

## **Audição na Assembleia da República - Comissão de Saúde - Grupo de Trabalho da Saúde Mental - 14 fevereiro de 2023**

Audição relacionada com a Proposta de Lei 24/XV/1ª - Aprova a Lei da Saúde Mental e altera legislação conexa.

Agradecemos o convite para participar nesta audição à Sra. Coordenadora do Grupo de Trabalho da Saúde Mental, Deputada Maria Antónia de Almeida Santos e a todos os deputados presentes a disponibilidade para participar nesta discussão.

Isabel Prata e Jorge Gravanita - Membros da Direção e representantes da Sociedade Portuguesa de Psicologia Clínica, que é uma associação científica de psicólogos com 33 anos de existência.

A nossa atividade principal diz respeito à formação profissional pós graduada dos psicólogos e outros profissionais de saúde mental, nomeadamente:

- formação especializada em psicoterapia de orientação psicanalítica;
- formação em diagnóstico psicológico;
- atividades de formação permanente e atualização científica ao longo de vida
- Temos também participado nos debates de âmbito nacional e europeu, sobre a formação dos psicólogos clínicos, sobre as intervenções psicológicas e psicoterapêuticas e o seu lugar nas redes de cuidados de saúde.

Para a SPPC é do maior relevo poder intervir neste debate na especialidade, da Lei da Saúde Mental.

Analisámos esta proposta de lei (Proposta de Lei 24/XV/1ª - Aprova a Lei da Saúde Mental e altera legislação conexa.), a partir do nosso lugar de cidadãos com uma especialidade profissional ligada à saúde mental.

Focaremos o nosso questionamento, tendo em consideração os pressupostos da lei, as lacunas que encontramos e dúvidas que nos surgiram ao longo da sua leitura.

### **1 - Apreciação global:**

Destacamos como aspectos positivos desta lei os seguintes:

A preocupação com os direitos humanos das pessoas que recorrem a cuidados de saúde mental; a centração na pessoa, nos seus direitos e nas suas necessidades de

cuidados; a proposta de participação das famílias e dos próprios; ter em conta a vontade e a opinião da pessoa que procura cuidados, na medida das suas capacidades;

Destacamos ainda,

a proposta de abordagem multidisciplinar na promoção da saúde mental, na prevenção da doença e na prestação de cuidados de tratamento e reabilitação; e a preferência por cuidados prestados na comunidade.

No entanto, preocupa-nos se haverá condições ou será possível criá-las para a efetiva realização do que a lei prevê, desde as equipas multidisciplinares, até à abordagem de proximidade. Concretizar estes objetivos implica recursos que não existem ou existem em número insuficiente para aquilo que é necessário.

Queremos ainda assinalar o espírito ambicioso da lei quando refere a orientação para a "recuperação integral da pessoa", que entendemos como um conceito que remete para um processo terapêutico de carácter sistémico, envolvendo não apenas a saúde física e psicológica, mas também a reabilitação e inserção social.

No entanto, considerando que muitas condições em saúde mental exigem continuidade de cuidados e/ou vários episódios de tratamento ao longo da vida, pensamos que é importante que isso seja reconhecido pela lei, recomendando a manutenção de alguma forma de acompanhamento clínico de proximidade.

## **2 - Contributos críticos:**

- Coa primeira crítica diríamos que no seu conjunto pensamos que a lei está muito ancorada num modelo biomédico. Isso é visível na "Exposição de Motivos", na pág 3, onde é referido que as inovações propostas estão "em linha com o progresso das ciências médicas e da farmacologia". Pensamos que tem de ser considerado igualmente, o progresso das ciências psicológicas e das práticas psicoterapêuticas, as quais têm mostrado a sua relevância, por exemplo na prevenção e promoção da saúde mental relacionada com a pandemia e na procura crescente de psicoterapia e de apoio psicológico por parte da população.

A nossa sugestão é que possa escrever-se:

"em linha com o progresso das ciências médicas, psicológicas e dos cuidados psicoterapêuticos, e da farmacologia."

No que diz respeito aos direitos das pessoas que procuram cuidados, pensamos que a informação sobre a possibilidade de recurso a terapêuticas não medicamentosas que se considerem adequadas, de acordo com o conhecimento disponível, deve ser garantido como direito universal.

- No artigo 4, alínea c, a lei preconiza a intervenção de equipas multidisciplinares. Concordamos com esta perspetiva, evidentemente, no entanto parece-nos que os outros profissionais podem ser vistos ainda apenas como subsidiários da intervenção psiquiátrica. Ora nos aspectos de prevenção e promoção da saúde, as perspetivas psicológica e social são fundamentais; uma abordagem preventiva que preconize cuidados psicoterapêuticos de primeira linha pode evitar intervenções e tratamentos mais invasivos e ainda evitar que as situações de perturbação psicológica e doença mental comportem maior risco, quer do ponto de vista da saúde, quer no que diz respeito à vida social e familiar.

- Sobre a expressão utilizada no texto da lei de “pessoas com necessidade de cuidados de saúde mental”, pensamos que esta expressão é discriminatória, pois divide as pessoas entre aquelas que necessitam de cuidados e aquelas que não necessitam. Na verdade, tal como na saúde global, todas as pessoas necessitam de cuidados. É um direito universal, o acompanhamento da saúde e receber cuidados preventivos ou terapêuticos adequados, incluindo na dimensão da saúde mental, desde o nascimento e durante toda a vida. Assumimos isso como óbvio na saúde física, há que torná-lo óbvio também na saúde mental.

- Num outro ponto, criticamos que não seja exigível um consentimento escrito para os tratamentos eletroconvulsivos, e que estes, a par com a estimulação intracraniana e a psicocirurgia, não sejam definidos como tratamentos de último recurso, tendo em consideração o carácter invasivo e em certos casos com consequências iatrogênicas potencialmente irreversíveis.

- Sobre a acessibilidade aos cuidados

Esta proposta de lei consagra o direito a aceder em condições de igualdade aos cuidados de saúde mental, o que é inquestionável (Cap. II - artº 4º d). Mas parece-

nos estar perante uma boa ideia que esbarra com a realidade do país, especialmente em relação aos recursos disponíveis.

No que diz respeito aos recursos humanos em psicologia, é reconhecida a insuficiência de psicólogos em todos os níveis do serviço nacional de saúde; mas parece-nos que atualmente acontece o mesmo em todas as profissões implicadas nas equipas multidisciplinares preconizadas.

Como psicólogos, para além da contratação de mais profissionais, o que tem sido amplamente proposto (pelas associações de profissionais, de utentes e pela própria Ordem) pensamos que é também fundamental a compreensão da diferença das respostas da psicologia, que têm de ser diferenciadas das respostas médico psiquiátricas, de enfermagem e de serviço social.

As consultas de psicologia e os cuidados psicoterapêuticos, são fundamentais para a saúde mental em várias fases da vida, desde a primeira infância, até ao final da vida, mas são muito dificilmente acessíveis.

- Sobre o Tratamento involuntário (Capítulo IV)

Sobre o articulado relativo ao tratamento involuntário, reconhecemos a importância das garantias que são dadas às pessoas com doença mental, face à proposta de tratamento involuntário, com ou sem internamento.

Para melhorar estas garantias e, ao mesmo tempo, favorecer a identificação dos casos em que esta necessidade existe, proporíamos:

- a criação de uma comissão de ética que possa definir o limite das intervenções que se julguem necessárias, nas situações agudas e crónicas;
- a sistematização de critérios de risco (incluindo critérios para reconhecer níveis de risco elevado) que possa ser orientadora para todos os clínicos, especialmente os de primeira linha, onde estas situações aparecem mais frequentemente.

Sobre a comissão de acompanhamento da execução da medida de tratamento involuntário (Seção V - Artº 38), questionamos porque esta só compreende um psicólogo clínico, e estão previstos dois juristas e três psiquiatras. Há especialidades relevantes na área da psicologia para estas situações, nomeadamente psicólogos especialistas em avaliação da personalidade e psicólogos especializados em psicoterapia cujos conhecimentos e experiências são complementares para a avaliação de risco.

- Para finalizar, consideramos que a Lei da Saúde Mental deve ter em conta a realidade atual da sociedade em que vivemos. Assim, sugerimos que possam ser preconizadas pela lei recomendações de prestação de cuidados, nomeadamente de cuidados psicoterapêuticos, em situações específicas de alto risco para a saúde mental, como situações traumáticas causadas por: abusos sexuais; violência doméstica; catástrofes naturais; situações de guerra e emergências resultantes de refúgio e migrações forçadas.

Obrigada

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# Recognition of Psychotherapy Effectiveness<sup>1</sup>

American Psychological Association

Council voted to adopt as APA policy the following Resolution on the Recognition of Psychotherapy Effectiveness:

**WHEREAS:** psychotherapy is rooted in and enhanced by a therapeutic alliance between therapist and client/patient that involves a bond between the psychologist and the client/patient as well as agreement about the goals and tasks of the treatment (Cuijpers, van Straten, Andersson, & van Oppen, 2008; Karver, Handelsman, & Bickman, 2006; Lambert, 2004; Norcross, 2011; Shirk & Karver, 2003; Wampold, 2007);

**WHEREAS:** psychotherapy (individual, group, and couple/family) is a practice designed varyingly to provide symptom relief and personality change, reduce future symptomatic episodes, enhance quality of life, promote adaptive functioning in work/school and relationships, increase the likelihood of making healthy life choices, and offer other benefits established by the collaboration between client/patient and psychologist (American Group Psychotherapy Association, 2007; APA Task Force on Evidence-Based Practice, 2006; Burlingame, Fuhriman, & Mosier, 2003; Carr, 2009a, 2009b; Kesters, Burlingame, Nachtigall, & Strauss, 2006; Shedler, 2010; Wampold, 2007, 2010).

## Definitions

**WHEREAS:** evidence-based practice in psychology is “the integration of the best available research with clinical expertise in the context of patient characteristics, culture and preferences” (APA Task Force on Evidence-Based Practice, 2006, p. 273);

**WHEREAS:** a working definition for Psychotherapy is as follows: “Psychotherapy is the informed and intentional application of clinical methods and interpersonal stances derived from established psychological principles for the purpose of assisting people to modify their behaviors, cognitions, emotions, and/or other personal characteristics in directions that the participants deem desirable” (Norcross, 1990, pp. 218–220);

**WHEREAS:** a working definition for Treatment is as follows: Treatments when used in the context of health care, refer to any process in which a trained health care provider offers assistance based upon his or her professional expertise to a person who has a problem that is defined as related to “health” or “illness.” In the case of “mental” or “behavioral” health, the conditions for which one may seek “treatment” include problems in living, conditions with discrete symptoms that are identified as or as related to illness or disease, and problems of interpersonal adjustment. The treatment consists of any act or services provided by a bona-fide health provider intended to correct, change

<sup>1</sup> While statements about the effectiveness of psychotherapy must be accurate yet generalized in a policy document format, research studies have not equitably investigated all factors that either enhance or diminish psychotherapy effectiveness. Full explication of the differential status of any given variable and the state of research of any given factor in the practice of psychotherapy is beyond the scope of this document. The research citations that accompany each statement provide specificity of scope, limitations, and implications for psychotherapy practice and identify the therapeutic circumstances in which research has determined that psychotherapy is soundly effective. Examples of these important moderating variables include client/patient characteristics, clinician characteristics, context factors, diagnostic classification and severity, developmental status, and factors related to such human and cultural diversity as race, ethnicity, gender, sexual orientation and disability status (Bernal, Jimenez-Chafey, & Domenech Rodriguez, 2009; Curry et al., 2006; Hinshaw, 2007; Kazdin, 2007; Kocsis et al., 2009; McBride, Atkinson, Quilty, & Bagby, 2006; Miklowitz et al., 2009; Ollendick, Jarrett, Grills-Tauchel, Hovey, & Wolff, 2008).

In August 2012, the APA Council of Representatives approved this resolution on the recognition of psychotherapy effectiveness.

This resolution is available online at: <http://www.apa.org/news/press/releases/2012/08/resolution-psychotherapy.aspx>

or ameliorate these conditions or problems (Beutler, 1983; Frank, 1973).

### Research on Effectiveness

**WHEREAS:** the effects of psychotherapy are noted in the research as follows: The general or average effects of psychotherapy are widely accepted to be significant and large, (Chorpita et al., 2011; Smith, Glass, & Miller, 1980; Wampold, 2001). These large effects of psychotherapy are quite constant across most diagnostic conditions, with variations being more influenced by general severity than by particular diagnoses—That is, variations in outcome are more heavily influenced by patient characteristics for example, chronicity, complexity, social support, and intensity—and by clinician and context factors than by particular diagnoses or specific treatment “brands” (Beutler, 2009; Beutler & Malik, 2002a, 2002b; Malik & Beutler, 2002; Wampold, 2001);

**WHEREAS:** the results of psychotherapy tend to last longer and be less likely to require additional treatment courses than psychopharmacological treatments. For example, in the treatment of depression and anxiety disorders, psychotherapy clients/patients acquire a variety of skills that are used after the treatment termination and generally may continue to improve after the termination of treatment (Hollon, Stewart, & Strunk, 2006; Shedler, 2010);

**WHEREAS:** for most psychological disorders, the evidence from rigorous clinical research studies has shown that a variety of psychotherapies are effective with children, adults, and older adults. Generally, these studies show what experts in the field consider large beneficial effects for psychotherapy in comparison to no treatment, confirming the efficacy of psychotherapy across diverse conditions and settings (Beutler, 2009; Beutler et al., 2003; Lambert & Ogles, 2004; McMains & Pos, 2007; Shedler, 2010; Thomas & Zimmer-Gembeck, 2007; Verheul & Herbrink, 2007; Wampold, 2001). In contrast to large differences in outcome between those treated with psychotherapy and those not treated, different forms of psychotherapy typically produce relatively similar outcomes. This research also identifies ways of improving different forms of psychotherapy by attending to how to fit the interventions to the

particular patient’s needs (Castonguay & Beutler, 2006; Miklowitz, 2008; Norcross, 2011);

**WHEREAS:** comparisons of different forms of psychotherapy most often result in relatively nonsignificant difference, and contextual and relationship factors often mediate or moderate outcomes. These findings suggest that (1) most valid and structured psychotherapies are roughly equivalent in effectiveness and (2) patient and therapist characteristics, which are not usually captured by a patient’s diagnosis or by the therapist’s use of a specific psychotherapy, affect the results (Castonguay & Beutler, 2006; Livesley, 2007; Norcross, 2011);

**WHEREAS:** in studies measuring psychotherapy effectiveness, clients often report the benefits of treatment not only endure, but continue to improve following therapy completion as seen in larger effect sizes found at follow-up (Abbass, Kisely, & Kroenke, 2006; Anderson & Lambert, 1995; de Maat, de Jonghe, Schoevers, & Dekker, 2009; Grant, Huh, Perivoliotis, Solar, & Beck, 2012; Leichsenring & Rabung, 2008; Leichsenring, Rabung, & Leibing, 2004; Shedler, 2010);

**WHEREAS:** research using benchmarking strategies has established that psychotherapy delivered in routine care is generally as effective as psychotherapy delivered in clinical trials (Minami et al., 2009; Minami & Wampold, 2008; Minami et al., 2008; Nadort et al., 2009; Wales, Palmer, & Fairburn, 2009);

**WHEREAS:** the research evidence shows that psychotherapy is an effective treatment, with most clients/patients who are experiencing such conditions as depression and anxiety disorders attaining or returning to a level of functioning, after a relatively short course of treatment, that is typical of well-functioning individuals in the general population (Baldwin, Berkeljon, Atkins, Olsen, & Nielsen, 2009; Minami et al., 2009; Stiles, Barkham, Connell, & Mellor-Clark, 2008; Wampold & Brown, 2005);

**WHEREAS:** research will continue to identify factors that make a difference in psychotherapy, and results of this research can then be reported to clinicians who can make better decisions (Gibbon et al., 2010; Kazdin, 2008);

**WHEREAS:** researchers will continue to examine the ways in which both positive and possible negative effects of psychotherapy occur, whether due to techniques, client/patient



variables, therapist variables, or some combination thereof, in order to continue to improve the quality of mental health interventions (Barlow, 2010; Dimidjian & Hollon, 2010; Duggan & Kane, 2010; Haldeman, 1994; Wilson, Grilo, & Vitousek, 2007).

