A Systematic Review of Psychotherapeutic Treatments for Common Mental Disorders in South Africa

by

Byron Schwartz and Michael Owen

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University of Cape Town

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Debbie Kaminer

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Abstract

Mental disorders are a significant contributor to the national burden of disease, and currently affect at least 16% of the South African population. However, there are few best practice guidelines for how to feasibly and effectively treat common mental illnesses in our resource-constrained, multi-cultural, multi-lingual context. This study sought to determine the extent of evidence-based treatments for Common Mental Disorders (CMDs) – depression, anxiety and substance use – reported in South Africa. A systematic review of randomised controlled trials (RCTs) for CMDs in the adult South African population was conducted. A total of 17 RCTs satisfied the inclusion criteria. Eligible treatment studies were assessed for scientific rigour using a structured evaluation tool. The results show that substance use RCTs mostly used single session interventions but used rigorous study designs; depression RCTs employed more intensive treatments however with less rigorous study designs; while anxiety has received the least research. The results indicate that to improve the existing evidence base for treating CMDs in South Africa, more attention needs to be paid to research design issues, specifically blinding procedures, treatment provider training, monitoring of fidelity to treatment protocol, and the inclusion of effect sizes, intent-to-treat analyses, and between group statistical comparisons during data analysis. Specific recommendations towards this goal are offered.

Mental disorders are responsible for 7.4% of the global burden of disease, which represents a greater share than any of HIV/AIDS, tuberculosis, diabetes or transport injuries (Whiteford et al., 2013). It is estimated that by 2030, major depression alone will be the second largest contributor to the worldwide disease burden (Mathers & Loncar, 2006). The disabling role played by mental disorders in both high-income countries (HIC) and low- and middle-income countries (LMIC) is being increasingly recognised as a worldwide problem (Prince et al., 2007).

Before the South African Stress and Health Study (SASH) was conducted, little was known about the prevalence, risk factors and available access to treatments of common mental disorders (CMDs) in the country (Herman, Stein, Seedat, Heeringa, Moomal, & Williams, 2009). Conducted between 2002 and 2004, in conjunction with the World Health Organisation (WHO), it was the first attempt at acquiring nationally representative data, and used a sample of 4,351 South African adults (Seedat et al., 2008). Prior research focused on clinic and community samples, leading to variations and bias in prevalence estimates (Herman et al., 2009).

The SASH study used *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV) classifications for anxiety, mood, impulse control and substance abuse disorders (Williams et al., 2007). Thirty percent of respondents reported a lifetime prevalence of at least one of the surveyed disorders, which was twice the prevalence rate reported in Nigeria, and the highest among all other surveyed LMICs except for Colombia and Ukraine (Jack et al., 2014; Stein et al., 2008). The current prevalence of CMDs in South Africa was 16%, with anxiety disorders as the most prevalent class, followed by substance abuse and then mood disorders (Williams et al., 2007). Furthermore, the SASH survey found that only one in four respondents with a current mental disorder had received treatment in the preceding year, indicating a substantial treatment gap (Seedat et al., 2008; Williams et al., 2007).

Globally there is a disparity between the burden of mental disorders and the psychiatric, psychological and counselling resources available to meet treatment needs; however, this gap is particularly serious in LMICs (Saxena, Thornicroft, Knapp, & Whiteford, 2007). The WHO (2004) locates the treatment gap at between 35.5% and 50.3% in economically developed countries and at between 76.3% and 85.4% in less developed countries. The inadequate and oftentimes non-existent provision of public mental health care is a recognised problem within LMICs (Saxena et al., 2007). Given their limited resources, physical health conditions (such as HIV/AIDS and tuberculosis) are typically given primacy. Weak or non-existent mental health policies, poor communication between governments and

mental health NGOs, as well as stigma at the community and policy-making levels, contribute to the scarcity of treatments in LMICs (Omar et al., 2010).

Although South Africa fares better than many other African countries, the current allocation of resources remains insufficient to meet the nation's mental health needs (Lund, Kleintjies, Kakuma, & Flisher, 2010). In 2005 the Northern Cape, North West and Mpumalanga respectively allocated only 1%, 5% and 8% of their provincial health budgets towards mental health services (Lund et al., 2010). In KwaZulu-Natal the budget of psychiatric hospitals grew by an average of 19% over a period of five years, while budgets of general hospitals increased by 64% (Burns, 2010). With respect to human resources, there are 12 mental health workers available per 100,000 people, consisting of 0.3 psychiatrists, 0.5 medical doctors not specialised in psychiatry, 0.3 psychologists, 0.3 social workers, 10.1 nurses and 0.4 other mental health workers (Lund et al., 2010). Although these figures should be interpreted cautiously, given inter-provincial variability, they reflect the scarcity of mental health resources relative to mental health needs in South Africa.

An additional burden to the disability and suffering experienced by those with untreated mental disorders is the income loss associated with an inability to retain employment. It is estimated that the economic cost to South Africans with severe depression and anxiety disorders may be $4,798 (R59,543[1]) per adult per year, resulting in lost national earnings of $3.6 billion (R44,676 billion) (Lund, Myer, Stein, Williams, & Flisher, 2013). While significant in themselves, these figures fail to capture the indirect costs of mental disorders. These include the productivity forfeited by caregiver family members; household resources spent on medication or psychotherapeutic treatments; transport costs to and from mental health centres; as well as the developmental impact that the absence of parents with mental disorders has on children (Jack et al., 2014).

Given that mental healthcare in South Africa is underfunded, and that public-sector clinicians work in resource-restricted settings, it is important that effective and cost-efficient treatments are developed and implemented. To ensure that patients receive interventions most likely to treat their mental disorders, there is a need for empirically-supported treatments that consistently show outcome improvement. By randomly allocating participants and using a control arm for comparison, randomly controlled trials (RCTs) allow researchers to draw causal conclusions about treatment impact by minimising the influence of confounds and

[1]Currency conversion calculated from Lund et al.'s (2013) data.

systematic bias (Drake et al., 2001; Higgins & Green, 2009). The study design of RCTs is considered superior to others, because of the ability to accurately measure a treatment's true effect and limit drawing inaccurate conclusions from the data (Higgins & Green, 2009). They ensure that variables not of interest to a particular study are evenly distributed across conditions so that any difference between the experimental group and the control group can be causally attributed to the intervention (Drake et al., 2001). RCTs also permit researchers to identify sham therapies and refute exaggerated treatment claims. Although held as the gold standard of research within the scientific community, there are limits to the use of RCT findings. Because of their usually strict inclusion criteria, their results tend to be generalisable to specific populations only, which may be uncharacteristic of the populations that clinicians typically treat (Cohen, Stavri, & Hersh, 2003). An uncritical application of RCT findings may therefore result in those too unlike the mean participant receiving unsuitable treatment (Cohen et al., 2003). Furthermore, generalising findings from HICs to LMICs may be problematic because of various social, cultural and economic differences (Patel et al., 2007). Therefore, the generalisability of Euro-American RCT results to other populations cannot always be assumed. Treatments from a Euro-American evidence base should be tested on populations with a different socio-cultural and economic demographic to ensure their effectiveness in local settings.

