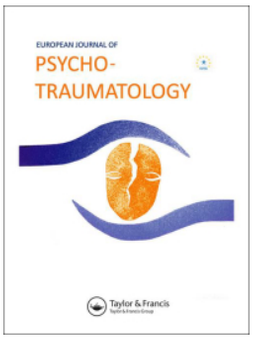

European Journal of Psychotraumatology

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/zept20

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To cite this article: Natalie Simon, Catrin E. Lewis, Kim Smallman, Lucy Brookes-Howell, Neil P. Roberts, Neil J. Kitchiner, Cono Ariti, Claire Nollett, Rachel McNamara & Jonathan I. Bisson (2023) The acceptability of a guided internet-based trauma-focused self-help programme (Spring) for post-traumatic stress disorder (PTSD), European Journal of Psychotraumatology, 14:2, 2212554, DOI: 10.1080/20008066.2023.2212554

To link to this article: https://doi.org/10.1080/20008066.2023.2212554

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EUROPEAN JOURNAL OF PSYCHOTRAUMATOLOGY
2023, VOL. 14, NO. 2, 2212554
https://doi.org/10.1080/20008066.2023.2212554

EUROPEAN JOURNAL OF PSYCHO-TRAUMATOLOGY
THE OFFICIAL JOURNAL OF THE EUROPEAN SOCIETY FOR TRAUMATIC STRESS STUDIES

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CLINICAL RESEARCH ARTICLE

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The acceptability of a guided internet-based trauma-focused self-help programme (Spring) for post-traumatic stress disorder (PTSD)

Natalie Simon [a,b], Catrin E. Lewis [a], Kim Smallman [c], Lucy Brookes-Howell [a], Neil P. Roberts [a,b], Neil J. Kitchiner [a,b], Cono Ariti [c], Claire Nollett [c], Rachel McNamara[c,a], and Jonathan I. Bisson [a]

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ABSTRACT

Background: Guided internet-based, cognitive behavioural therapy with a trauma-focus (i-CBT-TF) is recommended in guidelines for post-traumatic stress disorder (PTSD). There is limited evidence regarding its acceptability, with significant dropout from individual face-to-face CBT-TF, suggesting non-acceptability at least in some cases.

Objective: To determine the acceptability of a guided internet-based CBT-TF intervention, 'Spring', in comparison with face-to-face CBT-TF for mild to moderate PTSD.

Method: Treatment adherence, satisfaction, and therapeutic alliance were measured quantitatively for participants receiving 'Spring' or face-to-face CBT-TF as part of a Randomised Controlled Trial. Qualitative interviews were conducted with a purposive sample of therapists and participants.

Results: 'Spring' guided internet-based CBT-TF was found to be acceptable, with over 89% participants fully or partially completing the programme. Therapy adherence and alliance for 'Spring' and face-to-face CBT-TF did not differ significantly, apart from post-treatment participant-reported alliance, which was in favour of face-to-face CBT-TF. Treatment satisfaction was high for both treatments, in favour of face-to-face CBT-TF. Interviews with participants receiving, and therapists delivering 'Spring' corroborated its acceptability.

Conclusions: Guided internet-based CBT-TF is acceptable for many people with mild to moderate PTSD. Findings provide insights into future implementation, highlighting the importance of personalising guided self-help, depending on an individual's presentation, and preferences.

La aceptabilidad de un programa de auto-ayuda centrado en el trauma basado en internet (Spring) para el trastorno de estrés postraumático (TEPT)

Antecedentes: La terapia cognitivo conductual guiada por internet con un enfoque en el trauma (i-CBT-TF por sus siglas en inglés) se recomienda en las guías clínicas para el trastorno de estrés postraumático (TEPT). Existe evidencia limitada en relación a su aceptabilidad, con un abandono significativo de la CBT-TF presencial, lo que sugiere no aceptabilidad al menos en algunos casos.

Objetivo: Determinar la aceptabilidad de una intervención de CBT-TF guiada por internet, 'Spring', en comparación con CBT-TF presencial para TEPT de leve a moderado.

Método: Se midieron cuantitativamente la adherencia al tratamiento, satisfacción y alianza terapéutica para los participantes que recibieron CBT-TF Spring o presencial como parte de un Estudio Controlado Aleatorizado. Se condujeron entrevistas cualitativas con una muestra intencional de terapeutas y participantes.

Resultados: Se encontró que la CBT-TF guiada por internet 'Spring' era aceptable, con más del 89% de los participantes completando total o parcialmente el programa . La adherencia al tratamiento y la alianza para la CBT-TF sea 'Spring' y presencial no difirieron significativamente, aparte de la alianza informada por los participantes después del tratamiento, que estaba a favor de la CBT-TF presencial. La satisfacción con el tratamiento fue alta para ambos tratamientos, en favor de la CBT-TF presencial. Las entrevistas con los participantes que recibieron y los terapeutas que entregaron 'Spring' corroboraron su aceptabilidad.

