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A clinician-monitored 'PTSD Coach' intervention: findings from two pilot feasibility and acceptability studies in a resource-constrained setting

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ABSTRACT

Background: The high prevalence of trauma exposure and consequent post-traumatic stress disorder (PTSD) is well documented in low- and middle-income countries, and most individuals with PTSD have limited access to treatment in these settings. Freely available internet-based interventions, such as PTSD Coach (web-based and mobile application), can help to address this gap and improve access to and efficiency of care.

Objective: We conducted two pilot studies to evaluate the feasibility, acceptability, and preliminary effectiveness of PTSD Coach in a South African resource-constrained context.

Method: Pilot 1: Participants with PTSD ($n = 10$) were randomized to counsellor-supported PTSD Coach Online (PCO) or enhanced treatment as usual. Pilot 2: Participants ($n = 10$) were randomized to counsellor-supported PTSD Coach Mobile App or self-managed PTSD Coach Mobile App. Feasibility and acceptability were assessed by comparing attrition rates (loss to follow-up), reviewing participant and counsellor feedback contained in fieldnotes, and analysing data on the 'Perceived helpfulness of the PTSD Coach App' (Pilot 2). PTSD symptom severity was assessed with the Clinician Administered PTSD Scale for DSM-5 (CAPS-5), changes between treatment and control groups were compared, the reliable change index (RCI) was calculated, and clinically significant changes were determined.

Results: Three participants in Pilot 1 and two participants in Pilot 2 were lost to follow-up. Fieldnotes indicated that PTSD Coach Mobile App addressed identified computer literacy challenges in Pilot 1 (PCO); and a shorter duration of intervention (from 8 to 4 weeks) was associated with less attrition. The RCI indicated that four participants in Pilot 1 and eight participants in Pilot 2 experienced significant improvement in PTSD symptom severity.

Conclusions: The preliminary results suggest that both platforms can alleviate PTSD symptoms, and that the involvement of volunteer counsellors is beneficial. The use of PTSD Coach Mobile App may be more feasible than the online version (PCO) in our setting.

Una intervención con la aplicación 'PTSD Coach' monitoreada por un clínico: Hallazgos de dos estudios piloto de viabilidad y aceptabilidad en un entorno con recursos limitados

Antecedentes: La alta prevalencia de exposición a trauma y el consecuente trastorno de estrés postraumático (TEPT) están bien documentadas en países de bajos y medianos ingresos y la mayoría de los individuos con TEPT tiene acceso limitado a los tratamientos necesarios en estos entornos. Las intervenciones basadas en internet de acceso gratuito, como el 'PTSD Coach', nombre de la aplicación en inglés (disponible vía aplicación móvil y a través de la web), pueden ayudar a abordar esta brecha y mejorar el acceso y la eficiencia de la atención. Condujimos dos estudios piloto para evaluar la viabilidad, aceptabilidad y preliminarmente la efectividad del 'PTSD Coach' en un contexto con recursos limitados de Sudáfrica.

Metodología: Piloto 1: Los participantes con TEPT ($n = 10$) fueron asignados al azar al 'PTSD Coach' en modalidad online (PCO en sus siglas en inglés) apoyado por un consejero o al tratamiento habitual mejorado. Piloto 2: Los participantes ($n = 10$) fueron asignados al azar al 'PTSD Coach' en modalidad de aplicación móvil apoyado por un consejero o a la aplicación móvil 'PTSD Coach' de manera auto-gestionada. La viabilidad y aceptabilidad se evaluaron comparando las tasas de deserción (perdida durante el seguimiento), revisando los comentarios de retroalimentación dados por los participantes y consejeros, los cuales se encontraban contenidos en las notas de campo, y analizando los datos en la 'Utilidad percibida de la aplicación PTSD Coach' (Piloto 2). La gravedad de los síntomas del TEPT se evaluaron con la Escala de TEPT Administrada por el Clínico (CAPS-5), donde se compararon los cambios entre los grupos de tratamiento y control, el índice de cambio confiable fue

HIGHLIGHTS
- Research on supported PTSD Coach interventions is limited in resource-constrained settings.
- Both volunteer counsellor-supported PTSD Coach Online and the PTSD Coach Mobile App showed preliminary reliable and clinically significant changes.
- The use of PTSD Coach Mobile App seems more feasible than the volunteer counsellor-supported PTSD Coach Online.

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calculado y el cambio clínicamente significativo fue determinado.

Resultados: En el Piloto 1 se perdieron en el seguimiento tres participantes y en el Piloto 2 se perdieron en el seguimiento dos participantes. Las notas de campo indicaron que la aplicación móvil del 'PTSD Coach' abordó los desafíos de la alfabetización informática en el Piloto 1 (PCO); y una intervención de duración más breve (de ocho a cuatro semanas) se asoció con menos deserción. En el Piloto 1 el RCI indicó que cuatro participantes experimentaron una mejoría significativa en la gravedad de los síntomas del TEPT, mientras que ocho indicaron una mejoría significativa en la gravedad de los síntomas del TEPT en el Piloto 2.

Conclusiones: Los resultados preliminares sugieren que ambas plataformas pueden aliviar los síntomas de TEPT y que la participación de un consejero voluntario es beneficiosa. La aplicación móvil 'PTSD Coach' puede ser más factible que la versión en línea (PCO) en nuestro medio.