There is some RCT evidence supporting the transferability of Euro-American treatments to LMICs in Africa and Asia. In Uganda, group Interpersonal Therapy consisting of 90-minute sessions for 16 weeks was found to significantly reduce major depression (Bass et al., 2006). A culturally sensitive intervention based on Cognitive Behaviour Therapy (CBT), delivered to internally displaced persons also in Uganda, significantly reduced symptoms of depression and anxiety in participants (Sonderegger, Rombouts, Ocen, & McKeever, 2011). In Pakistan, an intervention incorporating CBT principles was found to be effective in treating women with perinatal depression (Rahman, Malik, Sikander, Roberts, & Creed, 2008). It has been suggested that evidence-based therapies administered by non-professionals (an approach known as task-shifting) should be developed in LMICs, due to the limited number of mental health professionals relative to the treatment needs of the population (Chipps & Ramlall, 2012; Jack et al., 2014; Lund et al., 2013; Petersen, Lund, Bhana, & Flisher, 2012; Petersen et al., 2009).

While studies from LMICs indicate that Euro-American treatments could be effective in South Africa, the country's unique post-apartheid context, daily experiences of violence, economic hardship, as well as social inequality make research with local samples necessary

(Young, 2014). Other obstacles to the transferability of psychotherapeutic treatments to South African populations include: the comorbity of CMDs with HIV/AIDS; the frequent absence of a shared first language amongst mental health workers and patients; and diverse culturally- and spiritually-shaped beliefs about the aetiology and treatment of CMDs, which are often at odds with conceptions in HICs (Petersen & Lund, 2011; Young, 2014). These differences are significant enough to warrant research into the effectiveness of HIC-developed treatments on South African population groups, which could indicate the need for locally-relevant adaptations.

A systematic review involves the distillation, evaluation and presentation of the best available evidence for interventions or treatments (Petticrew & Roberts, 2006). It provides clinicians with a critical summary of existing research, and assists researchers in establishing the current state of evidence-based practice in a particular area (Petticrew & Roberts, 2006; Uman, 2011). The current study aimed to conduct a systematic review of RCTs for the treatment of depression, substance use and anxiety among South African adults. Its objective is to identify which psychotherapeutic treatments for CMDs have been evaluated with South African samples, critically assess the robustness of existing RCTs with regards to methodological rigour, develop CMD treatment recommendations and offer suggestions for future RCT research in the South African context.

Methods

Study design

This systematic review is largely based on the guidelines and techniques formulated by Petticrew and Roberts (2006). A review based on the *Cochrane Handbook for Systematic Reviews of Interventions* was deemed unsuitable, as it is typically used when a number of studies have been conducted using the same intervention, on comparable populations, measuring the same outcome (Higgins & Green, 2011). The South African context does not yet lend itself to this type of systematic review, given that an initial inquiry into the literature indicated a scarcity of RCTs, as well as the heterogeneity of outcomes and populations.

Sample

The Cochrane Collaboration review (Higgins & Green, 2011) encourages the exclusive inclusion of RCTs in systematic reviews, because their strict design is considered the best approach for minimising systematic bias and obtaining a treatment's true effect. This systematic review's sample was therefore confined to RCTs that evaluated psychotherapeutic treatments for CMDs on heterogeneous South African samples measuring different outcomes. Specifically, these studies evaluate trials of treatments for depression symptoms or depressive

disorders, anxiety symptoms or anxiety disorders and substance use symptoms or disorders (alcohol and drugs) as these have been identified as the three most prevalent disorder classes in South Africa (Herman et al., 2009). Although post-traumatic stress disorder (PTSD) is no longer classed as an anxiety disorder in DSM-V, it is included in the review as it was a DSM-IV anxiety disorder and included in the SASH study. Other research designs such as case studies, pre-post test evaluations with no control group, or controlled studies that did not use randomisation were excluded. Because the SASH study limited its investigation to South African adults, this systematic review was restricted to research using adult participants (Seedat et al., 2008).

Data collection

Using the University of Cape Town's electronic library, the following 11 databases were identified as relevant and included in the systematic search: Academic Search Premier, Africa-Wide Information, CINAHL, e-book Collection (EbscoHOST), Health Source: Nursing/Academic Edition, Humanities International Complete, MasterFILE Premier, MEDLINE, PsycARTICLES, PsychINFO and SocINDEX. The aim of this extensive search was to identify all relevant, peer-reviewed studies that pertain to the research question. Hand searches of *The South African Journal of Psychology* and *The South African Journal of Psychiatry* were conducted as an additional checking measure; in addition to later examining reference lists of the studies selected at the third stage of analysis.

Using the above databases through EbscoHOST, the following key words and phrases were combined in different ways to form the search terms: "trials", "common mental disorders", "random", "control", "study OR review OR evaluation OR research", "South Africa", "depression", "anxiety", "substance abuse and use", "treatment", "intervention", "therapy", "clinical trial" and "programme". To refine the search, we truncated certain words, which entailed the shortening of a word to capture all possible variations. This was carried out to ensure that all targeted studies were found within the databases (Petticrew & Roberts, 2006). For example, *random** found studies that included randomisation, randomization, random assignment and randomised/randomized controlled trial in their titles.

The data collection process consisted of two more stages: selecting studies that contained titles and/or abstracts suggestive of CMD treatment research (second stage), and then strictly applying the inclusion criteria discussed above (third stage) to obtain a final sample. Once the data set had been established through this process of elimination, the data extraction and critical appraisal process began.