### Effectiveness Related to Health Care Policies

**WHEREAS:** the effects produced by psychotherapy, including the effects for different age groups (i.e., children, adults, and older adults) and for many mental disorders, exceed or are comparable to the size of effects produced by many pharmacological treatments and procedures for the same condition, and some of the medical treatments and procedures have many adverse side effects and are relatively expensive vis-à-vis the cost of psychotherapy (Barlow, 2004; Barlow, Gorman, Shear, & Woods, 2000; Hollon, Stewart, & Strunk, 2006; Imel, McKay, Malterer, & Wampold, 2008; Mitte, 2005; Mitte, Noack, Steil, & Hautzinger, 2005; Robinson, Berman, & Neimeyer, 1990; Rosenthal, 1990; Walkup et al., 2008; Wampold, 2007, 2010);

**WHEREAS:** a substantial body of scholarly work (e.g., Henggeler & Schaeffer, 2010; Roberts, 2003; Walker & Roberts, 2001; Weisz, Sandler, Durlak, & Anton, 2005) have documented the effectiveness of psychotherapy across a range of problems affecting children and adolescents;

**WHEREAS:** large multisite studies as well as meta-analyses have demonstrated that courses of psychotherapy reduce overall medical utilization and expense (Chiles, Lambert, & Hatch, 2002; Linehan et al., 2006; Pallak, Cummings, Dörken, & Henke, 1995). Furthermore, patients diagnosed with a mental health disorder and who received treatment had their overall medical costs reduced by 17% compared to a 12.3% increase in medical costs for those with no treatment for their mental disorder (Chiles, Lambert, & Hatch, 2002);

**WHEREAS:** there is a growing body of evidence that psychotherapy is cost-effective, reduces disability, morbidity, and mortality, improves work functioning, decreases use of psychiatric hospitalization, and at times also leads to reduction in the unnecessary use of medical and surgical services including for

those with serious mental illness (Dixon-Gordon, Turner, & Chapman, 2011; Lazar & Gabbard, 1997). Successful models of the integration of behavioral health into primary care have demonstrated a 20%–30% reduction in medical costs above the cost of the behavioral/psychological care (Cummings, O'Donahue, & Ferguson, 2003). In addition, psychological treatment of individuals with chronic disease in small group sessions resulted in medical care cost savings of \$10 for every \$1 spent (Lorig et al., 1999);

**WHEREAS:** there is strong scientific evidence to support the links between mental and physical health, and a growing number of models and programs support the efficacy of the integration of psychotherapy treatment within the primary health care system (Alexander, Arnkoff, & Glass, 2010; Felker et al., 2004; Roy-Byrne et al., 2003). In fact, early mental health treatments that include psychotherapy reduce overall medical expenses, simplifies and provides better access to appropriate services and care to those in need, and improves treatment seeking;

**WHEREAS:** many people prefer psychotherapy to pharmacological treatments because of medication side effects and individual differences and people tend to be more adherent if the treatment modality is preferred (Deacon & Abramowitz, 2005; Paris, 2008; Patterson, 2008; Solomon, Keitner, Ryan, Kelley, & Miller, 2008; Vocks et al., 2010). Research suggests that there are very high economic costs associated with high rates of antidepressant termination and nonadherence (Tournier et al., 2009), and psychotherapy is likely to be a more cost-effective intervention in the long term (Cuijpers, van Straten, Hollon, & Andersson, 2010; Hollon et al., 2005; Pyne et al., 2005).

### Effectiveness With Diverse Populations

**WHEREAS:** the best research evidence conclusively shows that individual, group and couple/family psychotherapy are effective for a broad range of disorders, symptoms and problems with children, adolescents, adults, and older adults (American Group Psychotherapy Association, 2007; Burlingame et al., 2003; Carr, 2009a, 2009b; Chambless et al., 1998; Horrell, 2008; Huey & Polo, 2008, 2010; Knight, 2004; Kosters et al., 2006; Lambert &



Archer, 2006; Norcross, 2011; Pavuluri, Birmaher, & Naylor, 2005; Sexton, Alexander, & Mease, 2003; Sexton, Robbins, Hollimon, Mease, & Mayorga, 2003; Shadish & Baldwin, 2003; Stice, Shaw, & Marti, 2006; Wampold, 2001; Weisz & Jensen, 2001);

**WHEREAS:** the development and/or adaptation of evidence-based psychotherapy practices for each age group have further demonstrated effectiveness in reducing symptoms and improving functioning across the life span. Specific challenges that emerge with age are addressed by developmental research that pinpoints the most efficacious content, vocabulary, and techniques used for different ages. As a result, substantial evidence supports psychotherapy as a front line intervention for community dwelling older adults, older adults with medical illnesses, who are low-income, ethnic minority and have co-occurring mild cognitive impairments. In addition, increasing evidence has documented that older adults respond well to a variety of forms of psychotherapy and can benefit from psychological interventions to a degree comparable with younger adults. Furthermore, many older adults prefer psychotherapy to antidepressants, and psychotherapy is an important treatment option for older adults who are often on multiple medications for management of chronic conditions and are more prone to the adverse effects of psychiatric medications than younger adults (Alexopoulos et al., 2011; American Psychological Association, 2004; Areán, Ayalon, et al., 2005; Areán, Gum, et al., 2005; Areán, Gum, Tang, & Unutzer, 2007; Areán et al., 2010; Arnold, 2008; Cuijpers, van Straten, & Smit, 2006; Gum, Areán, & Bostrom, 2007; Kaslow, Broth, Smith, & Collins, 2012; Kazdin et al., 2010).

**WHEREAS:** researchers and practitioners continue to develop culturally relevant, socially proactive approaches and modalities that will allow psychologists to extend psychotherapeutic services to vulnerable and currently underserved populations such as adults, children, and families living in poverty (Ali, Hawkins, & Chambers, 2010; Belle & Doucet, 2003; Goodman, Glenn, Bohlig, Banyard, & Borges, 2009; Smith, 2005, 2010; Smyth, Goodman, & Glenn, 2006);

**WHEREAS:** both evidence-based psychotherapy practice for the general population and culturally adapted interventions are generally

effective with racial/ethnic minorities, psychologists who work with marginalized populations, such as people living in poverty and/or other socially excluded groups, can improve the effectiveness of their interventions through awareness of unintentional age, race, class, and/or gender bias. The acquisition of multicultural competence and the adaptation of psychotherapy, whether in content, language, or approach, can improve client engagement and retention in treatment and can enhance development of the therapeutic alliance (Griner & Smith, 2006; Horrell, 2008; Huey & Polo, 2008, 2010; Miranda et al., 2005; Miranda et al., 2006; Vasquez, 2007; Whaley & Davis, 2007);

**WHEREAS:** the research continues to support that psychotherapy, both group and individuals models of clinical interventions, is effective treatment for individuals with disabilities. The studies also indicate that psychotherapy is effective for a variety of disability conditions including cognitive, intellectual, physical, visual, auditory, and psychological impairments. The research supports that psychotherapy is effective for individuals with disabilities over the life span. A sample of the research reflecting the effectiveness of therapy with individuals with disabilities include: Glickman (2009); Hibbard, Grober, Gordon, and Aletta (1990); Kurtz and Mueser (2008); Livneh and Sherwood (2001); Lysaker, Glynn, Wilkniss, and Silverstein (2010); Olkin (1999); Perlman et al. (2010); Rice, Zitzelsberger, Porch, and Ignagni (2005); Radnitz (2000), and Vail and Xenakis (2007);

**WHEREAS:** research indicates the beneficial effects of psychotherapy as a means of improving mood and reducing depression among individuals with acute and chronic health conditions (e.g., arthritis, cancer, HIV/AIDS; Fisch, 2004; Himelhoch, Medoff, & Oyeniyi, 2007; Lin et al., 2003);

**WHEREAS:** although some cultural adaptations already have demonstrated effectiveness as mentioned above, many underserved communities can continue to benefit from specific adaptations or demonstrated effectiveness of evidence-based psychotherapy practice. For example, current psychotherapy research suggests that racial/ethnic minorities, those with low socioeconomic status, and members of the LGBT community may face specific challenges not addressed by current evidence-based treatment.

In conducting psychotherapy, practitioners are sensitive to these challenges and pursue appropriate adaptations (Butler, O'Donovan, & Shaw, 2010; Cabral & Smith, 2011; Gilman et al., 2001; Smith, 2005; Sue & Lam, 2002);

**THEREFORE:** Be It Resolved that, as a healing practice and professional service, psychotherapy is effective and highly cost-effective. In controlled trials and in clinical practice, psychotherapy results in benefits that markedly exceed those experienced by individuals who need mental health services but do not receive psychotherapy. Consequently, psychotherapy should be included in the health care system as an established evidence-based practice.

Be It Further Resolved that APA increase its efforts to educate the public about the effectiveness of psychotherapy; support advocacy efforts to enhance formal recognition of psychotherapy in the health care system; help ensure that policies will increase access to psychotherapy in the health care system, with particular attention on addressing the needs of underserved populations and encourage integration of research and practice; and support advocacy for funding.

Be It Further Resolved that APA encourages continued and further research on the comparative effectiveness and efficacy of psychotherapy.

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# Community-Based Randomized Controlled Trial of Psychological First Aid With Crime Victims

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**Objective:** The first randomized controlled trial of psychological first aid (PFA) was conducted, using crime victims as participants. For study Aim 1, investigators tested whether paraprofessional victim advocates could be trained to deliver PFA to crime victims. For study Aim 2, investigators tested the effect of PFA delivery on victims' psychiatric (i.e., symptoms of PTSD, somatization, depression, anxiety, and substance use) and adaptive functioning outcomes. **Method:** Two law enforcement agencies served as study sites. A dynamic wait-listed design included a phase when advocates at both sites delivered usual services (US) to victims, a phase when one site was randomly selected to deliver PFA while the other delivered US, and a phase when both sites delivered PFA. Across all phases, 172 crime victims (mean age = 36.4 years; 81% female) were recruited, and a battery assessed their psychiatric symptoms and adaptive functioning at baseline and 1, 2, and 4 months postbaseline. **Results:** From the US to PFA phases, advocates' PFA adherence (i.e., their delivery of PFA components) increased significantly. PFA did not outperform US with regard to improvement on victims' individual psychiatric and adaptive functioning outcomes. However, on a composite global functioning outcome created for this trial, PFA yielded significantly greater improvement relative to US. **Conclusion:** Paraprofessional victim advocates have the capacity to deliver PFA. Conclusions regarding the effectiveness of PFA for crime victims vary depending on the nature of the scored outcome variable (individual vs. global), highlighting the importance of careful outcome measurement considerations in future research on PFA.

### *What is the public health significance of this article?*



Paraprofessional victim advocates can feasibly deliver psychological first aid (PFA) to crime victims, and this brief intervention might yield improvement in victims' global functioning. PFA is designed for delivery soon after a traumatic event, with the goal of minimizing acute suffering and preventing future problems.

**Keywords:** victimization, crime, trauma, psychological first aid, early intervention

**Supplemental materials:** <http://dx.doi.org/10.1037/ccp000588.supp>

This article reports results from a randomized controlled trial of an acute preventive intervention, psychological first aid (PFA),

implemented with victims of violent crime. Violent crime (defined as rape/sexual assault, physical assault, or armed robbery) is a

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serious public health problem. More than six million violent crimes were committed against U.S. citizens aged 12 years and older in 2018 (Morgan & Oudekerk, 2019). Fortunately, many victims experience only transient distress in the aftermath of a traumatic event (Bonanno, Westphal, & Mancini, 2011). However, a sizable minority (i.e., 6–13%) develop serious psychiatric problems (Breslau, 2009; Kilpatrick et al., 2013). The most common psychiatric outcomes of crime victimization include symptoms of posttraumatic stress disorder (PTSD; Dworkin, Menon, Bystrynski, & Allen, 2017; Santiago et al., 2013); somatization, depression, and/or anxiety (Eberhard-Gran, Schei, & Eskild, 2007; Taft, Resick, Watkins, & Panuzio, 2009); and substance use (Hedtke et al., 2008; Nayak, Lown, Bond, & Greenfield, 2012). When victims develop these problems, their symptoms tend to follow a chronic course and cause impairment in functioning (Hanson, Sawyer, Begle, & Hubel, 2010). One study reported that over 50% of adults with PTSD remained symptomatic over 3 years (Perkonig et al., 2005). Likewise, 50% of adults with a major depressive episode will have one or more recurrent episodes during their lifetime (Eaton et al., 2008). Further, individuals with PTSD and other psychiatric problems exhibit reduced work productivity and elevated unemployment (Greenberg, Fournier, Sisitsky, Pike, & Kessler, 2015; Zatzick et al., 2008), creating an obvious economic burden for individuals, families, and society.

The risk for negative outcomes among crime victims underscores the need for preventive interventions to mitigate that risk. For trauma victims who have already developed serious psychiatric problems, there are well-validated treatments available to trained clinicians (e.g., prolonged exposure, cognitive processing therapy; see Foa, Keane, Friedman, & Cohen, 2009). In addition, a few brief cognitive-behavioral interventions (containing elements of relaxation training, imaginal/in vivo exposure, and/or cognitive restructuring) have shown promise for victims who show persistent distress for several weeks postincident but who have not yet met the duration criterion for PTSD (see Agorastos, Marmar, & Otte, 2011; Forneris et al., 2013). In contrast, research has not yet validated any acute preventive interventions for use with crime victims prior to their development of significant problems. Such interventions would be implemented in short temporal proximity to a traumatic event with the aim of reducing risk for long-term psychiatric outcomes and costs (Roberts, Kitchiner, Kenardy, & Bisson, 2009).