一项临床医生监测'PTSD教练'干预：在资源受限环境中，两项试点可行性和可接受性研究的结果

背景：创伤暴露和随之而来的创伤后应激障碍 (PTSD) 在低收入和中等收入国家的高流行率已得到充分证明，大多数 PTSD 患者在这些环境中获得所需治疗的机会有限。可免费获取的基于互联网的干预措施，如 PTSD 教练（基于网络和移动应用程序），可以帮助解决这一缺口并提高护理的可及性和效率。我们在一个南非资源受限的环境下进行了两项试点研究评估 PTSD 教练的可行性、可接受性和初步有效性。

方法：试点 1：患有 PTSD 的参与者（$n = 10$）被随机分配到辅导员支持的在线PTSD 教练（PCO）或强化的常规治疗。试点 2：参与者（$n = 10$）被随机分配到辅导员支持的 PTSD 教练移动应用程序或自我管理的 PTSD 教练移动应用程序。可行性和可接受性通过比较流失率（失访）、回顾现场记录中参与者和辅导员的反馈，并分析'感知到的 PTSD 教练应用程序的帮助性'数据（试点 2）来评估。通过临床用 PTSD 量表 (CAPS-5) 评估PTSD 症状严重程度，比较治疗组和对照组之间的变化，计算可靠的变化指数，并确定有临床意义的变化。

结果：在试点 1 中，三名参与者失访，在试点 2 中，两名参与者失访。现场记录表明，PTSD 教练移动应用程序解决了试点 1 (PCO) 中确定的计算机读写能力挑战；较短的干预时间（从 8 周到 4 周）与较少的流失相关。在试点 1 中，RCI 表明四名参与者体验到 PTSD 症状严重程度显著改善，而试点 2 中八名参与者表现出 PTSD 症状严重程度显著改善。

结论：初步结果表明，两个平台都可以缓解 PTSD 症状，并且志愿辅导员的参与是有益的。在我们的环境中，PTSD 教练移动应用程序可能比在线版本 (PCO) 更可行。

1. Background

Post-traumatic stress disorder (PTSD) is a prevalent and impairing disorder in the general population (De Vries & Olff, 2009; Kessler et al., 2017). If left untreated, it can become chronic and unremitting, and have substantial negative effects on social, occupational, and relational functioning (Olff, Langeland, Witteveen, & Denys, 2010; Shalev et al., 2019). The World Health Organization's World Mental Health Surveys initiative, spanning 26 countries, reported a cross-national PTSD lifetime prevalence of 3.9% (Koenen et al., 2017). Prevalence rates of trauma and consequent PTSD in South Africa, a resource-constrained setting, are also well documented (Gass, Stein, Williams, & Seedat, 2010; Herman et al., 2009; Kaminer et al., 2008; Seedat, Nyamai, Njenga, Vythilingum, & Stein, 2004). The largest nationwide epidemiological study to date in South African adults documented a 12 month PTSD prevalence of 2.3% ($n = 4351$) (Herman et al., 2009).

At the same time, up to 85% of people in low- and middle-income countries (LMICs) have limited access to the treatments that they need (Jenkins, Baingana, Ahmad, McDaid, & Atun, 2011; Stafford, Morrison, Godfrey, & Mahalu, 2014). LMICs are often resource-constrained settings, which are characterized by a scarcity of human and material resources and, more pertinent to this study, a shortage of mental health services and personnel (Jenkins et al., 2011; Petersen & Lund, 2011). These constraints may exist in high-income countries too but are more common in LMICs. Similarly, psychological services in the South African public sector are limited (Health Professions Council of South Africa, 2021; Petersen & Lund, 2011; Petersen, Lund, Bhana, Flisher, & Mental Health and Poverty Research Programme Consortium, 2012). As an example, statistics from the Health and Professions Council of South Africa (HPCSA) show that there are currently 9183 registered psychologists in South Africa, which for an estimated population size of 60,000,000 translates into a ratio of approximately one psychologist per 6533 documented citizens (Health Professions Council of South Africa, 2021; Stats SA, 2021).

Trauma-focused therapies (TFTs), such as prolonged exposure therapy, trauma-focused cognitive behavioural therapy (CBT), and eye movement desensitization and reprocessing, are first-line treatments for reducing symptoms of both acute and chronic PTSD, as demonstrated by several randomized controlled trials (RCTs) and meta-analyses (Bisson & Olff, 2021; Brand, McEnery, Rossell, Bendall, &

Thomas, 2018; Lewis, Roberts, Andrew, Starling, & Bisson, 2020; Roberts, Kitchiner, Kenardy, Lewis, & Bisson, 2019). Unfortunately, they require specific training and qualifications and few clinicians are trained in TFTs, which are costly and not often available in public mental health services (Feeny, Hembree, & Zoellner, 2003; Olatunji, Deacon, & Abramowitz, 2009; van Minnen, Hendriks, & Olff, 2010).

Against this backdrop of disease burden and treatment barriers, it is crucial that innovative solutions are found to widen access to psychological treatments and services (Charlson, Diminic, Lund, Degenhardt, & Whiteford, 2014; Patel, Kieling, Maulik, & Divan, 2013). Creative alternatives are, therefore, required to make services more accessible and more efficient. With increased internet access both internationally and locally, internet-based interventions, also referred to as mobile health (mHealth), are one way to broaden access to psychological interventions and address the paucity of treatments (Bakker, Riper, & Olff, 2020; Ben-Zeev, Davis, Kaiser, Krzos, & Drake, 2013; Evans, 2019; Olff, 2015; Steubl et al., 2021; van der Meer, Bakker, van Zuiden, Lok, & Olff, 2020). Olff (2015) provides a list of advantages of mHealth, including greater capacity, availability, equity, immediate support, anonymity, tailored approach, linking to other systems, and lower cost. Around 90% of the world's population is now covered by a mobile cellular signal (Ben-Zeev et al., 2013). In addition, the general rate of smartphone adoption in LMICs is increasing and in South Africa, a 2022 report indicated that 68.2% of people use the internet in one form or another (Anthes, 2016; Kemp, 2022). Thus, while many South Africans do not have access to psychologists, statistics show that they have access to the internet on their cellular phones and, with that in mind, access to treatment alternatives (QWERTY Digital, 2017; Kemp, 2022).