Data Analysis

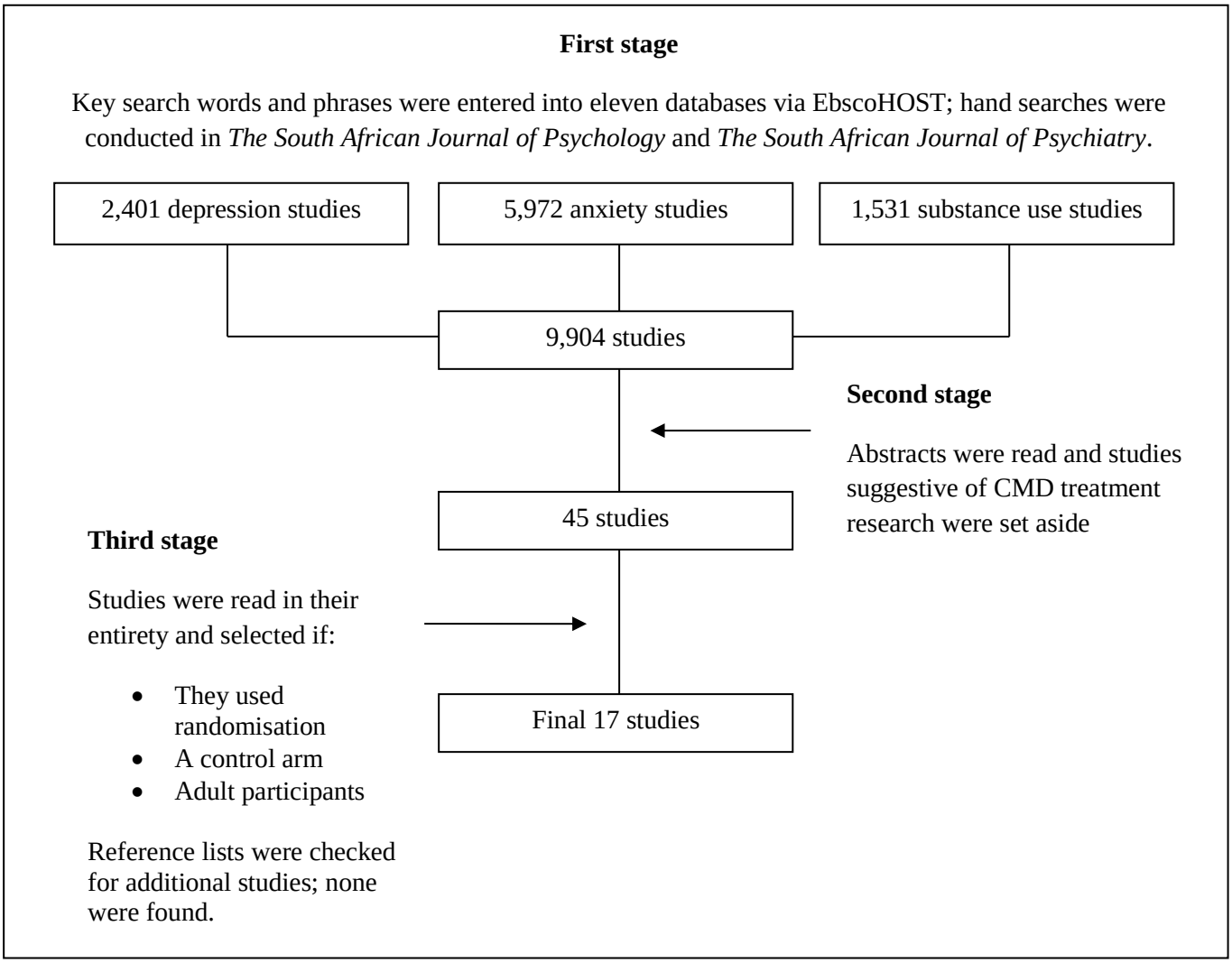
The analysis began with extracting descriptive data from the included studies and summarising it in a data table. Thereafter, a structured critical appraisal was applied on all the RCTs, in order to evaluate the designs employed by each of these studies in finer detail. Critical appraisals are the foundation of rigorous systematic reviewing, and entail a thorough engagement with each study, through closely scrutinising important study design properties (Petticrew & Roberts, 2006). The aim of the critical appraisal process is to evaluate judiciously the quality of the study, paying attention to possible shortcomings that may undermine its overall effectiveness, and in this way guide future research (Petticrew & Roberts, 2006). For this systematic review, the included studies were critically appraised using an adapted quality assessment tool (see Appendix A). This tool drew on items from the qualitative assessment tool for quantitative studies developed by the Effective Public Health Practice Project (EPHPP) (Thomas, Ciliska, Dobbins, & Micucci, 2004) and the Cochrane Collaboration's tool for assessing risk of bias (Higgins & Green, 2011). The adapted critical appraisal tool is an 11-item rating scale covering different areas of study design, including group allocation, treatment personnel, data collection and data analysis. This tool allowed the findings of the RCTs within each CMD category to be compared according to their methodological robustness. The two authors of this review evaluated each study independently using the critical appraisal tool. Any disagreements were referred to the research supervisor and resolved through a consensus process (Van Tulder, Furlan, Bombardier, & Bouter, 2003).

Ethical considerations

This systematic review used primary research located on publicly accessible electronic databases and did not need ethical clearance, as it does not involve human participants. Ethical implications of systematic reviews focus on author conduct and upholding respectable publication standards (Wager & Wiffen, 2011). Areas of ethical concern which pertain to systematic reviews include authorship, good publication practices, accuracy and reporting suspected fraudulent or plagiarised research (Wager & Wiffen, 2011). Firstly, this review consists of two authors and one supervisor, all named above and clearly credited. Secondly, this review forms part of an Honour's degree commitment and may be put forward for publication at the discretion of the research supervisor, with the student researchers being the primary authors. Thirdly, Wager and Wiffen (2011) state that data extraction and analysis should be undertaken by two researchers, and this recommendation was upheld. Finally, if the researchers encountered fraudulent or plagiarised material during

data extraction or the analysis phase, this would be reported to the supervisor. It did not occur.

Figure 1. Selection of studies



Results

Identification of eligible studies

The search of databases yielded a total of 9,904 studies – 2,401 for depression, 1,531 for substance use and 5,972 for anxiety. All 9,904 titles and abstracts were read to determine whether the studies were treatment studies employing an experimental or quasi-experimental design. This process generated 45 studies. The remainder of the studies were not treatment studies. For example, they reported on the prevalence of depression, substance use or anxiety, risk factors associated with these outcomes, or they were qualitative studies that included

interviews, focus groups and case studies. In the next round of selection, all 45 studies were read in their entirety to assess whether they used adult participants, assessed an intervention using an experimental and a control group, and used randomisation methods. Those that met these criteria were selected for inclusion in the study.

Only 17 studies met all the inclusion criteria. See Figure 1 for a flowchart summarising the selection process. Below, a descriptive summary of each of the 17 included RCTs is presented. Thereafter, the studies were critically appraised with regard to methodological rigour.

Descriptive summary

Table 1 presents a summary of each study with regard to the type of intervention, the setting in which the intervention was conducted, the number of sessions delivered, the nature and number of participants, the outcome measures used, and the main reported results. The nature of the RCTs conducted for each of three types of CMD is described below.

Depression. Eight studies assessed depression as an outcome. Two studies examined the use of cognitive therapies; two looked at the use of Interpersonal Therapy (IPT); three investigated craft workshops, hypnotherapy and animal-assisted therapy; and, one study examined the effect that acquiring a loan has on depression[2]. Four of the studies were conducted at public community health clinics and hospitals. One was based at a private hospital and one at an old age home. The loan study (Fernald, Hamad, Karlan, Ozer, & Zinman, 2008) sampled from households in three South African cities. Moller and Steel (2002) did not report on the setting for their study. Apart from the credit study by Fernald et al. (2008), in which the notion of "sessions" is not appropriate, the remaining studies examined treatments consisting of between five and 12 sessions, so were all short-term interventions. With regard to sample size the largest consisted of 237 participants (Fernald et al., 2008), while the smallest involved 16 (Le Roux & Kemp, 2009). The BDI was the most widely used measure of depression, employed in four out of the eight studies. Other depression measures include the POMS, the CES-D, the HAMD, the SRQ-20, PHQ-9 and HSCL-25. Four of the eight studies reported a statistically significant difference in depression between intervention and control groups on at least one depression measure. Two studies reported a significant decrease in depression scores for the intervention groups but both studies failed to make between group comparisons. The loan study by Fernald et al. (2008) found that credit access was associated with an improvement in male, but not female,

[2]Due to the word limit, citations in the text will only be provided when a specific study is being discussed. All information for each study is summarized in the tables.

depression; and, Moller and Steel (2002) found that the intervention was associated with clinically significant changes in depression for the intervention group.

