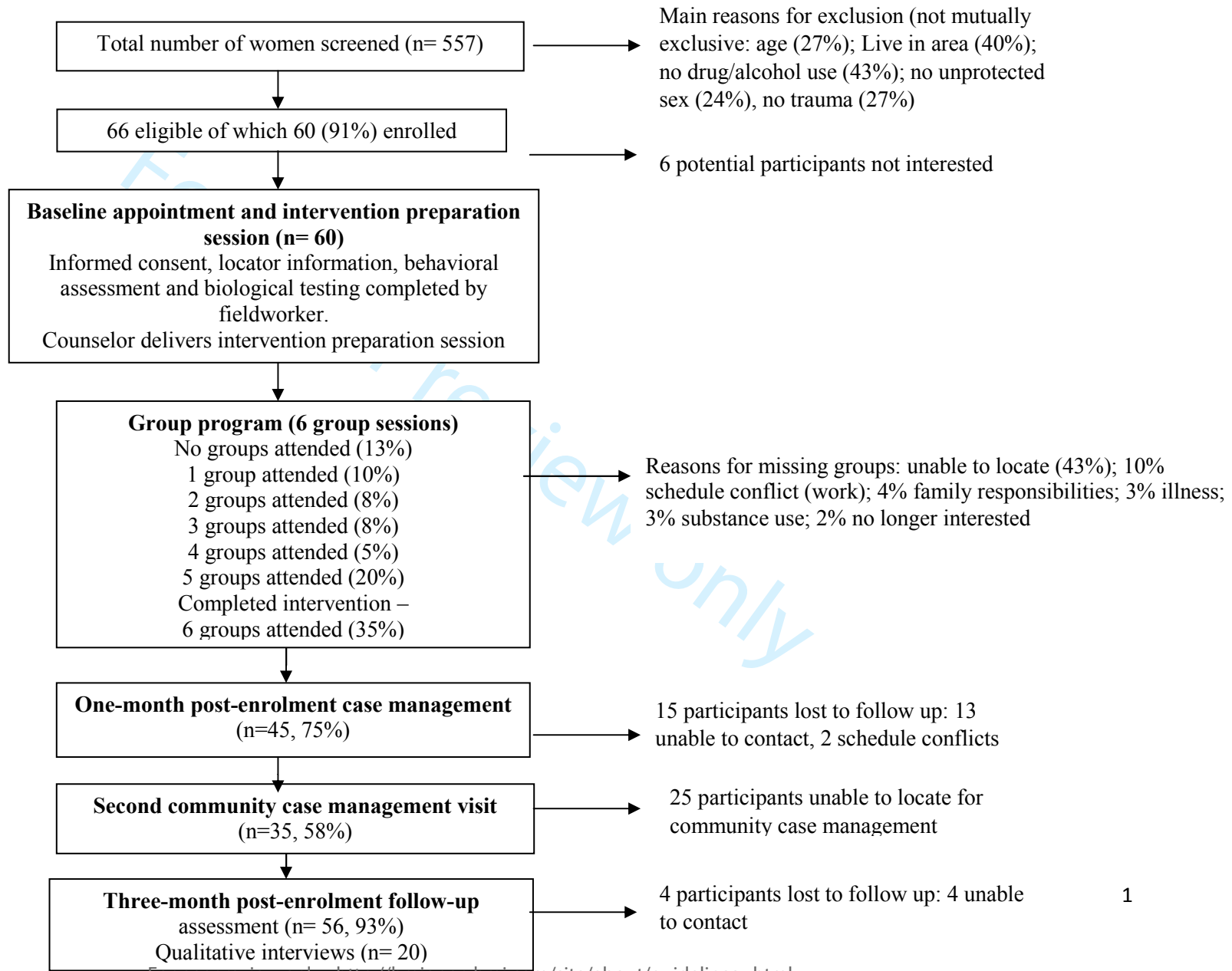
Variable	Overall	Treatment completion		
		Yes (n= 21)	No (n= 39)	<i>p</i>
<b>Socio-demographic variables</b>				
In a relationship (N, %)	55 (91.7%)	20 (95.2%)	35 (89.7%)	0.649
Employment (no; N, %)	55 (91.7%)	20 (95.2%)	35 (89.7%)	0.649
HIV status (positive; N, %)	28 (46.7%)	9 (42.9%)	19 (48.7%)	0.788
Sexual abuse (yes; N, %)	41 (68.3%)	13 (61.9%)	28 (71.8%)	0.562
Physical abuse (yes; N, %)	55 (91.7%)	19 (90.5%)	36 (92.3%)	0.602
Sexual and physical abuse (yes; N, %)	34 (56.7%)	10 (47.6%)	24 (61.5%)	0.414
<b>Substance use outcomes</b>				
Days of heavy drinking in past month (M, SD)	8.2 (6.4)	8.1 (6.0)	8.3 (6.7)	0.906
Days of cannabis use in past month (M, SD)	11.4 (11.9)	10.4 (11.7)	11.8 (12.1)	0.715
Days of methamphetamine in past month (M, SD)	18.4 (11.6)	13.5 (13.2)	20.2 (10.7)	0.227
Days of methaqualone use in past month (M, SD)	14.0 (11.9)	11.1 (13.1)	15.1 (11.6)	0.498
Cannabis positive (biological; N, %)	30 (50.0%)	9 (42.9%)	21 (53.8%)	0.589
Methamphetamine positive (biological; N, %)	27 (45.0%)	8 (38.1%)	19 (48.7%)	0.587
Methaqualone positive (biological; N, %)	29 (48.3%)	8 (38.1%)	21 (53.8%)	0.287
Opiate positive (biological; N, %)	4 (6.7%)	0 (0.0%)	4 (6.7%)	0.287
<b>Mental health outcomes</b>				
CES-D (M, SD)	26.1 (9.5)	27.4 (11.1)	25.4 (8.6)	0.489
K-10 (M, SD)	25.7 (6.8)	25.1 (7.6)	25.9 (6.5)	0.693

Trauma symptom (M, SD)	33.6 (5.6)	34.9 (7.6)	31.9 (7.4)	0.154
MOS-social support (M, SD)	60.1 (13.6)	59.2 (14.4)	61.3 (13.4)	0.593
<b>Sexual risk outcomes</b>				
Number of partners in last month (M, SD)	1.7 (1.5)	1.5 (0.7)	1.9 (1.8)	0.204
Condom use last sex (yes; N, %)	10 (16.9%)	2 (10.0%)	8 (20.5%)	0.469
Number of STI symptoms in last month (M, SD)	1.2 (0.9)	1.2 (0.6)	0.9 (1.1)	0.159

**Table 2. Change in substance use, mental health and sex risk outcomes (n= 56).**

<b>Outcomes</b>	<b>Baseline</b>	<b>3-month follow up</b>	<b>Baseline to follow up Mean difference (95% CI)</b>
<b>Substance use outcomes</b>	<i>M (SD)</i>	<i>M (SD)</i>	
Days of heavy drinking in past month	8.4 (6.1)	5.3 (6.9)	3.2 (0.9; 5.4)*
Days of cannabis use in past month	12.3 (12.4)	6.0 (9.2)	6.3 (2.6; 9.9)*
Days of methamphetamine in past month	19.5 (11.0)	11.7 (11.3)	7.8 (1.8; 13.7)*
Days of methaqualone in past month	14.9 (11.8)	9.9 (11.4)	4.9 (-0.7; 10.5)
Cannabis positive (biological) (N; %)	26 (46.4%)	21 (37.5%)*	-
Methamphetamine positive (biological) (N; %)	25 (44.6%)	20 (35.7%)*	-
Methaqualone positive (biological) (N; %)	27 (48.2%)	21 (37.5%)*	-
<b>Mental health outcomes</b>			
CES-D score	26.3 (9.6)	17.7 (7.3)	8.5 (5.3; 11.7)*
K-10 score	25.7 (6.9)	17.8 (7.3)	7.9 (5.6; 10.3)*
Trauma symptom score	32.9 (7.6)	21.7 (8.6)	11.2 (8.8; 13.6)*
MOS-social support score	60.6 (14.1)	63.5 (15.7)	-2.8 (-6.7; 1.1)
<b>Sex risk outcome</b>			
Number of partners in last month	1.7 (1.1)	1.0 (0.4)	0.6 (0.3; 1.1)*
Condom use at last sex (N; %)	8 (14.5%)	25 (45.5%)*	-
STI symptoms in past month	1.1 (0.9)	0.2 (0.8)	0.8 (0.5; 1.2)*

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**Good Reporting of a Mixed Methods Study (GRAMMS) checklist**

<b>Guideline</b>	<b>Section: page</b>
Describe the justification for using a mixed methods approach to the research question	Methods- under procedures and discussion p. 6, 18
Describe the design in terms of the purpose, priority and sequence of methods	Methods- procedures pg. 5-7
Describe each method in terms of sampling, data collection and analysis	Procedures pg 5-7 Analysis: pg. 8
Describe where integration has occurred, how it has occurred and who has participated in it	Design, discussion pg17-19
Describe any limitation of one method associated with the present of the other method	Discussion pg. 18
Describe any insights gained from mixing or integrating methods	Discussion: pg. 18

# BMJ Open

## A trauma-informed substance use and sexual risk reduction intervention for young South African women: a mixed-methods feasibility study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-024776.R1
Article Type:	Research
Date Submitted by the Author:	15-Nov-2018
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Manuscripts

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3 **A trauma-informed substance use and sexual risk reduction intervention for young South**  
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5 **African women: a mixed-methods feasibility study**  
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## ABSTRACT

**Objectives:** Sexual and physical trauma and substance use are intersecting risks for HIV among young women. This study assesses the feasibility, acceptability and preliminary effects of a novel trauma-informed substance use and sexual risk reduction intervention for young South African women.

**Design:** A single arm feasibility test and qualitative interviews of participants.

**Participants:** Sixty women, between 18 and 25 years of age who reported trauma exposure, substance use and recent condom-less sex were recruited. Twenty participants were randomly selected for qualitative interviews.

**Intervention:** A six session group-based intervention.

**Main Outcome Measures:** We examined the proportion of women who provided consent, completed counselling, and were retained in the study. Qualitative interviews explored intervention acceptability. Preliminary effects of the intervention on substance use, mental health (depression, psychological distress, trauma symptoms) and sexual risk outcomes (STI symptoms, number of partners, condom-less sex) were explored.

**Results:** Of the 66 eligible women, 91% were enrolled. Rates of intervention completion were low; 35% attended all sessions, although 68% completed at least three sessions. A 93% follow-up rate was achieved at the three-month end-point. In this single group design, significant reductions in the proportion of participants who tested positive for methamphetamine, cannabis, and methaqualone were observed at the three-month end-point. Symptoms of depression, psychological distress, and trauma, number of STI symptoms and number of sexual partners also decreased. Outcomes were similar for participants who completed three or fewer and those who

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3 completed four or more sessions. Participants thought the intervention was highly beneficial, and  
4  
5 proposed modifications to enhance acceptability.  
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7  
8 **Conclusions:** This novel intervention seems acceptable and holds potential benefits for trauma-  
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10 exposed women who use substances. Truncating the intervention may enhance the likelihood of  
11  
12 its implementation. The efficacy of the intervention for improving substance use, sexual risk and  
13  
14 mental health outcomes requires testing in a controlled design.  
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## 17 18 19 **ARTICLE SUMMARY**

### 20 21 **Strengths and limitations of this study**

- 22  
23 • One of the first studies to compare the feasibility and acceptability of a trauma-informed  
24  
25 substance use and sexual risk reduction intervention for young women  
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- 28  
29 • The use of mixed methods enables triangulation of findings, increasing confidence in the  
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31 results.  
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34 • Qualitative interviews provide a rich description of young women's experiences of the  
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36 intervention and recommendation for intervention enhancement.  
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- 38  
39 • As this single arm feasibility test lacked a comparison group, we cannot make inferences  
40  
41 about intervention efficacy.  
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45 **Keywords:** gender, substance use, mental health, sexual risk, low-and-middle-income country  
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## BACKGROUND

Substance use<sup>1</sup> and exposure to physical and sexual trauma<sup>2</sup> are highly prevalent, intersecting risks for HIV acquisition among young women in South Africa.<sup>3</sup> Substance use is a common coping strategy among trauma-exposed women who use substances to avoid or numb the negative emotions associated with traumatic experiences.<sup>4-5</sup> As substance use impairs decision-making which leads to inconsistent condom use,<sup>6</sup> this coping response may increase young women's risk for HIV. Substance use also places women in high-risk environments and fuels conflict in interpersonal relationships,<sup>7-8</sup> increasing risk of further exposure to physical and sexual trauma<sup>9</sup> and directly contributing to HIV risk.<sup>10</sup> With a high incidence of HIV among young women in emerging adulthood,<sup>11</sup> South Africa needs innovative programmes that address these syndemic risks for HIV acquisition amongst this vulnerable population.