A review on the use of digital technology in PTSD treatment evaluated the evidence for internet-based interventions, telehealth, virtual reality exposure, and mobile applications. The results indicate that even though the evidence for the use of mobile applications is promising, more full-scale RCTs are needed (Kuhn & Owen, 2020). The freely available PTSD Coach (web-based and mobile application platforms) is one such internet-based treatment alternative for PTSD in the absence of access to mental health professionals, which requires further evidence, particularly in resource-constrained settings. PTSD Coach, a smartphone application (app) designed by the United States' Department of Defense and Veteran Affairs to support trauma survivors and their families, was launched in 2011 (Hoffman et al., 2011). This smartphone app (hereafter referred to as PTSD Coach Mobile App) platform provides psychoeducation, includes tools to manage the core symptoms of PTSD, and provides resources for further support. The application's interface has four core sections, namely (1) 'Learn', (2) 'Track progress', (3) 'Manage symptoms', and (4) 'Get support'. The first section, 'Learn', provides psychoeducation about PTSD (symptoms, professional care, and how it can impact the individual's family), while 'Track progress' offers ways for individuals to track their symptoms and/or progress and provides feedback based the individual's self-report. 'Manage symptoms' offers three sections, namely 'symptoms', 'tools', and 'favourites'. The 'symptoms' section includes eight core symptoms of PTSD, namely: reminded of the trauma, avoiding triggers, disconnected from people, disconnected from reality, sad/hopeless, worried/anxious, angry, and unable to sleep. The 'tools' sections consist of 21 tools that can be used to address core symptoms and allows for tools that work for the individual to be added to the 'favourites' bar. Lastly, 'Get support' offers additional resources for support, and the application also allows the individual to manually add other support systems/people. Since launching PTSD Coach Mobile App, the application has been both improved and adapted in six countries (Kuhn et al., 2018). In 2020, additional features and improvements were announced that include the following: no identifiable data collected and/or transmitted during usage, no data usage post-download, reduced phone memory usage due to adapted content, and accommodation for visual- and hearing-impaired needs (Hallenbeck et al., 2022). Emerging research on PTSD Coach Mobile App is promising, with results suggesting high user satisfaction and acceptability, as well as improvements in post-traumatic stress symptoms. However, most of the research to date has been conducted in higher-income settings, where there is higher smartphone ownership and greater access to mental health resources (Kuhn et al., 2018).

The web-based PTSD Coach Online program, developed from the successful mobile application platform, entails 17 tools in the form of videos providing background and instructions on completing various computer-based interactive activities. This web-based online version was designed as a self-management tool for anyone experiencing distress post-trauma; however, additional assistance from a mental healthcare provider may be needed in the event of persistent distress. In comparison, the web-based PTSD Coach Online platform provides additional opportunities to evaluate values and goals and problem solve, while the mobile application PTSD Coach provides tailored support based on the distress of the individual in the moment. The feasibility, acceptability, and preliminary effectiveness of a self-managed Arabic version of a PTSD Coach Online intervention has been piloted

in Egypt (Miller-Graff et al., 2021). This large pilot study (*N* = 87) translated the original version into Arabic in its entirety. Participants' use of the platform was intermittent and the benefit of additional support to promote intervention engagement was noted for future studies. The latter is supported by previous studies of PTSD Coach Mobile App as well as other internet-based interventions (Cernvall, Sveen, Bergh Johannesson, & Arnberg, 2018; Clarke et al., 2005; Mohr, Cuijpers, & Lehman, 2011; Possemato et al., 2016; Titov et al., 2010). In terms of acceptability, with the exception of three tools that were rated lower with regard to likability and may require some adaptation, most of the intervention tools were liked by participants. With regard to PTSD-related symptom reduction, effect sizes were small at post-intervention at 6 weeks (post-test, *d* = −0.14) and at 3 month follow-up (*d* = −0.25) (Miller-Graff et al., 2021).

Supplementing intervention delivery with volunteer counsellors (i.e. registered counsellors, lay counsellors, psychology students) who can provide support and promote engagement is an example of task-shifting (World Health Organization, 2013; Rossouw et al., 2018; Spedding, Stein, & Seedat, 2015). In 2003, the HPCSA created a qualification and registration category for registered counsellors with the aim of increasing accessibility to mental heathcare services in diverse and underresourced settings. Volunteer counsellors are often motivated individuals who have not had an opportunity to gain experience or study further (De Kock & Pillay, 2016). Except for in the study by Miller-Graff et al. (2021), PTSD Coach Online has not been evaluated in a resource-constrained setting, such as South Africa. The aforementioned study did not evaluate PTSD Coach Online as a supported intervention.

This laid the foundation for our research question: Is counsellor-supported PTSD Coach Online feasible and effective compared to enhanced treatment as usual in reducing PTSD and related symptoms in adults with PTSD in a resource-constrained setting? In the context of an RCT where 'treatment as usual' (TAU) is used as a comparator, the term 'usual care' does not imply that patients ordinarily receive a specific treatment for the target problem (Freedland et al., 2011). Instead, it suggests a broader range of possibilities. In an enhanced treatment-as-usual (e-TAU) condition, usual care is systematically improved by the research protocol to overcome ethical or methodological problems that would accompany ordinary TAU, such as contacting the clinic to arrange appointments and offering alternative support services.