Substance use. Of the seven substance use studies, six focussed primarily on alcohol misuse and only one study looked at both drug and alcohol misuse (Mertens, Ward, Bresick, Broder, & Weisner, 2014). The settings of the studies varied – one was conducted at a university (Pengpid, Peltzer, van der Heever, & Skaal, 2013b), two took place in non-clinic community settings, while the majority were conducted at community clinics. All the studies employed single sessions, using brief cognitive behavioural and counselling techniques, apart from Marais et al. (2011) whose treatment consisted of four sessions incorporating a combination of approaches adapted from brief cognitive interventions. In terms of sample sizes, all were large – the biggest study (Peltzer et al., 2013) sampled 1,196 participants while the smallest (Pengpid, Peltzer, Skaal, & van der Heever, 2013a) included 152 participants. The AUDIT scale, used to record alcohol scores, was employed by all the studies; however, Mertens et al. (2014) included the ASSIST scale to measure drug misuse, while Burnhams, London, Laubscher, Nel and Parry (2015) developed the Workplace Questionnaire (WQ) which they used to assess alcohol misuse, HIV-alcohol knowledge and workplace alcohol consumption. Five studies reported a significant effect for the primary outcome related to the delivered intervention, with lower reported scores on measures. The Pengpid et al. (2013a) and Peltzer et al. (2014) studies both found non-significant results.

Anxiety. Studies of interventions for anxiety produced the smallest yield, with three studies looking at anxiety symptoms as the primary outcome. Constant, de Tolly, Harries and Meyer (2014) investigated an anxiety reducing intervention that sent 13 timed text messages to women undergoing medical abortion; Linde and Stuart (2002) developed a single session cognitive-visual-relaxation intervention to reduce anxiety in women diagnosed with breast cancer. Nortje et al. (2008) investigated cognitive behavioural group techniques (CBGT) with exposure to anxiety inducing stimuli and exposure alone, consisting of 12 sessions. Two of the three anxiety studies took place in clinics, while Nortje, Posthumus and Moller (2008) did not report a setting. Samples sizes ranged from 469 participants in Constant et al. (2014) to 44 in Nortje et al. (2008). Anxiety measures included the HAD Scale, Adler's 12-item Emotional Scale, the IES-R, the IPAT, the SPS, SAS, STF and FNE scales. Constant et al. (2014) found a significant between-group difference in anxiety, and Nortje et al. (2008) found that both CBGT with exposure and exposure alone resulted in reduced anxiety. Linde and Stuart (2002), however, found a reduction in anxiety in both intervention and control groups. Moller and Steel (2002) and De Klerk, du Plessis, Steyn and Botha (2004), whose

results are presented in the depression section above, also measured anxiety with the former finding no significant between-group difference and the latter showing a clinically significant change in anxiety.

Study evaluation

Each study was evaluated for methodological rigour using the evaluation tool adapted for use in this study. Results are summarised in Tables 2(a) and 2(b) and reported below for each category of CMD in turn.

Depression. Only five out of the eight studies reported on their method of randomisation, which included hand selecting cards from a hat, throwing dice, and random allocation via computer programmes. Four of the eight studies used treatment-as-usual control groups, consisting of access to antidepressants, HIV-medication or standard HIV-counselling services. The study by Moller and Steel (2002) used a delayed treatment control group, while the control groups in the remaining three studies were not allocated to any treatment. Treatment providers varied widely across the depression studies – they included psychiatric nurses and volunteers whose level of training in the intervention was not reported, an experienced Rational-emotive Behaviour therapist, a "Pets as Therapy" handler, and lay HIV counsellors who received four days of training. Only two studies reported on the language of treatment delivery. Petersen et al. (2014) was the only study to report on how fidelity to treatment was assessed and on procedures for assessor blinding. In terms of controlling for confounding variables (apart from using randomisation), two studies attempted to do so by employing strict exclusion and inclusion criteria, while three others used statistical methods, such as the chi square analysis used by Moosa and Jeenah (2012). Attrition rates were generally low at between 0 and 6%, however a higher rate of 45% was reported by Petersen et al. (2014) for a number of reasons, which included lack of transport, employment opportunities on treatment days and discomfort among males in groups dominated by females. Only the Fernald et al. (2008) study used an intent-to-treat analysis. None of the studies reported on effect size. Out of the depression RCTs, Petersen et al. (2014), despite a high attrition rate, meets the most components of the evaluation tool by using a task-shifting approach with a consideration of training, treatment fidelity and language of delivery, as well as including controls of confounding variables and assessor blinding in the trial design.

Table 1 Descriptive summary

Authors	Year published	Intervention(s)	Setting	Number of sessions	Participants	Measures	Main result
Depression							
Chetty, D., & Hoque, M. E.	2011	Nurse facilitated cognitive group intervention	Public psychiatric clinic in urban KwaZulu-Natal	15 sessions	30 Indian South African women on antidepressants (15 intervention, 15 control)	Beck Depression Inventory (BDI)	Significant difference in depression between groups at 12 weeks (study ended at 15 weeks but final data was captured at 12), decrease in intervention group and increase in control
Chetty, D., & Hoque, M. E.	2012	Volunteer-led crafts group intervention	Public psychiatric clinic in urban KwaZulu-Natal	15 sessions	30 Indian South African women on antidepressants (15 intervention, 15 control)	BDI	Significant difference in depression between groups at 12 weeks (study ended at 15 weeks but final data was captured at 12), decrease in intervention group and increase in control
De Klerk, J. E., Steyn, H. S., du Plessis, W. F., & Botha, M.	2004	Individual Hypnotherapeutic Ego Strengthening (HES)	Unitas Hospital in Pretoria, Gauteng	2 preoperative sessions, 3 postoperative sessions, daily postoperative	50 white Afrikaans-speaking males scheduled for coronary artery bypass surgery (25 intervention, 25	BDI-II, Profile of Mood States (POMS)	Significant difference in depression between groups at follow-up on the BDI-II but not POMS; no significant difference in anxiety

				audio recordings	control)		between groups at follow-up on the POMS
Fernald, C. H., Hamad, R., Karlan, D., Ozer, M., & Zinman, J.	2008	Small individual loan	Households in Cape Town, Port Elizabeth and Durban	Not applicable	237 participants (109 intervention, 128 control)	Centre for Epidemiologic Studies-Depression Scale (CES-D), Cohen's Perceived Stress Scale (PSS)	Credit access was associated with a significant decrease in depression in men only
Le Roux, M. C., & Kemp, R.	2009	Group Animal-assisted Therapy	Nerina Place, old age home in Cape Town, Western Cape	6 sessions	16 residents at an old age home (8 intervention, 8 control)	BDI, Beck Anxiety Inventory (BAI)	Significant decrease in depression for intervention group at post-intervention, but no between group comparison was reported
Moller, A. T., & Steel, H. R.	2002	Group Rational-emotive Behaviour Therapy	Not reported	10 sessions	42 female victims of childhood sexual abuse (28 intervention, 14 control)	Trauma Symptom Checklist (TSC-40), BDI, State-Trait Anxiety Inventory (STAI), State-Trait Anger Expression Inventory (STAXI), Guilt-Inventory (GI), Coppersmith Self-esteem Inventory (CSEI)	Intervention was associated with clinically significant change in state anxiety for 46% of participants, in depression for 23%, in state anger for 48%, in self-esteem for 69% and in guilt for 77%

