Project ASPIRE: A feasibility randomised controlled trial of a brief intervention for reducing risk of depression and alcohol-related harms among South African adolescents

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Abstract

Objective. Brief interventions could reduce adolescents' risk of depression and alcohol-related harms, but evidence of their feasibility and acceptability for low-and middle-income countries is lacking. To address this gap, we conducted a feasibility trial of the ASPIRE intervention, a four-session multi-component counselling intervention for South African adolescents.

Method. We recruited 117 adolescents who met our inclusion criteria. Participants were randomly assigned to the ASPIRE intervention or a comparison condition. Outcomes were assessed at baseline, six-week, and three-month post-randomisation time points. Primary outcomes were based on feasibility of study procedures and intervention delivery (assessed on seven predetermined progression criteria). Clinical outcomes (risk of depression and alcohol harms) were secondary.

Results. Despite modifications to all study procedures arising from Covid-19 restrictions, five of the seven key progression criteria were fully met, including: feasibility of data collection and outcome measures, counsellor competencies, randomization and blinding, adverse advents, and acceptability of the intervention. The progression criterion for recruitment and intervention retention were not fully met.

Conclusion. Findings suggest that the ASPIRE intervention was generally feasible to deliver and acceptable to adolescents. However, modifications to the trial design and intervention delivery are needed to optimise the validity of a definitive randomized controlled trial of the ASPIRE intervention.

Keywords: Adolescents; Low-and-middle-income country; global mental health; psychological intervention.

Introduction

Mental and substance use disorders among adolescents are highly prevalent and leading contributors to the global burden of disease among young people, accounting for over a third (34.8%) of years lived with disability (Erskine et al., 2015). A recent systematic review estimated that approximately 27% of adolescents in sub-Saharan Africa will be living with depression, 30% anxiety and 41% with emotional and behavioural problems at any given time (Jörns-Presentati et al., 2021).

In South Africa, adolescents comprise 19% of the total population (Statistics South Africa, 2018). Although South African data regarding the prevalence of child and adolescent mental health concerns are scarce, a South African provincial school survey reported that 56% of 10, 301 learners were at moderate to high risk of mental health problems and 23% had consumed alcohol in the last month with a substantial proportion of these adolescents engaging in heavy episodic drinking (Francis et al., 2019; Plüddemann, 2014). This unhealthy pattern of alcohol use increases adolescents' risk of injury, self-harm, poor mental health and alcohol use disorders (Pedrelli et al., 2016).

Although adolescence is a period for biological, cognitive and social opportunities where key life decisions regarding employment and relationships are made, it's also a time of vulnerability (Snyder, 2013). Adolescence is the peak age of onset for most mental disorders, (Kessler et al., 2007). Several health risk behaviours such as unhealthy alcohol use also emerge during adolescence. According to a recent systematic review, adolescents with depression and other mental health concerns are more likely to engage in unhealthy alcohol use compared to adolescents without depression (Pozuelo et al., 2022). Potential mechanisms proposed to account for associations between depression and unhealthy alcohol use include the use of alcohol as a mechanism for coping with symptoms of depression (Khantzian, 1997).

Alternatively, depression may impact executive functioning, affecting cognitive control and decision-making, thereby increasing propensity for risky behaviour (Snyder, 2013).

When unaddressed, depression and unhealthy alcohol use during adolescence increase risk of physical health comorbidities and injury (Harker et al., 2020; Prince et al., 2007), poor educational outcomes, unemployment and unplanned pregnancy or parenthood (Clayborne et al., 2018; Wechsberg et al., 2012), and may lead to more severe mental health problems that persist across the lifespan (Eyre & Thapar, 2014; Kessler et al., 2007). Given the serious consequences associated with unaddressed mental health and alcohol use problems, the early identification of these problems is critical for risk reduction. Unfortunately, like many other low- and middle-income countries (LMICs), adolescent-friendly mental health and substance use services are scarce in South Africa (Flisher et al., 2012; Otwombe et al., 2015), with available services tending to focus on treatment of severe presentations and little attention given to early intervention (Docrat et al., 2019). Further, adolescents in these settings have low rates of service access due to under-detection, poor awareness, stigma and in particular, poor help-seeking (Bantjes et al., 2020; McGorry et al., 2014; Patel et al., 2007) with only 30% of adolescents at-risk for mental health problems seeking help (Gulliver, 2010).

While there is some promising evidence for the effectiveness of early interventions for reducing risk of mental health and substance use problems among adolescents globally (González-Valero et al., 2019; Huang et al., 2018; Stockings et al., 2016; Tindall et al., 2017; Weersing et al., 2017), most studies come from high income countries. The few interventions tested in LMICs tend to be delivered in school settings, focus on a single concern (behavioural problems) (Burkey et al., 2018) or post-traumatic stress disorder (PTSD) (Morina et al., 2017) with few interventions (Fazel et al., 2014; Mitchell et al., 2013) targeting the major concerns for adolescent mental health in LMICs, namely risk of depression and unhealthy alcohol use (Jörns-Presentati et al., 2021; Ma et al., 2018).