We conducted a pilot feasibility study to evaluate (1) the feasibility of recruiting, assessing, and monitoring individuals with PTSD; (2) the utilization of volunteer counsellors; and (3) the utility of a supported PTSD Coach Online intervention in a resource-constrained setting such as South Africa (hereafter referred to as Pilot 1). In addition, we evaluated reliable and clinically significant change in PTSD symptom severity to ascertain preliminary effectiveness of the intervention and whether volunteer counsellors can be involved in supporting intervention delivery. Based on challenges identified in Pilot 1, we conducted a second pilot. This second pilot feasibility study set out to answer the same research question but using a different delivery mode of the PTSD Coach intervention, namely the PTSD Coach Mobile App version instead of the web-based PTSD Coach Online. Pilot 2 also assessed acceptability. In the second pilot (hereafter referred to as Pilot 2), we also modified the comparison arm, informed by the procedures and results of a pilot study by Possemato et al. (2016). The aim, here, was to evaluate and compare the feasibility and acceptability of the mobile app platform to the web-based platform in our setting, to evaluate and compare reliable and clinically significant change in PTSD symptom severity, and to ultimately inform final RCT proper procedures. The results of these two pilot studies informed the planning of an RCT of PTSD Coach Mobile App.

2. Method

2.1. Study design

Both pilot studies used a single-blind, parallel-arm RCT design. In Pilot 1, 10 participants were randomized to either counsellor-supported PTSD Coach Online (PCO-CS) or enhanced treatment as usual (e-TAU). Similarly, in Pilot 2, 10 participants were randomized to either counsellor-supported PTSD Coach Mobile App (PTSD Coach-CS) or self-managed PTSD Coach (PTSD Coach-SM). Participants were randomized in a 1:1 ratio by means of a computer-generated randomization schedule.

Allocations were sealed in envelopes labelled with participants' numbers (1–10) and stored securely by the research assistant. The volunteer counsellor received an envelope upon confirmation of eligibility at the pre-intervention visit. The study was approved by the Health Research Ethics Committee (HREC) at Stellenbosch University (SU) (N18/05/058). Table 1 summarizes the key dimensions of the interventions evaluated in the two pilot studies.

Pilot 1 entailed three assessment visits: (T1) pre-intervention at baseline, mid-point at 4 weeks (T2), and post-intervention at 8 weeks (T3). Pilot 2 entailed two assessment visits: pre-intervention at baseline (T1) and post-intervention at 4 weeks (T2). At baseline, all participants completed a demographic

Table 1. Key dimensions of the pilot studies.

Pilot 1

Intervention arm	Intervention delivery mode	Duration of intervention	Session length	Comparison arm
PTSD Coach Online (PCO) (web-based) (requires computer)	Supplemented with counsellor support	Eight sessions over 8 weeks	40–60 min	Enhanced treatment as usual (e-TAU)

Pilot 2

Intervention arm	Intervention delivery mode	Duration of intervention	Session length	Comparison arm
PTSD Coach (CS) (mobile application) (requires smartphone)	Supplemented with counsellor support	Four sessions over 4 weeks	30–40 min	PTSD Coach (SM) (mobile application) (self-managed use)

questionnaire which included information on age, gender, educational level, marital status, contact details, employment and income, and psychiatric history. The Life Events Checklist (LEC) captured traumatic event exposure, including the most traumatic event (index trauma) (Gray, Litz, Hsu, & Lombardo, 2004). The Clinician Administered PTSD Scale for DSM-5 (CAPS-5) was keyed to the index trauma and administered to confirm the presence and severity of PTSD symptoms (scores range from 0 to 76, with higher scores indicating greater symptom severity) (Weathers et al., 2013).

2.2. Measures

The volunteer counsellors were instructed to document (in fieldnotes) all verbal feedback received from participants over the course of the studies, as well as to document challenges experienced and to make recommendations for future amendments to study procedures for the future planned RCT. Formal assessment of intervention acceptability and satisfaction was unintentionally omitted in Pilot 1; therefore, with permission from the developer, the 'Perceived helpfulness of the PTSD Coach App' self-report measure was included and completed at the post-intervention visit (T2) in both arms of Pilot 2. This measure evaluates user satisfaction and perceived helpfulness of the PTSD Coach mobile application. Answers range from 'Not at all helpful' (0) to 'Extremely helpful' (4), and the measure shows good internal consistency (Cronbach's α of .96) (Kuhn et al., 2014).

Change in PTSD symptoms severity was assessed with the CAPS-5 at the assessment visits. At each visit, the LEC was revisited for additional trauma exposure since the last assessment visit and participants were reminded to endorse symptoms on the CAPS-5 interview in relation to their initially reported index trauma. Measures to address secondary outcomes of the RCT proper (namely, change in anxiety symptoms, change in depression, and change in neurocognitive functioning at post-treatment) are not presented in this report. All participants were

evaluated and monitored by a clinical psychologist blinded to treatment status.

2.3. Participants

Twenty participants were recruited: (1) from an existing database of participants who took part in a cross-sectional study of PTSD (Shared Roots N13/08/115) and who indicated a willingness to participate in additional intervention studies; (2) through recruitment flyers approved by the HREC of SU (N18/05/058); and (3) from referrals from clinicians aware of the study. An eligibility questionnaire designed specifically for this study was used to telephonically screen participants for inclusion. Potential participants with probable PTSD were invited for a clinical assessment visit to further confirm the presence of PTSD and eligibility based on study inclusion and exclusion criteria.