Conclusiones: La CBT-TF guiada por internet es aceptable para muchas personas con TEPT de leve a moderado. Los hallazgos brindan información sobre la implementación futura, destacando la importancia de personalizar la autoayuda guiada, según la presentación y preferencias de cada individuo.

ARTICLE HISTORY
Received 12 March 2023
Revised 21 April 2023
Accepted 2 May 2023

KEYWORDS
Post-traumatic stress disorder; internet-based cbt; guided self-help; acceptability; dropout

PALABRAS CLAVE
Trastorno de estrés postraumático; CBT basada en internet; autoayuda guiada; aceptabilidad; abandono

关键词
创伤后应激障碍; 在线cbt; 引导式自助; 可接受性; 流失

HIGHLIGHTS

- Guided internet-based trauma-focused CBT is an acceptable treatment for PTSD.
- A model of acceptability explained 45% of variance in treatment outcome.
- Importance of adapting guided self-help to suit presentation and preferences.

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一项针对创伤后应激障碍（PTSD）引导式在线聚焦创伤自助计划（春天）的可接受性

背景：创伤后应激障碍（PTSD）指南推荐引导式在线聚焦创伤认知行为疗法（i-CBT-TF）。其可接受性的证据有限，个体面对面的 CBT-TF 中有显著流失，表明至少在某些情况下是不可接受的。
目的：为了确定引导式在线 CBT-TF 干预'Spring'相较于面对面 CBT-TF对于轻度至中度 PTSD 的可接受性。
方法：作为随机对照试验的一部分，对接受'春天'或面对面 CBT-TF 的参与者的治疗依从性、满意度和治疗联盟进行了定量测量。对治疗师和参与者的立意抽样进行了定性访谈。
结果：发现'春天'引导式在线CBT-TF 是可以接受的，超过 89% 的参与者完全或部分完成了该计划。'春天'和面对面 CBT-TF 的治疗依从性和联盟没有显著差异，除了面对面 CBT-TF更好的治疗后参与者报告的联盟。两种治疗的治疗满意度都很高，面对面的 CBT-TF相对更高。接受访谈的参与者和提供'春天'的治疗师证实了它的可接受性。
结论：许多轻至中度 PTSD 患者可以接受引导式在线 CBT-TF。结果提供了对未来实施治疗的启示，强调了个性化引导式自助的重要性，这取决于个人表现和偏好。

1. Introduction

Post-traumatic stress disorder (PTSD) is a global mental health disorder, commonly co-occurring with other conditions (Bisson et al., 2015). Lifetime prevalence has been estimated at 4% (Karatzias et al., 2018), and can double in populations affected by conflict (Steel et al., 2009). High-risk professional groups such as military service members and first responders are at greater risk (Wilson, 2015), with healthcare workers at increased risk during pandemics (Carmassi et al., 2020). PTSD typically impacts a person's social and occupational functioning and some individuals may go on to develop maladaptive coping mechanisms, including substance use disorder (Roberts et al., 2022). The economic burden of PTSD is significant, for example, high rates of unemployment have been found due to symptomatology impacting ability to function in the work setting (Ferry et al., 2015).

Cognitive Behavioural Therapy with a trauma focus, delivered face-to-face (CBT-TF) (Lewis et al., 2020a), is a first choice treatment for PTSD (ISTSS, 2018; NICE, 2018b). CBT-TF typically includes psychoeducation, cognitive restructuring and behavioural exposure focusing on the traumatic event, with a view to updating the traumatic memory and addressing unhelpful beliefs and coping behaviours (Ehlers & Clark, 2000). There is a growing evidence base for internet-based CBT-TF that is therapist-guided, also known as guided self-help (Simon et al., 2021b), recommended in recent treatment guidelines (ISTSS, 2018; NICE, 2018b), and recently demonstrated as non-inferior to face-to-face CBT-TF in a large pragmatic RCT, RAPID (Bisson et al., 2022; Nollett et al., 2018).

Guided self-help may be advantageous for people less able to access outpatient services due to work, mobility, financial, and geographical restraints (Becker et al., 2004; Schumacher et al., 2018), and offers increased flexibility about when to undertake treatment-related activity (NHS, 2019), offering people greater choice and control regarding their health needs (Hollis et al., 2018a). Furthermore, guided internet-based CBT-TF typically requires fewer face-to-face sessions and less clinical support time than traditional CBT-TF (Lewis et al., 2020a).