There is evidence from LMICs, including South Africa, to suggest that brief, structured counselling interventions, when task-shared to trained community health workers (CHWs), may improve mental health outcomes among adults (Chibanda et al., 2015; Petersen et al., 2021; Sorsdahl et al., 2015; Spedding et al., 2014). Motivational interviewing (MI) and cognitive behavioural treatment (CBT) approaches (such as problem-solving therapy (PST) and behavioural activation) have successfully been used to intervene with adolescents in high-income countries (McCarty et al., 2019; Tanner-Smith & Lipsey, 2015; Weersing et al., 2017), with preliminary data emerging from LMICs (Michelson et al., 2020; Simms et al., 2022). Our team has successfully adapted and tested 3-4 sessions of counselling that included elements of MI and CBT to improve depression and alcohol outcomes among adult patients presenting to healthcare facilities in South Africa (Myers et al., 2018; Parry et al., 2014; Sorsdahl et al., 2015). However, this multi-component intervention had not yet been tested among adolescent populations.

To address this gap, we conducted a feasibility trial of the ASPIRE intervention, a four-session counselling intervention adapted for South African adolescents at risk for depression and alcohol-related harms with a control group receiving one session as mental healthcare is usually not available to adolescents in primary and community services. This trial aimed to test the feasibility of: (i) implementing the ASPIRE intervention, and (ii) study procedures to inform a fully-powered effectiveness trial of the intervention. We further explored the primary clinical outcomes to be examined in a future trial, namely unhealthy alcohol use and depression.

Methods

This feasibility trial is reported in accordance with the CONSORT 2010 statement: extension to randomised pilot and feasibility trials (Additional file 1) (Eldridge et al., 2016) and the

Template Intervention Description and Replication guidelines (Alvarez et al., 2016). Full details of the methods and outcome measures are described separately (Sorsdahl et al., 2021). Modifications to facilitate telephone recruitment, intervention and data collection were necessary due to COVID-19 restrictions (Myers, van der Westhuizen, et al., 2021). Briefly, on 27 March 2020, South Africa entered a strict national "level 5" lockdown that involved restrictions on social movement and the sale and distribution of alcohol (Stiegler & Bouchard, 2020). All patient-interfacing non-COVID-19 research was paused. By this time, the ASPIRE trial had enrolled 67 participants. Of these, 15 had completed the full protocol, 17 had outstanding intervention sessions, 38 required a six-week assessment, and 48 required a three-month assessment (Myers, van der Westhuizen, et al., 2021).

Trial design

An individually randomised two-arm feasibility trial was conducted (see CONSORT Diagram in Fig. 1). Adolescents were recruited from community settings and were randomly assigned to the ASPIRE intervention or a comparison condition. Follow-up assessments were held at six-weeks and three-months post-randomisation.

Study setting

Participants were recruited from several communities in greater Cape Town, South Africa. All these communities are characterised by high levels of unemployment (>70%), and high rates of community alcohol use and mental disorders among young people (Plüddemann, 2014).

Participants

To be eligible for study inclusion, participants had to: 1) be aged between 15 and 18 years old; 2) provide informed assent/consent to participate in the study; 3) have informed parental

consent to participate if younger than 18 years of age; 4) screen at risk for depression with a score ≥10 on the Center for Epidemiology Scale on Depression short form (CES-D-10) (Stockings et al., 2015) and/or screen at moderate or severe risk for alcohol-related health problems, with a score ≥ 5 on the Alcohol, Smoking and Substance Use Involvement Test-youth (ASSIST-Y) (Humeniuk et al., 2016) and report at least 2 episodes of heavy drinking (≥ 5 standard drinks on a single occasion) in the last month. Participants were excluded if they were receiving any form of mental health or substance use treatment.

Participant recruitment and study procedures

Fieldworkers approached potential participants in various community settings, switching to a fully remote process where adolescents could self-refer for eligibility screening via telephone following COVID-19 protocols. To facilitate accrual, we distributed study flyers and posters at places accessible to young people during the pandemic, on social media, and to organisations providing COVID-19 relief services to young people and their families.

After explaining the purpose of the study, the fieldworker requested verbal consent to screen the adolescent for possible study inclusion. If the adolescent was ineligible, they were thanked for their time and given health information materials. If they were eligible, but did not want to participate, reasons for lack of interest were recorded. Where parental consent was not required, an appointment was made for a study enrolment visit with eligible and interested adolescents. If parental consent was required, the fieldworker contacted the parent to obtain this prior to making an appointment for an enrolment visit. If the parent did not provide consent, the adolescent was not enrolled.

Baseline assessments either took place at the South African Medical Research Council's (SAMRC) clinical research site in Delft or telephonically if required based on COVID-19 regulations. The fieldworker re-screened the participant to confirm study eligibility

prior to obtaining written informed assent/consent to participate in the trial. Thereafter the fieldworker administered the baseline assessment in either English, Afrikaans, or isiXhosa, the three official languages of the region. All participants were assigned a trained ASPIRE counsellor to receive a counselling session.

After completion of the first session, the trial manager randomly assigned the participant to the intervention or comparison group. A further three counselling appointments were scheduled for adolescents allocated to the intervention group. These were spaced at least a week apart from each other. Participants had six weeks from enrolment to complete all four sessions before timing out of the intervention. Irrespective of study arm, all participants were asked to complete follow-up assessments at six-week and three-month post-enrolment when the fieldworker re-administered the baseline assessments. Participants had 30 days from their scheduled appointment to complete these follow-up assessments before timing out of that appointment. Participants received grocery vouchers for completing the baseline and follow-up assessments.