Although several HIV prevention programmes reach young South African women, these generally do not focus on women who have been trauma-exposed and may be using substances. Further, trauma and substance use services in South Africa are provided by separate systems of care.<sup>12-13</sup> As substance use services do not provide trauma counselling, women with histories of trauma are often reluctant to utilise these services and those that do tend to have poorer substance use outcomes than women without a history of physical or sexual abuse.<sup>9,14</sup>

In high-income countries, trauma-informed substance use interventions have been recommended as a means of overcoming barriers to trauma-exposed women's use of substance use services.<sup>15</sup> Evidence from systematic reviews suggests that this integrated approach leads to significant reductions in substance use and trauma symptoms among women with these multi-morbidities.<sup>16-17</sup> Despite global HIV prevention guidelines for adolescent girls and young women that recommend the provision of integrated mental health, substance use and HIV prevention

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3 services for young women,<sup>18</sup> trauma-informed substance use interventions have generally not  
4 included HIV prevention components,<sup>16</sup> reflecting a missed opportunity to address sexual safety  
5 among this highly vulnerable population. To illustrate, none of the 23 studies identified in a recent  
6 systematic review of interventions that address alcohol use, violence and sexual risk for HIV  
7 directly addressed psychological trauma and substance use coping.<sup>19</sup> To meet the intervention  
8 needs of this unique population, we developed a trauma-informed substance use and sexual risk  
9 reduction intervention for South African women in emerging adulthood.  
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19 This study aimed to (i) assess the feasibility of recruiting and retaining trauma-exposed  
20 women who use substances in this intervention; (ii) obtain preliminary information on the  
21 intervention's substance use, mental health and sex risk outcomes and (iii) explore participants'  
22 perceptions of the acceptability of the intervention. This information is needed to guide decision  
23 making about the future of the programme and whether it is worth investing in a randomised  
24 controlled trial (RCT) to establish its efficacy.  
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## 35 **METHODS**

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37 This manuscript follows the Consolidated Statement for Reporting Trials (CONSORT) guidelines  
38 for pilot and feasibility trials<sup>20</sup> (see Supplementary file 1). This Phase I feasibility study, conducted  
39 between July 2016 and February 2017, tested a trauma-informed substance use and sexual risk  
40 reduction intervention combined with post-programme qualitative interviews of participants.  
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### 49 **Participants and procedures**

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51 We recruited 60 young women from two low-income, peri-urban communities in Cape Town,  
52 South Africa. The estimated population size of these communities combined is more than 1.5  
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3 million people, of which 99% identify as Black African and are isiXhosa speaking, about 40% are  
4 unemployed, and over half live in informal dwellings or shacks. These communities have high  
5 rates of HIV (estimated prevalence is 35%) and have been identified as provincial “hotspots” for  
6 substance use and violent crime including violence against women and children.<sup>21-22</sup> From July  
7 2016 to September 2016, fieldworkers used established community-based street outreach  
8 techniques<sup>23</sup> to identify potential participants to whom they described the study before requesting  
9 verbal consent for eligibility screening. This involved the distribution of marketing flyers and  
10 posters in places frequented by women and approaching potential participants in locations  
11 frequented by women who use substances. Women were eligible if they were between 18 and 25  
12 years old; lived in the target communities; and reported lifetime experiences of sexual or physical  
13 abuse, using at least one illicit drug or heavy episodic drinking (defined as four or more alcoholic  
14 drinks on one occasion) weekly for the past three months, and condom-less sex in the past three  
15 months. Fieldworkers gave eligible women more information about the study and invited those  
16 who were eligible and interested to an enrolment appointment (see Fig 1).

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At the enrolment appointment, fieldworkers rescreened women to verify study eligibility and obtained their informed consent before collecting contact information, administering the baseline behavioural assessment, and conducting rapid biological testing for recent drug use, pregnancy and HIV. All data were collected through interviewer-administered questionnaires. The Medical Diagnostech drug test and NHMed tests were used to test urine samples for methamphetamine, cocaine, opiates, THC (cannabis) and methaqualone use in the past 72 hours. Following standard HIV testing and counselling, two rapid finger-prick tests were used to test for HIV (Unigold and Determine Rapid Tests). If either test was reactive or indeterminate, a confirmatory Tri-line HIV-1/2 Rapid Test was performed. A participant was considered HIV



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3 positive when at least two tests were reactive. Participants were also breathalysed to assess recent  
4 alcohol use. Immediately after this assessment, participants received information about the  
5 intervention programme, they developed a personalised action plan, and appointments were  
6 scheduled for the first available group session. Participants had three weeks to complete the  
7 intervention programme. All participants were offered two case management visits (at one and  
8 two-months post enrolment) either at the project site or in the community. The purpose of these  
9 visits was to enquire about the participant's barriers to accessing sexual and reproductive or mental  
10 health services and to provide referrals to care. Participants were tracked for a three-month post-  
11 enrolment follow-up appointment at which time participants were re-consented, the behavioural  
12 assessment was re-administered, and they were re-tested for recent substance use, HIV and  
13 pregnancy. In addition, twenty participants were randomly selected for a qualitative in-depth  
14 interview of their perceptions of the acceptability and utility of the programme. These interviews,  
15 conducted by an experienced qualitative researcher in isiXhosa (the primary language spoken by  
16 participants), occurred after their three-month assessment and lasted approximately 45 minutes.  
17 Interviews were audio-recorded and transcribed verbatim before being translated into English  
18 using standard forward-and back-translation techniques. All study-related activities (assessments  
19 and the intervention) occurred in private rooms at an established clinical research site located  
20 within a nearby local community.  
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44 After each contact, participants were given referrals to additional substance use and trauma  
45 counselling and appropriate sexual and reproductive health services. Participants received grocery  
46 vouchers for completing the baseline and follow-up appointments and the qualitative interviews  
47 as well as transport to these appointments. Participants were not incentivised to attend the  
48 intervention sessions, although transport and refreshments were provided.  
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## Intervention

We developed a novel trauma-informed substance use and sexual risk reduction intervention for young South African women, known as the trauma-informed Women's Health Coop (WHC). The process of developing this intervention has been described elsewhere.<sup>24</sup> The intervention comprises six open-group sessions delivered over a two-week period. As such, participants who missed sessions had the opportunity to make up these sessions by attending another group. As trauma-exposed women using substances in our formative work had expressed their preference for an intensive programme of a brief duration, the intervention was delivered over a two-week period.<sup>24</sup> Groups generally consisted of four to eight women.

The intervention is grounded in feminist empowerment theory and cognitive-behavioural therapy, which has strong evidence in support of its effectiveness for treating trauma and substance use disorders.<sup>17,25</sup> The intervention provides psychoeducation about substance use, trauma and HIV; cognitive-behavioural strategies for identifying emotional triggers for substance use, emotional regulation, adaptive coping and problem-solving, and managing cravings; conflict resolution and sexual safety skills training; and self-care strategies for sustaining recovery and creating a meaningful life. Participants were given opportunities for skills rehearsal and a handout summarising session content and containing exercises for further skills practice. At the end of the programme, participants review their personalised action plan, which was re-reviewed during case management activities that occurred one and two months after enrolment.

## Counsellor training and supervision

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3 A registered psychological counsellor, fluent in isiXhosa, was trained to deliver the programme.  
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5 She received two weeks of training in the intervention which included an assessment of her  
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7 competence to deliver the intervention. The training curriculum was manualised. We audio-  
8  
9 recorded the group sessions and reviewed a random sample for fidelity. During weekly  
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11 supervision, findings from these fidelity checks were used to provide feedback to the counsellor  
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13 on how to improve intervention quality.  
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## 19 **Measures**

### 20 *Sociodemographic variables*

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22 Sociodemographic variables included participants' employment status (employed versus  
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24 unemployed), relationship status (single versus in a relationship) and HIV status (positive or  
25  
26 negative). Type of trauma exposure was assessed using items from the Trauma History  
27  
28 questionnaire.<sup>26</sup> A positive response to any of the three items on sexual abuse was classified as  
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30 sexually abused; any of the three physical abuse questions as physically abused; and at least one  
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32 physical *and* one sexual abuse item as both physically and sexually abused.  
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### 40 *Substance use outcomes*

41  
42 Change in recent drug use was assessed through results of biological testing (positive versus  
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44 negative). Questions on the number of days of heavy episodic drinking (defined as four or more  
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46 drinks on one occasion), methamphetamine, cannabis, and methaqualone use in the past 30 days  
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48 assessed change in frequency of substance use.  
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### 53 *Mental health outcomes*

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3 The 20-item Centre for Epidemiologic Studies Depression Scale (CES-D) assessed change in  
4 depressive symptomatology.<sup>27</sup> For this scale, a cut-off score  $\geq 16$  indicates probable depression.<sup>28</sup>  
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6 The 10-item Kessler Psychological Distress Scale (K-10) measured change in symptoms of  
7 psychological distress. This scale has been shown to have good psychometric properties in South  
8 African studies, with a cut-off score  $\geq 20$  indicating psychological distress.<sup>29</sup> The 10-item Drug  
9 Abuse Treatment Outcome Study post-traumatic stress disorder (PTSD) scale,<sup>30</sup> adapted for use in  
10 South African populations, assessed changes in trauma symptoms. The 19-item Medical Outcomes  
11 Study Social Support Survey (MOS-SSS) assessed change in perceived social support. This scale  
12 has excellent psychometric properties.<sup>31</sup>  
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### 26 *Sexual risk outcomes*

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28 Change in condom use was assessed through a question on condom use at last sexual encounter.  
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30 Questions on the number of sexual partners and number of symptoms of sexually transmitted  
31 infections (STI) in the past month also assessed change in sexual risk behaviour.  
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### 38 **Patient and public involvement**

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40 The intervention and the design of the feasibility test were informed by focus group discussions  
41 with potential service users and interviews with providers of substance use, HIV and psychological  
42 trauma services.<sup>23</sup> Our community advisory board that comprises representatives from the  
43 Department of Health, Department of Social Development, non-government organisations, and  
44 service user organisations contributed to the design of the study and the interpretation of findings.  
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### 54 **Analyses**

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3 We used SPSS version 25.0 to describe the proportion of participants who completed the  
4 intervention and retention at three-month follow-up. We used Chi-square tests (or Fisher exact  
5 tests if cell sizes were small) for categorical and t-tests for continuous variables to explore whether  
6 participant attributes were associated with intervention and study completion. Chi-square tests  
7 explored change from baseline to three-month follow-up on the categorical outcome variables.  
8 Paired sample t-tests were used to examine whether there was change on the outcomes from  
9 baseline to follow-up. Results are presented as differences in mean scores with 95% confidence  
10 intervals. All testing was two-sided and a significance level of 0.05 was used.  
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22 The framework approach<sup>32</sup> was used for qualitative data analysis. Two people coded the  
23 interview transcripts using NVivo version 11; they met regularly to compare notes and resolved  
24 discrepancies through discussion. A third person was not needed to break coding ties. No new  
25 codes emerged after coding half the transcripts, implying thematic saturation. Inter-coder  
26 reliability was high, with a Kappa score of 0.93.  
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## 35 RESULTS

### 36 *Feasibility of patient recruitment and retention*

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38 Field staff screened 557 young women for potential study eligibility of which 66 met the study's  
39 eligibility criteria, the majority were ineligible based on their age (older), residence, and because  
40 they did not report recent unprotected sex. Almost three quarters (72.6%) of women screened  
41 reported trauma exposure and more than half (56.9%) heavy alcohol or drug use. Of the eligible  
42 women, 60 (90.7%) were interested in study participation and were enrolled (see Fig 1). Table 1  
43 describes the sociodemographic and clinical characteristics of the sample. Most participants  
44 (93.3%) had never received substance use or trauma care, and 85.0% reported not knowing where  
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3 to go for these services. Most (86.7%) participants had K-10 scores  $\geq 20$  indicating psychological  
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5 distress and 85.0% of participants had CES-D scores  $\geq 16$  indicating probable depression.  
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8 Of the 60 enrolled participants, 35.0% completed the intervention. On average,  
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10 participants attended four of the six group sessions (M= 3.8; SD = 2.2), with 13.3% (n=8) not  
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12 attending any group sessions. About two-thirds (68.0%) of the sample attended three or more of  
13  
14 these groups. Fig. 1 provides reasons for missed sessions. The association between being newly  
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16 diagnosed with HIV and not completing treatment approached significance; no other baseline  
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18 characteristics were associated with treatment completion (Table 1). Fifty-six participants (93.3%)  
19  
20 completed the three-month follow-up assessment. Fig. 1 provides reasons for attrition. There were  
21  
22 no baseline differences on socio-demographic or clinical characteristics between participants who  
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24 completed the three-month appointment and those who did not.  
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### 30 31 *Outcomes*