As both studies were primarily focused on feasibility and acceptability, we used the original form of PTSD Coach Online and PTSD Coach Mobile App (in everyday English) with the aim of adapting and translating the modality if it was found to be useful in our setting. As participants were required to have basic conversational English proficiency only, volunteer counsellors were available to assist with language and technical difficulties. The counsellors were trained to provide uniform support to all participants and assisted primarily with addressing language-related questions and technical support. Participants were included in the study if they were between the ages of 18 and 65 years, able to provide written informed consent, and could attend weekly sessions at the university campus during office hours. In addition, participants had to have a current diagnosis of PTSD, as indicated by the Mini-International Neuropsychiatric Interview 7.0 (MINI 7.0) and at least moderate PTSD symptom severity, as evident by a CAPS-5 total score > 23 (Sheehan et al., 1998; Weathers et al., 2013).

Participants on a stable dose of psychotropic medications for at least 2 months pre-study enrolment were included if they were able to maintain a stable dose

until post-study procedures. Participants with Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) current substance use disorder (past 6 months), as assessed by the MINI 7.0, were excluded, as this could potentially interfere with their ability to comply with study procedures.

On the basis of these eligibility criteria, four of 14 screened participants were excluded in Pilot 1. Two did not meet diagnostic criteria for PTSD, one met criteria for substance use disorder, current, and another participant was receiving psychotherapy at the time (see Figure 1: Pilot 1 CONSORT flow diagram, in the supplementary material). For Pilot 2, one of 11 screened participants was excluded for not meeting the criteria for PTSD (see Figure 2: Pilot 2 CONSORT flow diagram, in the supplementary material).

2.4. Treatment

All participants were referred to the volunteer counsellors directly after the pre-intervention visit (T1) for further management (counsellor 1 in Pilot 1 and counsellor 2 in Pilot 2). They received an information sheet with additional local mental health resources and were appropriately referred (e.g. for additional support) at the last assessment visit if this was indicated (T3 in Pilot 1 and T2 in Pilot 2).

2.4.1. Pilot 1: PCO-CS versus e-TAU

The web-based PCO platform contains 17 evidence-informed tools and activities designed to address trauma related symptoms (www.ptsd.va.gov/apps/ptsdcoachonline/default.htm). After careful consideration of the content, approximate duration of each tool, and the aims of the RCT proper, a tailored three-phase intervention spanning eight sessions over 8 weeks, with each session 40–60 min in duration, was decided upon. Sessions 5–8 had more flexibility than the other sessions, to allow for tailoring based on individual coping skills needs. This three-phase intervention approach sought to facilitate exposure of all participants to all 17 tools, thereby ensuring that all participants received the same intervention content. The three phases were: 'Psychoeducation and treatment planning', '"Active" treatment component (e.g. exposure)', and 'Relapse prevention and graduation'. (More details of the intervention protocol are available upon request.) Participants in the PCO-CS arm completed these sessions in a private room with the counsellor. The counsellor had a basic understanding of mental concepts, basic computer skills, and a good grasp of the English language, and was trained to provide language and technical support only to all participants in a standardized manner. So as not to exclude participants without access to a computer, adequate internet connection, and/or lack of privacy at home, the intervention was delivered at the study site (Tygerberg Medical Campus) in a private office with a computer and internet connection.

Participants in the e-TAU arm were referred to their nearest primary care clinic via a detailed referral letter that, with the consent of the participant, included information on their symptom profile and a request for psychological assistance. The volunteer counsellor also contacted local clinics to arrange appointments with the psychiatric nurse. Further treatment decisions were left up to mental health staff at the clinic. Participants in e-TAU were also informed that they could contact the volunteer counsellor at any time should they need support and/or incur delays with receiving assistance. Details on the receipt of care received at the clinic were documented by the same volunteer counsellor, at 4 and 8 weeks, respectively. Participants who had not received support by 8 weeks were provided with additional resources (e.g. details of non-governmental organizations) where alternative psychological assistance could be sought. Each case was evaluated on its merits to inform the most appropriate linkage to care. The current reality of our overburdened health system is that many individuals referred to primary care are 'lost' in the system and do not, in fact, receive the care that they need. We therefore sought to facilitate access by enhancing the usual care pathway by establishing contact with the clinic where possible, actively tracking participants, and offering alternative resources for support.

2.4.2. Pilot 2: PTSD Coach Mobile App-CS versus PTSD Coach Mobile App-SM

In both treatment arms, the volunteer counsellor downloaded the PTSD Coach Mobile App on to participants' smartphones.

Participants in the PTSD Coach Mobile App-CS arm received four supported sessions over 4 weeks of approximately 30–40 min each following a set protocol. These counsellor-supported sessions followed a CBT approach, with the following procedure: setting an agenda for the session and a review of the week, feedback about the last session, review of homework, working through two symptoms and selected tools, and agreeing on homework for the following week. (More details of the intervention protocol are available upon request.) PTSD Coach Mobile App has eight symptoms and 23 tools. The tools selected in this intervention arm were based on careful screening and assessments of feasibility in our setting. While Possemato et al. (2016) allowed free use of the application, this set way of working through the application features increases uniformity among participants, limits confounding factors, and aims to establish a task-shifting intervention that can be manualized (Spedding et al., 2015).

After handover and app download, participants in the PTSD Coach Mobile App-SM received a 30–40 min orientation session to familiarize them with the application. They also received a tailored handout detailing basic information about the app, including the primary features and where to access each feature. The 4 week set protocol described during PTSD Coach Mobile App-CS procedures was included at the back of the handout.