Randomisation & Blinding

Participants were randomly allocated in a 1:1 ratio to either the intervention or comparison arm. The randomisation sequence was prepared by the data manager (using a computer programme) and allocation was done by a trial manager. The fieldworkers contacted the trial manager when an individual was ready to be allocated, and the trial manager informed the fieldworker about the participant's allocation based on the randomisation sequence. The fieldworker then notified the participant about his/her allocation and associated activities. Investigators were blind to the sequence generation and the trial manager had no direct contact with participants. To reduce potential performance bias, allocations only occurred after the first counselling session had been completed, since the first session would be identical regardless

of allocation. Fieldworkers conducted the baseline and follow-up assessments, and trained counsellors delivered the intervention.

Interventions

Interventions were delivered either in a face-to-face format or telephonically by trained and experienced mental health counsellors. See Table 1 for a detailed description of the ASPIRE intervention package.

Comparison arm: Session 1 and referral to care

Participants assigned to this arm received session one of the ASPIRE intervention (~1 hour in duration) prior to allocation. The session included screening for unhealthy alcohol use and depression, feedback about the screening results, psychoeducation about how alcohol or feelings of depression can affect young people, and (depending on their primary condition), motivational interviewing to enhance motivation to reduce alcohol use or behavioural activation through activity scheduling to address symptoms of depression. The session concluded with goal setting. Participants were also given referrals to usual care providers for further follow up if required.

Intervention arm (ASPIRE intervention)

Participants assigned to this condition received session one as described above, plus an additional three counselling sessions. The duration of each session was approximately 45-60 minutes. Each session functioned iteratively to build readiness to change and adaptive problem-solving and coping skills. All sessions had a motivational component, a psychoeducation component, and a problem-solving component. More specifically, participants were taught steps for addressing problems that are important and can be solved; strategies for dealing with negative and intrusive worries that are less important; and steps for coping with problems that are important but cannot be solved (Sorsdahl et al., 2014; Sorsdahl et al., 2015). A client

handbook, summarizing the content of the counselling sessions and containing worksheets to practice the problem-solving method guided the counselling.

Counsellor training and supervision

The ASPIRE counsellors were selected as they already had basic counselling training and had previously been trained in understanding common mental disorders, MI and PST (with proficiency testing through role-playing and case examples). Training also included how to provide referrals and responding to distressed participants. Following training and continuing throughout the implementation of the interventions, counsellors received regular face-to-face and virtual supervision and debriefing provided by a registered psychological counsellor (see Table 1 for further details). The counsellor supervisor in turn was supervised by a psychologist. We have used this model of supervision successfully in our previous work (Jacobs et al., 2020).

Counsellor competency and monitoring

To assess and monitor treatment-specific and counsellor competency, we recorded all counselling sessions with consent from participants. For participants in the control group, we reviewed a random sample of 15 recorded sessions. For participants in the intervention group, we randomly selected one session from the total number of completed sessions of 18 participants to review (ranged from 1-3). For treatment-specific competencies (referred to as fidelity), an intervention delivery checklist was used including items pertaining to whether the objectives of the intervention session were addressed adequately. Further, a South African version of the ENhancing Assessment of Common Therapeutic Factors was used to measure core therapeutic competencies and skills thought to be required for a counsellor to adequately deliver any evidence-based intervention (Spedding et al., 2022).

Outcome measures

Primary outcomes: Feasibility outcomes

The primary aim of the trial was to assess feasibility of both the trial procedures and the intervention. Feasibility outcomes included: (i) feasibility of recruitment; (ii) appropriateness of data collection processes and outcome measures; (iii) retention in the ASPIRE intervention; (iv) counsellor competency; (v) feasibility of randomisation and blinding; (vi) presence of adverse advents; and (vii) acceptability of the ASPIRE intervention and study procedures. Based on these seven primary outcomes, a priori criteria for progressing to a full RCT were established (Avery et al., 2017), see Table 3. Not meeting one or more key progression criteria indicated that the study protocols required revision before conducting a full RCT.

More specifically, we used participant feedback to assess acceptability (criterion (vii)). Participants in both arms were asked to rate the acceptability of procedures for (i) screening, (ii) consent, (iii) assessment (length, type of questions, mode of administration), (iv) randomisation, (v) referrals (and uptake of referrals) and (vi) tracking to prevent loss to follow up. Each item was rated on a 5-point scale (from 1=not at all acceptable to 5=very acceptable). The Child Evaluation Inventory (CEI) was used to assess participants' satisfaction with the intervention and how the counselling was delivered (Kazdin et al., 1992; Thurber et al., 1990). The CEI consists of 20 questions rated on a 5-point Likert scale (1=not at all; 5=a whole lot). Scores range between 20-100, with higher scores indicating higher levels of acceptability.

Secondary clinical outcomes

Although clinical outcomes were secondary to the feasibility outcomes, we collected data on the primary and secondary clinical outcomes we planned for a future trial. These are described briefly below (more detail is provided in Sorsdahl et al., 2021).

Risk of alcohol-related harms was measured using the ASSIST-Y (Humeniuk et al., 2016). Assessment of this outcome was restricted to adolescents who reported alcohol problems at baseline. We also used the ASSIST-Y to measure changes in tobacco use.

Number of standard drinks in the past month. The Alcohol Timeline Follow Back (TLFB) technique collected self-reported frequency, quantity, volume, patterns and types of alcohol consumption in the past month (Sobell, 1992). We used this to calculate changes in number of standard drinks consumed.