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33 Participants reduced the frequency of past-month heavy episodic drinking (t =2.9 (df= 47), p =  
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35 0.006), methamphetamine use (t =2.7 (df= 25), p = 0.012) and cannabis use (t =3.4 (df= 43), p =  
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37 0.001) from the baseline to three-month assessment (Table 2). The proportion of participants who  
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39 tested positive for methamphetamine (p < 0.0001), cannabis (p < 0.0001), and methaqualone (p <  
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41 0.0001) decreased significantly from baseline to three-month follow up (Table 2).  
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45 Participants significantly reduced their CES-D (t =5.3 (df= 55), p < 0.0001) and K-10 (t  
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47 =6.8 (df= 55), p < 0.0001) scores over time as well as their trauma symptom scores (t =9.4 (df=  
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49 55), p <0.0001). The proportion of participants with probable depression decreased (85.7% to  
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51 53.6% Chi-square = 3.94 (df=1), p = 0.047) suggesting clinically significant improvements. Social  
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53 support did not improve from baseline to three-month time point (Table 2). For sexual risk  
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3 outcomes, participants reported significant reductions in the number of past-month STI symptoms  
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5 (t =5.7 (df= 55), p <0.0001) and the number of past-month sexual partners (t =3.5 (df= 55), p  
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7 <0.001; Table 2). The proportion of participants who reported condom use at last sexual encounter  
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9 increased from baseline to three-month follow up, although this increase was not statistically  
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11 significant (p = 0.069). Exploratory analyses found similar substance use, mental health and sexual  
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13 risk outcomes for participants who completed three or fewer sessions and those who completed  
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15 four or more sessions (Table 2).  
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### 21 *Participants' perceptions of the intervention*

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23 Three broad themes emerged from the qualitative data that reflect participants' perceptions of the  
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25 intervention. The first, *A moment to pause*, describes how the programme offered participants an  
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27 opportunity to reflect on changes they wished to make. The second theme, *Salient programme*  
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29 *content*, describes the intervention components that participants found most salient and useful for  
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31 behaviour change. The third theme, *Areas for programme strengthening*, reflects participants'  
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33 recommendations for how to modify the intervention for greater acceptability.  
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#### 40 *A moment to pause*

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42 Almost all participants described how the programme offered them respite from their daily  
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44 struggles. For many, this was their first opportunity to “share their problems with someone” and  
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46 reflect on their past experiences, current needs, and future goals. Many participants felt that the  
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48 intervention gave them “a different perspective on life” and helped them regain hope for their  
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50 future despite their troubled past:  
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3 This programme opened my eyes that I am still young, I still have a future ahead of me  
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5 despite everything that has happened to me. Now I can move on and still achieve big things.  
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8 [Participant 12]  
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10 The intervention also seemed to encourage participants to speak freely about their lives.  
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12 Several participants described seeking trauma counselling in the past, but not following through  
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14 because they felt judged and stigmatized. In contrast, participants were “thankful for how we were  
15  
16 treated” in this intervention. For many participants, the “respectful” staff made them feel “valued”  
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18 and “not alone with my problems.” Participants described how this made them feel safe enough to  
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20 engage in the intervention:  
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24 I felt free [to talk], there was no-one who was judging me, telling me how wrong I was, or  
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26 saying “you are doing such bad things” and judging my past. [Participant 15]  
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### 31 *Salient programme content*

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33 Despite some initial concerns that the intervention would be “boring”, all participants seemed to  
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35 gain new “knowledge and skills of how to live life positively.” Information about emotion-focused  
36  
37 coping responses to trauma (such as substance use and risky sexual behaviour) together with  
38  
39 strategies for managing emotion-related triggers for substance use was highly salient for  
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41 participants:  
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45 It’s these triggers that I need to overcome and through the program I’ve learned to  
46  
47 overcome them and handle abuse. [Participant 12]  
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49 For most participants, anger towards others and self-loathing were common emotional  
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51 triggers for substance use. Many participants reflected how they were now aware how a build-up  
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3 of these negative emotions led to “explosions” that created conflict in their intimate and family  
4 relationships, social isolation, and triggered substance use:  
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8 I was an angry person. Sometimes I would look at myself in the mirror and hate myself  
9 and end up crying. I was always sitting alone. [Participant 3]  
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11

12 I used to blame others or myself if bad things were happening. Sometimes I would be so  
13 angry out of the blue ... then you want to use drugs and then end up doing bad things and  
14 being hurt. [Participant 6]  
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19 Through the intervention, participants not only became aware of how these negative  
20 emotions were a response to unresolved trauma but also learned how to manage these negative  
21 emotions (and substance-related cravings) through exercise and mindfulness practice:  
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24 That mindfulness exercise we did with breathing. It helps me when I feel sad and lonely ...  
25 and to stop the cravings. [Participant 7]  
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30 Participants also reported that the communication and conflict resolution strategies taught  
31 in the programme helped them better manage relationship conflict that triggered substance use and  
32 violence:  
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36 My boyfriend used to hit me when he is angry. Now he speaks to me. I also know how to  
37 speak to him. We get along and do not fight anymore. [Participant 2]  
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42 Almost all participants reflected how these new skills and strategies for coping with  
43 emotional and other triggers for substance use helped them take steps towards change:  
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46 I can see change in my life. Ever since I came here I have become someone else, the person  
47 I want to become. It is happening step by step but there is some change.’  
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51 [Participant 17]  
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3 ‘I now know who I am and what I want from life. I learned how to control myself as I  
4 know what I want. I have learned to put the triggers away.’ [Participant 14]  
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7  
8 Mostly participants described reducing (rather than stopping) their substance use while  
9  
10 acknowledging that these reductions led to improvements in the quality of their family and  
11  
12 romantic relationships and impacted positively on their sexual risk behaviour:  
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14  
15 I was using drugs and it [the program] helped me to reduce. I wasn’t using the condom but  
16  
17 now I am using the condom when I am having sex. [Participant 5]  
18

19  
20 The self-care components of the intervention (including nutrition, budgeting and parenting)  
21  
22 were less salient for participants and were rarely mentioned in the interviews.  
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### 26 *Areas for programme strengthening*

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28 While participants seemed to benefit from the intervention, they highlighted some opportunities  
29  
30 for programme strengthening. The first relates to sustainability and duration of counsellor contact,  
31  
32 with participants remarking that they “felt bad” when the programme came to an end and “wished  
33  
34 it to continue.” Instead of proposing additional intervention sessions, they recommended reducing  
35  
36 the intensity of the programme by spreading the sessions over six rather than two weeks. They  
37  
38 thought this would not only enhance support for change but would also address some of the barriers  
39  
40 that prevent women from fully engaging in intensive programmes:  
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44  
45 The two weeks was very short, and I wish we could come back. It must be extended ... I  
46  
47 wish it could be expanded so we were here for longer. [Participant 13]  
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49  
50 A second concern for some participants was the group format. Several participants  
51  
52 described feeling “uncomfortable” sharing painful experiences with other women in the group due  
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3 to concerns about stigma and disclosure. This seemed a particularly salient issue in groups where  
4 participants came from the same neighbourhood and “all knew each other”:  
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7  
8 Like the other day I came with my friend. I noticed that she was not participating, maybe  
9  
10 it was because we know each other. I feel like if in the group we can come from different  
11  
12 communities so that we don't judge and share who is in the group outside, then we will be  
13  
14 free and share a lot. [Participant 4]  
15  
16

17 The degree to which participants were able to relate to the experiences of group members also  
18  
19 seemed to influence their views of the group. Where participants felt that they shared experiences  
20  
21 with others, they were more likely to report feeling satisfied with the group format and tended to  
22  
23 describe the groups as “supporting each other in the right way” and that “we were one group, we  
24  
25 would talk one thing all of us.” In contrast, participants who felt there were major differences  
26  
27 between group members were highly concerned about being judged by others:  
28  
29

30  
31 We did not understand each other into my group. I think we were different because there  
32  
33 were those who used drugs and those who drank alcohol. Those drinking alcohol would  
34  
35 separate themselves. It's going to be better if us people using drugs sit alone and have a  
36  
37 mutual conversation. [Participant 19]  
38  
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40

41 A further concern was limited post-intervention support for change. While there were one  
42  
43 or two exceptions, most participants did not develop emotionally supportive relationships with  
44  
45 other group members beyond the confines of the programme. Several participants expressed the  
46  
47 need for this community-based support but did not feel they could establish these support networks  
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49 themselves:  
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3 We were supporting each other but the support was not like on point ... usually when we  
4  
5 exit here we separate and never visit each other to see how they are doing. We never saw  
6  
7 each other after the sessions. [Participant 3]  
8  
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## 10 11 12 **DISCUSSION** 13

14  
15 Despite global HIV prevention guidelines that call for the provision of integrated substance use,  
16  
17 psychological trauma and sexual risk reduction services,<sup>18</sup> to the best of our knowledge there are  
18  
19 no interventions that address these intersecting risks for HIV among young trauma-exposed South  
20  
21 African women. During this Phase I study, we found high levels of unmet need for trauma-  
22  
23 informed substance use interventions among women from poor communities in the Western Cape.  
24  
25 Almost three-quarters of women screened disclosed physical or sexual trauma exposure, and more  
26  
27 than half reported heavy alcohol or drug use. Women who were eligible for our intervention  
28  
29 demonstrated a strong desire for change, with more than 90% accepting an offer of counselling.  
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33 As with other studies,<sup>12-13</sup> most of our participants had never initiated trauma or mental  
34  
35 health counselling. Along with concerns about stigma and discrimination, limited awareness of  
36  
37 services likely contributed to low rates of counselling initiation. Through continuous community-  
38  
39 based outreach and a person-centred approach, this study was able to reach and recruit a vulnerable  
40  
41 group of trauma-exposed young women with unmet substance use and mental health needs. This  
42  
43 confirms the feasibility of recruiting this vulnerable group of young women for a larger study.  
44  
45 Nonetheless, as this study's strict eligibility criteria around age, recent sexual activity and  
46  
47 residence limited the number of eligible women we identified, we plan to broaden these inclusion  
48  
49 criteria to ensure a future trial can recruit sufficient numbers of trauma-exposed women and to  
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3 enhance the generalizability of findings to the broad population of trauma-exposed women who  
4 use substances.  
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8 In addition, findings provide preliminary evidence of the potential benefits of this  
9  
10 intervention. Participants reported reducing the frequency of heavy drinking, cannabis and  
11  
12 methamphetamine use at the three-month assessment, with biological evidence of significant  
13  
14 reductions in the proportion of participants testing positive for methamphetamine, cannabis, and  
15  
16 methaqualone supporting self-report data. Depression, psychological distress and trauma severity  
17  
18 also diminished significantly, with improvements to depression reaching clinical significance.  
19  
20 Significant reductions in sexual risk behaviour were also noted with participants reporting fewer  
21  
22 sexual partners and STI symptoms at follow-up. Qualitative findings support these results and  
23  
24 suggest possible mechanisms of action. Women reflected how the intervention helped them make  
25  
26 positive changes to their substance use and sexual risk behaviour by enhancing their understanding  
27  
28 of substance use as a coping response to trauma and providing them with practical tools for  
29  
30 regulating negative emotions related to trauma and other stressors.  
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35  
36 Participants did however reflect that the programme might have greater success if it  
37  
38 provided extended support for change. We had initially hoped that the groups would evolve into  
39  
40 peer support networks, however these groups dissolved after the programme was completed. As  
41  
42 group membership was open rather than closed, this may have contributed to the lack of  
43  
44 sustainability. Quantitative findings support these observations: perceptions of social support did  
45  
46 not improve because of the intervention. Regardless of whether the intervention remains group-  
47  
48 based or transitions to an individual format, future studies should consider including community-  
49  
50 based peer support groups as part of the intervention. This modification may help support  
51  
52 continued development of coping skills and consequently help women sustain any initial behaviour  
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3 changes. Further qualitative work exploring potential service users' preferences for the facilitation,  
4 structure and content of these peer support groups is needed to guide the development of this  
5 intervention component.  
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10 Despite these promising outcomes, the poor rate of treatment completion raises concerns  
11 about the intervention's feasibility and highlights the need for additional modifications. Although  
12 we collected detailed contact information and actively tracked participants for intervention  
13 sessions, just over a third completed the programme. Several factors may have impacted on  
14 treatment completion rates. Participants who were newly diagnosed with HIV seemed less likely  
15 to complete treatment than those who were already aware of their status. This is not surprising  
16 given that other studies have shown that people are more likely to accept the offer of mental health  
17 counselling if they have been given time to adjust to their diagnosis.<sup>33</sup> To ensure optimal  
18 participation, future studies should consider providing this highly vulnerable sub-group with  
19 additional supports.  
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33 Additionally, given the short window within which participants could complete the  
34 intervention, there were limited opportunities to make up missed sessions. Other South African  
35 studies using lengthy interventions ( $\geq$  five sessions) with vulnerable populations have also reported  
36 low completion rates, with participants expressing a preference for shorter interventions of three  
37 to four sessions.<sup>33-35</sup> As more than two-thirds of women in this study completed at least three group  
38 sessions, it may be more efficient to offer three rather than six sessions. Participants found the  
39 content on substance use, coping with trauma, and sexual risk most helpful. As this content was  
40 concentrated in three sessions, it seems possible to reduce the number of sessions without affecting  
41 programme acceptability. Further support for this suggestion is provided by findings that  
42 participants who completed up to three intervention sessions had similar outcomes to those who  
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3 completed four or more sessions. Trimming the intervention will allow for better spacing of  
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5 intervention sessions (which participants explicitly requested as a means of extending contact with  
6  
7 the programme) which also could provide more opportunities for rescheduling missed sessions.  
8  
9  
10 This could improve rates of programme completion. We plan to use these findings to abridge the  
11  
12 intervention to three sessions, each spaced one week apart, with a six-week window within which  
13  
14 to complete the programme.  
15