Moosa, M. Y. Y., & Jeenha, F. Y.	2012	Individual Interpersonal Therapy (IPT) versus pharmacotherapy (citalopram)	Chris Hani Baragwanath Hospital in Johannesburg, Gauteng	5 to 12 sessions	62 HIV-positive patients on anti-retrovirals (ARVs) (19 antidepressant, 13 IPT, 30 control)	Hamilton Depression Rating Scale (HAMD)	Significant (and similar sized) decrease in depression in both IPT and pharmacotherapy groups at post-intervention, but no comparison with control group reported
Petersen, I., Hancock, J. H., Barner. A., & Govender. K.	2014	Group-based Interpersonal Therapy	Public health clinic in a peri-urban area outside Durban, KwaZulu-Natal	8 sessions	34 HIV-positive participants (17 intervention, 17 control)	Self-Reporting Questionnaire (SRQ-20), Patient Health Questionnaire (PHQ 9), Hopkins Symptom Checklist (HSCL-25)	Significantly greater decrease in depression (PHQ-9 scores) in intervention group compared to control group at post-intervention; Significant (and similar sized) decrease in depression (HSCL-25 scores) was found for both groups
Substance use							
Burnhams, H., London, L., Laubscher, R.,	2015	Group Behavioural-prevention Programme (Team	Two municipal safety and security departments,	Single session	325 municipal workers (168 intervention, 157	18-page questionnaire developed by the	Significant difference in alcohol use between groups at post-intervention; decrease in

& Parry, C.		Awareness)	Western Cape		control)	researchers	both groups but lower alcohol use in intervention group
Marais, P., et al.	2011	Individual Brief Cognitive-behavioural Interventions	Public health clinics, Western Cape	4 sessions	194 pregnant women (98 intervention, 96 control)	Alcohol Use Disorders Identification Test (AUDIT)	Significant difference in alcohol use between groups at post-intervention; decrease in both groups but lower alcohol use in intervention group
Mertens, J. R. et al.	2014	Individual Brief Motivational Intervention (BMI)	Public health clinic in Delft, Western Cape	Single session	403 clinic-sourced participants (206 intervention, 197 control)	AUDIT, Alcohol Smoking and Substance Involvement Screening Test (ASSIST)	Significant difference in alcohol use between groups at post-intervention; decrease in both groups but lower alcohol use in intervention group
Pengpid, S., Peltzer, K., Skaal, L., & Van der Heerver, H.	2013a	Group Brief Alcohol Counselling Intervention (based on BMI)	Hospital in Ga-Rankuwa, Gauteng	Single session	152 university students (81 intervention, 71 control)	AUDIT	No significant difference in alcohol use between groups at post-intervention, both groups decreased at 6 months and slightly increased at 12 months

Pengpid, S., Peltzer, K., Van der Heerver, H., & Skaal, L.	2013b	Group Brief Alcohol Counselling Intervention (based on BMI)	University, Gauteng	Single session	392 hospital outpatients (741 intervention, 455 control)	AUDIT	Significant difference in alcohol use between groups at post-intervention; decrease in both groups but lower alcohol use in intervention group
Peltzer et al.	2013	Group Brief Alcohol Counselling Intervention (based on BMI)	Public health clinics in Siyanda (Northern Cape), Nelson Mandela Metropol (Eastern Cape) and eThekwini (KwaZulu-Natal)	Single session	1196 clinic-sourced participants (741 intervention, 455 control)	AUDIT	No significant difference in alcohol use between groups at post-intervention; decrease in both intervention group and control
Anxiety							
Constant, D., de Tolly, K., Harries, J., & Myer, L.	2014	Mobile phone messaging intervention	Public health clinics in Cape Town, Western Cape	13 text messages	469 women undergoing medical abortion (234 intervention, 235 control)	Hospital Anxiety and Depression Scale (HADS) , Adler's 12-item emotional scale, Impact of Event Scale-Revised (IESR)	Significant difference in alcohol use between groups at post-intervention; decrease in both groups but lower anxiety in intervention group

Linde, C.D., & Stuart, A.D.	2002	Individual Cognitive-visual-relaxation Intervention	Two oncology centres, Gauteng	Single session	98 breast cancer patients (16 intervention, 72 control)	IPAT Anxiety Scale	Significant decrease in anxiety amongst intervention and control groups post-intervention, unclear if between group differences are significant
Nortje, C., & Postumus, T., & Moller, A. T.	2008	Group CBT (cognitive restructuring) versus exposure and exposure alone	Not reported	12 sessions	44 participants (15 CBT with exposure, 15 exposure alone, 14 control)	Social Phobia Scale (SPS), Social Anxiety Scale (SAS), Social target fear scale (STF), Fear of Negative Evaluation Scale (FNE)	For cognitive restructuring and exposure, six out of eight of the main effects were statistically significant, whereas the figure dropped to two for exposure alone

Substance use. All studies described their randomisation methods, which were robust, using either computer-generated sequences, opaque sealed envelopes with group allocation, or utilising researchers who were not involved in the study to carry out randomisation. The type of control groups employed by the studies were similar: four control groups received an information booklet or leaflet, the two community-setting controls received a one-hour counselling session, and only Mertens et al. (2014) implemented a treatment-as-usual control group. The treatment personnel were predominantly nurse-assistant counsellors who had received training through workshops, practice sessions and on-going supervision. The two studies that did not train local nurses recruited volunteers from the community, as well as lay counsellors, who underwent one week and three-week training respectively. Processes for ensuring fidelity to treatment were reported by all apart from Marais et al. (2011). Three studies delivered treatments in the mother tongue of participants, while the other two did not report on language. Five of the studies used techniques to keep assessors blind to group status; however this was not discussed by the remaining two studies. All seven studies attempted to control confounding variables – most used statistical techniques, while some made use of cluster randomisation and power calculations (to calculate an appropriate sample size). All seven studies factored attrition rates into their statistical analyses, however Peltzer et al. (2014) was the only study which employed an intent-to-treat analysis. Of all the studies that reported significant main results, only Mertens et al. (2014) calculated an effect size. Mertens et al. (2014) meets most of the evaluation criteria by considering task-shifting, assessor blinding, reporting on effect size and maintained a small amount of attrition.