Symptoms of depression. The CES-D-10 was used to assess change in symptom severity. This outcome was restricted to those with CES-D-10 scores ≥10 at baseline (Bradley et al., 2010; Kilburn et al., 2018)

Other secondary clinical measures included were the Generalised Anxiety Disorder Assessment (GAD-7) (Mossman et al., 2017; Tiirikainen et al., 2019), the Kessler-10 measure of psychological distress (Smout, 2019), the 8-item Global Self Worth subscale of the Self Esteem Questionnaire (DuBois et al., 1996), and the Difficulties of Emotion Regulation Scale (DERS-16) (Charak et al., 2019).

Sample size considerations

Given this was a feasibility trial, a power calculation was not required. Recommendations for sample size requirements to estimate key design parameters from external feasibility and pilot randomised controlled trials suggest that at least 70 measured participants (35 per group) are required when estimating the SD for a continuous outcome (Teare et al., 2014). Therefore, we

aimed to recruit 100 participants (50 per group) to account for attrition. Given the impact of the COVID-19 pandemic on the trial, we increased our sample size to 117 participants.

Data Analysis

Feasibility data (Table 3) is presented descriptively and participant flow through the trial is presented in a standard CONSORT diagram (Figure 1). Descriptive statistics (Table 5) are reported for all other relevant outcomes at each time-point by trial arm. Adjusted means differences were calculated for secondary clinical outcomes comparing intervention and control groups using linear regression models, adjusting for the baseline score of the given outcome. Due to concerns regarding heteroskedasticity, robust standard errors (H3) were used (Hayes & Cai, 2007). Separate models for alcohol and depression were developed and only included participants who screened at risk at baseline, while all other outcome measures included the entire sample. Data were analysed using SPSS version 28.

Results

Characteristics of sample

Table 2 shows the demographic and baseline characteristics of the sample by study arm. The majority (56%) of participants were female with equal distributions among the age groups. Most reported living in a stable home environment (69%) and a quarter had dropped out of school (25%).

Primary outcomes

Five out of the seven key progression criteria were fully met (See Table 3), findings for each criterion are described below.

Feasibility of Recruitment

Of the 205 participants who verbally consented to being screened, 154 were eligible to participate. Of these, seven were lost prior to randomisation: five expressed that they couldn't commit to the time required for full participation, one felt that they didn't need counselling, and another was not interested in participating. See CONSORT Diagram in Figure 1. Recruitment began November 6th, 2019, and the last participant was recruited February 26th, 2021. Due to school holidays, recruitment was paused over most of December and January in 2019 and 2020. Due to Covid-19 restrictions, recruitment was also suspended on March 18th and blended face-to-face and telephonic recruitment was initiated June 23rd, 2020. The last participant was recruited on February 26th, 2021. Over approximately 39 weeks of active recruitment, 117 participants were enrolled. This equates to approximately three participants per week which does not meet the predetermined progression criterion of 5 participants per week. Further exploration found a 52% reduction in monthly screening totals observed after switching to telephone screening. The proportion of eligible adolescents whom we were unable to locate for informed assent/consent increased from 8.7% to 16.3% ($p < 0.001$) and the proportion of parents from whom we were unable to obtain parental consent for their child's participation increased from 8.7% to 22.1% ($p < 0.001$) when using telephonic recruitment procedures.

Appropriateness of data collection processes and outcome measures

Of those participants recruited into the study, 80% completed the 6-week follow-up and 79% completed the 3-month follow-up, in line with the predetermined progression criterion. Most participants lost to follow-up could not be located with the telephone numbers and addresses

provided. Two participants explicitly stated that they wanted to withdraw from the study. An exploration of the completeness of the data collected at the three timepoints was conducted. The only missing data was for participants who were lost to follow-up.

Retention in Treatment

All participants in the control arm received one session of counselling. In the intervention arm, 52% received all 4 sessions, 67% received at least 3 sessions, 90% received at least 2 sessions and 100% received 1 session. With the projected feasibility progression criteria of 70% completing 3 sessions, this was narrowly not met. Treatment completion was not significantly associated with age, gender or baseline clinical characteristics such as tobacco and drug use, or severity of psychological distress, depression or alcohol use at baseline.

Counsellor Competency

Progression criteria for counsellor competency were fully met. Results for treatment-specific competencies of the counsellors was high at 87%. Further, 91% of the ENACT constructs were either partially addressed or done well.

Feasibility of randomisation and blinding

Randomisation was carried out successfully. No participants dropped out at the point of randomisation process, i.e., because of the group to which they were allocated, indicating acceptability of the randomisation process. Maintaining blinding was potentially problematic when assessments were being conducted face-to-face at the Delft Site, as the fieldworkers would sometimes see participants engaging with the counsellors. Further, despite being given guidance to the contrary, participants sometimes shared their experiences with the fieldworkers during the follow-up assessments.

Presence of adverse events

There were no study-related adverse events reported, meeting the progression criteria for less than 10% of participants reporting serious adverse events.

Acceptability of intervention and study procedures

Scores on the Child Evaluation Inventory (CEI) were used to assess participants' satisfaction with the intervention and how it was delivered. Out of possible scores between 20-100, the average score was 79.6 (SD=9.9; range 52-100) with more than 80% of participants scoring a total of 60 or more. The high scores may indicate a ceiling effect. Almost all participants reported that they would recommend Project ASPIRE to family or friends. More than 80% of participants scored ≥3 (on a scale of 1-5) for ratings on the acceptability of the study procedures, including (i) screening, (ii) parental consent, (iii) assessment (length, type of questions, mode of administration), and (iv) tracking for follow up assessments (See table 4).