International research, policy, and commissioning have prioritised digital therapies to widen access to evidence-based psychological care (Torous et al., 2019), with a number of such services developing across the UK (Wakefield et al., 2021). Its uptake and implementation was initially slow, however (Andersson et al., 2019a; Bennion et al., 2017), demonstrated in findings from eight European countries (Hadjistavropoulos et al., 2017; Topooco et al., 2017). One explanation for this slow uptake may relate to therapeutic alliance, important in enabling individuals to feel safe for trauma treatment engagement (Simon et al., 2021a; Wild et al., 2020), and perceived by some therapists to be a weakness in guided self-help (Thew, 2020), despite limited evidence for this (Andersson et al., 2019b; Berger, 2017). Slow uptake may relate to perceptions of dropout from trauma-focused treatment (Lewis et al., 2020b). Dropout may indicate non-acceptability in some cases, for example some may not wish to tolerate therapy that requires focusing on the traumatic memory they are trying to avoid (Becker et al., 2004; Schumacher et al., 2018). There are however many reasons for dropout, with research indicating that some individuals drop out of treatment with significant gains in symptomatology, and might be better defined as early treatment responders (Szafranski et al., 2017).

More recently, since the COVID-19 pandemic, findings demonstrate a shift in practice and increasingly positive views around internet-based and remotely-delivered therapies, with an increased willingness by both patients and therapists to engage with this approach (Békés & Aafjes-van Doorn, 2020; Simon et al., 2021b). These findings add to a growing, albeit

limited evidence base, for the acceptability of guided internet-based CBT-TF (Simon et al., 2019), and highlight that further research is needed.

Acceptability is a facet of healthcare quality (Maxwell. dimensions in quality revisited, 1992), and explicit definitions are lacking, though include 'judgements about the treatment procedures by nonprofessionals, lay persons, clients and other potential consumers of treatment' (Kazdin, 1980, p. 259). More recently, acceptability has been proposed as 'a multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention'. (Sekhon et al., 2017, p. 14). Studies of treatment acceptability are limited across the literature and are given less weight than efficacy by guideline developers when determining the evidence and putting forward recommendations (Hamblen et al., 2019). Yet treatment acceptability has been associated with treatment outcome (Swift & Callahan, 2009), and is likely to affect treatment implementation (Craig et al., 2008; Wallin et al., 2016). Acceptability is a consideration within personalised care and shared decision making, acknowledged by NICE (NICE, 2018a), shared decision making is evidenced as leading to improved patient experiences and treatment outcome (Swift & Callahan, 2009).

There is wide variability in operationalising and reporting acceptability, across the healthcare literature (Sekhon et al., 2017), not limited to internet-based therapies (Berry et al., 2016; Eysenbach, 2011). Dropout is a frequently reported acceptability indicator, however, as noted, its interpretation is hampered without reported reasons for dropout (Lewis et al., 2020b). Furthermore, treatment acceptability may be considered multifaceted and complex. To illustrate, an individual might preconceive a treatment to be unacceptable, yet they may adhere and may see an improvement in symptoms, thereby rating that treatment as satisfactory overall.

A systematic review of ten included studies has demonstrated that internet-based CBT for PTSD is acceptable, as indicated by i-CBT programme usage, study-specific acceptability measures ($k = 3$), satisfaction measures ($k = 2$), and a measure of therapeutic alliance ($k = 1$) (Simon et al., 2019). There was however evidence of greater dropout from internet-based CBT compared to waitlist in a meta-analysis of eight studies, though no difference was found between internet-based CBT and waitlist in a Cochrane systematic review update (Simon et al., 2021b). The certainty of the evidence was very low and none of the included studies considered guided internet-based CBT compared with face-to-face CBT.

This study aimed to determine if a guided internet-based CBT-TF intervention, 'Spring', was as acceptable to participants and therapists as its comparator, face-to-face CBT-TF, in a pragmatic RCT. A multicomponent evaluation was conducted to provide a broad and deep understanding of acceptability. Measures of treatment adherence, satisfaction, and participant and therapist therapeutic alliance were administered, and qualitative interviews were conducted to collect information from the perspective of individuals receiving and delivering 'Spring' through the RAPID trial, to aid our interpretation of findings. An assessment of the influence of treatment acceptability on treatment outcome was also conducted. Additional trial information can be accessed via the main results and protocol papers (Bisson et al., 2022; Nollett et al., 2018).

2. Materials and methods

2.1 Participants

Trial participants were consenting adults aged 18 or over with regular access to the internet and with mild to moderate severity PTSD to a single traumatic event as their only, or primary diagnosis, assessed via the Life Events Checklist-5 (LEC-5) (Weathers et al., 2013a) and Clinician Administered PTSD Scale for DSM-5 (CAPS-5) (Weathers et al., 2013b). Individuals were excluded on the basis of: inability to read and write fluently in English, previous completion of trauma-focused psychological therapy, current engagement in a psychological therapy, a change in psychotropic medication in the last four weeks, psychosis, substance dependence and active suicide risk. A purposive sample of participants and therapists were invited to take part in qualitative interviews.