2.4.3. Statistical analyses

Feasibility and acceptability were assessed by comparing attrition rates (lost to follow-up), reviewing documented verbal feedback from both participants and counsellors contained in the fieldnotes, and analysing data on the 'Perceived helpfulness of the PTSD Coach App' from Pilot 2. Descriptive statistics were generated to compare differences in demographic characteristics between the two treatment arms in each pilot. Owing to the small sample sizes, we calculated the reliable change index (RCI) and determined clinically significant change in PTSD symptom severity (CAPS-5 total score) to interpret the preliminary effectiveness of the interventions (Jacobson & Traux, 1991; Weathers et al., 2013). An RCI analysis formula specifies the required change on a psychometric instrument between assessment time-points to indicate that the change is reliable and meaningful for applied research practice (Blampied, 2016). As a result, significant RCI values (> 1.96 or < 1.96) represent a statistically reliable difference between two test scores with 95% certainty that the difference between the test scores is due to actual change rather than measurement error (Jacobson & Traux, 1991). Clinically significant change was defined as a shift in PTSD symptom severity based on the CAPS-5 symptom severity categories (0–10 = asymptomatic/few symptoms; 11–22 = mild PTSD/subthreshold; 23–34 = moderate PTSD/threshold; 35–46 = severe PTSD; and ≥ 47 = extreme PTSD), indicating whether the symptoms improved, remained unchanged, or worsened (Weathers et al., 2013). Our focus was on both reliable and clinically significant change in PTSD symptom severity.

3. Results

3.1. Pilot 1

Ten participants were enrolled, and data collection lasted from April to August 2019. Three of the five PCO participants and four of the five e-TAU participants completed mid-point and post-intervention assessment visits (T1–T3) (see Figure 1: Pilot 1 CONSORT flow diagram, in the supplementary material). One participant in the PCO treatment arm terminated treatment at mid-point as he experienced sufficient improvement that, according to him, did not warrant

further intervention. In each arm, one participant was lost to follow-up and could not be reached. The age of participants ranged from 24 to 64 years ($M = 46.3$; $SD = 13.82$). The sample was largely female (90%), and the majority of participants were of mixed ancestry (90%). The most common index trauma endorsed was experiencing sexual assault (50%). This was followed by learning about a sudden violent death (30%) and experiencing physical assault (20%). Additional demographic and clinical characteristics are presented in Table S1 in the supplementary material.

Verbal feedback from participants and feedback on process difficulties from the volunteer counsellor indicated positive and negative experiences in both treatment arms. PCO participants generally gave positive feedback regarding the assistance they received from the volunteer counsellor and the structured nature of working through the index trauma. Positive feedback from the volunteer counsellor included the PCO program being easily accessible, with the support offering containment and providing motivation to participants. She, however, highlighted that the level of computer literacy of participants impacted on the time commitment, and that other daily commitments made the time commitment required by participants challenging at times. Recommendations for the PCO intervention were that consideration be given to shortening the intervention and strict time boundaries being maintained.

Participants in the e-TAU arm generally expressed reservations about accessing help at the clinic level based on past experience, but all committed to trying to do so. After reportedly being unable to access care twice at her local clinic, one of the four participants followed up in this arm went to another local clinic, where she was placed on the waiting list to see a psychologist. After one failed attempt, and electing not to access further clinic-based assistance owing to expressing confidentiality concerns and a lack of faith in counselling services due to past experience, another participant was successfully connected to telephonic support services (South African Anxiety and Depression Group helpline). For another participant, the volunteer counsellor was able to set up an appointment with the psychiatric nurse within a month; however, upon arrival the participant was asked to come back the following week because of inadequate staffing, and eventually saw a psychologist by the 8 week follow-up visit. The fourth participant was reportedly prescribed antidepressants at his local clinic and sought additional support from another clinic, where he attended an intake session and was seen by a psychologist at the 8 week follow-up visit. According to the volunteer counsellor, she was often unable to establish contact with clinic-based mental health professionals. Screening by a psychiatric nurse was necessary before a referred participant could see

Table 2. Pilot 1: total CAPS-5 total score and RCI per patient from T1 to T2 and from T1 to T3.

Participants	Treatment arm	Baseline symptom severity T1	CAPS T1 to T2	CAPS RCI T1–T2	Mid-point symptom severity T1–T2	CAPS T1 to T3	CAPS RCI T1–T3	Post symptom severity T1–T3
PCO001	PCO	Severe	39 to 20	−5.26*	Mild			
PCO002	PCO	Severe	39 to 29	−2.77*	Moderate	39 to 20	−5.26*	Mild
PCO006	PCO	Severe	38 to 40	0.55**	Severe	38 to 20	−9.96*	Mild
PCO010	PCO	Severe	39 to 30	−2.49**	Moderate	39 to 30	−2.49**	Moderate
PCO003	e-TAU	Severe	45 to 31	−3.87*	Moderate	45 to 14	−8.57*	Mild
PCO005	e-TAU	Severe	41 to 45	1.11**	Severe	41 to 30	−3.04*	Moderate
PCO007	e-TAU	Moderate	32 to 26	−1.66**	Moderate	32 to 20	−3.32*	Mild
PCO009	e-TAU	Moderate	25 to 36	3.04***	Severe	25 to 37	3.32***	Severe

Note: *improved; **unchanged; ***worsened.
CAPS-5 = Clinician Administered PTSD Scale for DSM-5; RCI = reliable change index; PCO = PTSD Coach Online; e-TAU = enhanced treatment as usual.

a psychologist. This, in combination with backlogs, resulted in delays of a month or more to see a psychologist.