Secondary clinical outcomes

Descriptive statistics for the proposed clinical outcome measures to be used in a definitive controlled trial are presented in Table 5. All measures showed change in the expected direction (i.e., decreases in symptoms of depression and alcohol use) for both groups. For depressive symptoms and alcohol use, both groups showed a decrease in scores from baseline to 6 weeks, and a further decrease at the 3-month follow-up. There was little evidence of a difference between the control and intervention on symptoms of depression adjusting for baseline scores at 6 weeks (adjusted mean difference = −0.71, 95% CI [-2.3, 1.38]) or at 3 months (adjusted mean difference = −0.61, 95% CI [-1.82, 3.05]). There was also little evidence of a difference between the control and intervention group on alcohol use severity at 6 weeks (adjusted mean difference = −0.04, 95% CI [-5.84, 5.76]) or at 3 months (adjusted mean difference = −1.86,

95% CI [-7.36, 3.62]). Similarly, for quantity of alcohol consumed, there was no difference between the intervention and control groups at 6 weeks (adjusted mean difference = 2.94 [-7.61, 13.50]) or 3 months (adjusted mean difference = 0.94 [-3.51, 1.63]). For anxiety, there was evidence for a difference between groups at the 6-week follow-up in favour of the ASPIRE intervention (adjusted mean difference =-1.96 (-3.71, -0.22) but no evidence of differences was found at the 3-month endpoint. There were no differences between the arms for psychological distress, tobacco use, self-esteem or emotional regulation.

Discussion

This study is among the first to examine the feasibility and acceptability of a multi-component counselling intervention, for reducing risk of depression and unhealthy alcohol use among adolescents in a LMIC context. Despite modifications to recruitment, consent, data collection and interventions procedures due to COVID-19 restrictions (Myers, van der Westhuizen, et al., 2021), five out of the seven key criteria for progression to a definitive RCT were fully met. The data collection processes, and outcome measures were appropriate with 80% of participants completing the study. There were no missing data for those who were followed-up and counsellor competency was high (91%). There were limited concerns regarding randomization, blinding, and no adverse events associated with study involvement. The ASPIRE intervention and study procedures were viewed as highly acceptable by all study participants.

The progression criterion for recruitment was not fully met, with recruitment becoming more challenging after the shift from face-to-face to telephonic protocols necessitated by COVID-19 related research restrictions. Over 39 weeks of active recruitment, 117 participants were recruited averaging approximately three participants per week, slightly lower than the five participants per week we envisaged. In response to COVID-19 regulations which effectively banned in-community recruitment, we switched to a fully remote process where

adolescents could self-refer for eligibility screening via telephone. This change to a more passive recruitment process affected the trial's accrual rate, with more than a 50% reduction in monthly screening totals observed after switching to only screening via telephone. Given active case finding through community outreach is arguably more effective than self-referral for recruiting adolescents into psychological interventions (Jaffee et al., 2009), these findings are not surprising. With these changes, there was a substantial increase in potential participants lost between screening and informed assent/consent procedures, further slowing the recruitment process. As we move toward a more definitive RCT, implementing both active (face-to-face, community-based recruitment) and passive (telephonic, self-referral) recruitment strategies and offering adolescents the choice between in-person and telephonic screening and enrolment may increase recruitment numbers. Further, the utilisation of alternatives to obtaining consent of parents or legal guardians, e.g., through waivers as mature minors and/or through allowing adults in loco parentis, entrusted with caring for the adolescent (e.g. teachers), to provide consent may facilitate the provision of timely recruitment of vulnerable adolescents (Bonner et al., 2021).

The number of participants recruited meeting eligibility for depression only (N=80, 68%) was much higher than that for unhealthy alcohol use, where 32% (n=37) met the alcohol inclusion criteria, of which only 11 participants did not also meet the depression inclusion criterion. Previous research in South Africa where inclusion criteria included both depression and alcohol use, also recruited for depression and alcohol in a two to one ratio (Myers et al., 2018) and found similar patterns of co-occurring depression in the alcohol cohort (Myers, Lombard, et al., 2021). Another potential contributing factor was the country's intermittent bans on the sale and distribution of alcohol. These bans spanned from 27 March to 1 June 2020, 13 July to 16 August 2020, and 28 December 2020 to 1 February 2021 (Myers, Carney, et al.,

2021). As adolescent alcohol use is greatly influenced by community availability, these most likely would have impacted on alcohol use and in particularly frequency of heavy drinking.

Given the modifications to intervention delivery resulting from Covid-19 restrictions, the progression criteria for intervention retention were slightly lower than anticipated (67% rather than 70%). As documented previously by our team (Myers et al., 2021) the shift from face-to-face to tele-counselling may have influenced the establishment of a therapeutic alliance particularly for newly enrolled participants. We found that 95.0% of participants who received face-to-face counselling in session one completed session 2 compared to 84.2% of participants who obtained session 1 via telephone. Moving forward towards a larger trial, consideration for initial face-to-face engagement with options for virtual and/or telephonic counselling thereafter depending on the needs and preferences of the adolescent may facilitate better retention and engagement with the counselling intervention.