2.2 Procedure

The RAPID trial was conducted between August 2017 and January 2021, following favourable ethical opinion by the South East Wales Research Ethics Committee (17/WA/0008). Participants were identified from National Health Service (NHS) Improving Access to Psychological Therapies (IAPT) services in England, and NHS psychological treatment settings in primary and secondary care services in Scotland and Wales. Potential participants were approached by clinicians involved in their care and were screened and assessed by researchers after providing informed consent. The trial aimed to recruit 192 participants, according to a power calculation that considered a non-inferiority margin (Nollett et al., 2018). Full methodology details are described in the main trial paper (Bisson et al., 2022).

All therapists had previous experience of delivering CBT-TF for PTSD and were trained to deliver both

manualised treatments. Fidelity checks ensured treatment in both trial arms were delivered consistently. All outcome assessors were blinded to treatment allocation as far as possible, and participants were asked not to reveal their allocation at data collection follow-ups.

Participants and therapists were purposively sampled for qualitative interviews between February 2018 and November 2019; participant interviewees were identified according to gender, age, ethnicity, education level, nature of trauma, research site and outcome, and therapists according to their gender and research site. Over-sampling of participants receiving 'Spring', as opposed to those receiving CBT-TF allowed for an increased understanding to support the implementation of 'Spring', if indicated. The sample was guided by preliminary analysis and constant comparison at each data collection phase of themes from interviews, to ensure saturation.

2.3 Interventions

2.3.1. 'spring'

'Spring' (Santiago et al., 2013) was developed in line with Medical Research Council (MRC) guidance (Craig & Petticrew, 2013), co-produced with people with PTSD, and found to be effective compared to waitlist in a Phase II RCT (Lewis et al., 2017). 'Spring' utilises an eight-step internet and App-based programme based on CBT-TF. Programme steps include: psychoeducation; grounding techniques; relaxation techniques; behavioural re-activation; an exposure-based trauma written narrative exercise; cognitive restructuring; graded exposure to overcome avoidance; and reinforcement of learning to keep well. Steps are completed sequentially, with resource tools becoming activated as the participant progresses through the programme. Key content entered by the participant into the programme is visible to the therapist, with the participant's knowledge. The intervention commences with an hour-long face-to-face orientation session to introduce the programme, with further guidance and progress checks scheduled fortnightly in four 30-minute sessions, face-to-face or on the telephone, to offer support, monitoring, motivation, and problem solving.

2.3.2 CBT-TF comparator

The version of face-to-face CBT-TF used as a comparator in the trial was Cognitive Therapy for PTSD (CT-PTSD) (Clarke, 2000), which is an evidence-based approach adopted by IAPT services in England, and psychological therapy services in England, Scotland and Wales. CBT-TF seeks to identify and modify problematic appraisals, memory characteristics and triggers, behavioural and cognitive strategies that maintain PTSD symptoms. Individuals assigned to face-to-face CBT-TF met with a therapist for up to twelve sessions, each lasting 60–90 min, augmented by between session homework assignments.

2.4 Measures

The full set of trial measures and their psychometric properties are described in the main paper (Bisson et al., 2022). The current study utilised the Life Events Checklist-5 (LEC-5) at baseline (Weathers et al., 2013a); the past-month CAPS-5 (Weathers et al., 2013b) at baseline, and the past-week version at 16-week follow-up; the Patient Health Questionnaire-9 (PHQ-9) (Kroenke et al., 2001) at baseline; and the Client Satisfaction Questionnaire (CSQ-8) (Larsen et al., 1979) at 16-week follow-up. The CSQ-8 is a widely used 8-item, Likert Scale self-report statement of satisfaction with a high degree of internal consistency, good concurrent validity and reliability (Nguyen et al., 1983), with higher scores indicating higher satisfaction. In addition, this study utilised the Agnew Relationship Measure-5 (ARM-5), a validated shortened version of the 28-item ARM therapeutic alliance measure (Cahill et al., 2012). Patient and therapist versions of the ARM-5 were administered at three weeks and 16 weeks post-randomisation.

2.4.1 Adherence

Therapy session adherence was recorded by therapists and described categorically, defined *a priori* as: non-uptake (being offered, but not starting therapy sessions); partial adherence (completion of less than three 'Spring' therapy sessions, or less than eight CBT-TF therapy sessions); and full adherence (completion of three or more 'Spring' therapy sessions, or eight or more CBT-TF therapy sessions, or where earlier cessation had been agreed as no further treatment was deemed necessary). Total mean therapy session adherence was calculated (number of therapy sessions attended, as a percentage of the available number of sessions; five for 'Spring' and twelve for CBT-TF, or fewer where earlier cessation agreed). 'Spring' programme usage was described categorically: not-started (no steps started); partial completers (starting any number of, and/or completing up to, but not all of the eight steps); or full completers (all steps complete).