16  
17 Another plausible explanation for the low uptake of the intervention may lie in the  
18  
19 intervention's group format. Although participants expressed a desire for a group-based  
20  
21 intervention during our formative work<sup>24</sup> and we took several steps to promote comfort with the  
22  
23 group format (such as reinforcing group ground rules around respect and confidentiality at the  
24  
25 beginning of each session), several women still expressed discomfort with the group format during  
26  
27 the post-intervention qualitative interviews. This was largely due to concerns about stigma and  
28  
29 privacy, together with difficulties in relating to the diverse experiences of other group members.  
30  
31 Concerns about stigma and sexual trauma disclosure, along with the low uptake of group-based  
32  
33 intervention components have been reported in other studies of South African women with  
34  
35 histories of sexual trauma.<sup>36-37</sup> Given these findings, we plan to adapt the intervention for delivery  
36  
37 in an individual format, and test whether this improves intervention uptake amongst this vulnerable  
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39 population.  
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45 Despite the lower than anticipated treatment completion rate, 93% of women completed  
46  
47 their three-month follow-up assessment. This study completion rate is similar to that obtained in  
48  
49 other women-focused intervention studies conducted by our team<sup>8,9,14</sup> and demonstrates the  
50  
51 effectiveness of our protocols for limiting attrition and the feasibility of retaining this hard-to-  
52  
53 reach population in a larger trial.  
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3 These are some limitations to this study. The main limitation is that this is a single arm,  
4 uncontrolled feasibility study. Findings are preliminary and the efficacy of the intervention and  
5 whether outcomes of this trauma-informed approach differ from the original WHC still needs to  
6 be established in a RCT. Without an RCT of the intervention, we are unable to determine whether  
7 the changes observed are attributable to the intervention or other factors. However, our use of  
8 mixed methods allowed us to triangulate findings, thereby increasing our confidence in the  
9 potential benefits of this intervention. Second, while we used objective measures of recent drug  
10 use, we did not include an objective measure of recent alcohol use. In future studies we plan to  
11 include testing for phosphatidylethanol (a biomarker for alcohol use).<sup>38</sup> Third, as recruitment was  
12 limited to two low-income communities in the Western Cape, findings may not be generalizable  
13 to other communities. Nonetheless, this study begins to establish the feasibility, acceptability and  
14 preliminary effects of a novel, trauma-informed substance use and sexual risk reduction  
15 intervention for young South African women. Findings are being used to modify the intervention  
16 for greater efficiency and impact. We plan to assess the acceptability and initial efficacy of this  
17 modified trauma-informed substance use and sexual risk intervention in a Phase II RCT.  
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#### 40 **Author Contributions**

41  
42 BM and WMW jointly conceived the project, BM performed the analyses and drafted the  
43 manuscript. FAB and TC played major roles in developing and organizing the project, data  
44 collection and analyses, and revised draft versions of the manuscript critically. All authors read  
45 and approved the final manuscript.  
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11  
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16  
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20  
21 **Ethics approval:** The South African Medical Research Council (EC 003-2/2015) and RTI  
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23 International provided ethical approval for this study.  
24  
25

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27  
28 **Data sharing:** Quantitative data are available on reasonable request from the corresponding  
29  
30 author.  
31  
32

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38  
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40  
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**Table 1. Baseline demographic and clinical characteristics of the overall sample (n= 60) and by treatment completion status**

Variable	Overall	Treatment completion		
		Yes (n= 21)	No (n= 39)	<i>p</i>
<b>Socio-demographic variables</b>				
In a relationship (N, %)	55 (91.7%)	20 (95.2%)	35 (89.7%)	0.649
Employment (no; N, %)	55 (91.7%)	20 (95.2%)	35 (89.7%)	0.649
HIV status (positive; N, %)	28 (46.7%)	9 (42.9%)	19 (48.7%)	0.788
Newly diagnosed as HIV positive (yes; N, %)	10 (35.7%)	1(11.1%)	9 (47.4%)	0.06
Sexual abuse (yes; N, %)	41 (68.3%)	13 (61.9%)	28 (71.8%)	0.562
Physical abuse (yes; N, %)	55 (91.7%)	19 (90.5%)	36 (92.3%)	0.602
Sexual and physical abuse (yes; N, %)	34 (56.7%)	10 (47.6%)	24 (61.5%)	0.414
<b>Substance use outcomes</b>				
Days of heavy drinking in past month (M, SD)	8.2 (6.4)	8.1 (6.0)	8.3 (6.7)	0.906
Days of cannabis use in past month (M, SD)	11.4 (11.9)	10.4 (11.7)	11.8 (12.1)	0.715
Days of methamphetamine in past month (M, SD)	18.4 (11.6)	13.5 (13.2)	20.2 (10.7)	0.227
Days of methaqualone use in past month (M, SD)	14.0 (11.9)	11.1 (13.1)	15.1 (11.6)	0.498
Cannabis positive (biological; N, %)	30 (50.0%)	9 (42.9%)	21 (53.8%)	0.589
Methamphetamine positive (biological; N, %)	27 (45.0%)	8 (38.1%)	19 (48.7%)	0.587
Methaqualone positive (biological; N, %)	29 (48.3%)	8 (38.1%)	21 (53.8%)	0.287
Opiate positive (biological; N, %)	4 (6.7%)	0 (0.0%)	4 (6.7%)	0.287
<b>Mental health outcomes</b>				
CES-D (M, SD)	26.1 (9.5)	27.4 (11.1)	25.4 (8.6)	0.489

K-10 (M, SD)	25.7 (6.8)	25.1 (7.6)	25.9 (6.5)	0.693
Trauma symptom (M, SD)	33.6 (5.6)	34.9 (7.6)	31.9 (7.4)	0.154
MOS-social support (M, SD)	60.1 (13.6)	59.2 (14.4)	61.3 (13.4)	0.593
<b>Sexual risk outcomes</b>				
Number of partners in last month (M, SD)	1.7 (1.5)	1.5 (0.7)	1.9 (1.8)	0.204
Condom use last sex (yes; N, %)	10 (16.9%)	2 (10.0%)	8 (20.5%)	0.469
Number of STI symptoms in last month (M, SD)	1.2 (0.9)	1.2 (0.6)	0.9 (1.1)	0.159



**Table 2. Change in substance use, mental health and sex risk outcomes for the overall sample (n= 56) and by intervention exposure.**

Outcomes	Overall sample (n= 56)			Exposure to $\leq 3$ sessions		Exposure to $\geq 4$ sessions	
	Baseline	3-month follow up	Baseline to follow up Mean difference (95% CI)	Baseline	3-month follow up	Baseline	3-month follow up
<b>Substance use outcomes</b>	<i>M (SD)</i>	<i>M (SD)</i>		<i>M (SD)</i>	<i>M (SD)</i>	<i>M (SD)</i>	<i>M (SD)</i>
Days of heavy drinking in past month	8.4 (6.1)	5.3 (6.9)	3.2 (0.9; 5.4)*	8.7 (7.0)	6.3 (7.0)	8.3 (5.8)	4.8 (6.9)*
Days of cannabis use in past month	12.3 (12.4)	6.0 (9.2)	6.3 (2.6; 9.9)*	15.4 (13.7)	5.2 (8.1)*	11.0 (11.8)	6.4 (9.7)*
Days of methamphetamine in past month	19.5 (11.0)	11.7 (11.3)	7.8 (1.8; 13.7)*	22.7 (8.4)	9.4 (10.8)*	17.8 (12.0)	10.9 (11.7)
Days of methaqualone in past month	14.9 (11.8)	9.9 (11.4)	4.9 (-0.7; 10.5)	15.0 (11.3)	8.6 (10.1)	14.8 (12.5)	10.6 (12.3)
Cannabis positive (biological) (N; %)	26 (46.4%)	21 (37.5%)*	-	12 (63.2%)	8 (42.1%)*	18 (43.9%)	13 (31.7%)*
Methamphetamine positive (biological) (N; %)	25 (44.6%)	20 (35.7%)*	-	11 (57.9%)	8 (42.1%)*	18 (43.9%)	13 (31.7%)*
Methaqualone positive (biological) (N; %)	27 (48.2%)	21 (37.5%)*	-	11 (57.9%)	8 (42.1%)*	18 (43.9%)	13 (31.7%)*

<b>Mental health outcomes</b>							
CES-D score	26.3 (9.6)	17.7 (7.3)	8.5 (5.3; 11.7)*	24.4 (9.7)	17.4 (8.3)*	27.1(9.6)	17.9(6.9)*
K-10 score	25.7 (6.9)	17.8 (7.3)	7.9 (5.6; 10.3)*	25.0 (6.7)	17.3 (8.3)*	25.9 (6.9)	17.9 (7.0)*
Trauma symptom score	32.9 (7.6)	21.7 (8.6)	11.2 (8.8; 13.6)*	31.2(8.3)	21.8 (7.2)*	33.6 (7.3)	21.6 (9.2)*
MOS-social support score	60.6 (14.1)	63.5 (15.7)	-2.8 (-6.7; 1.1)	57.9 (13.8)	61.1 (16.8)	61.8 (14.2)	64.4 (15.3)
<b>Sex risk outcome</b>							
Number of partners in last month	1.7 (1.1)	1.0 (0.4)	0.6 (0.3; 1.1)*	2.3 (2.4)	1.3 (0.8)*	1.5 (0.9)	0.9 (0.4)*
Condom use at last sex (N; %)	2 (6.7%)	8 (24.0%)	-	0 (0%)	1 (12.5%)	2 (9.1%)	5 (29.4%)
STI symptoms in past month	1.1 (0.9)	0.2 (0.8)	0.8 (0.5; 1.2)*	1.1 (1.2)	0.4 (1.2)*	1.2 (0.8)	0.1 (0.6)*