The need for preventive interventions is particularly high given crime victims' underutilization of formal services. Próspero and Vohra-Gupta (2008) noted that only 16% of adults exposed to intimate partner violence sought help from a mental health professional. Sabina, Cuevas, and Schally (2012) reported a similarly low rate of help seeking in their representative sample of victimized Latino women, with only 10% reporting contact with social service professionals following the crime. In another study, Jaycox, Marshall, and Schell (2004) assessed service utilization among men hospitalized for an injury secondary to community violence. Although 34% of the sample had elevated PTSD symptoms at a 12-month follow-up, only 15% sought mental health treatment. Thus, despite availability of effective treatments for PTSD and related problems, few crime victims engage in formal services. As noted by McCart, Smith, and Sawyer (2010), barriers to service utilization include factors at the level of the individual (e.g., low perceived treatment need, limited transportation), com-

munity (e.g., few treatment programs available in proximity to victim), and service system (e.g., limited supply of trained clinicians, high cost of services). Considering these barriers, validation of acute preventive interventions seems critical. Further, even when treatments are readily available, preventive interventions might serve an important public health function. Specifically, symptoms might be easier to prevent than treat. In addition, preventive interventions could avert suffering and impairment during the time that victims spend with symptoms prior to accessing treatment.

Pertinent to the absence of acute preventive interventions for crime victims, researchers in the National Child Traumatic Stress Network (NCTSN) and at the National Center for PTSD developed PFA for individuals exposed to natural disasters or other catastrophic events (Brymer et al., 2006). PFA is comprised of eight components delivered by paraprofessionals soon after a traumatic event. The components are contact and engagement, stabilization, information gathering, safety and comfort, practical assistance, connection with social supports, information on coping, and linkage with collaborative services. PFA is rooted in research indicating that practical/social support soon after trauma exposure reduces distress and buffers against development of long-term problems (Brymer et al., 2006). Important for present purposes, experts assert that PFA likely has relevance for all types of trauma victims, including victims of crime (Gray & Litz, 2005; McNally, Bryant, & Ehlers, 2003). Further, unlike the treatments for already established psychiatric problems, PFA can be delivered by a paraprofessional workforce without specialized clinical training. Thus, PFA might fill the need for an acute intervention that reduces the severity and duration of crime-related distress. However, as described next, PFA's effectiveness has never been tested with any trauma-exposed group, highlighting the importance of the current study.

Leading experts (Gray & Litz, 2005; McNally et al., 2003) and several public health agencies, including the American Red Cross (*Lessons From Katrina and Other Major Disasters*, 2009) and the World Health Organization (2003), advocate for delivery of PFA to acute trauma victims. In addition, to facilitate dissemination of the model, the NCTSN developed a web-based PFA training course (NCTSN, 2019). Nevertheless, reviewers have noted that PFA's effectiveness has never been empirically tested (Dieljtens, Moonens, Van Praet, De Buck, & Vandekerckhove, 2014). At present, PFA is simply the "best guess" at what works. This lack of formal testing might be due to the logistical challenges with conducting intervention research in the context of unpredictable natural disasters (e.g., time invested waiting for event to occur, need for researchers that can travel to a disaster site at a moment's notice). However, in contrast to disaster victims, crime victims are a larger and more readily accessible population for research. Thus, an examination of PFA with crime victims might provide a unique opportunity to evaluate this promising, but currently untested, acute preventive intervention.

An evaluation of PFA is especially important given the negative effects associated with another once-advocated and widely disseminated preventive intervention, critical incident stress debriefing (CISD; Mitchell & Everly, 1996). CISD was initially developed for emergency service personnel who had experienced a traumatic event but was later applied to other trauma-exposed groups, including victims of crime (Marchand et al., 2006). The intervention



traditionally consists of a single group meeting where victims are encouraged to discuss their trauma-related cognitions and emotions. Although early studies suggested CISD held promise as an acute preventive intervention (Amir, Weil, Kaplan, Tocker, & Witztum, 1998; Yule, 1992), those studies suffered from methodological problems. More rigorous studies showed CISD was not effective at reducing acute psychiatric symptoms (Marchand et al., 2006; Mayou, Ehlers, & Hobbs, 2000). Moreover, in two randomized controlled trials, individuals assigned to receive CISD exhibited significantly higher levels of psychiatric symptoms at follow-up assessments relative to individuals assigned to the control group (Bisson, Jenkins, Alexander, & Bannister, 1997; Hobbs, Mayou, Harrison, & Worlock, 1996). PFA takes a different approach relative to CISD. Indeed, PFA reflects a form of robust case management with a focus on as-needed and individualized practical/social support. In contrast, CISD is more of a clinical intervention that encourages emotional processing in a group setting. Nevertheless, as revealed in the evaluations of CISD, rigorous testing of PFA is crucial in determining its safety (i.e., ruling out its potential to yield a paradoxical worsening of psychiatric symptoms) and effectiveness.

Thus, this study involved the first empirical test of PFA, using a sample of violent crime victims as participants (clinical trial registration NCT01934348). The project was conducted in collaboration with law enforcement agencies, the most common entry point for crime victims receiving acute services. Most law enforcement agencies in the United States employ paraprofessional law enforcement victim advocates (LEVAs) to provide victims with immediate assistance and support. LEVAs do not have a standardized intervention protocol. However, their services are characterized by key elements, such as addressing victims' basic needs, promoting safety, and serving as a resource for community referrals. Given the timing and nature of this interaction, LEVAs were selected as ideal providers of PFA for this study. That being said, the capacity of LEVAs to deliver PFA has not yet been empirically established. Hence, this trial had two aims. Aim 1 was to test whether LEVAs, as paraprofessionals, could be trained to deliver PFA. A key consideration was that LEVAs were likely to deliver—as part of their standard practice—some general components of PFA (e.g., assessing needs, making referrals for services). Likewise, LEVAs could not be required to deliver PFA, and the expected level of adoption was unknown. However, delivery of PFA was expected to increase following structured training. Aim 2 was to test the effect of PFA on key psychiatric (i.e., symptoms of PTSD, somatization, depression, anxiety, and substance use) and adaptive functioning (i.e., problems related to one's primary role [worker/student/homemaker] and social/leisure activities) outcomes in a sample of crime victims. The study hypotheses were as follows:

1. Following training in PFA, LEVAs will deliver more components of PFA relative to a usual services (US) control phase.
2. From baseline to a 4-month follow-up, crime victims receiving PFA will exhibit greater reductions in symptoms of PTSD, somatization, depression, anxiety, and substance use relative to crime victims receiving US.
3. From baseline to a 4-month follow-up, crime victims receiving PFA will exhibit greater reductions in problems related to their primary role and social/leisure activities relative to crime victims receiving US.

## Method

### Design

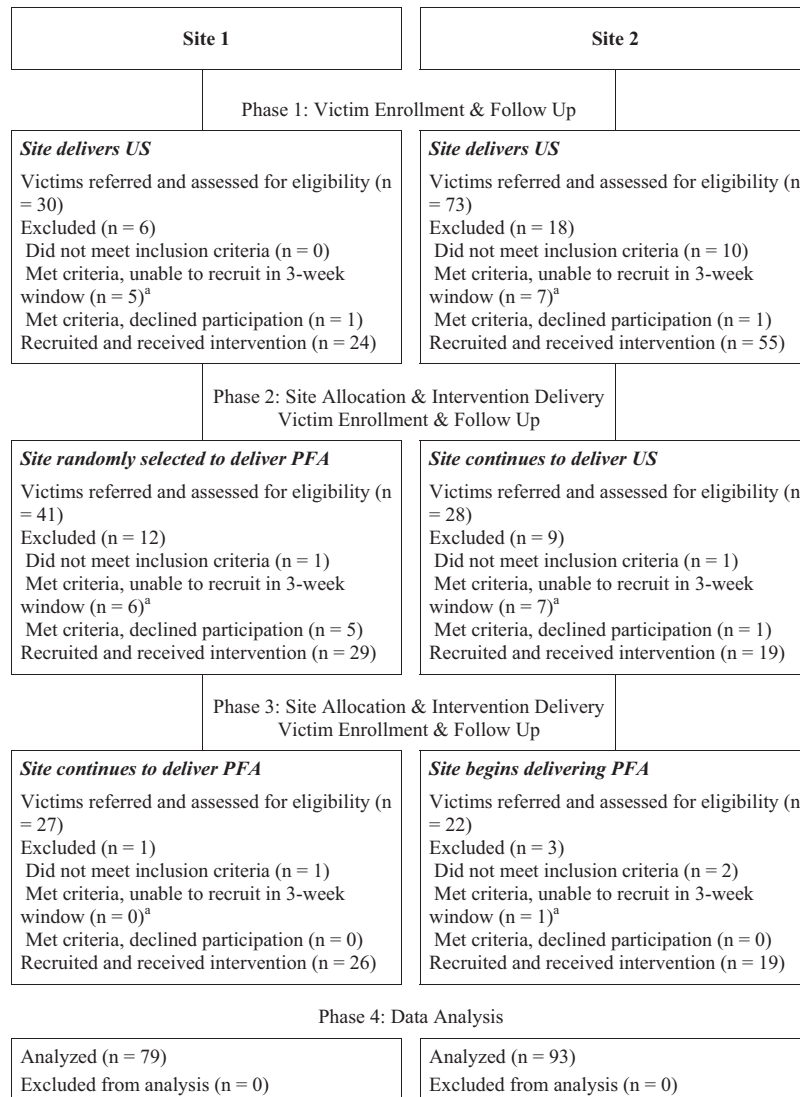
A start-up period involved development of PFA training and adherence monitoring protocols. Two law enforcement agencies (i.e., "sites") participated in the trial. With two sites, an important consideration was the method to allocate participants to intervention conditions. Randomization of crime victims was problematic due to contamination risk, specifically, from both services being delivered within each site (whether by a single or multiple LEVAs). Likewise, sites could not be randomized to *only* deliver PFA or US because, with site and condition being singular, the effect of PFA could not be disentangled from differences between sites. As illustrated in Figure 1, this challenge was addressed with a simplified version of a dynamic wait-listed design (Wyman, Henry, Knoblauch, & Brown, 2015). The design had three phases, each lasting 8 months. In the first phase, both sites delivered US, and crime victims were recruited and assessed at baseline and 1, 2, and 4 months postbaseline. At the beginning of the second phase, one site was randomly selected to be trained, monitored, and supported in the delivery of PFA, while the second site continued delivering US. At both sites, additional crime victims were recruited and assessed (baseline and 1, 2, and 4 months postbaseline). In the third phase, the second site was trained, monitored, and supported in the delivery of PFA. At both sites, additional victims were recruited and assessed, all receiving PFA. With this design, each crime victim received a single intervention, but the two sites, and all LEVAs, had longitudinal data for victims receiving either US or PFA. This has several benefits, the most important of which is the possibility to evaluate PFA's effect while controlling for site-specific effects.

### Site and LEVA Characteristics

Site 1 was a county sheriff's office, and Site 2 was a police department in a nearby city. In the first calendar year of the trial, the violent crime rate was higher at Site 2 (182 victims per 100,000 residents) relative to Site 1 (134 victims per 100,000 residents). However, Sites 1 and 2 had similar annual operating budgets, and each site employed three LEVAs. All six of the LEVAs participated in the trial. They averaged 55.8 years of age ( $SD = 4.1$ , range = 50–60); 100% were female; 67% were White, and 33% were Black. In terms of education, one LEVA had a high school diploma only, one had an associate degree, one had a bachelor's degree, and three had master's degrees, all in criminal justice or related fields. LEVAs averaged 8 years of victim advocacy experience ( $SD = 7.4$ , range = 1–16).

### Participants and Recruitment

Participants met the following criteria: (a) were aged 18 years or older; (b) were the victim of a recent rape/sexual assault, physical assault, and/or armed robbery; (c) sustained a physical injury or



*Figure 1.* Dynamic wait-listed study design and participant enrollment. US = usual services; PFA = psychological first aid. Phases 1–3 were each 8 months in duration. <sup>a</sup> To ensure this study's focus on an acutely victimized sample, recruitment and baseline assessments needed to occur within a 3-week period following the index crime. The most common reason for being unable to recruit during that time frame was missed/canceled appointments (i.e., victim not attending a scheduled recruitment visit and then being unable to reschedule before the end of the 3-week window).

perceived life threat during the event; and (d) had the ability to understand English. Criterion (c) was chosen because injury and life threat are risk factors for psychiatric problems among victims of crime (Jaycox, Marshall, & Orlando, 2003; Weaver & Clum, 1995). To enhance generalizability, no victims were excluded based on preexisting mental health, physical health, or intellectual difficulties.

Figure 1 depicts the flow from enrollment through data analysis. Victims learned about the research during their first contact with a LEVA. Victims expressing interest were referred to project staff for a telephone-based eligibility screen. If inclusion criteria were met, an in-person appointment was scheduled to complete informed consent and the baseline assessment. Recruitment and

baseline assessment needed to occur within 3 weeks of the index crime. Across sites and enrollment phases, 221 crime victims were referred and screened by the researchers. Of those referrals, 206 victims met inclusion criteria. Of those meeting inclusion criteria, 172 were recruited (83.5% recruitment rate).<sup>1</sup> All 172 were included in the data analyses.

<sup>1</sup> Participating victims ( $n = 172$ ) did not significantly differ from victims who either declined participation or were unreachable during the recruitment window ( $n = 34$ ) with regard to demographic characteristics or index crime type (all  $p$  values  $> .05$ ).



Participants averaged 36.4 years of age ( $SD = 12.9$ , range = 19–65), and 81% were female. The sample was 54% Black, 41% White, and 5% multiracial; 4% were Latino (of any race). Regarding the index crime, 51% experienced domestic violence, 42% aggravated assault, 4% sexual assault, and 3% armed robbery. Aside from the index crime, most participants (94%) reported having experienced at least one other potentially traumatic event (i.e., a violent crime or another type of event such as a serious accident) in their lifetime. The average number of lifetime traumatic events reported by participants was 4.69 ( $SD = 2.19$ , range = 1–10). A large proportion of the sample was socioeconomically disadvantaged; the median annual household income was in the \$10,000–\$15,000 range, median educational attainment was 12th grade, and 32% of participants were either unemployed or disabled. With the exception of age, there were no significant differences on demographic variables, index crime type, or trauma history across the two intervention conditions or the two sites (all  $p$  values  $> .05$ ). For age, there were significant differences by condition and site, with those receiving PFA ( $\beta = 5.910$ ,  $SE = 1.963$ ,  $p = .003$ ) and those at Site 2 ( $\beta = 5.688$ ,  $SE = 1.950$ ,  $p = .004$ ) being significantly older.

### Intervention Conditions

In both the US and PFA phases, LEVAs delivered their services to crime victims over the course of two to three interactions. These interactions occurred within two months of the crime event.

**US.** LEVAs at the two sites followed practices recommended by the [National Organization for Victim Assistance \(2019\)](#). Specifically, police reports were provided to LEVAs following a crime, and they attempted to contact victims within 24–48 hr. Once contact was made, LEVAs provided information to victims about their legal rights and the criminal justice system. In addition, LEVAs assessed victims' acute concerns. There was no standardized format for this assessment, and questions focused on basic needs and safety. A victim's basic needs (e.g., housing, food) were addressed through referral to social service agencies. Safety concerns were addressed via criminal justice interventions, including notifying the police about the potential for harm and assisting victims in filing orders of protection. Further, LEVAs assisted victims in completing victim compensation requests to cover costs pertaining to health care and lost/damaged property. LEVAs functioned independent of police officials and were not involved in investigation of the index crime.