2.4.2 Qualitative interviews

Interviews followed topic guides, co-produced with individuals with lived experience of PTSD from a Public Advisory Group (PAG), who contributed their lived experience to assist with RAPID design, management, conduct, analyses, and dissemination. Semi-structured interviews were conducted by KS, a researcher with experience across several qualitative methodologies. This approach ensured consistency in questioning, whilst also allowing for exploration of topics that were important to the interviewee, to

gather in-depth experiences and views. Interviews were audio-recorded and transcripts were anonymised during preparation for analysis.

2.5 Analyses

2.5.1 Quantitative

Descriptive and statistical analyses were conducted using SPSS version 23.0 (Corp I, 2015). The clinical importance of any potential baseline characteristics imbalance was considered, and ANCOVAs were conducted for therapy session adherence, satisfaction, and therapeutic alliance, each controlling for gender, site, baseline CAPS-5, and time since trauma. Baseline PHQ-9 was also controlled for, given that greater treatment dropout and smaller reduction in PTSD symptom severity post-treatment has been demonstrated for individuals with PTSD comorbid with depression (Barawi et al., 2020; Flory & Yehuda, 2015). Multiple regression was performed to assess whether CAPS-5 PTSD symptoms at 16-week follow-up was correlated with a multi-faceted model of acceptability, with the covariate of PTSD symptoms at baseline, to understand the contribution of these variables to the total variance explained.

2.5.2 Qualitative

Cleaned interview transcripts were imported into QSR NVivo 12 (Ltd. QIP, 2020), and data analyses occurred concurrently with data collection, using a constant comparison approach to explore themes and data saturation (Saunders et al., 2018). Thematic Framework Analysis was employed, allowing for an inductive approach and a systematic model for managing and mapping data (Gale et al., 2013), adhering to the principles of the Critical Appraisal Skills Programme qualitative checklist (Programme CCAS, 2019). Saturation was monitored through a double-coding process, with at least 20% of transcripts double coded. Interviewers made field notes including notes on self-reflection practice immediately following interviews (Stahl & King, 2020). Several authors discussed interpretations, with input and support from the PAG, initially developing analytic frameworks from the interview questions and the coding of the first few interview transcripts. The analytic frameworks were applied when coding the remainder of the transcripts and to populate the codes into framework matrices.

3. Results

3.1 Participants

The RAPID participant consort diagram is provided in the main trial paper (Bisson et al., 2022).

Seven hundred and twenty-six referrals were received, and 196 were recruited and randomised; 97 to 'Spring', and 99 to face-to-face CBT-TF. The 16-week follow-up was completed by 160 individuals; 77 'Spring' participants, and 83 CBT-TF participants.

3.1.1 Participant characteristics

Participant demographic and clinical characteristics across treatment groups are shown in Table 1. Around two-thirds of participants were female, 180 (91.8%) identified their ethnicity as white, the total mean age was 36.5 (SD = 13.4), and mean time since trauma was 37.4 months (SD = 77.2). Mean PHQ-9 baseline score was 15.1 (SD = 6.2), and CAPS-5 baseline score was 35.1 (SD = 6.7). One hundred and twenty-four (63.3%) participants had a level of education of '2+ A levels or equivalent', roughly equivalent to the German Abitur, and the French di Esame di Stato, for example.

3.1.2 Interviewee characteristics

As detailed in Table 2, five female, and three male 'Spring' participants were interviewed post-treatment, all identifying their ethnicity as white, with a mean age of 39.3 years. Three participants had PTSD to a transportation accident, two to an uncomfortable or unwanted sexual experience, one to a serious accident, one to a life-threatening illness or injury, and one to sudden or violent death. The mean interview length was 40.3 min, ranging from 20 to 60 min. Six interviews were conducted prior to the COVID-19 national lockdown commencing 23rd March 2020, and two were conducted after, having received 'Spring' just prior to national lockdown.

As detailed in Table 3, seven of the 23 RAPID therapists delivering treatment participated in post-delivery qualitative interviews, three male, and four female. Most were working in South Wales, the majority with low familiarity with 'Spring' prior to their involvement in the RCT. Interviews ranged from 28 to 78 min, with a mean of 59.3 (SD = 17.9). All interviews were conducted during COVID-19 UK national lockdown.

3.2 Adherence

3.2.1 Fidelity

As described in the main trial paper (Bisson et al., 2022), there was good fidelity, with all but one of the 74 audios of therapy sessions being rated as at least satisfactory.

3.2.2 Non-uptake, dropout, and adverse events

Acceptability was demonstrated, indicated by high uptake across treatments and low dropout, though the latter was in favour of CBT-TF. Five (5.2%) 'Spring' participants, and three (3%) CBT-TF participants were offered but did not attend any therapy sessions. Ten individuals withdrew from 'Spring', reporting reasons

Table 1. Demographic and clinical characteristics of RAPID participants at baseline.