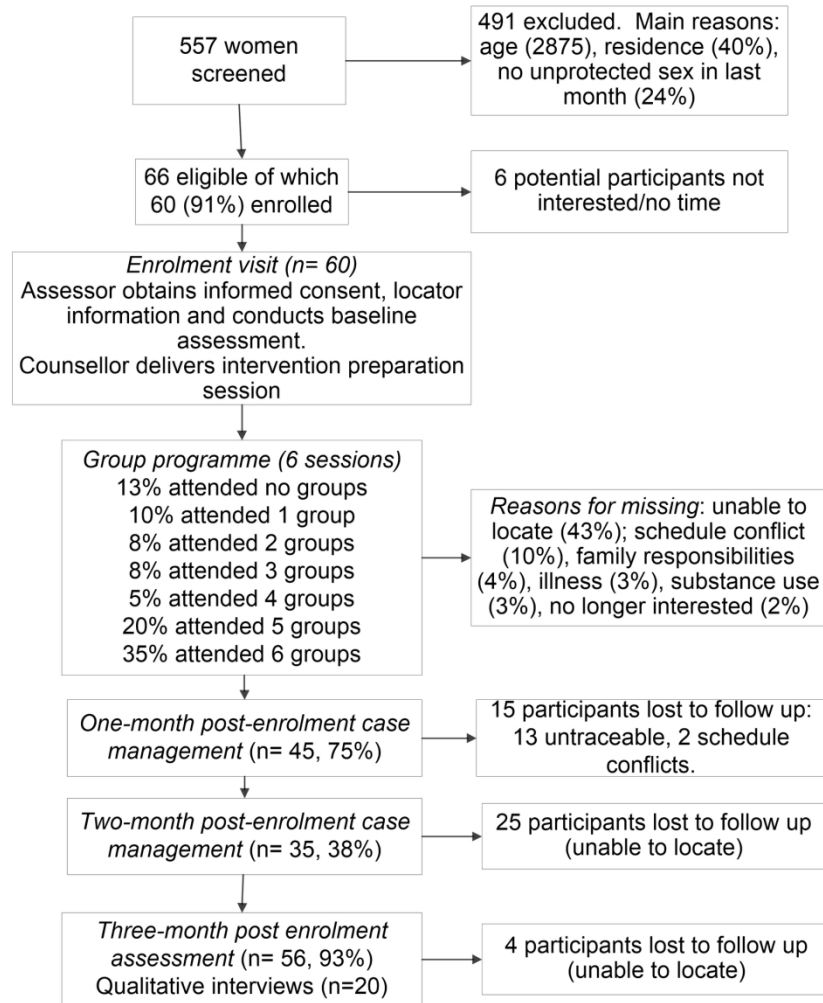
\*significant at p <0.05

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**Figure Legend:**

**Figure 1. Participant flow chart**

For peer review only



Participant flow

90x90mm (600 x 600 DPI)



## CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4
	2b	Specific objectives or research questions for pilot trial	5
<b>Methods</b>			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6-7
	4c	How participants were identified and consented	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	9-10
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	n/a
Sample size	7a	Rationale for numbers in the pilot trial	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	n/a
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	n/a
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	n/a

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	n/a
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	n/a
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	11
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	12
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
	14b	Why the pilot trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	n/a
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Table 2
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	12-18
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
	19a	If relevant, other important unintended consequences	n/a
<b>Discussion</b>			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	21-22
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	21-22
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	21-22
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	21-22
<b>Other information</b>			
Registration	23	Registration number for pilot trial and name of trial registry	n/a
Protocol	24	Where the pilot trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	25
	26	Ethical approval or approval by research review committee, confirmed with reference number	25

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).

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# BMJ Open

## A trauma-informed substance use and sexual risk reduction intervention for young South African women: a mixed-methods feasibility study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-024776.R2
Article Type:	Research
Date Submitted by the Author:	11-Dec-2018
Complete List of Authors:	Myers, Bronwyn; South African medical Research Council, Alcohol, Tobacco and Other Drug Research Unit Carney, Tara; South African Medical Research Council, Browne, Felicia; RTI International, Substance Use and Gender Research (SUGAR) program Wechsberg, Wendee; RTI International,
<b>Primary Subject Heading</b>:	Mental health
Secondary Subject Heading:	Addiction, HIV/AIDS
Keywords:	MENTAL HEALTH, Substance misuse < PSYCHIATRY, HIV & AIDS < INFECTIOUS DISEASES, Public health < INFECTIOUS DISEASES

SCHOLARONE™  
Manuscripts



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3 **A trauma-informed substance use and sexual risk reduction intervention for young South**  
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5 **African women: a mixed-methods feasibility study**  
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10 Bronwyn Myers<sup>1,2</sup>, Tara Carney<sup>1,2</sup>, Felicia A. Browne<sup>3</sup>, Wendee M. Wechsberg<sup>3-6</sup>  
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## ABSTRACT

**Objectives:** Sexual and physical trauma and substance use are intersecting risks for HIV among young women. This study assesses the feasibility, acceptability and preliminary effects of a novel trauma-informed substance use and sexual risk reduction intervention for young South African women.

**Design:** A single arm feasibility test and qualitative interviews of participants.

**Participants:** Sixty women, between 18 and 25 years of age who reported trauma exposure, substance use and recent condom-less sex were recruited. Twenty participants were randomly selected for qualitative interviews.

**Intervention:** A six session group-based intervention.

**Main Outcome Measures:** We examined the proportion of women who provided consent, completed counselling, and were retained in the study. Qualitative interviews explored intervention acceptability. Preliminary effects of the intervention on substance use, mental health (depression, psychological distress, trauma symptoms) and sexual risk outcomes (STI symptoms, number of partners, condom-less sex) were explored.

**Results:** Of the 66 eligible women, 91% were enrolled. Intervention completion rates were low; 35% attended all sessions. On average, participants attended four sessions (M= 3.8, SD= 1.3). A 93% follow-up rate was achieved at the three-month end-point. In this single group design, reductions in the proportion of participants who tested positive for methamphetamine, cannabis, and methaqualone were observed at the three-month end-point. Symptoms of depression, psychological distress, and trauma, number of STI symptoms and number of sexual partners also decreased. Outcomes were similar for participants who completed up to four and those who

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3 completed five or more sessions. Participants thought the intervention was highly beneficial, and  
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5 proposed modifications to enhance acceptability.  
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8 **Conclusions:** This novel intervention seems acceptable and holds potential benefits for trauma-  
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10 exposed women who use substances. Truncating the intervention may enhance the likelihood of  
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12 its implementation. The efficacy of the intervention for improving substance use, sexual risk and  
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14 mental health outcomes requires testing in a controlled design.  
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## 17 18 19 **ARTICLE SUMMARY**

### 20 21 **Strengths and limitations of this study**

- 22  
23 • One of the first studies to explore the feasibility and acceptability of a trauma-informed  
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25 substance use and sexual risk reduction intervention for young women  
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29 • The use of mixed methods enables triangulation of findings, increasing confidence in the  
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31 results.  
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34 • Qualitative interviews provide a rich description of young women's experiences of the  
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36 intervention and recommendation for intervention enhancement.  
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- 38  
39 • As this single arm feasibility test lacked a comparison group, we cannot make inferences  
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41 about intervention efficacy.  
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45 **Keywords:** gender, substance use, mental health, sexual risk, low-and-middle-income country  
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## BACKGROUND

Substance use<sup>1</sup> and exposure to physical and sexual trauma<sup>2</sup> are highly prevalent, intersecting risks for HIV acquisition among young women in South Africa.<sup>3</sup> Substance use is a common coping strategy among trauma-exposed women who use substances to avoid or numb the negative emotions associated with traumatic experiences.<sup>4-5</sup> As substance use impairs decision-making which leads to inconsistent condom use,<sup>6</sup> this coping response may increase young women's risk for HIV. Substance use also places women in high-risk environments and fuels conflict in interpersonal relationships,<sup>7-8</sup> increasing risk of further exposure to physical and sexual trauma<sup>9</sup> and directly contributing to HIV risk.<sup>10</sup> With a high incidence of HIV among young women in emerging adulthood,<sup>11</sup> South Africa needs innovative programmes that address these syndemic risks for HIV acquisition amongst this vulnerable population.

Although several HIV prevention programmes reach young South African women, these generally do not focus on women who have been trauma-exposed and may be using substances. Further, trauma and substance use services in South Africa are provided by separate systems of care.<sup>12-13</sup> As substance use services do not provide trauma counselling, women with histories of trauma are often reluctant to utilise these services and those that do tend to have poorer substance use outcomes than women without a history of physical or sexual abuse.<sup>9,14</sup>

In high-income countries, trauma-informed substance use interventions have been recommended as a means of overcoming barriers to trauma-exposed women's use of substance use services.<sup>15</sup> Evidence from systematic reviews suggests that this integrated approach leads to significant reductions in substance use and trauma symptoms among women with these multi-morbidities.<sup>16-17</sup> Despite global HIV prevention guidelines for adolescent girls and young women that recommend the provision of integrated mental health, substance use and HIV prevention

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3 services for young women,<sup>18</sup> trauma-informed substance use interventions have generally not  
4 included HIV prevention components,<sup>16</sup> reflecting a missed opportunity to address sexual safety  
5 among this highly vulnerable population. To illustrate, none of the 23 studies identified in a recent  
6 systematic review of interventions that address alcohol use, violence and sexual risk for HIV  
7 directly addressed psychological trauma and substance use coping.<sup>19</sup> To meet the intervention  
8 needs of this unique population, we developed a trauma-informed substance use and sexual risk  
9 reduction intervention for South African women in emerging adulthood.

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19 This study aimed to (i) assess the feasibility of recruiting and retaining trauma-exposed  
20 women who use substances in this intervention; (ii) obtain preliminary information on the  
21 intervention's substance use, mental health and sex risk outcomes and (iii) explore participants'  
22 perceptions of the acceptability of the intervention. This information is needed to guide decision  
23 making about the future of the programme and whether it is worth investing in a randomised  
24 controlled trial (RCT) to establish its efficacy.  
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## 35 **METHODS**

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37 This manuscript follows the Consolidated Statement for Reporting Trials (CONSORT) guidelines  
38 for pilot and feasibility trials<sup>20</sup> (see Supplementary file 1). This Phase I feasibility study, conducted  
39 between July 2016 and February 2017, tested a trauma-informed substance use and sexual risk  
40 reduction intervention combined with post-programme qualitative interviews of participants.  
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### 49 **Participants and procedures**

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51 We recruited 60 young women from two low-income, peri-urban communities in Cape Town,  
52 South Africa. The estimated population size of these communities combined is more than 1.5  
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3 million people, of which 99% identify as Black African and are isiXhosa speaking, about 40% are  
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5 unemployed, and over half live in informal dwellings or shacks. These communities have high  
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7 rates of HIV (estimated prevalence is 35%), and have been identified as provincial “hotspots” for  
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9 substance use and violent crime including violence against women and children.<sup>21-22</sup> From July  
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11 2016 to September 2016, fieldworkers used established community-based street outreach  
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13 techniques<sup>23</sup> to identify potential participants to whom they described the study before requesting  
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15 verbal consent for eligibility screening. This involved the distribution of marketing flyers and  
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17 posters in places frequented by women and approaching potential participants in locations  
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19 frequented by women who use substances. Women were eligible if they were between 18 and 25  
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21 years old; lived in the target communities; and reported lifetime experiences of sexual or physical  
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23 abuse, using at least one illicit drug or heavy episodic drinking (defined as four or more alcoholic  
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25 drinks on one occasion) weekly for the past three months, and condom-less sex in the past three  
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27 months. Fieldworkers gave eligible women more information about the study and invited those  
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29 who were eligible and interested to an enrolment appointment (see Fig 1).  
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35 At the enrolment appointment, fieldworkers rescreened women to verify study eligibility  
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37 and obtained their informed consent before collecting contact information, administering the  
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39 baseline behavioural assessment, and conducting rapid biological testing for recent drug use,  
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41 pregnancy and HIV. All data were collected through interviewer-administered questionnaires. The  
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43 Medical Diagnostech drug test and NHMed tests were used to test urine samples for  
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45 methamphetamine, cocaine, opiates, THC (cannabis) and methaqualone use in the past 72 hours.  
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47 Following standard HIV testing and counselling, two rapid finger-prick tests were used to test for  
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49 HIV (Unigold and Determine Rapid Tests). If either test was reactive or indeterminate, a  
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51 confirmatory Tri-line HIV-1/2 Rapid Test was performed. A participant was considered HIV  
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3 positive when at least two tests were reactive. Participants were also breathalysed to assess recent  
4 alcohol use. Immediately after this assessment, participants received information about the  
5 intervention programme, they developed a personalised action plan, and appointments were  
6 scheduled for the first available group session. Participants had three weeks to complete the  
7 intervention programme. All participants were offered two case management visits (at one and  
8 two-months post enrolment) either at the project site or in the community. The purpose of these  
9 visits was to enquire about the participant's barriers to accessing sexual and reproductive or mental  
10 health services, to provide referrals to care and to remain in contact with the participants for  
11 retention purposes. Participants were tracked for a three-month post-enrolment follow-up  
12 appointment at which time participants were re-consented, the behavioural assessment was re-  
13 administered, and they were re-tested for recent substance use, HIV and pregnancy. In addition,  
14 twenty participants were randomly selected for a qualitative in-depth interview of their perceptions  
15 of the acceptability and utility of the programme. These interviews, conducted by an experienced  
16 qualitative researcher in isiXhosa (the primary language spoken by participants), occurred after  
17 their three-month assessment and lasted approximately 45 minutes. Interviews were audio-  
18 recorded and transcribed verbatim before being translated into English using standard forward-and  
19 back-translation techniques. All study-related activities (assessments and the intervention)  
20 occurred in private rooms at an established clinical research site located within a nearby local  
21 community.