**PFA.** PFA augmented LEVAs' typical services while also providing new tools and techniques. PFA has two tenets. First, the model assumes that many victims will demonstrate resilience and that services should only be provided to victims requesting assistance after a traumatic event. Second, for individuals who ask for help, the provision of basic support might reduce their distress and minimize risk for future problems. These assumptions are supported by theory-based models of resilience (e.g., [Bonanno et al., 2011](#)) and an empirical literature showing that areas targeted by PFA have potential to buffer the negative effects of trauma exposure ([Arnberg, Hultman, Michel, & Lundin, 2012](#); [Bonanno, Galea, Bucciarelli, & Vlahov, 2007](#); [Ozer, Best, Lipsey, & Weiss, 2003](#)).

The eight broad PFA components are described next, which include some strategies that are common to different intervention

approaches and others that are specific to PFA. Victim engagement and stabilization are prioritized. Subsequent areas are targeted based on needs identified via the information gathering component. Skills are taught using forms and handouts.

**Contact and engagement.** As paraprofessionals, LEVAs have not had opportunities to learn skills for facilitating engagement with trauma survivors (e.g., reflective and empathic listening, open vs. closed questioning, normalization). The contact and engagement component filled this gap by providing LEVAs with training in those core engagement techniques.

**Stabilization (if needed).** For victims in extreme distress, LEVAs normalized their acute reactions. Then, a "grounding" exercise was used to orient the victim to the present by asking the individual to sit in a comfortable position, breathe slowly, and focus on nondistressing visual, auditory, and/or physical cues. If extreme distress persisted, LEVAs were prepared to link victims with services from a medical or mental health professional; however, such immediate linkage was never necessary for participants in the current trial.

**Information gathering.** In contrast to usual LEVA services, this component provided a structured form for conducting a thorough needs assessment. The PFA screening form covered problem areas common to victims of crime, including safety concerns, unmet basic needs, financial/legal issues, low social support, physical/mental health concerns, and problematic substance use. LEVAs chose which (if any) of the remaining five PFA components to deliver, based on information obtained during this structured assessment.

**Safety and comfort.** As needed, LEVAs worked to promote safety and reduce future victimization risk. If dangerous situations were identified, LEVAs helped victims develop safety plans. LEVAs reviewed these plans and offered visual cues (e.g., reminder card to place in purse/wallet) to increase the probability that they would be implemented at the appropriate time. LEVAs also verified that victims had a safe place to reside and referred them to relevant agencies (e.g., domestic violence shelters) as needed. Safety planning also included strategies to address suicide/homicide. If an individual was deemed at risk for suicide/homicide, LEVAs were prepared to take immediate action (e.g., facilitating the individual's transport to a hospital for a formal assessment, notifying potential victims in the event of homicidal plans).

**Practical assistance.** LEVAs provided victims with (as-needed) practical assistance. Such assistance included information on legal advocacy; contact information for agencies that provide short-term housing, food, financial assistance, and/or mental health/substance use counseling; information on individuals' eligibility for crime victim compensation; and phone numbers for relevant emergency and victim service agencies.

**Connection with social support.** This component helped victims establish contacts with primary support persons. LEVAs began by educating victims on the benefits of social support (e.g., emotional comfort, assistance with basic needs). LEVAs then determined victims' preferred sources of support (e.g., partner, family members) and assisted victims in initiating and maintaining regular contact with those individuals. When developing a plan, LEVAs helped victims consider when and how they would contact their support persons and what they would say once contact was made. Victims were encouraged to implement their social support plan once it was finalized. LEVAs contacted victims at a later date

to determine effectiveness of the plan, problem-solve barriers, and revise the plan as needed.

**Information on coping.** LEVAs used structured handouts to educate victims about common reactions to trauma, which aimed to validate their experiences, normalize emotions, and dispel faulty beliefs. In addition, LEVAs provided information and instruction on adaptive coping techniques (e.g., deep breathing, prosocial activity scheduling, helpful vs. unhelpful thinking). Finally, victims were discouraged from engaging in coping methods that are potentially harmful, such as substance use and withdrawal from family and friends.

**Linkage with collaborative services.** If victims experienced ongoing needs (e.g., persistence of distressing emotions for several weeks following the crime), LEVAs linked victims with professional services in the community. LEVAs provided written referral information and assisted victims in making appointments.

### Training and Sustaining PFA Implementation

LEVAs received a PFA intervention manual and participated in a 2-day workshop. The first workshop, at Site 1, was led by the first and third authors, with on-site support from two PFA developers (Patricia Watson and Josef Ruzek). The second workshop, at Site 2, was conducted by the first and third authors, with telephone consultation from Dr. Watson and Dr. Ruzek. Both workshops included didactic instruction and experiential role-plays aimed at orienting LEVAs to program philosophy and intervention methods.

Following each workshop, the first and third authors held bi-weekly group supervision sessions with the trained LEVAs. These sessions were 1 hr in length and provided LEVAs the opportunity to describe their efforts at implementing PFA with crime victims, problem-solve challenges, and share lessons learned. LEVAs also audio recorded a small portion of their PFA sessions with participating victims. Following qualitative review of these audio recordings, the first and third authors provided LEVAs with individualized feedback on their PFA delivery.

### Instruments

**Implementation outcome.** A new instrument was created to measure PFA adherence. The development of this instrument was guided by the *Standards for Educational and Psychological Testing* (American Educational Research Association, American Psychological Association, & National Council on Measurement in Education, 2014) and associated recommendations based on item response theory (IRT; Wilson, 2005; Wolfe & Smith, 2007). The instrument was intended to measure the delivery of PFA components. However, an important consideration was that some components of PFA could be delivered as part of usual LEVA services. To address this, PFA adherence was measured in both the US and PFA phases. The resulting scores were used to evaluate the impact of PFA training, specifically, by comparing the standard level of delivery (i.e., US phase) to the level—among the same LEVAs—after completing structured training (i.e., PFA phase). The instrument was developed for LEVAs to self-report their use of PFA components as a formal observational coding system was beyond the resources of this project. Although this is a limitation, several strategies were implemented to attenuate the impact of self-report

bias: (a) LEVAs completed the instrument immediately following each contact with a victim; (b) a straightforward dichotomous response format was used to reflect whether each component was delivered (i.e., 0 = no, 1 = yes); (c) LEVAs were trained on the intended use of the instrument, including the definition of each item; (d) a full range of PFA components was specified, with some endorsable even for low levels of adherence; (e) reports were obtained from the same LEVAs across both US and PFA phases of the study; and (f) components specific to PFA and not available during US—such as forms and handouts provided at the time of PFA training—were not administered during US and were scored as “not delivered.”

Additional details on the instrument development procedures, the final instrument, and a description of the psychometric evaluation are provided in the [online supplemental material](#). As detailed in that material, the sample for the PFA phase was comprised of study participants, but the sample for the US phase was comprised of de-identified victims. Because it was not possible to link de-identified victims to repeated adherence reports, the analyses (across phases) were based on data from the first contact between each victim and LEVA. The final instrument was comprised of 34 items. Of these, 20 could occur in PFA or as part of US (e.g., “asked the individual about needs/concerns,” “made a referral to a service provider”), and the remaining 14 were specific to PFA (e.g., “administered the PFA screening form,” “completed one or more of the PFA safety plans”). The instrument’s psychometric performance was evaluated using IRT-based Rasch (Bond & Fox, 2015) and bifactor (Gibbons et al., 2007) measurement models. Dimensionality analyses supported a single dimension of PFA adherence. Reliability was strong, with internal consistency and Rasch person separation reliability estimates of  $\alpha = .90$  and  $R_p = .86$ , and the items were suitable for differentiating three distinct levels of PFA adherence. Item fit statistics identified three items characterized by unpredictable responses. However, because their removal had minimal impact on the resulting scores and their content was critical to assess, these items were retained in the final model. In the models reported subsequently, PFA adherence scores are continuous Rasch-based logit scores, with higher values reflecting delivery of more PFA components, and vice versa.

**Intervention outcomes.** Participating crime victims completed an assessment battery measuring the psychiatric and adaptive functioning outcomes. Instruments included in this battery are described next.

**PTSD symptoms.** Victims’ PTSD symptoms were assessed using the National Stressful Events PTSD Survey (NSEPS; Kilpatrick et al., 2013). This 20-item instrument includes subscales corresponding to the intrusion, avoidance, cognitions and mood, and arousal clusters of PTSD, as delineated in the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (American Psychiatric Association, 2013). Respondents rate how much they are bothered by symptoms corresponding to each cluster using a Likert-type scale with the following response options: 0 = *not at all*, 1 = *a little bit*, 2 = *moderately*, 3 = *quite a bit*, and 4 = *extremely*. The NSEPS has good internal consistency (Cronbach’s  $\alpha = .94$ ), and it correlates highly ( $r = .82$ ) with other measures of PTSD (M. W. Miller et al., 2013).

**Somatization, depression, and anxiety symptoms.** Victims also completed the 18-item Brief Symptom Inventory (BSI-18; Derogatis, 2000). This instrument yields three norm-referenced

subscales: Somatization, Depression, and Anxiety. The BSI-18 is well validated, and it correlates highly ( $r_s > .90$ ) with the longer, 53-item version of the measure (Derogatis, 2000).

**Substance use.** Victims' substance use was assessed using the Addiction Severity Index-Self-Report (ASI-SR; Rosen, Henson, Finney, & Moos, 2000). The 11-item Alcohol and Drug Use module yields scores reflecting problematic alcohol and drug use. The ASI-SR has strong psychometric properties, and the Alcohol and Drug Use module correlates highly ( $r_s = .73-.87$ ) with corresponding ASI interview scores (Rosen et al., 2000).

**Adaptive functioning.** Victims' adaptive functioning was measured with the Social Adjustment Scale-Self Report (SAS-SR; Weissman & Bothwell, 1976). Using a Likert-type scale ranging from 1 to 5, respondents rate their perceived performance in their primary role as a worker, student, or homemaker. In addition, questions assess satisfaction with social relationships and leisure activities. Mean scores are generated for the Primary Role and Social and Leisure Problems subscales, with higher scores indicative of worse functioning. The SAS-SR has good test-retest reliability ( $r = .74$ ; Resick, Calhoun, Atkeson, & Ellis, 1981), correlates highly with clinician ratings ( $r = .70$ ; Weissman & Bothwell, 1976), and differentiates psychiatric and well patients (Weissman, Olfson, Gameroff, Feder, & Fuentes, 2001).

**Composite global functioning.** Across the abovementioned individual intervention outcomes, a combination of problem areas—or only a single area—could be applicable for each crime victim. This presented a potential challenge for evaluating PFA. For example, the interpretation of PFA's effect would differ for a victim reporting low PTSD symptoms at the final (4-month) assessment if, at baseline, the victim's PTSD symptoms had been high versus low. Likewise, victims with elevated symptoms in multiple areas likely would be more severe than victims with elevated symptoms in only a single area. To address these challenges, methods from IRT were used to develop a composite global functioning outcome to reflect overall problem severity and to apply across victims. For each abovementioned study outcome (i.e., Intrusion, Avoidance, Cognitions and Mood, and Arousal subscales from NSEPS; Somatization, Depression, and Anxiety subscales from BSI-18; Alcohol and Drug Use module from ASI-SR; Primary Role and Social and Leisure Problems subscales from SAS-SR), a clinical versus nonclinical threshold was defined, resulting in 10 dichotomous indicators. Because most crime victims were expected to present with elevated symptoms and then recover to a subclinical level of functioning, the thresholds were applied in the direction of improved functioning (i.e., 0 = clinical, 1 = subclinical). The indicators were evaluated using item bifactor measurement models (Gibbons et al., 2007; Reise, Moore, & Haviland, 2010) implemented in IRTPRO software (Cai, Thissen, & du Toit, 2015). The results determined that, when combined, the indicators measured a general construct rather than the respective source constructs. The one exception was the ASI-SR, which loaded weakly on the general construct and was removed from the model. Across measurement occasions, the resulting global functioning scores had an average reliability of .62. For analysis, the global functioning scores were logit-based expected a posteriori measures from the general dimension of the bifactor model. Additional details regarding the development and psychometric evaluation of the composite global functioning outcome are available in the online supplemental material. Table 1 presents descriptive

data for the proportion of crime victims scoring at the subclinical level on each global functioning indicator by phase, site, and time.

## Procedure

As noted previously, LEVAs completed the PFA adherence instrument following each contact with a victim. Trained researchers administered assessments to the participating crime victims. At baseline, victims completed the NSEPS, BSI-18, and ASI-SR, in addition to instruments measuring participants' demographic characteristics and lifetime traumatic event exposure.<sup>2</sup> For the NSEPS, BSI-18, and ASI-SR, the reporting window at baseline was "since the index crime." Subsequent assessments completed by victims at the 1-, 2-, and 4-month follow-ups repeated the baseline instruments, except the demographics and trauma exposure surveys, and added the SAS-SR. The reporting window at the follow-up assessments was "past 30 days." Most victims (86%) completed the baseline assessment within 2 weeks of the index crime. The mean duration between the crime and baseline assessment was 8.3 days ( $SD = 6.7$ ). Regarding retention, 90%, 85%, and 81% of participants completed assessments at the 1-, 2- and 4-month follow-ups, respectively. Victims were compensated \$25 for completing each assessment. Researchers administering assessments were blind to intervention condition. Study procedures were approved by the institutional review board at the Medical University of South Carolina.

## Data Analysis Strategy

Two types of prediction models were performed, the first evaluating the impact of PFA training on adherence and the second evaluating the effect of PFA on crime victim outcomes. Recalling that LEVAs were not required to adopt PFA and that some components of PFA could be delivered as part of usual LEVA services, tests for the impact of training on PFA adherence required consideration of PFA components delivered in both the US and PFA phases. A Rasch measurement model was formulated as a hierarchical generalized linear measurement model (e.g., Beretvas & Kamata, 2005; Kamata, 2001)—a two-level mixed-effects formulation, with item responses (Level 1) nested within crime victims (Level 2). At Level 1, dummy-coded indicators differentiated the items (with one serving as a reference item). This, combined with a Bernoulli outcome distribution and logit link function, replicates the item and person parameters of the standard Rasch model (of note, prior to analysis, the item responses were reverse-coded so the direction of item parameters matches that for IRT models). Simultaneously, the model permits inclusion and evaluation of predictor variables at the level of crime victims. In this case, a dichotomous indicator was included to reflect the intervention received (US = 0, PFA = 1). At Level 2, a dichotomous indicator differentiated victims in the PFA and US phases. The model was then extended to control for systematic differences across sites and, in a separate model, differences across LEVAs. The latter was important because LEVAs self-reported their delivery of PFA

<sup>2</sup> A demographics survey was created for this project. Lifetime traumatic event exposure was assessed using the well-validated Trauma Assessment for Adults (Gray, Elhai, Owen, & Monroe, 2009; Resnick, Best, Kilpatrick, Freedy, & Falsetti, 1993).