	Total (n = 196)	GSH (n = 97)	TF-CBT (n = 99)
Female gender (%)	125 (63.8%)	62 (63.9%)	63 (63.6%)
Age at assessment	36.5 (13.4)	35.4 (13.5)	37.6 (13.4)
Time since trauma (in months)	37.4 (77.2)	36.3 (80.9)	38.5 (73.6)
Mean Total Baseline PTSD Symptoms Clinician Administered PTSD Scale for the Diagnostic and Statistical Manual of Mental Disorders Version 5 (CAPS-5) (SD)	35.1 (6.7)	34.6 (6.8)	35.6 (6.7)
Mean Total Baseline Depression Patient Health Questionnaire Version 9 (PHQ-9) (SD)	15.1 (6.2)	15.1 (6.7)	15.1 (5.7)
Ethnicity			
White: Welsh/English/Scottish/Northern Irish/British	172 (87.8%)	86 (88.7%)	86 (86.9%)
White: Irish	2 (1.0%)	1 (1.0%)	1 (1.0%)
White: Any other White background	6 (3.1%)	3 (3.1%)	3 (3.0%)
Mixed/Multiple ethnic groups: White and Black Caribbean	1 (.5%)	_	1 (1.0%)
Mixed/Multiple ethnic groups: White and Black African	1 (.5%)	1 (1.0%)	_
Mixed/Multiple ethnic groups: Any other Mixed / Multiple ethnic background	1 (.5%)	1 (1.0%)	_
Asian/Asian British: Indian	3 (1.5%)	2 (2.1%)	1 (1.0%)
Asian/Asian British: Pakistani	1 (.5%)	1 (1.0%)	_
Asian/Asian British: Bangladeshi	1 (.5%)	_	1 (1.0%)
Asian/Asian British: Chinese	2 (1.0%)	1 (1.0%)	1 (1.0%)
Black / African / Caribbean / Black British: African	3 (1.5%)	1 (1.0%)	2 (2.0%)
Black / African / Caribbean / Black British: Caribbean	1 (.5%)	_	1 (1.0%)
Black / African / Caribbean / Black British: Any other Black / African / Caribbean background	1 (.5%)	_	1 (1.0%)
Any other ethnic group	1 (.5%)	_	1 (1.0%)
Highest level of qualification			
'No qualifications'	8 (4.1%)	7 (7.2%)	1 (1.0%)
'1-4 UK General Certificate of Secondary Education (GCSE) or equivalent' (the UK GCSE is equivalent to the International General Certificate of Secondary Education (IGCSE))	24 (12.3%)	12 (12.4%)	12 (12.1%)
'5+ GCSEs or equivalent'	36 (18.4%)	17 (17.5%)	19 (19.2%)
'Apprenticeship'	4 (2.0%)	1 (1.0%)	3 (3.0%)
'2+ A Levels or equivalent' (the UK A level is roughly equivalent to the German Abitur, and the French di Esame di Stato, for example)	46 (23.5%)	24 (24.7%)	22 (22.2%)
'Degree level or above'	64 (32.7%)	27 (27.8%)	37 (37.4%)
'Other qualifications' (level unknown)	14 (7.1%)	9 (9.3%)	5 (5.0%)
Recruitment Site			
Aneurin Bevan University Health Board (UHB)	9 (4.6%)	5 (5.2%)	4 (4.0%)
Cardiff & Vale UHB	77 (39.3%)	40 (41.2%)	37 (37.4%)
Coventry and Warwickshire Partnership National Health Service (NHS) Trust	20 (10.2%)	9 (9.3%)	11 (11.1%)
Cwm Taf Morgannwg UHB	19 (9.7%)	8 (8.3%)	11 (11.1%)
East London NHS Foundation Trust	7 (3.6%)	3 (3.1%)	4 (4.0%)
NHS Lothian	34 (17.4%)	17 (17.5%)	17 (17.2%)
Pennine Care NHS Foundation Trust	27 (13.8%)	13 (13.4%)	14 (14.1%)
South West Yorkshire Partnership NHS Foundation Trust	3 (1.5%)	2 (2.1%)	1 (1.0%)

including physical health, not being ready to engage in therapy, or to commit to therapy, or feeling better due to a medication change. Four individuals withdrew from CBT-TF, reporting reasons including serious illness in the family, difficulty getting time off work, or feeling that solutions were not offered. There were six serious adverse events, though none were found to be related to involvement in the trial.

3.2.3 Therapy session adherence

Therapy session adherence was described categorically and on a continuous scale. Seventy-eight (80.4%) 'Spring' participants, and 55 (55.6%) CBT-TF participants fully adhered. Twelve (12.4%) 'Spring' participants and 34 (34.3%) CBT-TF participants partially adhered to therapy sessions. The percentage of planned sessions was recorded by therapists and was available for 94 'Spring' and 96 CBT-TF participants. Mean percentage therapy adherence was 79.6 (SD = 36.5), for 'Spring', and 72.4 (SD = 28.9), for CBT-TF. There was a 4.8% higher therapy adherence for 'Spring' compared to CBT-TF, 95% CI: −3.5–13.1%, p = .259.