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47 After each contact, participants were given referrals to additional substance use and trauma  
48 counselling and appropriate sexual and reproductive health services. Participants received grocery  
49 vouchers for completing the baseline and follow-up appointments and the qualitative interviews  
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3 as well as transport to these appointments. Participants were not incentivised to attend the  
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5 intervention sessions, although transport and refreshments were provided.  
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## 10 **Intervention**

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12 We developed a novel trauma-informed substance use and sexual risk reduction intervention for  
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14 young South African women, known as the trauma-informed Women's Health Coop (WHC). The  
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16 process of developing this intervention has been described elsewhere.<sup>24</sup> The intervention  
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18 comprises six open-group sessions delivered over a two-week period. As such, participants who  
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20 missed sessions had the opportunity to make up these sessions by attending another group. As  
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22 trauma-exposed women using substances in our formative work had expressed their preference for  
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24 an intensive programme of a brief duration, the intervention was delivered over a two-week  
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26 period.<sup>24</sup> Groups generally consisted of four to eight women.  
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31 The intervention is grounded in feminist empowerment theory and cognitive-behavioural  
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33 therapy, which has strong evidence in support of its effectiveness for treating trauma and substance  
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35 use disorders.<sup>17,25</sup> The intervention provides psychoeducation about substance use, trauma and  
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37 HIV; cognitive-behavioural strategies for identifying emotional triggers for substance use,  
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39 emotional regulation, adaptive coping and problem-solving, and managing cravings; conflict  
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41 resolution and sexual safety skills training; and self-care strategies for sustaining recovery and  
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43 creating a meaningful life. Participants were given opportunities for skills rehearsal and a handout  
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45 summarising session content and containing exercises for further skills practice. At the end of the  
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47 programme, participants review their personalised action plan, which was re-reviewed during case  
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49 management activities that occurred one and two months after enrolment.  
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### **Counsellor training and supervision**

A registered psychological counsellor, fluent in isiXhosa, was trained to deliver the programme. She received two weeks of training in the intervention which included an assessment of her competence to deliver the intervention. The training curriculum was manualised. We audio-recorded the group sessions and reviewed a random sample for fidelity. During weekly supervision, findings from these fidelity checks were used to provide feedback to the counsellor on how to improve intervention quality.

### **Measures**

#### *Sociodemographic variables*

Sociodemographic variables included participants' employment status (employed versus unemployed), relationship status (single versus in a relationship) and HIV status (positive or negative). Type of trauma exposure was assessed using items from the Trauma History questionnaire.<sup>26</sup> A positive response to any of the three items on sexual abuse was classified as sexually abused; any of the three physical abuse questions as physically abused; and at least one physical *and* one sexual abuse item as both physically and sexually abused.

#### *Substance use outcomes*

Change in recent drug use was assessed through results of biological testing (positive versus negative). Questions on the number of days of heavy episodic drinking (defined as four or more drinks on one occasion), methamphetamine, cannabis, and methaqualone use in the past 30 days assessed change in frequency of substance use.

### *Mental health outcomes*

The 20-item Centre for Epidemiologic Studies Depression Scale (CES-D) assessed change in depressive symptomatology.<sup>27</sup> For this scale, a cut-off score  $\geq 16$  indicates probable depression.<sup>28</sup>

The 10-item Kessler Psychological Distress Scale (K-10) measured change in symptoms of psychological distress. This scale has been shown to have good psychometric properties in South African studies, with a cut-off score  $\geq 20$  indicating psychological distress.<sup>29</sup> The 10-item Drug Abuse Treatment Outcome Study post-traumatic stress disorder (PTSD) scale,<sup>30</sup> adapted for use in South African populations, assessed changes in trauma symptoms. The 19-item Medical Outcomes Study Social Support Survey (MOS-SSS) assessed change in perceived social support. This scale has excellent psychometric properties.<sup>31</sup>

### *Sexual risk outcomes*

Change in condom use was assessed through a question on condom use at last sexual encounter. Questions on the number of sexual partners and number of symptoms of sexually transmitted infections (STI) in the past month also assessed change in sexual risk behaviour.

### **Patient and public involvement**

The intervention and the design of the feasibility test were informed by focus group discussions with potential service users and interviews with providers of substance use, HIV and psychological trauma services.<sup>23</sup> Our community advisory board that comprises representatives from the Department of Health, Department of Social Development, non-government organisations, and service user organisations contributed to the design of the study and the interpretation of findings.

## Analyses

We used SPSS version 25.0 to describe the proportion of participants who completed the intervention and retention at three-month follow-up. We used Chi-square tests (or Fisher exact tests if cell sizes were small) for categorical and t-tests for continuous variables to explore whether participant attributes were associated with intervention and study completion. Chi-square tests explored change from baseline to three-month follow-up on the categorical outcome variables. Paired sample t-tests were used to examine whether there was change on the outcomes from baseline to follow-up. Results are presented as differences in mean scores with 95% confidence intervals. All testing was two-sided and a significance level of 0.05 was used.

The framework approach<sup>32</sup> was used for qualitative data analysis. Two people coded the interview transcripts using NVivo version 11; they met regularly to compare notes and resolved discrepancies through discussion. A third person was not needed to break coding ties. No new codes emerged after coding half the transcripts, implying thematic saturation. Inter-coder reliability was high, with a Kappa score of 0.93.

## RESULTS

### *Feasibility of patient recruitment and retention*

Field staff screened 557 young women for potential study eligibility of which 66 met the study's eligibility criteria, the majority were ineligible based on their age (older), residence, and because they did not report recent unprotected sex. Almost three quarters (72.6%) of women screened reported trauma exposure and more than half (56.9%) heavy alcohol or drug use. Of the eligible women, 60 (90.7%) were interested in study participation and were enrolled (see Fig 1). Table 1 describes the sociodemographic and clinical characteristics of the sample. Most participants

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3 (93.3%) had never received substance use or trauma care, and 85.0% reported not knowing where  
4 to go for these services. Most (86.7%) participants had K-10 scores  $\geq 20$  indicating psychological  
5 distress and 85.0% of participants had CES-D scores  $\geq 16$  indicating probable depression.  
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10 Of the 60 enrolled participants, 35.0% completed the intervention. On average,  
11 participants attended four of the six group sessions ( $M = 3.8$ ;  $SD = 1.3$ ), with 13.3% ( $n = 8$ ) not  
12 attending any group sessions. For the case management visits, 45 participants (75%) received a  
13 case management visit one month after enrolment and 35 (38%) received a case management visit  
14 two months post-enrolment. Fig. 1 provides reasons for missed appointments. The association  
15 between being newly diagnosed with HIV and not completing treatment approached significance;  
16 no other baseline characteristics were associated with treatment completion (Table 1). Fifty-six  
17 participants (93.3%) completed the three-month follow-up assessment. Fig. 1 provides reasons for  
18 attrition. There were no baseline differences on socio-demographic or clinical characteristics  
19 between participants who completed the three-month appointment and those who did not.  
20 Although not significant, 97% ( $n = 34$ ) of the 35 participants who received case management  
21 completed the three-month assessment compared to 88% ( $n = 22$ ) of the 25 participants without  
22 case management.  
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#### 44 *Outcomes*

45 Participants reduced the frequency of past-month heavy episodic drinking ( $t = 2.9$  ( $df = 47$ ),  $p =$   
46  $0.006$ ), methamphetamine use ( $t = 2.7$  ( $df = 25$ ),  $p = 0.012$ ) and cannabis use ( $t = 3.4$  ( $df = 43$ ),  $p =$   
47  $0.001$ ) from the baseline to three-month assessment (Table 2). The proportion of participants who  
48 tested positive for methamphetamine ( $p < 0.0001$ ), cannabis ( $p < 0.0001$ ), and methaqualone ( $p <$   
49  $0.0001$ ) decreased significantly from baseline to three-month follow up (Table 2).  
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3 Participants significantly reduced their CES-D ( $t = 5.3$  ( $df = 55$ ),  $p < 0.0001$ ) and K-10 ( $t$   
4  $= 6.8$  ( $df = 55$ ),  $p < 0.0001$ ) scores over time as well as their trauma symptom scores ( $t = 9.4$  ( $df =$   
5  $55$ ),  $p < 0.0001$ ). The proportion of participants with probable depression decreased (85.7% to  
6 53.6% Chi-square = 3.94 ( $df = 1$ ),  $p = 0.047$ ) suggesting clinically significant improvements. Social  
7 support did not improve from baseline to three-month time point (Table 2). For sexual risk  
8 outcomes, participants reported significant reductions in the number of past-month STI symptoms  
9 ( $t = 5.7$  ( $df = 55$ ),  $p < 0.0001$ ) and the number of past-month sexual partners ( $t = 3.5$  ( $df = 55$ ),  $p$   
10  $< 0.001$ ; Table 2). The proportion of participants who reported condom use at last sexual encounter  
11 increased from baseline to three-month follow up, although this increase was not statistically  
12 significant ( $p = 0.069$ ). As participants generally completed four group sessions, we explored  
13 whether there were differences in outcomes among participants who completed up to four sessions  
14 and those who completed five or six sessions. Participants who completed up to and including four  
15 sessions and participants who completed five or more sessions had similar substance use, mental  
16 health and sexual risk outcomes (Table 2). We also explored whether there were differences in  
17 outcomes among participants who received at least one case management visit and those who did  
18 not participate in case management. Only participants who received case management reported  
19 reducing the frequency of past-month heavy episodic drinking ( $t = 2.1$  ( $df = 29$ ),  $p = 0.045$ ) and  
20 cannabis use ( $t = 3.4$  ( $df = 27$ ),  $p = 0.002$ ) from the baseline to three-month assessment. No other  
21 differences in outcomes were observed between these two groups.

### 22 23 24 *Participants' perceptions of the intervention*

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27 Three broad themes emerged from the qualitative data that reflect participants' perceptions of the  
28 intervention. The first, *A moment to pause*, describes how the programme offered participants an

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3 opportunity to reflect on changes they wished to make. The second theme, *Salient programme*  
4 *content*, describes the intervention components that participants found most salient and useful for  
5  
6 behaviour change. The third theme, *Areas for programme strengthening*, reflects participants'  
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8 recommendations for how to modify the intervention for greater acceptability.  
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#### 11 12 13 14 15 *A moment to pause*

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17 Almost all participants described how the programme offered them respite from their daily  
18  
19 struggles. For many, this was their first opportunity to “share their problems with someone” and  
20  
21 reflect on their past experiences, current needs, and future goals. Many participants felt that the  
22  
23 intervention gave them “a different perspective on life” and helped them regain hope for their  
24  
25 future despite their troubled past:  
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29 This programme opened my eyes that I am still young, I still have a future ahead of me  
30  
31 despite everything that has happened to me. Now I can move on and still achieve big things.