Table 2 summarizes the CAPS-5 total score and RCI for Pilot 1 completers from pre-intervention (T1) to the mid-point at 4 weeks (T2), from T2 to post-intervention (T3), and from pre- to post-intervention (T1–T3). The RCI was significant for all participants at both follow-up visits. Four participants experienced significant symptom improvement, two remained unchanged, and one had a worsening of symptoms.

Two of the three PCO intervention completers improved from pre- to post-intervention (T1–T3), while the third remained unchanged. Two of the four e-TAU completers improved from T1 to T3, one remained unchanged, and one experienced worsening of symptoms.

3.2. Pilot 2

Ten participants were enrolled, and data collection lasted from March 2020 to May 2021. Completion of data collection was significantly delayed as study procedures were interrupted after enrolment of the first participant due to coronavirus disease 2019 (COVID-19)-related campus regulations preventing active study recruitment and assessment. All five PTSD Coach Mobile App-CS participants and three of the five PTSD Coach Mobile App-SM participants completed pre- and post-intervention assessment visits (T1–T2). The two PTSD Coach-SM participants were lost to follow-up and could not be reached (see

Figure 2: Pilot 2 CONSORT flow diagram, in the supplementary material).

The age of participants ranged from 27 to 54 years ($M = 39.4$; $SD = 8.14$). In terms of ethnicity, the majority self-identified as white (50%), while 20% identified as mixed ancestry, and 20% identified as black. One participant preferred not to identify in terms of ethnicity. Similarly to Pilot 1, the sample was largely female ($n = 9$). The most common index trauma endorsed was experiencing sexual assault (40%). This was followed by trauma related to experiencing physical assault (30%), assault with a weapon (10%), serious accident at work (10%), and learning about the sudden accidental death of a loved one (10%). Additional demographic and clinical characteristics are presented in Table S1 in the supplementary material.

According to verbal feedback from the counsellor, the 30–40 min sessions worked well in the PTSD Coach Mobile App-CS arm, with these participants being less inclined to miss or postpone scheduled visits. Smartphone ownership was not a limitation; however, on one occasion insufficient phone memory to download the application was a problem. PTSD Coach Mobile App-CS participants found it a great on-demand tool and that the self-assessment tools were helpful in monitoring growth, and felt empowered to manage their emotions better. One participant shared that at times she was unmotivated to access and use the app and that counsellor support was helpful. PTSD Coach Mobile App-SM participants also reported that it was a powerful tool depending on one's ability to be involved, they experienced it as a direct form of stress management, and that anyone

Table 3. Pilot 2: total CAPS-5 total score and RCI per patient from T1 to T2.

Participants	Treatment arm	Baseline symptom severity T1	CAPS T1 to T2	CAPS RCI T1–T2	Post-symptom severity T1–T2
PTSD002	PTSD Coach-CS	Severe	44 to 21	−5.40*	Mild
PTSD003	PTSD Coach-CS	Extreme	48 to 15	−7.75*	Mild
PTSD005	PTSD Coach-CS	Severe	41 to 33	−1.88*	Moderate
PTSD006	PTSD Coach-CS	Severe	42 to 23	−4.46*	Moderate
PTSD007	PTSD Coach-CS	Extreme	55 to 26	−6.81*	Moderate
PTSD001	PTSD Coach-SM	Severe	43 to 33	−2.35*	Moderate
PTSD004	PTSD Coach-SM	Severe	42 to 27	−3.52*	Moderate
PTSD009	PTSD Coach-SM	Extreme	61 to 45	−3.37*	Severe

Note: *improved.
CAPS-5 = Clinician Administered PTSD Scale for DSM-5; RCI = reliable change index; PTSD Coach-CS = counsellor-supported PTSD Coach; PTSD Coach-SM = self-managed PTSD Coach.

who could not afford therapy could educate and help themselves. Preliminary analysis of the 'Perceived helpfulness of the PTSD Coach App' measure indicated that generally participants found the application helpful (PTSD Coach-CS: $M = 3.4$; $SD = 0.55$; and PTSD Coach-SM: $M = 2.33$; $SD = 0.58$). In comparison, PTSD Coach Mobile App-CS participants found it more helpful ($p=.04$); however, these results must be interpreted with caution because of the very small sample size.

As seen in Table 3, the results are significant in terms of both RCI and clinical change in PTSD symptom severity at post-intervention (T2), with all participants indicating improvement. In terms of PTSD symptom severity, two of the five PTSD Coach Mobile App-CS completers indicated an improvement from extreme to mild, two indicated a change from severe to moderate, while one indicated a change from extreme to moderate. Among PTSD Coach Mobile App-SM completers, two experienced a change from severe to moderate, and one a change from extreme to severe.

4. Discussion

We conducted two pilot feasibility and acceptability studies (1) to evaluate the feasibility of recruiting, assessing, and monitoring individuals with PTSD; (2) to evaluate the involvement of volunteer counsellors as a task-shifting approach; (3) to evaluate and compare the feasibility and acceptability of the online platform to the mobile application platform in our setting; and (4) to ultimately inform the final RCT proper procedures. In addition, we undertook a preliminary evaluation and comparison of reliable and clinically significant change in PTSD symptom severity between PCO-CS and e-TAU in Pilot 1, and PTSD Coach Mobile App-CS and PTSD-Coach-SM in Pilot 2.