Although our clinical outcomes were not the focus of this feasibility study, and the sample size is too small to make any robust conclusions regarding treatment effects, symptoms of anxiety was the only clinical outcome on which the treatment and control groups differed. Given this finding, a future trial may wish to consider anxiety as a primary clinical outcome. Given the high prevalence of anxiety disorders in the country (Herman et al., 2009) and the increase in anxiety globally as a result of COVID-19 (Covid Mental Health Collaborators, 2021), reducing symptoms of anxiety is an important intervention target for adolescent mental health. While this feasibility trial showed a significant reduction in symptoms of anxiety at 6 weeks, these findings are not surprising given that problem-solving therapy and behavioural activation have been shown to reduce symptoms of psychological distress and anxiety in adult populations (Stein et al., 2021; van't Hof et al., 2011).

The findings of this study should be considered in light of a number of limitations. Due to the low numbers of recruited adolescents, we did not have sufficient power to elucidate the

effects of the ASPIRE intervention (particularly for alcohol use). However, as this was a feasibility trial, the potential to learn lessons for future trials was the primary priority. Further, the COVID-19 pandemic may have impacted the study findings in several ways. Not only have studies suggested a deterioration in mental health and wellbeing during the pandemic (de Sousa et al., 2021), the restrictions on movement and alcohol policy changes are likely to have influenced our study findings. Despite these limitations, this feasibility trial suggests that the ASPIRE intervention was generally feasible with regards to delivery and acceptable to adolescents. Although we do not anticipate a future trial to be conducted under pandemic restrictions, our findings support several amendments to improve feasibility of recruitment and retention when progressing towards a future definitive trial.

Ethics approval and consent to participate

The South African Medical Research Council **(**EC 012-8-2018**),** the University of Cape Town (276/2018) and the London School of Hygiene and Tropical Medicine (17873) provided ethical approval for this study. The trial is registered with the Pan African Clinical Trials Registry (PACTR20200352214510). Informed consent was obtained from all participants prior to participating in the study.

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Authors' contributions

KS, BM, CVW made substantial contributions to the conception and design of the study and contributed to intervention adaptation and training. BM took overall responsibility for trial governance, reporting and conduct. MP and NH contributed to data collection, intervention delivery and trial management. HW and MN contributed to measures and data analysis section. The first draft of the manuscript was written by KS and critically revised by all authors for important intellectual content. All authors read and approved the final manuscript.

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Table 1

Components of the ASPIRE Intervention Package

Delivering Agents	• Training in generic counselling skills and 2-5 years of counselling experience
Structure of Intervention Package	4 sessions of blended multi-component counselling intervention, to be delivered weekly. Participants have a 6-week window to complete all sessions before timing out of the intervention.
Structure of Sessions	
Session #1 (participants in both arms receive this)	• Conduct screening/assessment of mental health • Provide feedback on results of screening/assessment • Increase knowledge of how depression and/or alcohol use impacts on adolescents • MI to build rapport and develop readiness to change (for alcohol) • Behavioural activation strategies to address symptoms of depression, such as exploring how actions impact on emotions , listing activities that result in feelings of pleasure or achievement and activity planning.

Session #2
(intervention arm only)
	• Patient check-in using MI
	• Build the rationale for PST
	  o Explain the structure and rationale for PST
	  o Establish positive problem orientation
	• Teach the steps of PST
	• First problem-solving exercise with counsellor and homework

Session #3 (intervention arm only)	• Patient check-in using MI • Review practice exercises from session 2 and discuss challenges • *Coping with negative thoughts*: Explain how to cope with problems that are not important • Second problem-solving exercise with counsellor and an exercise • *Emotional regulation* • Explain how to cope with "big" feelings such as anger • Practice emotional regulation techniques

	• Third problem-solving exercise with counsellor and homework
Session #4 (intervention arm only)	• Patient check-in using MI • Review practice exercises from session 3 and discuss challenges • *Advance process of acceptance*: teach how to deal with problems that are important and cannot be solved • Fourth problem-solving exercise with counsellor and recap • *Bringing it all together*
ASPIRE Training	
Structure and format of training	• 40 hours of formal training (the equivalent of five working days) • Mixture of didactic teaching and experiential group activities including skills rehearsal exercises and role plays • Counselling proficiency assessed during role plays using a competency checklist
Characteristics of Supervisor	• Psychological counsellor, registered with the HPCSA • 5 years previous counselling experience in cognitive-behavioural therapy-based brief interventions • 3 years previous experience in delivering MI-PST and training healthcare workers • Conduct guided by the professional standards and ethics - Professional Board for Psychology and the HPCSA