Table 1  
*Proportion of Crime Victims Scoring at the Subclinical Level on Each Global Functioning Indicator by Phase, Site, and Time*

| Outcome                     | Site 1   |      |      |      |           |      |      |      | Site 2   |      |      |      |           |      |      |      |
|-----------------------------|----------|------|------|------|-----------|------|------|------|----------|------|------|------|-----------|------|------|------|
|                             | US phase |      |      |      | PFA phase |      |      |      | US phase |      |      |      | PFA phase |      |      |      |
|                             | M0       | M1   | M2   | M4   | M0        | M1   | M2   | M4   | M0       | M1   | M2   | M4   | M0        | M1   | M2   | M4   |
| <b>NSEPS</b>                |          |      |      |      |           |      |      |      |          |      |      |      |           |      |      |      |
| Intrusion                   | 0.21     | 0.54 | 0.71 | 0.73 | 0.20      | 0.57 | 0.68 | 0.79 | 0.32     | 0.65 | 0.70 | 0.77 | 0.16      | 0.59 | 0.78 | 0.87 |
| Avoidance                   | 0.33     | 0.67 | 0.63 | 0.77 | 0.44      | 0.49 | 0.75 | 0.79 | 0.36     | 0.62 | 0.74 | 0.80 | 0.32      | 0.76 | 0.78 | 0.87 |
| Cognitions                  | 0.46     | 0.58 | 0.67 | 0.86 | 0.44      | 0.74 | 0.80 | 0.86 | 0.36     | 0.76 | 0.82 | 0.83 | 0.26      | 0.71 | 1.00 | 0.80 |
| Arousal                     | 0.33     | 0.54 | 0.58 | 0.73 | 0.42      | 0.55 | 0.70 | 0.79 | 0.39     | 0.64 | 0.75 | 0.78 | 0.26      | 0.59 | 0.89 | 0.93 |
| <b>BSI-18</b>               |          |      |      |      |           |      |      |      |          |      |      |      |           |      |      |      |
| Somatization                | 0.67     | 0.58 | 0.71 | 0.82 | 0.58      | 0.85 | 0.82 | 0.83 | 0.72     | 0.82 | 0.84 | 0.83 | 0.58      | 0.76 | 0.83 | 0.80 |
| Depression                  | 0.63     | 0.71 | 0.71 | 0.77 | 0.60      | 0.85 | 0.77 | 0.81 | 0.58     | 0.79 | 0.75 | 0.82 | 0.58      | 0.88 | 1.00 | 0.93 |
| Anxiety                     | 0.54     | 0.67 | 0.75 | 0.77 | 0.53      | 0.74 | 0.77 | 0.81 | 0.58     | 0.79 | 0.82 | 0.87 | 0.47      | 0.82 | 0.83 | 1.00 |
| <b>SAS-SR</b>               |          |      |      |      |           |      |      |      |          |      |      |      |           |      |      |      |
| Primary Role Problems       |          | 0.96 | 1.00 | 0.95 |           | 0.93 | 0.95 | 1.00 |          | 0.97 | 0.98 | 0.90 |           | 0.94 | 1.00 | 1.00 |
| Social and Leisure Problems |          | 0.79 | 0.83 | 0.86 |           | 0.89 | 0.84 | 0.95 |          | 0.92 | 0.95 | 0.93 |           | 1.00 | 1.00 | 1.00 |

Note. M = month; PFA = psychological first aid; US = usual services; NSEPS = National Stressful Events PTSD Scale; BSI-18 = Brief Symptom Inventory 18; SAS-SR = Social Adjustment Scale-Self Report.

components. This model compared the overall level of PFA adherence in the PFA phase to that, among the same LEVAs, in the US phase.

For victim outcomes, the sample included all crime victims who were study participants across the US and PFA phases. Each outcome was evaluated using a two-level mixed-effects regression model (Raudenbush & Bryk, 2002), with a maximum of four repeated measurements (Level 1) nested within crime victims (Level 2). To test for change over time, linear and quadratic polynomial terms were included at Level 1. For each crime victim, a PFA indicator was included to reflect the intervention received, as well as the site indicator, and cross-level interactions were specified between these indicators and the Level-1 time terms. Controlling for site-specific effects, this formulation tests for an overall difference between PFA and US in the initial level, early rate of change, and acceleration of change over time in victim outcomes.<sup>3</sup> Because of the high proportion of female participants (i.e., 81%), exploratory follow-up models were performed with male participants excluded from the sample. Likewise, for the global functioning outcome, the formulation was extended to include an interaction between the PFA indicator and site indicator. This tested for (a) differences between sites in their change from the US to PFA phase, (b) change from the US to PFA phase for each site, and (c) differences between the sites in the US and PFA phases. The models were performed using HLM software (Raudenbush, Bryk, & Congdon, 2013). Random effects were specified using the deviance test, and to obtain all comparisons of interest, planned contrasts were specified using the hypothesis testing interface.

## Results

### Effect of Training on PFA Adherence

Controlling for differences across LEVAs, PFA adherence scores were significantly higher for crime victims in the PFA phase relative to the US phase,  $\beta = 1.150$ ,  $SE = 0.214$ ,  $t(276) = 5.36$ ,  $p < .001$ , 95% CI [0.729, 1.570],  $OR = 3.16$ . In an uncon-

trolled model, as well as a model controlling for differences across sites, the estimates were highly consistent and statistically significant. A follow-up model tested whether the two sites differed on their change in PFA adherence from the US to the PFA phase. The two sites did not differ significantly during the US phase,  $\beta_{\text{Site2}} = 0.079$ ,  $SE = 0.188$ ,  $t(280) = 0.418$ ,  $p = .677$ , [-0.289, 0.447],  $OR = 1.08$ . From the US phase to the PFA phase, PFA adherence increased significantly for both sites,  $\beta_{\text{Site1}} = 0.935$ ,  $SE = 0.261$ ,  $t(280) = 3.58$ ,  $p < .001$ , [0.423, 1.446],  $OR = 2.55$ ,  $Est_{\text{Site2}} = 2.130$ ,  $SE = 0.414$ ,  $\chi^2(1) = 26.44$ ,  $p < .001$ , [1.318, 2.942],  $OR = 8.41$ , but the increase was significantly greater for Site 2,  $\beta = 1.195$ ,  $SE = 0.497$ ,  $t(280) = 2.41$ ,  $p = .017$ , [0.221, 2.170],  $OR = 3.30$ . To highlight these effects, raw scores were computed. During the US phase, and for an average first contact, Sites 1 and 2 delivered 27% and 30% of the PFA components, and during the PFA phase, their delivery increased to 39% and 54%, respectively.

### Primary Intervention Outcomes

**NSEPS.** Results are reported in Table 2. At baseline, PFA and US did not differ significantly on Intrusion, Avoidance, Cognition, or Arousal. Crime victims receiving US had significant early reductions (i.e., linear change) in each domain, and for Intrusion only, there was significant slowing of change over time. Crime victims receiving PFA had significant early reductions and slowing of change over time in each domain. PFA and US did not differ significantly on linear or quadratic change across the four domains. When restricting the sample to the subset of female victims, conclusions did not change.

**BSI-18.** Results are reported in Table 3. At baseline, crime victims receiving PFA and US did not differ significantly on any of the BSI-18 subscales. The US group had statistically significant early reductions (i.e., linear change) in Anxiety that slowed significantly over time (quadratic change), but Depression and Som-

<sup>3</sup> Of note, preliminary models included controls for victim age; however, conclusions about the effect of PFA did not change, and for parsimony, this term was omitted from the final models.



Table 2  
Results of Mixed-Effects Regression Models Testing for Differences in PTSD Symptoms by Phase and Site

| Term                | Intrusion |       |       | Avoidance    |       |       | Cognitions |       |       | Arousal |       |       |
|---------------------|-----------|-------|-------|--------------|-------|-------|------------|-------|-------|---------|-------|-------|
|                     | Coeff.    | SE    | p     | Coeff.       | SE    | p     | Coeff.     | SE    | p     | Coeff.  | SE    | p     |
| Baseline            |           |       |       |              |       |       |            |       |       |         |       |       |
| Intercept           | 2.119     | 0.189 | <.001 | 2.425        | 0.213 | <.001 | 1.721      | 0.165 | <.001 | 1.842   | 0.153 | <.001 |
| PFA phase           | -0.042    | 0.198 | .833  | -0.148       | 0.214 | .489  | -0.076     | 0.178 | .671  | -0.089  | 0.163 | .585  |
| Site 2              | -0.173    | 0.198 | .383  | -0.088       | 0.216 | .685  | 0.001      | 0.177 | .994  | -0.181  | 0.162 | .265  |
| Linear              |           |       |       |              |       |       |            |       |       |         |       |       |
| Month               | -0.860    | 0.154 | <.001 | -0.611       | 0.224 | .007  | -0.403     | 0.157 | .011  | -0.408  | 0.128 | .002  |
| PFA phase           | 0.088     | 0.153 | .566  | -0.124       | 0.227 | .585  | -0.194     | 0.152 | .203  | -0.008  | 0.121 | .947  |
| Site 2              | 0.057     | 0.154 | .710  | -0.240       | 0.225 | .286  | -0.305     | 0.153 | .049  | -0.148  | 0.126 | .240  |
| Quadratic           |           |       |       |              |       |       |            |       |       |         |       |       |
| Month               | 0.140     | 0.030 | <.001 | 0.074        | 0.050 | .143  | 0.040      | 0.034 | .245  | 0.053   | 0.027 | .050  |
| PFA phase           | -0.033    | 0.031 | .297  | 0.033        | 0.053 | .530  | 0.048      | 0.032 | .138  | -0.002  | 0.026 | .922  |
| Site 2              | -0.004    | 0.031 | .911  | 0.060        | 0.052 | .247  | 0.077      | 0.033 | .019  | 0.037   | 0.027 | .161  |
| Planned contrasts   |           |       |       |              |       |       |            |       |       |         |       |       |
| Term                | Est.      | SE    | p     | Est.         | SE    | p     | Est.       | SE    | p     | Est.    | SE    | p     |
| PFA phase           |           |       |       |              |       |       |            |       |       |         |       |       |
| Linear              | -0.772    | 0.122 | <.001 | -0.735       | 0.188 | <.001 | -0.597     | 0.116 | <.001 | -0.416  | 0.085 | <.001 |
| Quadratic           | 0.107     | 0.027 | <.001 | 0.107        | 0.044 | .015  | 0.088      | 0.025 | <.001 | 0.051   | 0.018 | .006  |
| Variance components |           |       |       |              |       |       |            |       |       |         |       |       |
| Term                | Var.      | SD    | p     | Var.         | SD    | p     | Var.       | SD    | p     | Var.    | SD    | p     |
| Error               | 0.372     | 0.610 |       | 0.964        | 0.982 |       | 0.255      | 0.505 |       | 0.237   | 0.487 |       |
| Linear              | 0.265     | 0.515 | .001  | <sup>a</sup> |       |       | 0.352      | 0.593 | <.001 | 0.186   | 0.431 | .001  |
| Quadratic           | 0.006     | 0.079 | .082  | <sup>a</sup> |       |       | 0.011      | 0.107 | <.001 | 0.005   | 0.068 | .109  |
| Intercept           | 1.073     | 1.036 | <.001 | 0.729        | 0.854 | <.001 | 0.960      | 0.980 | <.001 | 0.734   | 0.857 | <.001 |

Note. PFA = psychological first aid; Coeff. = coefficient; SE = standard error; Est. = estimate; Var. = variance. Due to space limitations, 95% confidence intervals are not reported, but for each coefficient/estimate, they can be computed as coefficient  $\pm$  1.96  $\times$  SE.

<sup>a</sup>This term was modeled as a fixed effect only.

atization did not change significantly over time. In contrast, PFA had significant early reductions and slowing over time for all three subscales (with the exception of quadratic change in Somatization). PFA and US did not differ significantly on linear or quadratic change across the subscales. For the female subset, the PFA group had significantly greater early reductions in Depression ( $\beta_{Lin} = -4.059$ ,  $SE = 1.991$ ,  $p = .043$ ) and Somatization ( $\beta_{Lin} = -4.478$ ,  $SE = 1.906$ ,  $p = .020$ ), along with more rapid slowing of change in Somatization ( $\beta_{Quad} = 0.856$ ,  $SE = 0.411$ ,  $p = .039$ ) relative to the US group.

**ASI-SR.** At baseline, PFA and US did not differ significantly on the log-odds of substance use ( $\beta_{PFA} = -0.621$ ,  $SE = 0.588$ ,  $p = .293$ ). For the US group, linear and quadratic change over time were not significant ( $\beta_{Lin} = 0.271$ ,  $SE = 0.588$ ,  $p = .645$ ;  $\beta_{Quad} = -0.051$ ,  $SE = 0.123$ ,  $p = .680$ ), as was the case for the PFA group (Est.<sub>Lin</sub> = 0.085,  $SE = 0.422$ ,  $p > .500$ ; Est.<sub>Quad</sub> = 0.003,  $SE = 0.101$ ,  $p > .500$ ). PFA and US did not differ significantly on linear or quadratic change ( $\beta_{Lin} = -0.186$ ,  $SE = 0.586$ ,  $p = .751$ ;  $\beta_{Quad} = 0.053$ ,  $SE = 0.126$ ,  $p = .672$ ). Conclusions were consistent for the subset of female victims.

**SAS-SR.** As noted previously, the SAS-SR was not administered at baseline, and as such, the models tested for change across Months 1, 2, and 4. Results are reported in Table 4. At Month 1, PFA and US did not differ significantly on the Primary Role or Social and Leisure Problems subscales. For both groups, linear and

quadratic change over time were not statistically significant. Likewise, the groups did not differ significantly on linear or quadratic change. Conclusions were consistent for the subset of female victims.