With regard to feasibility, we were able to recruit our target sample with relative ease, despite strict inclusion criteria, effectively assess them for inclusion (using both the MINI 7.0 and the CAPS-5), and monitor symptoms for the duration of both pilot studies. The CAPS-5 been successfully administered in numerous South African studies, and in this study was found to be sensitive in detecting change in our population (Kagee, Bantjes, Saal, & Sterley, 2022; Suliman, Stein, & Seedat, 2014; van den Heuvel et al., 2020). Other mHealth studies in resource-constrained settings reported smartphone ownership as a barrier to mHealth interventions (Bommakanti et al., 2020; Potdar et al., 2020; Sinha Deb et al., 2018). However, smartphone ownership did not appear to be a barrier in our sample, and local research suggests that other studies have not found this to be a barrier and that, generally, ownership is increasing annually (Kreutzer, 2009; Mogoba et al., 2019; Venter et al., 2019). Phone memory space was a concern for one participant and should be considered in future (e.g. allocating extra time in the first session of the larger RCT to prepare the phone for app download). The PTSD Coach Mobile App may be more feasible in our context when compared to the web-based PTSD Coach Online since it addresses computer literacy challenges among participants and a shorter duration of intervention (from 8 to 4 weeks) was associated with less attrition. Furthermore, considering the limited mental health resources in South Africa and other LMICs, the feasibility of task-shifting with the involvement of volunteer counsellors and a freely available app is encouraging (De Kock & Pillay, 2018; Petersen et al., 2012; Rossouw et al., 2016, 2018; Spedding et al., 2015). A low-cost, volunteer-based intervention may aid in alleviating some of the burden on healthcare resources through upskilling and task-shifting of mental healthcare services in South Africa.

In terms of acceptability, participants in the PCO arm found the technical support offered by the volunteer counsellor helpful and they also found that the supported structured weekly sessions helped them to work through their index trauma. This is consistent with other PTSD Coach research that has found that some form of support yields better outcomes than self-management alone (Miner et al., 2016; Possemato et al., 2016). Participants in the e-TAU arm were reluctant to go to their local clinic but were more encouraged by the detailed referral letter, being provided with the name of a psychiatric nurse and a date and time for the clinic visit. This hesitancy to access healthcare at a primary healthcare level and the crucial role of psychiatric nurses is well documented (Kigozi, Ssebunnya, Kizza, Cooper, & Ndyanabangi, 2010; McCabe & Leas, 2008; Mesidor, Gidugu, Rogers, Kash-MacDonald, & Boardman, 2011; Walker, Barker, & Pearson, 2000). Participants in both PTSD Coach Mobile App-CS and PTSD Coach Mobile App-SM reported a positive experience with the app, with PTSD Coach Mobile App-CS participants noting that the assistance of support helped with motivation to use the app. This again resonates with user satisfaction and acceptability research on both PTSD Coach Mobile App as a self-management tool and the added benefit of supportive accountability generally (Cernvall et al., 2018; Mohr et al., 2011; Possemato et al., 2016).

Lastly, both PTSD Coach delivery platforms showed preliminary effectiveness in alleviating symptoms of PTSD as measured by changes in CAPS-5 scores, which is encouraging. As previously mentioned, mental healthcare services are underresourced, and finding innovative ways to provide support is much needed.

4.1. Limitations and intervention adjustments

Although our findings are encouraging, there are some limitations that need to be noted. Both pilot studies included a small, albeit targeted, sample size. This, combined with the majority female sample, limits the generalizability of our findings. This probably reflects the higher documented prevalence of PTSD in women, who are also more likely to seek treatment, consistent with other studies (Olff, 2017; Olff et al., 2010). Hence, for the RCT proper, we will make a concerted effort to recruit a more balanced sample to enable greater generalizability.

Another limitation is the comparatively high attrition rate within the web-based platform, which limits our conclusions regarding its effectiveness. However, together with the mentioned challenges, this also indicates that the web-based platform is not as feasible and acceptable as the mobile application platform in our setting. We will therefore utilize PTSD Coach Mobile App and deliver a shortened intervention (4 weeks) in the RCT proper.

We did not include any formal assessment of acceptability and satisfaction in Pilot 1, although this was addressed during Pilot 2. While fieldnotes and observations did provide valuable insights for the RCT that will follow, we intend to include a semi-structured questionnaire as well as structured measures of acceptability and satisfaction (the 'Perceived helpfulness of the PTSD Coach App' measure).

Lastly, additional follow-ups were not included in the study procedures, and maintenance of the effect of the interventions on PTSD symptoms was therefore not evaluated. This needs to be considered in light of the aim of these pilot studies, which was primarily to determine feasibility rather than effectiveness in the short and long term. The RCT proper will entail follow-up until 3 months post-intervention.

5. Conclusion

Compared to supported web-based PTSD Coach Online, the PTSD Coach Mobile App platform seems more feasible in our setting, although both produced clinically significant change in PTSD symptom severity. The findings also suggest that volunteer counsellors can be involved, and if corroborated by data from the RCT proper, are promising in terms of capacity building and task-shifting efforts in an overburdened South African health system.

Ethics approval and consent to participate

The study was approved by the Health Research Ethics Committee of Stellenbosch University (N18/05/058). Participants consented to participate in the trial and to the publication of anonymized data.

Availability of data and materials

The data that support the findings reported in this study are not shared publicly for reasons of privacy; however, they can be made available from the corresponding author (E. Bröcker) upon reasonable request.

Authors' contributions

E. B. was the project leader, collected the data, prepared the article, and addressed critical revisions. B. M. and L. G. were the involved as volunteer counsellors and were instrumental in assisting with data collection. S. K. contributed to editing of the article. M. K. assisted with data analyses and interpretation. S. Suliman and M. O. assisted with conceptual and experimental project design and with critical revision of the article. S. Seedat assisted with conceptual and experimental project design, and critical revision. All authors approved this manuscript for publication.

Disclosure statement

No potential conflict of interest was reported by the authors.

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