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33 [Participant 12]  
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36 The intervention also seemed to encourage participants to speak freely about their lives.  
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38 Several participants described seeking trauma counselling in the past, but not following through  
39  
40 because they felt judged and stigmatized. In contrast, participants were “thankful for how we were  
41  
42 treated” in this intervention. For many participants, the “respectful” staff made them feel “valued”  
43  
44 and “not alone with my problems.” Participants described how this made them feel safe enough to  
45  
46 engage in the intervention:  
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50 I felt free [to talk], there was no-one who was judging me, telling me how wrong I was, or  
51  
52 saying, “you are doing such bad things,” and judging my past. [Participant 15]  
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3 *Salient programme content*  
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6 Despite some initial concerns that the intervention would be “boring”, all participants seemed to  
7  
8 gain new “knowledge and skills of how to live life positively.” Information about emotion-focused  
9  
10 coping responses to trauma (such as substance use and risky sexual behaviour) together with  
11  
12 strategies for managing emotion-related triggers for substance use was highly salient for  
13  
14 participants:  
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16  
17 It’s these triggers that I need to overcome and through the program I’ve learned to  
18  
19 overcome them and handle abuse. [Participant 12]  
20

21  
22 For most participants, anger towards others and self-loathing were common emotional  
23  
24 triggers for substance use. Many participants reflected how they were now aware how a build-up  
25  
26 of these negative emotions led to “explosions” that created conflict in their intimate and family  
27  
28 relationships, social isolation, and triggered substance use:  
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31 I was an angry person. Sometimes I would look at myself in the mirror and hate myself  
32  
33 and end up crying. I was always sitting alone. [Participant 3]  
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35  
36 I used to blame others or myself if bad things were happening. Sometimes I would be so  
37  
38 angry out of the blue ... then you want to use drugs and then end up doing bad things and  
39  
40 being hurt. [Participant 6]  
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43 Through the intervention, participants not only became aware of how these negative  
44  
45 emotions were a response to unresolved trauma but also learned how to manage these negative  
46  
47 emotions (and substance-related cravings) through exercise and mindfulness practice:  
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50 That mindfulness exercise we did with breathing. It helps me when I feel sad and lonely ...  
51  
52 and to stop the cravings. [Participant 7]  
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3 Participants also reported that the communication and conflict resolution strategies taught  
4 in the programme helped them better manage relationship conflict that triggered substance use and  
5 violence:  
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10 My boyfriend used to hit me when he is angry. Now he speaks to me. I also know how to  
11 speak to him. We get along and do not fight anymore. [Participant 2]  
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14 Almost all participants reflected how these new skills and strategies for coping with  
15 emotional and other triggers for substance use helped them take steps towards change:  
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18  
19 I can see change in my life. Ever since I came here I have become someone else, the person  
20 I want to become. It is happening step by step but there is some change.’  
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24 [Participant 17]  
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26 ‘I now know who I am and what I want from life. I learned how to control myself as I  
27 know what I want. I have learned to put the triggers away.’ [Participant 14]  
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30 Mostly participants described reducing (rather than stopping) their substance use while  
31 acknowledging that these reductions led to improvements in the quality of their family and  
32 romantic relationships and impacted positively on their sexual risk behaviour:  
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36 I was using drugs and it [the program] helped me to reduce. I wasn’t using the condom but  
37 now I am using the condom when I am having sex. [Participant 5]  
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40 The self-care components of the intervention (including nutrition, budgeting and parenting)  
41 were less salient for participants and were rarely mentioned in the interviews.  
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#### 45 46 47 48 49 *Areas for programme strengthening* 50

51 While participants seemed to benefit from the intervention, they highlighted some opportunities  
52 for programme strengthening. The first relates to sustainability and duration of counsellor contact,  
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3 with participants remarking that they “felt bad” when the programme came to an end and “wished  
4 it to continue.” Instead of proposing additional intervention sessions, they recommended reducing  
5 the intensity of the programme by spreading the sessions over six rather than two weeks. They  
6 thought this would not only enhance support for change but would also address some of the barriers  
7 that prevent women from fully engaging in intensive programmes:  
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14 The two weeks was very short, and I wish we could come back. It must be extended ... I  
15 wish it could be expanded so we were here for longer. [Participant 13]  
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19 A second concern for some participants was the group format. Several participants  
20 described feeling “uncomfortable” sharing painful experiences with other women in the group due  
21 to concerns about stigma and disclosure. This seemed a particularly salient issue in groups where  
22 participants came from the same neighbourhood and “all knew each other”:  
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28 Like the other day I came with my friend. I noticed that she was not participating, maybe  
29 it was because we know each other. I feel like if in the group we can come from different  
30 communities so that we don't judge and share who is in the group outside, then we will be  
31 free and share a lot. [Participant 4]  
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38 The degree to which participants were able to relate to the experiences of group members also  
39 seemed to influence their views of the group. Where participants felt that they shared experiences  
40 with others, they were more likely to report feeling satisfied with the group format and tended to  
41 describe the groups as “supporting each other in the right way” and that “we were one group, we  
42 would talk one thing all of us.” In contrast, participants who felt there were major differences  
43 between group members were highly concerned about being judged by others:  
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52 We did not understand each other into my group. I think we were different because there  
53 were those who used drugs and those who drank alcohol. Those drinking alcohol would  
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3 separate themselves. It's going to be better if us people using drugs sit alone and have a  
4 mutual conversation. [Participant 19]  
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8 A further concern was limited post-intervention support for change. While there were one  
9 or two exceptions, most participants did not develop emotionally supportive relationships with  
10 other group members beyond the confines of the programme. Several participants expressed the  
11 need for this community-based support but did not feel they could establish these support networks  
12 themselves:  
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19 We were supporting each other but the support was not like on point ... usually when we  
20 exit here we separate and never visit each other to see how they are doing. We never saw  
21 each other after the sessions. [Participant 3]  
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## 29 **DISCUSSION**

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31 Despite global HIV prevention guidelines that call for the provision of integrated substance use,  
32 psychological trauma and sexual risk reduction services,<sup>18</sup> to the best of our knowledge there are  
33 no interventions that address these intersecting risks for HIV among young trauma-exposed South  
34 African women. During this Phase I study, we found high levels of unmet need for trauma-  
35 informed substance use interventions among women from poor communities in the Western Cape.  
36  
37 Almost three-quarters of women screened disclosed physical or sexual trauma exposure, and more  
38 than half reported heavy alcohol or drug use. Women who were eligible for our intervention  
39 demonstrated a strong desire for change, with more than 90% accepting an offer of counselling.  
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49 As with other studies,<sup>12-13</sup> most of our participants had never initiated trauma or mental  
50 health counselling. Along with concerns about stigma and discrimination, limited awareness of  
51 services likely contributed to low rates of counselling initiation. Through continuous community-  
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3 based outreach and a person-centred approach, this study was able to reach and recruit a vulnerable  
4 group of trauma-exposed young women with unmet substance use and mental health needs. This  
5 confirms the feasibility of recruiting this vulnerable group of young women for a larger study.  
6  
7 Nonetheless, as this study's strict eligibility criteria around age, recent sexual activity and  
8 residence limited the number of eligible women we identified, we plan to broaden these inclusion  
9 criteria to ensure a future trial can recruit sufficient numbers of trauma-exposed women and to  
10 enhance the generalizability of findings to the broad population of trauma-exposed women who  
11 use substances.  
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21 In addition, findings provide preliminary evidence of the potential benefits of this  
22 intervention. Participants reported reducing the frequency of heavy drinking, cannabis and  
23 methamphetamine use at the three-month assessment, with biological evidence of significant  
24 reductions in the proportion of participants testing positive for methamphetamine, cannabis, and  
25 methaqualone supporting self-report data. Depression, psychological distress and trauma severity  
26 also diminished significantly, with improvements to depression reaching clinical significance.  
27  
28 Significant reductions in sexual risk behaviour were also noted with participants reporting fewer  
29 sexual partners and STI symptoms at follow-up. Qualitative findings support these results and  
30 suggest possible mechanisms of action. Women reflected how the intervention helped them make  
31 positive changes to their substance use and sexual risk behaviour by enhancing their understanding  
32 of substance use as a coping response to trauma and providing them with practical tools for  
33 regulating negative emotions related to trauma and other stressors.  
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49 Participants did however reflect that the programme might have greater success if it  
50 provided extended support for change. We had initially hoped that the groups would evolve into  
51 peer support networks, however these groups dissolved after the programme was completed. As  
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3 group membership was open rather than closed, this may have contributed to the lack of  
4 sustainability. Quantitative findings support these observations: perceptions of social support did  
5 not improve because of the intervention. Regardless of whether the intervention remains group-  
6 based or transitions to an individual format, future studies should consider including community-  
7 based peer support groups as part of the intervention. This modification may help support  
8 continued development of coping skills and consequently help women sustain any initial behaviour  
9 changes. Further qualitative work exploring potential service users' preferences for the facilitation,  
10 structure and content of these peer support groups is needed to guide the development of this  
11 intervention component.  
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24 Despite these promising outcomes, the poor rate of treatment completion raises concerns  
25 about the intervention's feasibility and highlights the need for additional modifications. Although  
26 we collected detailed contact information and actively tracked participants for intervention  
27 sessions, just over a third completed the programme. Several factors may have impacted on  
28 treatment completion rates. Participants who were newly diagnosed with HIV seemed less likely  
29 to complete treatment than those who were already aware of their status. This is not surprising  
30 given that other studies have shown that people are more likely to accept the offer of mental health  
31 counselling if they have been given time to adjust to their diagnosis.<sup>33</sup> To ensure optimal  
32 participation, future studies should consider providing this highly vulnerable sub-group with  
33 additional supports.  
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47 Additionally, given the short window within which participants could complete the  
48 intervention, there were limited opportunities to make up missed sessions. Other South African  
49 studies using lengthy interventions ( $\geq$  five sessions) with vulnerable populations have also reported  
50 low completion rates, with participants expressing a preference for shorter interventions of up to  
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3 four sessions.<sup>33-35</sup> As participants completed four sessions on average, it may be more efficient to  
4 offer four rather than six sessions. As the content that the participants found most helpful (namely  
5 the content on substance use, coping with trauma, and sexual risk) was concentrated in four  
6 sessions, it seems possible to reduce the number of sessions without affecting programme  
7 acceptability. Further support for this suggestion is provided by findings that participants who  
8 completed up to four intervention sessions had similar outcomes to those who completed more  
9 sessions. Trimming the intervention will allow for better spacing of intervention sessions which  
10 would reduce the intensity of the programme. In the qualitative interviews, several participants  
11 expressed a preference for a lower intensity programme. Reducing the intensity of the programme  
12 could also provide more opportunities for facilitators to reschedule missed sessions. This could  
13 improve rates of programme completion. We plan to use these findings to abridge the intervention  
14 to four group sessions, each spaced one week apart, with an eight-week window within which to  
15 complete the programme.

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33 Another plausible explanation for the low uptake of the intervention may lie in the  
34 intervention's group format. Although participants expressed a desire for a group-based  
35 intervention during our formative work<sup>24</sup> and we took several steps to promote comfort with the  
36 group format (such as reinforcing group ground rules around respect and confidentiality at the  
37 beginning of each session), several women still expressed discomfort with the group format during  
38 the post-intervention qualitative interviews. This was largely due to concerns about stigma and  
39 privacy, together with difficulties in relating to the diverse experiences of other group members.  
40 Concerns about stigma and sexual trauma disclosure, along with the low uptake of group-based  
41 intervention components have been reported in other studies of South African women with  
42 histories of sexual trauma.<sup>36-37</sup> Given these findings, we plan to adapt the intervention for delivery

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3 in an individual format, and test whether this improves intervention uptake amongst this vulnerable  
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5 population.  
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8 Despite the lower than anticipated treatment completion rate, 93% of women completed  
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10 their three-month follow-up assessment. This study completion rate corresponds with those  
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12 obtained in other women-focused intervention studies conducted by our team<sup>8,9,14</sup> and  
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14 demonstrates the effectiveness of our protocols for limiting attrition and the feasibility of retaining  
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16 this hard-to-reach population in a larger trial. In particular, the addition of case management visits  
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18 may have contributed to this high retention rate. Although case management activities did not  
19  
20 seem to contribute to the outcomes of the programme, we noted a trend towards better retention  
21  
22 among those participants who received case management. This is not surprising as these visits  
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24 provided opportunities to keep participants engaged in the study and allowed staff to explore and  
25  
26 address potential barriers to retention. As such, we plan to include case management activities in  
27  
28 a future trial.  
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32  
33 These are some limitations to this study. The main limitation is that this is a single arm,  
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35 uncontrolled feasibility study. Findings are preliminary and the efficacy of the intervention and  
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37 whether outcomes of this trauma-informed approach differ from the original WHC still needs to  
38  
39 be established in a RCT. Without an RCT of the intervention, we are unable to determine whether  
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41 the changes observed are attributable to the intervention or other factors. However, our use of  
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43 mixed methods allowed us to triangulate findings, thereby increasing our confidence in the  
44  
45 potential benefits of this intervention. Second, while we used objective measures of recent drug  
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47 use, we did not include an objective measure of recent alcohol use. In future studies we plan to  
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49 include testing for phosphatidylethanol (a biomarker for alcohol use).<sup>38</sup> Third, as recruitment was  
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51 limited to two low-income communities in the Western Cape, findings may not be generalizable  
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3 to other communities. Nonetheless, this study begins to establish the feasibility, acceptability and  
4 preliminary effects of a novel, trauma-informed substance use and sexual risk reduction  
5 intervention for young South African women. Findings are being used to modify the intervention  
6 for greater efficiency and impact. We plan to assess the acceptability and initial efficacy of this  
7 modified trauma-informed substance use and sexual risk intervention in a Phase II RCT.  
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### 14 15 16 17 **Author Contributions**