### Composite Global Functioning Outcome

Controlling for differences across sites, at baseline, crime victims receiving PFA and US did not differ significantly on the average level of global functioning,  $\beta = -0.117$ ,  $SE = 0.137$ ,  $t(169) = -0.85$ ,  $p = .395$ , 95% CI [-0.386, 0.152]. For the US group, global functioning improved significantly over time, with positive linear and negative quadratic slopes,  $\beta_{Lin} = 0.390$ ,  $SE = 0.111$ ,  $t(169) = 3.52$ ,  $p = .001$ , [0.172, 0.608],  $\beta_{Quad} = -0.057$ ,  $SE = 0.024$ ,  $t(169) = -2.43$ ,  $p = .016$ , [-0.104, -0.010]. For the PFA group, the linear and quadratic terms also were statistically significant, Est.<sub>Lin</sub> = 0.632,  $SE = 0.082$ ,  $\chi^2(1) = 59.53$ ,  $p < .001$ , [0.471, 0.793], and Est.<sub>Quad</sub> = -0.100,  $SE = 0.018$ ,  $\chi^2(1) = 31.87$ ,  $p < .001$ , [-0.135, -0.065]. For both groups, these terms reflect rapid early gains in global functioning that slow over time. Tests for the PFA intervention effect—differences between PFA and US on linear and quadratic change—indicated that, relative to US, early gains in global functioning were significantly more rapid for PFA,  $\beta_{Lin} = 0.242$ ,  $SE = 0.110$ ,  $t(169) = 2.21$ ,  $p = .029$ , [0.026, 0.458]. The PFA and US groups did not differ on the

Table 3

Results of Mixed-Effects Regression Models Testing for Differences in Somatization, Depression, and Anxiety Symptoms by Phase and Site

| Term                | Somatization |       |          | Depression |       |          | Anxiety |       |          |
|---------------------|--------------|-------|----------|------------|-------|----------|---------|-------|----------|
|                     | Coeff.       | SE    | <i>p</i> | Coeff.     | SE    | <i>p</i> | Coeff.  | SE    | <i>p</i> |
| Baseline            |              |       |          |            |       |          |         |       |          |
| Intercept           | 54.540       | 1.920 | <.001    | 57.859     | 1.809 | <.001    | 61.398  | 2.099 | <.001    |
| PFA phase           | 2.061        | 2.100 | .328     | 0.930      | 1.997 | .642     | -0.090  | 2.352 | .970     |
| Site 2              | 0.529        | 2.068 | .799     | -0.698     | 1.978 | .725     | -1.256  | 2.311 | .587     |
| Linear              |              |       |          |            |       |          |         |       |          |
| Month               | -0.545       | 1.575 | .730     | -2.217     | 1.731 | .202     | -7.976  | 1.815 | <.001    |
| PFA phase           | -3.112       | 1.722 | .073     | -2.825     | 1.780 | .114     | 0.070   | 1.906 | .971     |
| Site 2              | -3.548       | 1.694 | .038     | -1.534     | 1.779 | .390     | -0.539  | 1.899 | .777     |
| Quadratic           |              |       |          |            |       |          |         |       |          |
| Month               | -0.141       | 0.335 | .675     | 0.242      | 0.379 | .525     | 1.391   | 0.378 | <.001    |
| PFA phase           | 0.657        | 0.368 | .076     | 0.455      | 0.388 | .242     | -0.187  | 0.400 | .640     |
| Site 2              | 0.884        | 0.360 | .015     | 0.303      | 0.388 | .436     | 0.080   | 0.395 | .840     |
| Planned contrasts   |              |       |          |            |       |          |         |       |          |
| Term                | Est.         | SE    | <i>p</i> | Est.       | SE    | <i>p</i> | Est.    | SE    | <i>p</i> |
| PFA phase           |              |       |          |            |       |          |         |       |          |
| Linear              | -3.656       | 1.292 | .004     | -5.042     | 1.356 | <.001    | -7.906  | 1.454 | <.001    |
| Quadratic           | 0.516        | 0.269 | .052     | 0.697      | 0.289 | .015     | 1.204   | 0.299 | <.001    |
| Variance components |              |       |          |            |       |          |         |       |          |
| Term                | Var.         | SD    | <i>p</i> | Var.       | SD    | <i>p</i> | Var.    | SD    | <i>p</i> |
| Error               | 37.93        | 6.16  |          | 36.11      | 6.01  |          | 40.18   | 6.34  |          |
| Linear              | 34.58        | 5.88  | <.001    | 48.54      | 6.97  | <.001    | 63.97   | 8.00  | <.001    |
| Quadratic           | 0.80         | 0.89  | .055     | 1.58       | 1.26  | <.001    | 1.79    | 1.34  | .001     |
| Intercept           | 102.36       | 10.12 | <.001    | 112.97     | 10.63 | <.001    | 163.32  | 12.78 | <.001    |

Note. PFA = psychological first aid; Coeff. = coefficient; SE = standard error; Est. = estimate; Var. = variance. Due to space limitations, 95% confidence intervals are not reported, but for each coefficient/estimate, they can be computed as coefficient  $\pm 1.96 \times SE$ .

slowing of change in global functioning over time,  $\beta_{\text{Quad}} = -0.043$ ,  $SE = 0.024$ ,  $t(169) = -1.81$ ,  $p = .072$ ,  $[-0.090, 0.004]$ .

A follow-up model was performed with an interaction added between site and phase, testing whether slopes differed by site (across phases), by phase (across sites), or both. The results are reported in Table 5, and there were significant differences in two cases: For Site 2, the linear slope was significantly more positive in the PFA phase than the US phase (see Site 2: PFA vs. US), and in the PFA phase, the linear slope for Site 2 was more positive than the linear slope for Site 1 (at a borderline level of significance; see PFA phase: Site 2 vs. 1).

## Discussion

This study represents the first empirical test of PFA, using a sample of violent crime victims as trial participants. The first aim was to test the effectiveness of a PFA training protocol with LEVAs. As noted, LEVAs were expected to deliver some general elements of PFA as part of their standard practice. However, following training in PFA, we expected LEVAs to deliver more elements of the model. Consistent with that expectation, LEVAs at the two sites delivered a significantly higher percentage of PFA components during the PFA phase (39–54%) than they did during the US phase (27–30%). To understand this modest increase, there

are important considerations. First, the adherence levels were based on a single interaction between each LEVA and victim. This was necessary because interactions in the US phase were de-identified. However, for the PFA phase, adherence data were available for multiple interactions between LEVAs and victims. Across those multiple interactions (PFA phase only), the descriptive level of overall adherence was higher at 62–68%. Second, the PFA protocol does not intend for all components to be delivered during each interaction; indeed, this would be problematic. This highlights a common challenge with measuring adherence to interventions that, by definition, are flexible in the timing and frequency of component delivery (Schoenwald et al., 2011). Third, LEVAs were not obligated to adopt PFA. On the one hand, the trial aimed to provide a rigorous test of PFA, and on the other, it occurred in a real-world setting, with the intervention delivered by paraprofessionals. LEVAs were not hired by the study, nor were they required to deliver the model. Finally, a strength of our design was that the same LEVAs had adherence data for the US and PFA phases, and as such, the observed increase in adherence was not simply attributed to existing differences across independent samples of LEVAs. Generally, these findings support the effectiveness of the PFA training protocol and indicate that LEVAs have the capacity to deliver this intervention. However, the increase in delivery of components was modest, and for future efforts, this



Table 4  
Results of Mixed-Effects Regression Models Testing for Differences in Adaptive Functioning by Phase and Site

| Term                       | Primary Role |       |       | Social and Leisure |       |       |
|----------------------------|--------------|-------|-------|--------------------|-------|-------|
|                            | Coeff.       | SE    | p     | Coeff.             | SE    | p     |
| <b>Baseline</b>            |              |       |       |                    |       |       |
| Intercept                  | 1.777        | 0.099 | <.001 | 2.317              | 0.116 | <.001 |
| PFA phase                  | -0.078       | 0.111 | .485  | -0.176             | 0.106 | .098  |
| Site 2                     | -0.182       | 0.108 | .096  | -0.272             | 0.109 | .014  |
| <b>Linear</b>              |              |       |       |                    |       |       |
| Month                      | -0.095       | 0.153 | .533  | -0.060             | 0.145 | .679  |
| PFA phase                  | -0.021       | 0.174 | .904  | 0.026              | 0.139 | .854  |
| Site 2                     | 0.027        | 0.174 | .876  | -0.013             | 0.142 | .926  |
| <b>Quadratic</b>           |              |       |       |                    |       |       |
| Month                      | 0.030        | 0.045 | .502  | 0.007              | 0.043 | .861  |
| PFA phase                  | 0.002        | 0.052 | .964  | -0.011             | 0.042 | .789  |
| Site 2                     | 0.004        | 0.052 | .941  | 0.015              | 0.043 | .733  |
| <b>Planned contrasts</b>   |              |       |       |                    |       |       |
| Term                       | Est.         | SE    | p     | Est.               | SE    | p     |
| <b>PFA phase</b>           |              |       |       |                    |       |       |
| Linear                     | -0.116       | 0.132 | >.500 | -0.034             | 0.103 | >.500 |
| Quadratic                  | 0.032        | 0.039 | >.500 | -0.004             | 0.032 | >.500 |
| <b>Variance components</b> |              |       |       |                    |       |       |
| Term                       | Var.         | SD    | p     | Var.               | SD    | p     |
| Error                      | 0.253        | 0.503 |       | 0.143              | 0.378 |       |
| Intercept                  | 0.116        | 0.341 | <.001 | 0.180              | 0.425 | <.001 |

Note. PFA = psychological first aid; Coeff. = coefficient; SE = standard error; Est. = estimate; Var. = variance. Due to space limitations, 95% confidence intervals are not reported, but for each coefficient/estimate, they can be computed as coefficient  $\pm 1.96 \times SE$ .

warrants further attention to ongoing training and supervision practices as well as adherence measurement methods.

The second aim was to test the effect of PFA on crime victims' psychiatric symptoms and adaptive functioning. Across each primary intervention outcome, the PFA and US groups did not differ significantly with regard to linear or quadratic change, suggesting a lack of intervention effects. One exception is that when the sample was limited to women only, the PFA group had significantly greater early reductions in depression and somatization symptoms and a more rapid slowing of change in somatization symptoms relative to the US group. Secondary analyses examined the effect of PFA on a composite global functioning outcome. When interpreting the results for each of the primary intervention outcomes, we realized an important limitation—each outcome was potentially applicable to only a subgroup of victims. To describe the effect of PFA, or even change over time for the PFA group, our interpretations highlighted that the baseline level of each outcome could be anywhere from high to low. Further, we realized that, for a given victim, baseline levels could fluctuate from outcome to outcome. This highlighted the value of a global outcome that would apply equally across victims. Results indicated that victims receiving PFA demonstrated significantly greater linear change (i.e., early gains) in global functioning over time relative to victims receiving US. In terms of clinical significance, and as illustrated in Figure 2, both the PFA and US groups—within 2 months of the

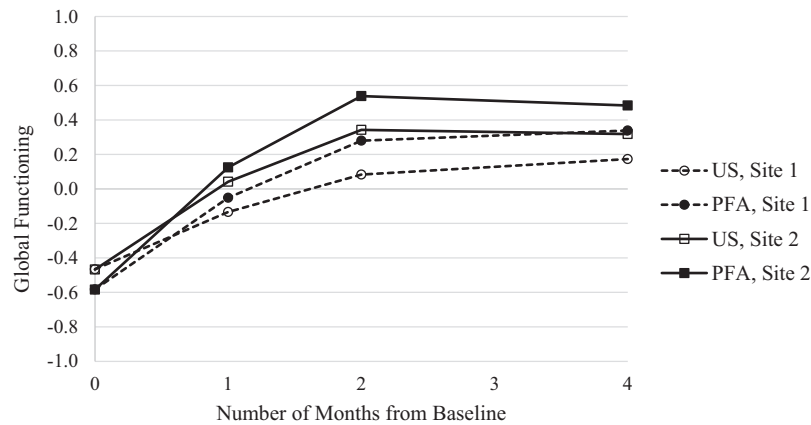
index event—had achieved their highest levels of global functioning. However, for victims receiving PFA, the gains occurred more quickly and reached a higher level, which was maintained through 4 months postbaseline, than for victims receiving US. As an example, this is reflected by the rates of subclinical functioning on the anxiety indicator (see Table 1), which, for both conditions and sites, reflected rapid gains from baseline to Month 1. However, by Month 4 and in both sites, the rates were higher for victims receiving PFA. This pattern tends to hold, though modestly in some cases, across each global functioning indicator.

Of note, follow-up models indicated that the early gains in global functioning associated with PFA were significantly greater at Site 2 compared to Site 1. Perhaps related to this, Site 2 also demonstrated a greater increase in, and a higher absolute level of, PFA adherence relative to Site 1. These findings are consistent with research on other behavioral interventions, which has demonstrated the importance of high protocol adherence in achieving good clinical outcomes (e.g., Feeley, DeRubeis, & Gelfand, 1999; Henggeler, Melton, Brondino, Scherer, & Hanley, 1997; Hogue et al., 2008). In the current study, LEVAs were observed to meet moderate levels of PFA adherence, with some variability across LEVAs and sites. However, the training and support procedures used in this trial were intensive. The initial training was conducted in a workshop format. Yet it became evident that additional training would be required to achieve proficiency with the model. This is not surprising as there is a large literature on the failure of the “train and hope” approach to teaching behavioral interventions

Table 5  
Results of Mixed-Effects Regression Models Testing for Differences in Global Functioning by Phase and Site

| Term                           | Coeff. | SE    | p     | 95% CI           |
|--------------------------------|--------|-------|-------|------------------|
| <b>Baseline</b>                |        |       |       |                  |
| Intercept                      | -0.530 | 0.167 | .002  | [-0.857, -0.203] |
| PFA phase                      | -0.024 | 0.193 | .900  | [-0.402, 0.354]  |
| Site 2                         | 0.084  | 0.194 | .665  | [-0.296, 0.464]  |
| Site $\times$ PFA              | -0.195 | 0.273 | .476  | [-0.730, 0.340]  |
| <b>Linear</b>                  |        |       |       |                  |
| Month                          | 0.419  | 0.143 | .004  | [0.139, 0.699]   |
| PFA phase                      | 0.200  | 0.169 | .239  | [-0.131, 0.531]  |
| Site 2                         | 0.184  | 0.165 | .264  | [-0.139, 0.507]  |
| Site $\times$ PFA              | 0.086  | 0.216 | .690  | [-0.337, 0.509]  |
| <b>Quadratic</b>               |        |       |       |                  |
| Month                          | -0.060 | 0.030 | .052  | [-0.119, -0.001] |
| PFA phase                      | -0.040 | 0.036 | .268  | [-0.111, 0.031]  |
| Site 2                         | -0.044 | 0.035 | .213  | [-0.113, 0.025]  |
| Site $\times$ PFA              | -0.005 | 0.047 | .922  | [-0.097, 0.087]  |
| <b>Planned contrasts</b>       |        |       |       |                  |
| Term                           | Est.   | SE    | p     | 95% CI           |
| <b>Site 2: PFA vs. US</b>      |        |       |       |                  |
| Baseline                       | -0.219 | 0.193 | .255  | [-0.597, 0.159]  |
| Linear                         | 0.286  | 0.135 | .032  | [0.021, 0.551]   |
| Quadratic                      | -0.045 | 0.030 | .128  | [-0.104, 0.014]  |
| <b>PFA phase: Site 2 vs. 1</b> |        |       |       |                  |
| Baseline                       | -0.111 | 0.192 | >.500 | [-0.487, 0.265]  |
| Linear                         | 0.271  | 0.140 | .050  | [-0.003, 0.545]  |
| Quadratic                      | -0.049 | 0.031 | .109  | [-0.012, 0.110]  |

Note. PFA = psychological first aid; US = usual services; Coeff. = coefficient; Est. = estimate; SE = standard error; CI = confidence interval.



*Figure 2.* Predicted global functioning slopes for each site in the psychological first aid (PFA) phase versus the usual services (US) phase. Global functioning scores are logit-based expected a posteriori victim scores from the general dimension of an item bifactor measurement model. A score of 0 reflects the average level of global functioning across victims and measurement occasions, and higher scores reflect better functioning.