3.2.4 'spring' usage

'Spring' acceptability was indicated by usage. Ten participants (10.3%) did not start, and as log-in details were provided at the first therapy session, at least five of these participants did not have the means to log in, due to not attending sessions. Forty-eight (49.5%) participants, partially completed 'Spring', starting any number of steps, and/or completing up to seven steps, and 39 (40.2%) fully completed 'Spring'.

3.3 Therapeutic alliance

As shown in Table 4, acceptability may be indicated by mean scores found for participant and therapist-reported alliance, at both treatment timepoints, across treatment groups.

ARM-5 scores were available mid-treatment for 44 'Spring' and 52 CBT-TF participants, and for 52

Table 2. Participant (pseudonym) characteristics, 'Spring' GSH i-CBT-TF steps completed, and interview length.

Pseudonym	Gender	Age band	Ethnicity	Education level	Clinician Administered PTSD Scalefor the Diagnostic and Statistical Manual of Mental Disorders Version 5 (CAPS-5) Baseline Total score	Clinician Administered PTSD Scalefor the Diagnostic and Statistical Manual of Mental Disorders Version 5 (CAPS-5) 16week Total score	'Spring' completion	Pre/Post COVID-19 UK national lockdown	Interview length (minutes)
Mike	Male	50–60	White Irish	Other vocational/work-related qualifications (level unknown)	39	36	Full completion	No	46
Kay	Female	60–70	White British	Other vocational/work-related qualifications (level unknown)	33	3	Full completion	No	46
Ellen	Female	20–30	White	5 + GCSEs	32	9	Partial completion	No	38
Stewart	Male	50–60	White	Other vocational/work-related qualifications (level unknown)	39	24	Full completion	No	43
Becky	Female	20–30	White	2+ A levels	40	16	Full completion	No	28
Clare	Female	20-3-0	White	Degree level or above	49	40	Full completion	No	20
Emma	Female	30–40	White	Degree level or above	27	11	Partial completion	Yes	60
Luke	Male	30–40	White	5+ GCSEs	39	7	Full completion	Yes	41

therapists delivering 'Spring' and 51 therapists delivering CBT-TF; and post-treatment for 58 'Spring' and 65 CBT-TF participants and 52 therapists delivering 'Spring' and 51 therapists delivering CBT-TF. No statistically significant differences between groups was found for: *Participant-reported therapeutic alliance* at mid-treatment which was 0.2% higher for CBT-TF than 'Spring', 95% CI: −1.0% to 1.4%, $p = .715$; *therapist-reported therapeutic alliance at mid-treatment* which was 0.6% higher for CBT-TF than 'Spring', 95% CI: −3.2% to 1.5%, $p = .51$; and *therapist-reported therapeutic alliance score at post-treatment* which was 0.6% higher for CBT-TF than 'Spring', 95% CI: −.4% to 1.6%, $p = .218$. A statistically significant difference between groups was however found for *participant-reported post-treatment therapeutic alliance,* which was 1.1% higher and in favour of CBT-TF compared with 'Spring', 95% CI: .1% to 2.1%, $p = .030$.

3.4 Treatment satisfaction

CSQ-8 scores were available for 70 of the 97 'Spring' participants and for 75 of the 99 participants randomised to CBT-TF. The mean scores were 26.9 (SD = 6.3) for 'Spring' participants, and 29.8 (SD = 3.3) for CBT-TF participants, indicative of acceptability for both interventions. Treatment satisfaction was 3.3% higher for CBT-TF compared with 'Spring', 95% CI: 1.6% to 5.0%, $p < .001$.

3.5 Treatment acceptability and treatment outcome

Multiple regression was conducted to explore associations between PTSD symptoms at 16-weeks follow-up and the following variables, pooled across groups; therapy adherence, treatment satisfaction, participant- and therapist-reported therapeutic alliance, mid- and post-treatment. Missing data were excluded pairwise, resulting in 65 cases included due to a number of missing therapist record sheets and ARM-5 measures. The overall regression model was a good fit for the data; the model of acceptability explained 45% of the variance in treatment outcome across treatment groups ($R^2 = .450$, $F(7, 57) = 6.675$, $p < .001$). As shown in Table 5 treatment satisfaction and baseline PTSD symptoms were significant correlates of PTSD symptoms at 16-week follow-up (Beta = -.482, $p = .002$ and Beta = .355, $p = .001$ respectively) within the model. Post-hoc analyses revealed that the regression model remained a good fit for the data even with the removal of baseline PTSD symptoms ($R^2 = .337$, $F(6, 58) = 4.912$, $p < .001$).

3.6 Qualitative interviews

'Spring' was described as calming, containing, empowering, essential, progressive, and structured, with good

Table 3. Therapist (pseudonym) characteristics, familiarity with 'Spring' (prior to RAPID RCT), and interview length.