Anxiety. Of the anxiety studies, only Constant et al. (2014) described their randomisation method, which involved stratifying the clinics by site before randomly allocating participants to groups using sealed envelopes. Nortje et al. (2008) waitlisted the control group and the other two studies used treatment-as-usual controls. In Nortje et al. (2008) the treatment was delivered by two clinical psychologists; while, in the remaining anxiety studies, the researchers delivered the treatments themselves. All three studies considered confounding variables and statistically controlled for them, although, Linde and Stuart (2002) attained homogeneity through a strict inclusion criteria. Assessor blinding was either not reported or not applicable where the treatment took the form of text messages. Language delivery was not reported apart from Constant et al. (2014) who arranged for participants to receive text messages in their first language. This was also the only study to report on attrition and employ an intent-to-treat analysis. Nortje et al. (2008) was the only

study to consider effect size, which was moderate to small at post-intervention and even less at follow-up for social target fears and social anxiety disorder. This suggests that the treatment gains may not have been sustained and that this specific treatment may need further studies in order to generate a stronger evidence base for dissemination.

Table 2a Evaluation of RCTs summary

Study and year	Randomisation method	Type of Control Group	Treatment personnel	Extent of training	Fidelity to Treatment	Language of treatment delivery
Depression						
Chetty & Hoque (2011)	Participants hand-selected allocation from folded cards kept in a hat	Treatment as usual (including antidepressant medication)	Psychiatric nurses	Not reported	Not reported	English
Chetty & Hoque (2012)	Participants hand-selected allocation from folded cards kept in a hat	Treatment as usual (including antidepressant medication)	Volunteers	Not reported	Not reported	English
De Klerk et al. (2004)	Not reported	No treatment (counselling was offered at 6-week follow up)	Not reported	Not reported	Not reported	Not reported
Fernald et al. (2008)	Participants were allocated to a "have a second look for eligibility" group and control using software developed for the study	Did not receive loan	Bank branch managers	Not reported	Not reported	Not applicable

	(however the final decision rested with the lender)					
Le Roux & Kemp (2009)	Not reported	No treatment	A qualified "Pets as Therapy" dog and handler	Not reported	Not reported	Not reported
Moller & Steel (2002)	Not reported	Delayed treatment control group	A Rational-emotive Behaviour therapist	Therapist described as "experienced", no further information provided.	Not reported	Not reported
Moosa & Jeenha (2012)	Participants were assigned by throwing dice	Treatment as usual (antiretroviral medication)	The research investigator	Not reported	No supervision	Not reported
Petersen et al. (2014)	Participants were allocated using computer-generated random allocation	Treatment as usual (access to antiretroviral medication and standard HIV counselling)	Lay HIV counsellors	Four-day training by a clinical psychologist and clinical psychology trainees	Weekly supervision for two months, thereafter once monthly	Not reported

Substance use

Burnhams et al. (2015)	Systematic, cluster randomisation process which randomised intact workgroups geographically into control and intervention through a coin toss	Received a one-hour wellness session	Locally recruited volunteers	Week-long training and peer review	Monitoring of session notes, debriefing and spot visits	English
Marais et al. (2011)	Cluster randomisation by clinic	Received an alcohol misuse booklet	Not reported	Not reported	Not reported	Not reported
Mertens et al. (2014)	Participants hand-selected group allocation from sealed envelopes	Treatment as usual	Nurses	Three-day BMI training	Weekly supervision for 6 weeks, thereafter monthly. Random assessment of taped nurse sessions to confirm fidelity to treatment	Not reported
Peltzer et al. (2013)	A secure, remote cluster randomisation service allocated clinics into intervention or control	Received an alcohol misuse health education leaflet	Lay counsellors and nurses	Extensive training and supervision including orientation, practice, simulated	Sessions were taped and monitored	English, Afrikaans, isiXhosa, isiZulu and Tswana

	arms			taped sessions and on-going supervision		
Pengpid et al. (2013a)	Sequentially numbered opaque sealed envelopes prepared according to a computer generated allocation sequence	Received an education leaflet on responsible drinking	Nurse assistant counsellors	Five-day workshop	Bi-weekly site visits provided support and supervision	English and Tswana
Pengpid et al. (2013b)	Sequentially numbered opaque sealed envelopes prepared by computer-generated allocation sequence	Received an education leaflet on responsible drinking	Nurse assistant counsellors	Five-day workshop	Bi-weekly site visits provided support and supervision	Not reported
Anxiety						
Constant et al. (2014)	Stratification by site; sequentially numbered, opaque, sealed envelopes contained assignment	Treatment as usual	Not reported	Not reported	Not reported	English, Afrikaans and isiXhosa

Linde & Stuart (2002)	Not reported	Treatment as usual	The research investigator	Not reported	Not reported	Not reported
Nortje, Posthumus & Moller (2008)	Not reported	Wait-listed	Clinical psychologists	Not reported	Not reported	Not reported

Table 2b Evaluation of RCTs summary

Study and year	Assessor blinding	Additional consideration of confounds	Attrition rates	Effect size	Intention to treat analysis
Depression					
Chetty & Hoque (2011)	Not reported	Inclusion criteria attempted to control for confounds	0% at 6 weeks and at 12-weeks, no report on attrition at end of treatment	Not reported	Not reported
Chetty & Hoque (2012)	Not reported	Inclusion criteria attempted to control for confounds	0% at 6 weeks, and at 12-weeks, no report on attrition at end of treatment	Not reported	Not reported
De Klerk et al. (2004)	Not reported	Statistically controlled (test not stated)	0% at end of treatment and 0% at 6 week follow-up	Not reported	Not reported
Fernald et al. (2008)	Assessors not informed of group status	Statistically controlled (t-tests)	Not reported	Not reported	Yes
Le Roux & Kemp (2009)	Not reported	Not reported	6% at end of treatment*	Not reported	Not reported

Moller & Steel (2002)	Not reported	Not reported	5% at end of treatment*	Not reported	Not reported
Moosa & Jeenha (2012)	Not reported	Statistically controlled (chi square)	2% at end of treatment*	Not reported	Not reported
Petersen et al. (2014)	Assessors not informed of group status	Statistically controlled (chi square)	45% at end of treatment*	Not reported	Not reported
Substance use					
Burnhams et al (2015).	No	Power calculation produced a large sample size that attempted to control for confounds	27% at end of treatment and 42% at 3-month follow up	Not reported	Not reported

Marais et al. (2011)	No	Cluster randomisation attempted to control for confounds	8% at end of treatment	Not reported	Not reported
Mertens et al. (2014)	Assessors not informed of group status	Statistically controlled (chi square and Fisher's Exact test)	10% at end of treatment	38.3 (for alcohol scores on the ASSIST)	Not reported
Peltzer et al. (2013)	Assessors not informed of group status	Cluster randomisation attempted to control for confounds	49% at 3-month follow-up and 31% at 6-month follow-up*	Not reported	Yes
Pengpid et al. (2013a)	Assessors not informed of group status	Statistically controlled (chi square)	40% at 6-month follow-up and 29% at 12-month follow-up*	Not reported	Not reported
Pengpid et al. (2013b)	Assessors not informed of group status	Statistically controlled (ANCOVA)	29% at 3-month follow-up and 4 % at 6-month follow-up*	Not reported	Not reported