(see Herschell, Kolko, Baumann, & Davis, 2010), and experts have concluded that intensive training procedures are needed to support delivery of new practices in real-world settings (Beidas & Kendall, 2010; W. R. Miller, Sorensen, Selzer, & Brigham, 2006). Therefore, biweekly supervision sessions were conducted. In addition, LEVAs audio recorded a limited number of their interactions with study participants. This allowed the study team to observe LEVAs' skills and provide individualized feedback. Such supervision techniques seemed critical for promoting PFA adherence among the LEVAs. It is not clear that similar, ongoing supervision is included as part of the PFA trainings being offered nationally and internationally. However, the data from this trial, and the investigators' anecdotal experience, suggest that ongoing quality assurance procedures should be an important consideration for future research and implementation efforts involving PFA.

The strengths of this study include its use of manualized PFA and adherence monitoring protocols, high recruitment and retention rates, blinding of research staff to intervention condition, use of a real-world workforce and setting, and inclusion of all participants in the analyses even if they missed an assessment. Additionally, this study contributes to the literature by developing the first tool for measuring PFA adherence. Importantly, our PFA adherence tool was found to have good psychometric properties for the use described in this study, and it therefore might serve as a resource for others attempting to deliver PFA to victims of crime. Further, although a few items are specific to PFA delivery with crime victims, researchers might easily adapt this tool for use with other trauma-exposed groups.

This study also has some weaknesses. First, due to funding limitations, the trial had a small number of sites and LEVAs, had a modest sample size, and relied on self-report methods for quantitative measurement of LEVAs' adherence to PFA. Second, the sample is comprised primarily of women and individuals exposed to domestic violence or physical assault. This limits generalizability of the findings for men and victims of other types of traumatic events. Third, the study would have benefitted from a longer follow-up period. However, the decision to conduct a 4-month follow-up was based on research suggesting that by 4 months

posttrauma, PTSD and related psychiatric symptoms have typically become chronic and are unlikely to recover spontaneously (McFarlane, 1988; Rothbaum, Foa, Riggs, Murdock, & Walsh, 1992).

## Conclusions and Implications

Several conclusions can be drawn from the findings. First, PFA seems amenable to adoption by members of the paraprofessional LEVA workforce, which has favorable implications for PFA transport. Second, results speak to the importance of a well-informed quality assurance protocol to ensure PFA is delivered as intended. Despite the simplicity of PFA, particularly in comparison to full-scale treatments for trauma victims, it is unlikely that a one-time workshop is sufficient to promote high-quality PFA delivery. Rather, ongoing supervision, including observation of delivery and associated feedback, is probably needed to ensure adequate adherence to the model. Third, PFA is likely a safe intervention for crime victims. That is, across each outcome domain, victims in the PFA group evidenced either significant improvement or no change over time. There was no evidence of symptom worsening among victims receiving PFA. This is relevant because when another acute intervention for trauma victims (i.e., CISD) was put to the test, results showed it to be potentially iatrogenic (Bisson et al., 1997; Hobbs et al., 1996). Fourth, evidence regarding the clinical effectiveness of PFA for crime victims is mixed. Indeed, the PFA and US groups did not significantly differ on any of the primary intervention outcomes. In follow-up models that excluded male victims from the sample, PFA outperformed US on two primary outcomes. Also, due to variability in participants' problem presentation at baseline, we suspected that results from analysis of the individual outcomes might tell an incomplete story. Thus, a composite global functioning outcome was created and analyzed. Over the 4-month follow-up, victims receiving PFA had significantly greater early gains in global functioning relative to victims receiving US. That being said, our decision to create this global functioning outcome was post hoc, and planned use of an existing, validated global functioning instrument would have been stronger.

Taken together, results indicate that PFA might be a useful acute intervention for victims of crime, but more research is clearly needed.

Future studies should test the effectiveness of PFA in a larger randomized trial that (a) includes more sites, LEVAs, and crime victims; (b) incorporates observational methods to measure PFA adherence; (c) uses existing and well-established global outcome instruments that consider the multitude of problem areas relevant to victims; and (d) is sufficiently powered to investigate gender as a putative moderator of intervention effects. Future research also should include more frequent outcome measurement over a longer follow-up period. Implementation outcomes such as perceived intervention acceptability, feasibility, and sustainability also would be important to measure in future studies. Additionally, the incremental costs associated with PFA seem critical to examine, especially given the intensive training and supervision efforts that might be needed to achieve and maintain high levels of adherence to the model. Finally, the results of this trial are generalizable to crime victims only, and formal testing of PFA with other types of trauma-exposed groups (e.g., victims of natural disasters) is recommended.

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# Evidence for the treatment of moderate depression: a systematic review

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**Objectives.** This study aims to investigate existing evidence for the effectiveness of psychological treatments and/or antidepressant medication as a treatment for those diagnosed with moderate levels of depression.

**Methods.** A PRISMA systematic review of articles using electronic research databases (2000–2014) was conducted to identify studies investigating the effectiveness of psychotherapy and/or medication as a treatment for people with moderate levels of depression. Search terms included moderate depression, psychotherapy and/or medication, depressive disorders, antidepressants, psychotherapy, mental health services, and randomized-controlled trial (RCT). The included studies were then assessed, extracted, and synthesised.

**Results.** A total of 14 studies met the inclusion criteria (11 RCTs and three additional studies) for this review. The findings of the systematic review indicate that there is limited evidence available specific to the treatment of moderate depression and that this research seems to suggest that psychotherapy or combined treatment has a beneficial effect.

**Conclusions.** Given that depression is one of the biggest challenges the world faces at present, further research is required to examine the effectiveness of treatment for different levels of depression severity.

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**Key words:** Antidepressant medication, depression, psychological treatments, systematic review, treatment.

## Introduction

Depression is one of the most prevalent and disabling of psychological problems related to diminished quality of life and role functioning, medical morbidity and mortality (Spijker *et al.* 2004; Üstün *et al.* 2004; Paykel *et al.* 2012). There are over 350 million people experiencing depression annually [World Health Organisation (WHO), 2012]. In addition, depression is a significant public health concern across all regions of the world (Bromet *et al.* 2011). Within an EU context, research carried out by Wittchen *et al.* (2011) reported that ~38% of the EU population (164.8 million people) struggle with mental health difficulties each year. Major depression affects 30 million people in the EU, becoming the most burdensome disorder of all diseases. The existing evidence for the effectiveness of psychological treatments and/or antidepressant medication treatments for those diagnosed with moderate levels of depression is ambiguous and a review of such evidence is, therefore, warranted.

Based on severity of symptoms, depression can be reported and experienced at different levels of severity. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) classifies major

depressive disorder into three distinct levels, namely mild, moderate, or severe, based on the intensity of depressive symptoms, symptom count, and degree of functional impairment (American Psychiatric Association, 2013). Studies investigating depression in the general population have reported that the prevalence of Major Depressive Disorder (MDD) for 12 months as 6.6%, affecting between 13.1 and 14.2 million US adults. Kessler *et al.* (2003) has shown that, of those with MDD, 10.4% were reported as 'mild', 38.6% 'moderate', and 51% 'severe or very severe' depression. Another study by Kessler *et al.* (2005) reported that of 9282 respondents, 6.7% identified as depressed and within that group, 30.4% reported 'severe' depression, 50.1% 'moderate' depression, and 19.5% 'mild' depression. Epidemiological data depicting the severity of depression are largely restricted to populations from North America, and there is a need for data depicting the severity of depression from a representative European sample.

Many treatments have been recommended for depression including different medications, a range of psychological therapies, exercise regimes, and alternative remedies. One of the influencing factors in determining the efficacy of any or all of these treatments is the level of severity of the depressive symptoms [see National Institute of Care and Excellence (NICE), 2009].

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### *Severity of depression as a significant factor in treatment*

The severity of depression is a significant factor in examining treatment effectiveness. The effectiveness of antidepressant medication and placebo was investigated by Fournier *et al.* (2010), which concluded that the benefits of antidepressant medication over placebo were only substantial for patients with severe depression. Similar studies by Khan *et al.* (2002) and Kirsch *et al.* (2008), identified that clinically meaningful improvements could only be achieved where initial Hamilton Depression Rating Scale (HDRS) scores exceeded 28 (where a score of 23 is indicative of very severe depression). Fournier *et al.* pointed out that there is a paucity of investigations of the true effects of antidepressant medication as a treatment for patients with less than severe depression. Fournier *et al.* also commented that evidence concerning the effects of antidepressant medication in patients with mild and moderate MDD has been sparse. An important conclusion of these findings was that high levels of depression symptom severity was required for clinically meaningful drug/placebo differences to emerge. These findings are surprising, particularly, given the evidence that the majority of patients receiving antidepressant medication in clinical practice present with scores below this level of severity. Fournier *et al.* concluded that prescribers, policy makers, and consumers might not be aware that the efficacy of medications has been largely established on the basis of studies that have included only those individuals with more severe forms of depression.

Given that research suggests that a significant proportion of the population experiencing depression are identified as moderately depressed (e.g. Kessler *et al.* 2005), the present paper systematically reviews studies of treatment effectiveness for adults experiencing depression at this level of severity.

### *Current treatment guidelines for moderate depression*

The NICE guidelines provide recommendations for professional standards of practice in relation to a range of psychological difficulties in the United Kingdom, and are based on the DSM-V [American Psychiatric Association (APA), 2013]. NICE (2009) guidelines state, 'if you have moderate or severe depression, you should be offered both an antidepressant and a psychological treatment'. The present paper examines the evidence supporting this recommendation by carrying out a systematic review of all studies on the treatment of moderate depression over a 16-year period. To date, there is no evidence to indicate that treatment intervention for moderate depression is the same as that for either mild or severe depression, it is important,

therefore, that evidence for the treatment efficacy of this specific level of depression severity is examined.

### *Levels of severity of depression in research designs*

Studies of depression tend to examine an amalgamation of severity levels within their samples, such as 'mild to moderate', and 'moderate to severe' (e.g. van der Lem *et al.* 2012). The criteria used do not identify moderate depression as a specific severity level to be examined. For example, the specific severity band of depression was not a consideration in Cuijpers *et al.* (2009) meta-analysis on treatment effectiveness for chronic depression. Similarly, Cuijpers *et al.* (2010a) looked at the effects of psychotherapy for depression and used bands of 'moderate to severe', 'severe', and 'mild to moderate depression'. No conclusions were made in relation to moderate depression. In another meta-analysis of 16 randomised-controlled trials (RCTs) examining the effects of psychotherapy on chronic depression, Cuijpers *et al.* (2010b) included studies where participants met diagnostic criteria for 'a depressive disorder' but likewise no reference was made to a specific categorisation to be examined. More recently, Cuijpers *et al.* (2014) reported that combined treatments were found to be more effective than either psychotherapy or medication alone and the criteria for inclusion used was 'depressive disorder'. In this meta-analysis, the effect size was reported to be influenced by the severity of depression. Individual depression scores, however, were not considered, but rather an average score was taken for the sample as a whole. Meta-analytic studies have been carried out to establish guidelines on the treatment for different levels of depression. For example, Fournier *et al.* (2010) conducted a meta-analysis of RCTs of antidepressants in the treatment of the different severity levels of depression conducted between 1980 and 2009. In this study, the sample chosen was grouped into 'mild to moderate', 'severe', and 'very severe' based on the HDRS scores offered by the APA. Notably, there were no known studies on 'moderate' depression reported.

Numerous systematic reviews have also been carried out in order to assist with clarifying treatment effectiveness for depression. Conclusions, however, refer to MDD rather than the different severity levels of depression (e.g. Khan *et al.* 2001; Zhou *et al.* 2014; Linde *et al.* 2015). To date, however, there are no known systematic reviews carried out on treatment effectiveness solely for moderate depression.

In summary, the different bands of depression have been predominantly amalgamated so that moderate depression has been either considered in combination with mild depression or with severe depression, but not as a stand-alone band of depression. Past research has

predominantly focussed on the efficacy of pharmacotherapy and psychotherapy treatments for depression across a wide range of symptom severity in individuals diagnosed with depression, without paying particular attention to the three main categories of depression severity stated in DSM-V. The present paper, therefore, addresses a gap in the literature by systematically reviewing the efficacy of treatments for those diagnosed with moderate levels of depression.

## Method

### *Inclusion criteria: data sources and search strategy*

The present review examines studies of the treatment effectiveness for moderate depression alone. The systematic review was written up according to the PRISMA standard (a protocol used to evaluate systematic reviews; Moher *et al.* 2015). In order to identify studies which included antidepressant pharmacotherapy and psychotherapy (psychological treatment), a search of EBSCO and SCOPUS was carried out that included the following databases: Medline, Cumulative Index to Nursing and Allied Health Literature, Psych Articles, Psych Info, Omnifile, Amed, Academic search complete, Social Sciences, UK and Ireland reference centre. The final database to be used was the Cochrane Database of Systematic Reviews. All searches were restricted to the period from January 2000 to January 2014 and included all keywords ordered as the following; 'Moderate Depression' and/or 'Psychotherapy', and/or 'Medication'. Subject headings included were as follows: depression, depressive disorders, antidepressants, psychotherapy, mental health services, and RCTs. Search terms for moderate depression, treatment, psychotherapy, medication (antidepressants), and combination treatments were explored.

Primary studies, including RCTs and systematic reviews that investigated pharmacotherapy, psychotherapy alone, and pharmacotherapy and psychotherapy combined, with moderate depression alone, were retained. Studies where moderate depression was investigated in combination with mild and/or severe depression or other types of depression were therefore excluded from this review. In order to classify the definition of psychological treatment, our review followed the system of Rush & Thase (1999) who regard interpersonal, cognitive, behavioural, and psychodynamic therapies as psychological treatment. Although each of these therapeutic interventions hold very different conceptual backgrounds, the rationale for including them all is that each treatment is focussed on the reduction in symptoms of depression and the prevention of reoccurrence and relapse (Pampallona *et al.* 2004).

### *Study selection*

Published and unpublished studies were eligible. Studies that included the treatment of moderate depression solely were selected. All the abstracts of the papers for inclusion in the review were screened and the full paper was obtained where there was insufficient information in the abstract.

### *Data extraction and quality assessment*

The quality of the studies were assessed in terms of methodological strength and limitations, that is recruitment procedure, sample size, and sufficient reporting of primary outcomes. Specific to RCTs, random allocation sequences, concealment of allocation sequences, blinding, and reporting of proportions of patients lost to follow-up were also assessed. An ad hoc form was designed for data extraction including information such as setting, number of participants, diagnosis, sex, mean age, type of intervention, measures used, and antidepressant drug administered. A data extraction table was developed detailing each of the variables of interest for the present review. Using the extraction table as a template, two reviewers extracted relevant data from all of the articles. After completion of the initial data extraction, a second independent reviewer checked the accuracy of the extracted data. In the case of disagreements between two reviewers, a third reviewer examined the full article to make a determination about whether to include or exclude the article. Review authors carefully considered the potential limitations of the included studies. Methodological appraisal of each study was conducted according to PRISMA standard.