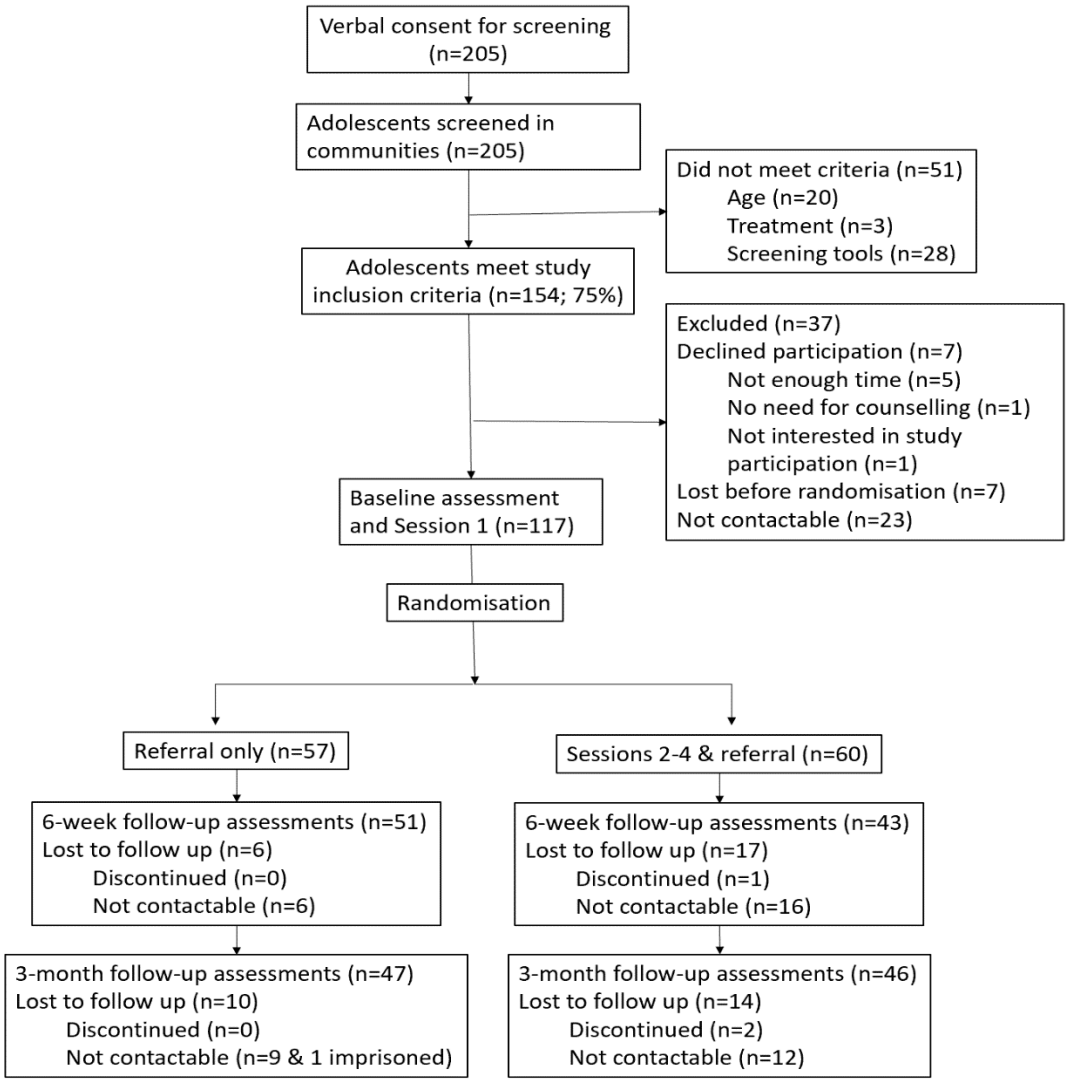

Figure 1

CONSORT diagram of the study design

Table 2

	Total Sample (N, %) (N=117)	**Control (N, %) (N=57)**	**Intervention (N, %) N=60)**
Variables			
Gender			
Male	51 (44)	25 (44)	26 (43)
Female	66 (56)	32 (56)	34 (57)
Age in years			
15	30 (26)	10 (18)	20 (33)
16	29 (25)	18 (32)	11 (18)
17	28 (24)	13 (23)	15 (25)
18	30 (26)	16 (28)	14 (23)
Dropped out of school (yes)	29 (25)	10 (18)	19 (32)
Living situation			
Stable	80 (69)	38 (67)	42 (70)
Unstable	37 (30)	19 (33)	18(30)
Food insecurity (yes)	44 (38)	20 (35)	25 (40)
Social support (m, sd)	5.33 (0.86)	5.40 (0.88)	5.26 (0.85)
Current tobacco use (yes, in past 3 months)	49 (42)	22 (49)	27 (45)
Current alcohol use (yes, in past 3 months)	47 (35)	18 (32)	23 (38)
Eligibility			
Alcohol only	11 (9.4)	8 (14)	3 (5)

Depression only	75 (64.1)	33 (57.9)	42 (70.0)
Both depression & alcohol	31 (26.5)	16 (28.1)	15 (25.0)
Any Alcohol (total)	42 (35.9)	24 (42)	18 (30)
Any Depression (total)	106 (90.6)	49 (86)	57 (95)

Sociodemographic and Mental Health Characteristics of Sample

Table 3

Feasibility Outcomes and Progression Criteria to Trial

Outcome	Evaluation	Progression criteria to trial*	Progression criteria met
1. **Feasibility of recruitment**	• Numbers screened, number of eligible participants, number invited to participate, consent rates (for parents and adolescents), refusal rates and reasons for refusal	• Enrolment of at least 5 participants per week	• **No** (approximately 3 participants per week)
2. **Appropriateness of data collection and outcome measures**	• Number of missing items and follow-up rates	• 80% follow-up rates • Less than 15% missing items for each measure	• **Yes** (80% retention at T1 and 79% at T2 • **Yes**
3. **Retention in the ASPIRE intervention**	• Number of participants who completed at least 3 sessions	• At least 70% of participants complete at least 3 sessions	• **No** (67% received at least 3)
4. **Counsellor competencies**	• Scores on a counsellor competency checklists	• 75% competency	• **Yes** (91% competency)
5. **Feasibility of randomisation & blinding**	• Number of consent/assent • Number of refusals to be randomised • Field staff perceived contamination	• At least 80% participation • Very minimal perceived contamination (less than 5%)	• **Yes** (no drop-outs following randomization) • **Yes** (less than 5%)