Anxiety

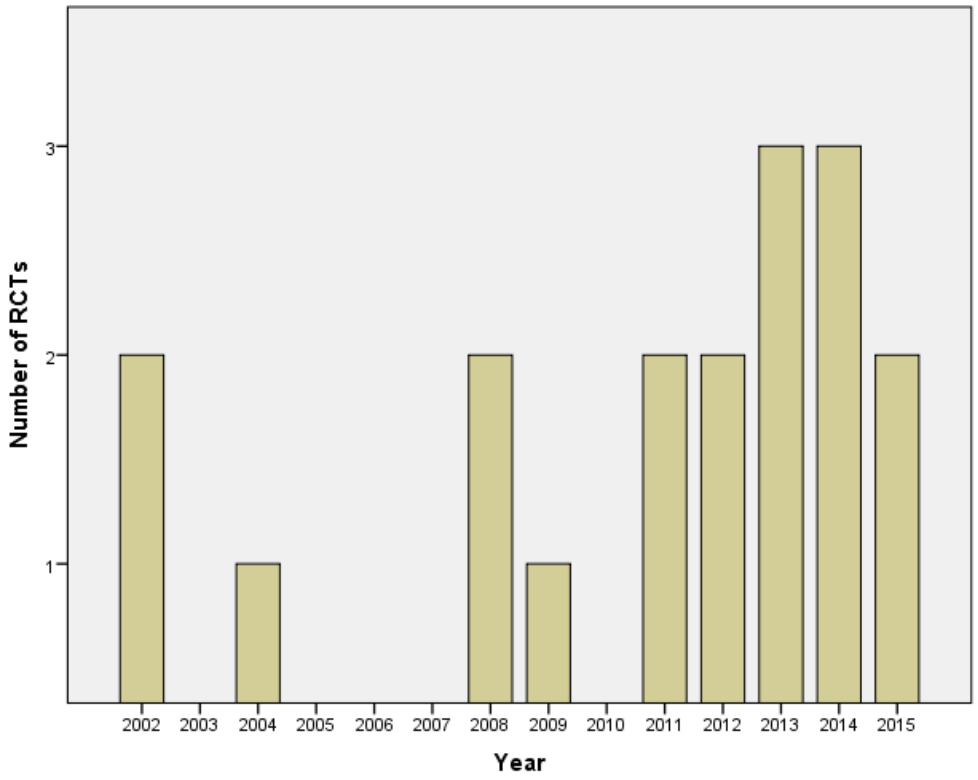
Constant et al. (2014)	No	Statistically controlled	19% (participants assessed at different follow-up times)*	Not reported	Yes
Linde & Stuart (2002)	Not reported	Inclusion criteria attempted to control for confounds	Not reported	Not reported	Not reported
Nortje, Posthumus & Moller (2008)	Not reported	Statistically controlled	Not reported	Reported	Not reported

*Attrition rates calculated by the authors

Discussion

The objective of this study was to systematically review treatments for CMDs that have been conducted in South Africa using an RCT study design. Our search yielded 17 South African RCTs that have evaluated treatments for CMDs in adults since 2000 – a small number over a 15-year period. Eleven of these studies were conducted between 2011 and 2015 (see Figure 2), indicating an emerging trend amongst researchers in more recent years to incorporate both control groups and randomisation into their study designs. This trend is further supported by the recent publication of the protocol for an upcoming RCT evaluating a CMD treatment (Lund et al., 2014). Below, the findings of the systematic review are considered, first with regard to a general description of existing RCTs and thereafter with regard to the methodological rigour of these studies.

Figure 2. RCTs evaluating treatments for CMDs in South Africa



Despite the SASH study's (2004) finding that anxiety disorders are the most prevalent class of CMDs in South Africa, only three RCTs have evaluated treatments specifically targeting anxiety, compared to eight investigating depression (including two which looked at anxiety co-occurring with depression) and six investigating substance use (Williams et al., 2007). Furthermore, Mertens et al. (2014) was the only study to target drug use, even though

drug use is a large-scale social problem particularly in the Western Cape (Herman et al., 2009). This suggests that the current evidence base does not yet reflect the prevalence of CMDs in South Africa. It is further important to note that very few studies used participants who had received a DSM or International Classification of Diseases (ICD) diagnosis. Rather measures such as the BDI (for depression) or AUDIT (for alcohol use) were typically used to determine a baseline level of dysfunction. Therefore, it may be more accurate to say that existing RCTs have largely evaluated treatments addressing symptoms of CMDs, rather than treatments that target individuals meeting the full criteria for a psychiatric diagnosis.

Ten out of the 17 studies evaluated group treatments. There are two benefits to conducting studies of this kind. From a research perspective, this generates a larger sample size that may represent a population more accurately, reduces the influence of outliers, and offers scope for attrition (Patel, Doku, & Tennakoon, 2003). From a practical perspective, group treatments are a feasible way of addressing South Africa's treatment gap. In a resource-scarce context, group interventions allow for multiple individuals to receive treatment at the same time and are therefore potentially more scaleable than individual treatments.

While the depression studies investigated a number of different treatments, a common trend is the absence of statistical comparisons at post-test between the intervention and control groups. Many studies only report intra-group differences, and consequently fail to address whether their results are due to the treatment or placebo effect. The substance use studies, however, conducted both intra-group and importantly between-group tests, which produces a more accurate reflection of a treatment's true effect.

Depression studies used small samples, but tended to incorporate multiple treatment sessions. The substance use treatments consisted of single sessions, except for the study by Marais et al. (2011), making it easier to reach a number of individuals and have large sample sizes. Nevertheless, two of these studies generated non-significant results, indicating that these single session treatments were insufficient for producing lasting change. All included studies used treatments that were short-term and based on Cognitive and Behavioural principles, an IPT protocol or a Brief Motivational Interviewing framework. Similar short-term treatments have been evaluated in Uganda and were found to be effective (Bass et al., 2006; Neuner, Schauer, Klaschik, Karunakara, & Elbert, 2004; Sonderegger et al., 2011).

Most studies were conducted in community settings, such as public health clinics. An RCT's setting is an important consideration for researchers, because it affects the usefulness of a study's findings. Research conducted in community settings may be subjected to

uncontrollable factors and therefore typically resembles real world environments better than carefully controlled studies at clinics or universities, and are therefore likely to generate a truer picture of the treatment's effects and attrition. This is encouraging, because there is a need for evidence-based, resource-efficient treatments that can be rolled out at community clinics.

The findings of these RCTs cannot be considered a useful guide to best clinical practice without first assessing the robustness of their study designs. This systematic review can only rely on what has been reported in the published studies. An attempt to contact each researcher to clarify unreported methodological procedures was not possible due to the timeline constraint. In terms of the methodological rigour of the RCTs under review, however, all 17 studies discussed the value of their research methods as well as reporting on limitations. Reported limitations across the 17 RCTs ranged from a loss of participants at each follow-up stage, unaccounted for differences at baseline due to large sample variation across intervention and control groups, an overreliance on participant self-reporting of symptoms, small sample sizes and an absence of processes to monitor fidelity to treatments. Using the evaluation tool (see Appendix A), we were able to assess in greater detail both the successes and shortfalls of the reported methods of the RCTs.