18  
19 BM and WMW jointly conceived the project, BM performed the analyses and drafted the  
20 manuscript. FAB and TC played major roles in developing and organizing the project, data  
21 collection and analyses, and revised draft versions of the manuscript critically. All authors read  
22 and approved the final manuscript.  
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40 **Competing Interests:** None declared.  
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44 **Patient Consent:** Not required  
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49 **Ethics approval:** The South African Medical Research Council (EC 003-2/2015) and RTI  
50 International provided ethical approval for this study.  
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3 **Data sharing:** Quantitative data are available on reasonable request from the corresponding  
4 author.  
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7

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**Table 1. Baseline demographic and clinical characteristics of the overall sample (n= 60) and by treatment completion status**

Variable	Overall	Treatment completion		
		Yes (n= 21)	No (n= 39)	<i>p</i>
<b>Socio-demographic variables</b>				
In a relationship (N, %)	55 (91.7%)	20 (95.2%)	35 (89.7%)	0.649
Employment (no; N, %)	55 (91.7%)	20 (95.2%)	35 (89.7%)	0.649
HIV status (positive; N, %)	28 (46.7%)	9 (42.9%)	19 (48.7%)	0.788
Newly diagnosed as HIV positive (yes; N, %)	10 (35.7%)	1(11.1%)	9 (47.4%)	0.06
Sexual abuse (yes; N, %)	41 (68.3%)	13 (61.9%)	28 (71.8%)	0.562
Physical abuse (yes; N, %)	55 (91.7%)	19 (90.5%)	36 (92.3%)	0.602
Sexual and physical abuse (yes; N, %)	34 (56.7%)	10 (47.6%)	24 (61.5%)	0.414
<b>Substance use outcomes</b>				
Days of heavy drinking in past month (M, SD)	8.2 (6.4)	8.1 (6.0)	8.3 (6.7)	0.906
Days of cannabis use in past month (M, SD)	11.4 (11.9)	10.4 (11.7)	11.8 (12.1)	0.715
Days of methamphetamine in past month (M, SD)	18.4 (11.6)	13.5 (13.2)	20.2 (10.7)	0.227
Days of methaqualone use in past month (M, SD)	14.0 (11.9)	11.1 (13.1)	15.1 (11.6)	0.498
Cannabis positive (biological; N, %)	30 (50.0%)	9 (42.9%)	21 (53.8%)	0.589
Methamphetamine positive (biological; N, %)	27 (45.0%)	8 (38.1%)	19 (48.7%)	0.587
Methaqualone positive (biological; N, %)	29 (48.3%)	8 (38.1%)	21 (53.8%)	0.287
Opiate positive (biological; N, %)	4 (6.7%)	0 (0.0%)	4 (6.7%)	0.287
<b>Mental health outcomes</b>				
CES-D (M, SD)	26.1 (9.5)	27.4 (11.1)	25.4 (8.6)	0.489

K-10 (M, SD)	25.7 (6.8)	25.1 (7.6)	25.9 (6.5)	0.693
Trauma symptom (M, SD)	33.6 (5.6)	34.9 (7.6)	31.9 (7.4)	0.154
MOS-social support (M, SD)	60.1 (13.6)	59.2 (14.4)	61.3 (13.4)	0.593
<b>Sexual risk outcomes</b>				
Number of partners in last month (M, SD)	1.7 (1.5)	1.5 (0.7)	1.9 (1.8)	0.204
Condom use last sex (yes; N, %)	10 (16.9%)	2 (10.0%)	8 (20.5%)	0.469
Number of STI symptoms in last month (M, SD)	1.2 (0.9)	1.2 (0.6)	0.9 (1.1)	0.159

**Table 2. Change in substance use, mental health and sex risk outcomes for the overall sample (n= 56) and by intervention exposure.**

Outcomes	Overall sample (n= 56)			Intervention dosage of up to and including 4 sessions (n=23)		Intervention dosage of five or more sessions (n=33)	
	Baseline	3-month follow up	Baseline to follow up Mean difference (95% CI)	Baseline	3-month follow up	Baseline	3-month follow up
<b>Substance use outcomes</b>	<i>M (SD)</i>	<i>M (SD)</i>		<i>M (SD)</i>	<i>M (SD)</i>	<i>M (SD)</i>	<i>M (SD)</i>
Days of heavy drinking in past month	8.4 (6.1)	5.3 (6.9)	3.2 (0.9; 5.4)*	8.8 (6.7)	6.7 (8.2)	8.1 (5.8)	4.3 (5.8)*
Days of cannabis use in past month	12.3 (12.4)	6.0 (9.2)	6.3 (2.6; 9.9)*	14.1 (13.5)	4.7 (7.7)*	11.1 (11.5)	6.7 (9.8)*
Days of methamphetamine in past month	19.5 (11.0)	11.7 (11.3)	7.8 (1.8; 13.7)*	22.0 (9.3)	9.2 (11.4)*	17.0 (12.3)	14.2 (11.0)
Days of methaqualone in past month	14.9 (11.8)	9.9 (11.4)	4.9 (-0.7; 10.5)	15.3 (10.6)	7.6 (9.5)*	14.4 (13.6)	12.5 (13.2)
Cannabis positive (biological) (N; %)	26 (46.4%)	21 (37.5%)*	-	13 (56.5%)	11 (47.8%)*	13 (39.4%)	10 (30.3%)*
Methamphetamine positive (biological) (N; %)	25 (44.6%)	20 (35.7%)*	-	11 (47.8%)	9 (39.1%)*	14 (42.4%)	11 (33.3%)*



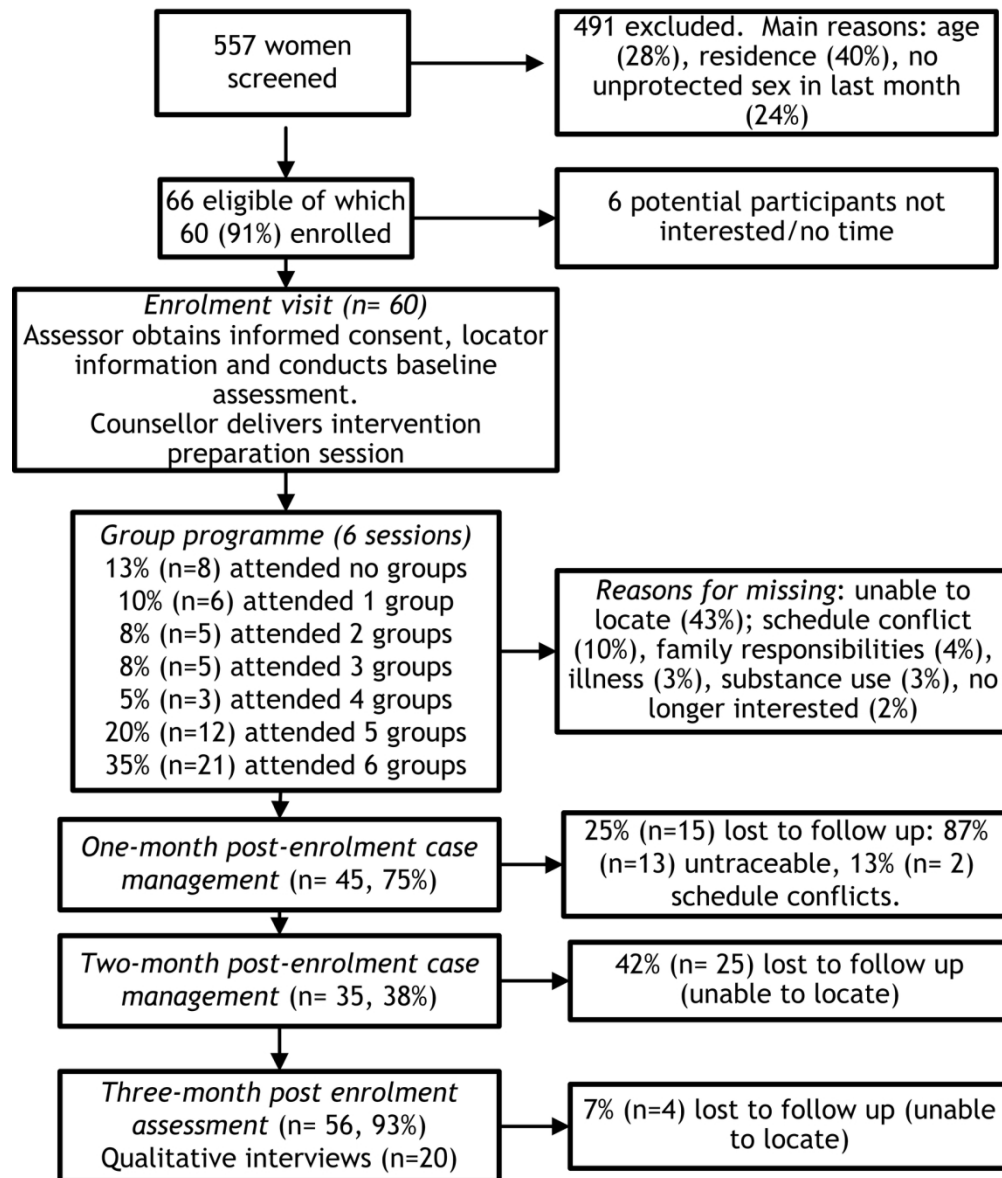
Methaqualone positive (biological) (N; %)	27 (48.2%)	21 (37.5%)*	-	13 (56.5%)	10 (43.5%)*	14 (42.4%)	11 (33.3%)*
<b>Mental health outcomes</b>							
CES-D score	26.3 (9.6)	17.7 (7.3)	8.5 (5.3; 11.7)*	24.7 (8.9)	17.3 (7.5)*	27.5 (10.1)	18.1 (7.2)*
K-10 score	25.7 (6.9)	17.8 (7.3)	7.9 (5.6; 10.3)*	25.4 (7.2)	17.6 (8.3)*	25.9 (6.8)	17.7 (6.5)*
Trauma symptom score	32.9 (7.6)	21.7 (8.6)	11.2 (8.8; 13.6)*	33.9 (3.5)	22.2 (7.8)*	33.4 (6.7)	21.7 (9.2)*
MOS-social support score	60.6 (14.1)	63.5 (15.7)	-2.8 (-6.7; 1.1)	60.5 (14.5)	63.8 (16.6)	60.8 (14.1)	63.3 (15.3)
<b>Sex risk outcome</b>							
Number of partners in last month	1.7 (1.1)	1.0 (0.4)	0.6 (0.3; 1.1)*	2.1 (2.2)	1.2 (0.7)*	1.4 (0.6)	0.9 (0.4)*
Condom use at last sex (N; %)	8 (14.5%)	25 (45.5%)	-	2 (8.7%)	10 (43.5%)	6 (18.8%)	15 (46.9%)
STI symptoms in past month	1.1 (0.9)	0.2 (0.8)	0.8 (0.5; 1.2)*	0.8 (1.1)	0.3 (1.0)*	1.3 (0.8)	0.2 (0.6)*

\*significant at p <0.05

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5 **Figure 1. Participant flow chart**  
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For peer review only



Participant flow chart

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## CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4
	2b	Specific objectives or research questions for pilot trial	5
<b>Methods</b>			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6-7
	4c	How participants were identified and consented	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	9-10
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	n/a
Sample size	7a	Rationale for numbers in the pilot trial	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	n/a
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	n/a
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	n/a

1	Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	n/a
2	Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	n/a
3		11b	If relevant, description of the similarity of interventions	n/a
4	Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	11
5	<b>Results</b>			
6	Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	12
7		13b	For each group, losses and exclusions after randomisation, together with reasons	12
8	Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
9		14b	Why the pilot trial ended or was stopped	n/a
10	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
11	Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	n/a
12	Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Table 2
13	Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	12-18
14	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
15		19a	If relevant, other important unintended consequences	n/a
16	<b>Discussion</b>			
17	Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	21-22
18	Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	21-22
19	Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	21-22
20		22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	21-22
21	<b>Other information</b>			
22	Registration	23	Registration number for pilot trial and name of trial registry	n/a
23	Protocol	24	Where the pilot trial protocol can be accessed, if available	n/a
24	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	25
25		26	Ethical approval or approval by research review committee, confirmed with reference number	25

1 Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

2 \*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important  
3 clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological  
4 treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).  
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