6. Presence of adverse events	• Presence of study-related adverse events reported	• Less than 10% of participants reporting severe adverse events related to the study	• **Yes** (no study-related adverse events reported
7. Participants experiences			
i. Acceptability of the ASPIRE intervention	• Scores on the Child Evaluation Inventory (CEI) used to assess participants' satisfaction with the intervention and how it was delivered	• More than 80% of participants scored a total of 60 or more on the CEI	• **Yes**
ii. Acceptability of the study design and procedures	• Ratings on the acceptability of the study procedures, including (i) screening, (ii) consent, (iii) assessment (length, type of questions, mode of administration), (iv) randomisation, (v) and tracking for follow up assessments (5-point scale)	• More than 80% of participants score 3 or more for each rating	• **Yes**

Table 4

Acceptability and Feasibility of Intervention and Study Procedures

	6 week follow-up		**3 month follow-up**	
	Control	Treatment	Control	Treatment

	(n=51)	(n=43)	(n=47)	(n=46)
Acceptability of intervention				
Total CEI (60 or more)	48 (96%)	40 (98%)	43 (91%)	40 (89%)
Happy with treatment (1-5) proportion of 3 or more	50 (100%)	41 (95%)	44 (94%)	43 (93%)
Satisfied with treatment (1-5) proportion of 3 or more	50 (100%)	42 (98%)	45 (96%)	43 (93%)
Usefulness of counselling (1-5) proportion of 3 or more	49 (98%)	42 (98%)	44 (94%)	46 (100%)
Acceptability of study procedures				
Comfortable with screening (1-5) proportion of 3 or more	46 (92%)	35 (81%)	43 (91%)	43 (93%)
Comfortable with parental permission (1-5) proportion of 3 or more*	33 (94%)	30 (91%)	33 (100%)	35 (95%)
Comfortable with baseline questions (1-5) proportion of 3 or more**	45 (90%)	38 (88%)	42 (89%)	41 (89%)
Recommend study to friends/family (1-5) proportion of 3 or more	50 (100%)	42 (98%)	44 (94%)	46 (100%)
Comfortable with follow-up questions (1-5) proportion of 3 or more	49 (98%)	43 (100%)	44 (94%)	45 (98%)
Happy with length of appointments (1-5) proportion of 3 or more	48 (96%)	41 (98%)	41 (87%)	43 (93%)

Table 5

Means and standard deviations of groups at baseline, 6 weeks and 3 months follow-up

Variable	N	Control (mean [sd])	N	ASPIRE (mean [sd])	Adjusted Mean Differences (95% CI)
Depression (CES-D)					
Baseline	49	14.27 (3.98)	57	14.47 (3.97)	
6 week follow-up	45	10.20 (5.40)	40	9.65 (4.92)	-0.71 (-2.30, 1.38)
3 month follow-up	41	9.61 (5.91)	43	10.21 (5.34)	0.61 (-1.82, 3.05)
Alcohol Severity (Assist-Y)					
Baseline	24	13.00 (5.52)	18	15.11 (6.7)	
6 week follow-up	21	6.52 (6.9)	13	7.00 (8.02)	-0.04 (-5.84, 5.76)
3 month follow-up	19	5.68 (7.40)	13	4. 51 (7.32)	-1.86 (-7.36, 3.62)
Number of standard drinks in the past month					
Baseline	24	23.51 (32.0)	18	24.38 (27.12)	
6 week follow-up	21	4.38 (8.24)	13	7.31 (16.43)	2.94 (-7.61, 13.50)
3 month follow-up	19	2.03 (4.45)	13	1.10 (2.37)	-0.94 (-3.51, 1.63)
Anxiety (GAD-7)					

Baseline	57	9.04 (4.96)	60	9.17 (4.75)	
6 week follow-up	51	7.67 (4.99)	43	5.63 (3.92)	-1.96 (-3.71, 0.22) *
3 month follow-up	47	6.77 (5.14)	46	6.48 (4.56)	-0.10 (-2.04, 1.83)
Psychological distress (K-10)					
Baseline	57	25.04 (7.85)	60	26.37 (7.55)	
6 week follow-up	51	21.39 (7.29)	43	20.42 (7.91)	-1.38 (-4.41, 1.66)
3 month follow-up	47	20.60 (8.50)	46	20.63 (8.30)	-0.05 (-3.40, 3.29)
Tobacco use (Assist-Y)					
Baseline	37	7.92 (8.63)	36	9.58 (9.00)	
6 week follow-up	19	12.68 (7.51)	18	14.56 (9.28)	-1.69 (-6.90, 3.51)
3 month follow-up	13	13.92 (8.53)	12	12.33 (5.83)	-0.13 (-6.72, 3.33)
Self-esteem (global-self worth scale)					
Baseline	57	21.95 (3.37)	60	21.50 (3.38)	
6 week follow-up	51	23.82 (3.19)	43	22.93 (3.49)	0.39 (-1.62, 0.84)
3 month follow-up	47	23.17 (3.07)	46	23.07 (3.26)	0.04 (-0.96,1.40)
Emotional Regulation (DERS-16)					
Baseline	57	40.02 (14.51)	60	42.00 (13.88)	

6 week follow-up	51	33.73 (12.40)	43	32. 84 (11.83)	-1.45 (-6.23, 3.33)
3 month follow-up	47	31.26 (12.91)	46	31.41 (10.76)	-0.32 (-4.89, 4.25)