Randomisation methods were most robust in the substance use studies, where computer-generated randomisation was common, while randomisation processes in the depression and anxiety studies varied across the studies or were frequently just not reported. The substance use RCTs were conducted most recently, and used larger samples, which may explain the greater consistency of computerised randomisation methods. Furthermore, substance use RCTs carefully considered the type of control groups used, in contrast to the depression and anxiety studies, which mostly used treatment-as-usual controls. The use of an active control potentially blinds participants to their group status, and the changes in the intervention groups can more accurately be attributed to an effect of the treatment rather than pre-testing effects (Higgins & Green, 2011). An active control, however, would be easier to incorporate in the substance use studies as these study designs used single-session interventions compared to multiple sessions in the depression RCTs.

The depression studies used a variety of treatment personnel while the anxiety treatments were delivered primarily by the researchers themselves. It is worth noting that treatments delivered by researchers, who are both treatment providers and evaluators, are at increased risk of bias. The assessment of outcomes should be performed by personnel not aware of group status. Substance use RCTs (half of which were conducted by the same

research team) predominantly recruited nurse-assistant counsellors as their treatment personnel, provided training and monitored their fidelity to administering treatments. The shortage of psychiatrists, psychologists and social workers in South Africa makes it necessary for nurses, community volunteers and workers to be skilled in delivering short-term treatments (Lund et al., 2010). Task-shifting, as an approach to delivering treatments for CMDs, is another way of improving public access to mental healthcare and widening the sector's reach.

Dissemination issues are also reflected in the language delivery of the treatments. In half of the substance use RCTs participants received treatments in their first language, which was facilitated by task-shifting to non-professionals. However in the depression and anxiety studies, English was the only language of delivery or language of delivery was not reported, indicating little consideration of how language may have impacted delivery and effectiveness of treatment and what the potential implications for dissemination of the treatment might be. The lack of generalisability to other populations, most pressingly in under-serviced communities where English may not be the mother tongue, is an important concern.

Assessor blinding was, again, reported more frequently in the substance use studies compared to depression and anxiety. In good experimental design practice, assessors must be blind to the status of participants when interpreting results to avoid expectancy bias and ensure that the study accurately measures the effect of the treatment (Higgins & Green, 2011). This is an area in which RCTs for CMDs in South Africa, or at least the reporting of these RCTs, could improve.

While there were some cases of non-reporting, controlling confounding variables was considered by most of the 17 RCTs, either through statistical methods or through strict inclusion criteria. Controlling confounds is necessary, again, to ensure any changes in the intervention groups can be attributed to the treatment. Apart from Petersen et al. (2014), attrition rates in the depression studies were low, as the samples were generally smaller, compared to the higher rates in the substance use studies. Attrition, through the loss of participants at follow-ups, is noted by the substance use RCTs as a serious limitation. The reasons given for attrition vary across the studies, and although most attempted to statistically control attrition rates, attrition may have skewed the reported effects of the treatments at follow-up. Process evaluations would be a standard supplement to outcome evaluations in local RCTs, to qualitatively explore the main reasons for attrition so that these can be addressed in future. Petersen et al. (2014) was the only study to conduct process evaluations.

Of all the 17 RCTs, only Mertens et al. (2011) and Nortje et al. (2008) reported on effect sizes. Although all the studies under review reported *p* values, this is insufficient in terms of each study's practical significance (Sun, Pan & Wang, 2010). While the *p* value indicates if a particular treatment produces a statistically significant change, the effect size quantifies the size and strength of its effect (Sun et al., 2010). This information is decidedly important for guiding policy decisions about which is the most effective treatment to invest in (though cost-efficiency also has to be factored in to these decisions). Similarly, only three of the 17 RCTs adopted an intention-to-treat analysis. An intention-to-treat analysis endeavours to analyse all randomised participants, not only those who have received the treatment and from whom data is collected (Ten Have, Brown, Lavori, & Duan, 2008). It is necessary to include an intention-to-treat analysis especially when assessing the efficacy of the public health benefits of a particular treatment (Ten Have et al., 2008). An intention-to-treat analysis accounts for all assigned participants, and more accurately predicts the effect of a treatment in a particular population, by accounting for attrition, rather than presenting a potentially inflated significant effect.

In light of the discussion above, the design strengths of several existing RCTs can guide future treatment outcome research in South Africa. With regard to depression, group-based Interpersonal Therapy has one rigorously designed RCT (Petersen et al., 2014) to support its use within a task-shifting model in public health settings. Further RCTs for this intervention therefore seem indicated, but these should pay attention to issues of retention. No other existing studies for treatment of depression yet have a strong evidence base to support them and further – rigorously designed – RCTs are needed. Substance use RCTs are more homogeneous in terms of study design with most using task-shifting approaches in community settings, and single session BMI-based interventions. However, results for the effectiveness of these single session interventions have been contradictory across studies and a solid, consistent evidence base has not yet been established. Finally, anxiety studies were under-represented with none looking at trauma or PTSD.

This systematic review has several limitations. Firstly it is possible that, despite a comprehensive search strategy, studies meeting the inclusion criteria may have been overlooked. This could have occurred during the search for studies within the databases or during the reading of study titles and abstracts that followed. Secondly, as discussed, grey literature was not included in this review. This strategy may have omitted RCTs that have been conducted but not yet published. Given the increasing rate of RCTs in South Africa in recent years, we suggest that systematic reviews of this kind should be conducted every five

years to monitor the growing evidence base. Thirdly, this review relied on the content reported in the journal articles published by the researchers. The researchers may have sometimes failed to report on procedures they in fact had carried out. Where information was noticeably absent, we did not contact the researchers directly to clarify their omission, rather we have indicated in our review where information was not reported.

Conclusion

Reviewing the content and quality of these 17 RCTs has enabled a thorough assessment of research conducted on the treatment of CMDs in South Africa, and revealed how research design and reporting practices could be enhanced in the future. Seventeen RCTs for CMDs in 15 years is not a large amount and more studies need to be conducted, particularly for anxiety, depression and drug use treatments, in line with the SASH findings (Williams et al., 2007). Although the methods of the RCTs are reported in detail above, all 17 RCTs reviewed contain considerable study design or reporting flaws, which need to be addressed if these studies are to be clinically useful or replicated by researchers. Going forward, RCTs need to evaluate treatments that are as cost effective as possible considering the financial constraints facing South African mental health services. With regard to design rigour, more attention needs to be paid to blinding procedures, treatment provider training, monitoring of fidelity to treatment protocol, and to the inclusion of effect sizes, intent-to-treat analyses, and between-group statistical comparisons during data analysis.

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Appendix A

Assessment Tool

Based on the Cochrane Collaboration's tool for assessing risk of bias, and the quality assessment tool for quantitative studies taken from the EHPP.

Group allocation

1) What randomisation technique was used to allocate participants to groups?
2) What type of control group did the researchers use?

Treatment personnel

3) Who delivered the intervention (e.g. clinician, lay-counsellor, community members)?
4) What was the extent of the treatment personnel's training?
5) Was fidelity to the treatment protocol reported?
6) Did the researchers report on the language of treatment delivery?

Data collection

7) Were the assessors aware of the group status (treatment or control) of participants?

Data analysis

8) Did the researchers consider confounding variables in the analysis?
9) Were attrition rates reported?
10) Was effect size reported?
11) Did the researchers use an intent-to-treat analysis?