To assess study quality, six quality rating criteria were selected in order to inform whether or not each study should be rated as high, medium, or low quality. These criteria were selected based on the researchers reading of what elements should be required to ensure high research quality (mainly based on a RCT design). The six criteria were as follows: (1) the study addressed an appropriate and clearly focussed question, (2) random assignment allocation, (3) participants and investigators were 'blind' about treatment allocation, (4) treatment and control groups were equivalent at baseline, (5) the only difference between groups was the treatment under investigation, and (6) all relevant outcomes were measured in a standard, valid and reliable way. A quality checklist table was developed based on these criteria. Two reviewers independently assigned a quality rating ('yes', 'no', 'can't say') to each study; results were compared and differences discussed until agreement was obtained. The decision for low, medium, and high-quality ratings were as follows: (a) low: two criteria were present and four were not/can't say, (b) medium: four criteria were present and

two were not/can't say, and (c) high: all six criteria were met.

## Results

### Data extraction

From the initial searches on depression, over 78 800 articles were identified investigating depression. Based on broad inclusion criteria, that is studies of the treatment effectiveness solely for moderate depression between January 2000 and January 2014, 278 were relevant for further screening. The identified abstracts lead to the exclusion of 264 papers due to the inclusion of mild and severe severity depression levels, and the inability to reach the set inclusion criteria, namely primary studies including RCTs and systematic reviews that investigated pharmacotherapy, psychotherapy, and combination treatments with moderate depression. For each of the 14 remaining studies meeting our inclusion criteria, available information regarding the sample (i.e. sample size, basic demographics, and recruitment setting), study design, intervention type, and any descriptive findings related to behavioural and mental health outcome variables (see Table 1) were extracted.

A total of 14 studies with a total of 1743 participants met the inclusion criteria. Five of the studies used the Hamilton Depression Scale (HAMD-17) to measure the levels of moderate depression in the sample. The Beck Depression Inventory (BDI) was also used as a measure in five of the studies reviewed, with the remaining studies using measures such as The Center for Epidemiologic Studies Depression Scale (CES-D) and the ICD-10 Guide for Depression Diagnosis. Six of the studies examined medical treatments (including herbal), four studies examined psychological treatments, and a further four studies examined combined treatments of both medical and psychological interventions.

### Study quality

With regard to study quality, the methodological quality of the 14 studies included in this review was standard. Of the 14 studies, eight studies were rated as high quality, while six studies were rated as medium. For those studies rated as medium, all met at least four of the six quality criteria; three did not blind the investigators and participants to treatment allocation, while two studies did not contain sufficient information to permit assessment. Two of the studies rated as medium did not randomly assign participants to treatment conditions. A bias check was also carried out on all studies with no reference to bias mentioned in any study, with the exception of Bastos *et al.* (2013) who employed bias-adjusted  $\kappa$  statistic.

### Medical interventions

Of the six studies which investigated the effectiveness of medical interventions to treat moderate depression, four investigated the effectiveness of herbal remedies including Hypericum extract (St. Johns Wort) and Jieyu Pill (Chinese medicine) compared to traditional antidepressants (Uebelhack *et al.* 2004; Gastpar *et al.* 2005, 2006; Yeung *et al.* 2014). Each of these studies found that the herbal remedy was as effective as antidepressants when treating moderate depression. One study examined the effectiveness of pharmacotherapy in treating moderate depression when compared with the combination of pharmacotherapy and an aerobic training programme (Cerdeira *et al.* 2011) and found a decrease of depression symptoms only when the aerobic training programme was included. One study solely investigated the effectiveness of antidepressants in the treatment of moderate depression when compared with a placebo (Klein *et al.* 2014). The results indicated no significant difference between treatment and placebo groups in cases of moderate depression.

### Psychological interventions

Four studies focused on psychological interventions such as cognitive behavioural therapy (CBT). Results showed CBT to be effective in reducing moderate depressive systems when used as an individual treatment, compared with usual care and a control condition (Antoni *et al.* 2001; Le *et al.* 2011; Carter *et al.* 2013). Results also indicated that CBT was effective in treating moderate depression when integrated with other forms of psychotherapy (Hamamci, 2006).

### Combined interventions

Of the 14 studies that were included in this review, two studies investigated antidepressants and psychological interventions combined as an effective treatment. Stötter *et al.* (2013) investigated the effectiveness of an 8-week mindfulness intervention with antidepressants compared to antidepressants treatment only. Results showed that the use of mindfulness therapy demonstrated significant additional benefits in the treatment of moderate depression when combined with the use of antidepressants. Bastos *et al.* (2013) investigated the use of long-term psychodynamic therapy (LTPP) alone, pharmacotherapy alone and both combined. Results indicated that LTPP and pharmacotherapy combined were more effective in modifying specific areas of cognition than antidepressants alone or LTPP alone, in patients with moderate depression. Results of this systematic review also indicated that the use of self-help and biblio-therapy were effective in reducing the symptoms of moderate depression. Songprakun &

**Table 1.** Studies in the review that matched inclusion criteria

| Study <sup>a</sup>                           | Intervention  | Design           | Sample (Male:female)<br>Mean age          | Assessment tools                     | Primary outcome  |
|--|---|------------------|---|--------------------------------------|--|
| <b>Medical</b>                               |   |                  |   |                                      |  |
| Cerda <i>et al.</i> (2011) Spain             | Control group; pharmacotherapy (Fluoxetine 20 mg) <i>v.</i> study group; pharmacotherapy + aerobic training for 8 weeks, 3 days/week                    | Pre and post RCT | <i>n</i> = 82<br>(0:100)<br>32.4 years    | BDI & ICD-10 Guide                   | An aerobic training programme as a complementary therapy diminishes depressive symptoms  |
| Gastpar <i>et al.</i> (2006) Germany         | 6-week treatment with either 900 mg Hypericum extract, 20 mg Citalopram or placebo once/day   | RCT              | <i>n</i> = 388                            | HAMD-17                              | Hypericum extract STW3-VI is a good alternative to antidepressants in the treatment of outpatients with moderate depression  |
| Gastpar <i>et al.</i> (2005) Germany         | 12 weeks with 612 mg Hypericum extract <i>v.</i> 50 mg Sertraline once/day. A total of 161 patients were treated after week 12 for additional 12 weeks. | RCT              | <i>n</i> = 200                            | HAMD-17                              | Hypericum extract STW3 is therapeutically non-inferior to Sertraline after the first 12 weeks of interventions   |
| Klein <i>et al.</i> (2014) Canada            | Citalopram or placebo administered to HIV-HCV coinfecting patients  | RCT              | <i>n</i> = 76<br>(66:10)<br>46.4 years    | BDI-II                               | Incidence of moderate depression did not differ significantly by group   |
| Tao (2006) China                             | Jieyu Pill treatment group 4 g x3 times/for 6 weeks <i>v.</i> Venlafaxine extended release (ER) treatment group 75 mg once/day for 6 weeks.             | RCT              | <i>n</i> = 86                             | HAMD-17                              | The curative effect of Jieyu Pill in the treatment of moderate depression is the same as venlafaxine ER  |
| Uebelhack <i>et al.</i> (2004) Germany       | Hypericum extract STW 3-VI 900 mg once/day <i>v.</i> placebo  | RCT              | <i>n</i> = 140<br>(46:94)<br>45 years     | HAMD-17                              | Hypericum extract STW 3-VI in a once-daily dosing regimen is an effective option for patients with moderate depressive disorder                                      |
| <b>Psychological</b>                         |   |                  |   |                                      |  |
| Antoni <i>et al.</i> (2001) United States    | Study group; 10-week group cognitive behavioural stress management  | Single study     | <i>n</i> = 100<br>(0:100)<br>50.2 years   | CES-D scale                          | Intervention reduced prevalence of moderate depression   |
| Carter <i>et al.</i> (2013) United States    | CBT-I in chronically bereaved hospice nurses  | Single study     | <i>n</i> = 9<br>(1:8)<br>54 years         | CES-D scale                          | The CBT-I had a positive effect on sleep onset latency, total sleep time, and sleep efficiency scores at 3 weeks post-intervention                                   |
| Hamamci (2006) Turkey                        | Study group; attended psychodrama integrated with CBT + group therapy for 11 sessions for 3 months <i>v.</i> control group                              | RCT              | <i>n</i> = 31<br>(16:15)<br>19.5 years    | BDI                                  | Psychodrama integrated with CBT, and cognitive behavioural group therapy alone, led to reduction in the level of moderate depression                                 |
| Le <i>et al.</i> (2011) United States        | Usual care (UC) <i>v.</i> 8-week CBT group intervention during pregnancy + three individual sessions <i>postpartum</i>                                  | RCT              | <i>n</i> = 217<br>(0:100)<br>25.5 years   | BDI & Mood Screener                  | Intervention group had significantly lower depressive symptoms and fewer cases of moderate depression at Time 2 than UC group  |
| <b>Medication and psychological combined</b> |   |                  |   |                                      |  |
| Bastos <i>et al.</i> (2013) Brazil           | LTPP, Fluoxetine monotherapy or combination for 24 months   | RCT              | <i>n</i> = 272<br>(103:169)<br>29.6 years | BDI & WAIS-III                       | LTPP and combined treatment seemed to be more efficacious in modifying specific areas of cognition than Fluoxetine alone   |
| Songprakun & McCann (2012a) Thailand         | Study group received 'The Good Mood Guide: A Self-Help Manual for Depression' <i>v.</i> control group   | RCT              | <i>n</i> = 56<br>(16:40)<br>42.1 years    | CES-D scale                          | Between baseline and post-test, a sharp decrease in depression was evident in the intervention group, whereas the level of depression increased in the control group |
| Songprakun & McCann (2012b) Thailand         | Intervention group received a self-help manual + standard care and treatment <i>v.</i> control group  | RCT              | <i>n</i> = 56<br>(16:40)<br>42.1 years    | Kessler Psychological Distress Scale | Lower psychological distress scores in the intervention group than those in the control group  |

RCT, randomized-controlled trial; BDI, Beck Depression Inventory; HAMD-17, Hamilton Depression Scale; BDI-II, Beck Depression Inventory-II; CES-D, The Center for Epidemiological Studies Depression Scale; LTPP, long-term psychodynamic psychotherapy; WAIS-III, Wechsler Adult Intelligence Scale Version III; CBT-I, cognitive behavioural therapy for insomnia. Details missing in Table 1 is due to such information being unattainable from the studies cited.

<sup>a</sup> Country of origin.



McCann (2012a) demonstrated that the inclusion of a self-help manual for depression with usual care (including medication treatment) marginally reduced levels of moderate depression over time. In a further study, Songprakun & McCann (2012b) demonstrated the effectiveness of including a self-help manual with usual care in reducing psychological distress in individuals with moderate depression and therefore improving treatment outcomes.

## Discussion

In the present systematic review, 14 studies were identified, that were carried out between 2000 and 2014, specifically examining the treatment of moderate depression. Results indicate that psychological therapy on its own has been shown to be effective with this level of severity in depression in a small number of studies. In the present review, there is no evidence to support the effectiveness of antidepressant medication on its own in the treatment of moderate depression. In addition, this review highlights the lack of well-designed studies examining the effective treatments for moderate depression. Only one of the studies under investigation was identified that specifically compared psychotherapy alone with medication alone (i.e. Bastos *et al.* 2013,  $n = 272$ ) and one further study compared psychotherapy with usual care (Le *et al.* 2011,  $n = 217$ ). In both studies, psychological treatment out-performed the medication. Given the limited number of studies in this review, it is argued that this small body of research is not sufficient to inform clinical guidelines and recommendations.

From reviewing the published research, the current review draws attention to the use of classifications of depression such as 'mild to moderate' and 'moderate to severe' within research (e.g. van der Lem *et al.* 2012) and suggests that such classifications, whilst at times clinically useful perhaps, may not be the most useful to inform research. DSM-V is the standard bearer for categorisation but does not categorise the severity of depression using 'mild to moderate' or 'moderate to severe' as bands of depression.

The adherence to clear guidelines for the differential diagnosis of mild, moderate, and severe depression may be necessary in order to more accurately inform treatment guidelines. Large-scale epidemiological studies, such as Wittchen *et al.* (2011), which refer to the gross figures of depression in Europe may in future consider including prevalence rates for the categories of mild, moderate, and severe depression. Gross figures for depression can lead to misinterpretation, due to the varying intervention approaches that may be indicated for the differing levels of severity (see NICE, 2009). This review found that the majority of research investigating

depression, typically distinguishes between levels of depression using identification tools such as the HDRS (Hamilton, 1960), BDI (Beck *et al.* 1961), and the General Health Questionnaire (Goldberg & Williams, 1991). Identification tools such as these cannot be the sole measure used to identify a patient's severity or type of depression and the resulting treatment recommendations incorporated. It is also important to take into account the degree of functional impairment and/or disability associated with the possible depression, the duration of the episode, and the clients' own preferences, motivations, intentions, and likelihood of engaging successfully with a treatment modality. In this context, further research needs to conduct studies using diagnostic interviews as a gold standard to identify those with moderate levels of depression. Rather than seeing major depressive disorder as an all-or-nothing condition, it may be more practical and realistic to view it as occurring across a continuum of severity, with DSM categories of mild, moderate, and severe being considered as useful markers/bands or cutoff points for research purposes.

A search of studies from 2000 to 2014 was used in the present study. This resulted in a small number of studies being identified for further review. The decision to only include 'moderate depression' in our search terms in this review was deliberate in order to focus solely on available treatment evidence for moderate depression. Had we adopted a broader approach in our systematic review of studies, incorporating studies on depression other than specifically on moderate depression, it is likely that we would have generated a far larger number of studies for inclusion. This, however, would have defeated the purpose of the study, which was to do a specific review of moderate depression only, resulting in a small number of studies meeting the inclusion criteria. A limitation of this period of research is that it does not include the most recent of studies (i.e. 2014–2017). We would not expect changes in our conclusions from a more up to date review, however, as the results are representative of the historical paucity of research specifically related to 'moderate' depression. Nonetheless, future research studies may follow up on this issue now that it has been highlighted here.

The clinical implication of these findings is that current treatment guidelines for moderate depression, that is 'both an antidepressant and a psychological treatment', may need to be revisited. The treatment of moderate depression needs to be approached with more caution, as this research suggests that there is no evidence for a combined approach for the treatment of moderate depression specifically, as recommended in current guidelines, for example NICE.

In conclusion, given that depression is one of the biggest health challenges the world faces at present



(The Economist, 2014), we advocate for more research to examine the effectiveness of treatment for different levels/bands of depression severity. Further research may lead to different recommendations for treatment by symptom severity. The present study highlights the urgent need for comprehensive data to be collected on the incidence of and effective treatments, specifically, for moderately depressed people so as to further inform public policy, mental health care strategies, and service delivery. There is currently no funded research that the authors are aware of that is collecting data of this nature in Europe and the present paper hopefully contributes toward encouraging such research to be carried out in future.

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### Conflicts of Interest

Dr Declan Aherne, Dr Amanda Fitzgerald, Dr Cian Aherne, Dr Noelle Fitzgerald, Meghan Slattery, and Neal Whelan have no conflicts of interest to disclose.

### Ethical Standards

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committee on human experimentation with the Helsinki Declaration of 1975, as revised in 2008. The current study is a review paper that does not involve human experimentation. Appropriate ethical standards were upheld throughout whereby research standards were held to the highest quality.

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