Pseudonym	Research Region	Gender	Familiarity with 'Spring' (prior to RAPID RCT)	Interview Length (minutes)
Christian	South Wales	Male	Very high	46
Laura	South Wales	Female	Low	62
Jenny	South Wales	Female	Low	78
William	South Wales	Male	Low	28
Annabel	Central England	Female	Low	78
Meg	Central Scotland	Female	Low	57
Gavin	Central Scotland	Male	Low	66

outcomes from treatment including a better understanding of PTSD. Interviewees shared a mixture of views about its pace, length and flexibility and also about therapeutic alliance, with most, but not all interviewees viewing the treatment approach as motivating towards treatment engagement and recovery. Treatment components such as the grounding tools and the trauma narrative exercise were viewed as beneficial, though some therapists expressed concern about exposure work through the guided self-help approach, highlighting resistance and avoidance from some participants. Some raised concern about 'Spring' use for individuals with PTSD symptoms to particular traumas, for example traumas involving grief and loss. Some therapists told us that their preconceptions of 'Spring' had changed through experience and spoke of internet-based therapies widening and diversify treatment access. Themes generated from interviews are described in Table 6.

4. Discussion

The RCT demonstrated good acceptability for 'Spring' guided internet-based CBT-TF and its comparator, face-to-face CBT-TF. Over 89% of participants partially or fully completed 'Spring'. Therapy session adherence and therapeutic alliance did not differ across treatment groups, apart from post-treatment participant-reported alliance, which was slightly in favour of CBT-TF. Treatment satisfaction was high in both groups, and slightly in favour of CBT-TF. An evaluation of acceptability as multi-faceted, valuing several measures alongside each other explained 45.0% of the variance in treatment outcome across groups.

Non-uptake of 'Spring' therapy sessions was 5.2%, and non-uptake of 'Spring' programme steps was 10.3%, which contrasts with higher non-uptake rates in some other studies as reported in a systematic review of i-CBT for PTSD (Simon et al., 2019). Most 'Spring' participants fully adhered to therapy sessions (79.4%), and partial adherence (12.4%) was lower than for CBT-TF participants (34.3%), lower than guided self-help dropout rates found in a review of eMental health for PTSD (Gaebel et al., 2017), and at the lower end of rates found in another review of i-CBT for PTSD (Simon et al., 2019).

In-depth interviews with purposively selected participants receiving, and therapists delivering 'Spring', provided a mixture of views and overall corroborated acceptability ratings. Interviews revealed 'Spring' opportunities and barriers and provided insights into future implementation, including an appreciation for the importance of adapting 'Spring' to suit an individual's needs and preferences. In line with the literature, interviews revealed that flexibility facilitated engagement (Davies et al., 2020).

Digital therapeutic alliance was voted a top ten research priority in a UK study involving 600 mental health stakeholders (Hollis et al., 2018b). The findings of this study contribute to this research priority, aligning with the literature in demonstrating the equality of online and face-to-face therapies (Pihlaja et al., 2018; Schumacher et al., 2018). It should however be noted that equality of alliance was not demonstrated post-treatment by participants, which was in favour of CBT-TF, though this did not appear to impact on symptom outcomes, with 'Spring' showing non-inferiority to CBT-TF at follow-up (Bisson et al., 2022). This equality of alliance difference might therefore reflect perceptions of a relationship that had strengthened over several sessions, or an improvement in symptoms at the end of treatment. Participant alliance ratings were however stable across timepoints, suggesting acceptability of alliance throughout treatment.

The mean 'Spring' satisfaction rating was 26.4 (SD = 6.5), of a possible total of 32, comparable with

Table 4. Therapeutic alliance scores reported by participants and therapists at mid- and post-treatment, across groups.

	Mean Total Therapeutic Alliance (Agnew Relationship Measure Version 5) (SD)			
	Participant Mid-Treatment	Therapist Mid-Treatment	Participant Post-Treatment	Therapist Post-Treatment
'Spring' guided internet-based Cognitive Behavioural Therapy with a trauma-focus	26.9 (3.0) ($n = 44$)	25.5 (2.5) ($n = 52$)	26.9 (3.6) ($n = 58$)	23.3 (14.1) ($n = 56$)
Face-to-face Cognitive Behavioural Therapy with a trauma-focus	27.4 (3.1) ($n = 52$)	26.1 (1.95) ($n = 51$)	28.1 (1.8) ($n = 65$)	25.7 (6.2) ($n = 55$)
Total	27.2 (3.0) ($n = 96$)	25.8 (2.3) ($n = 103$)	27.5 (2.8) ($n = 123$)	24.5 (11.0) ($n = 111$)

Table 5. Summary of multiple linear regression analyses for therapy adherence, treatment satisfaction, therapeutic alliance, and baseline CAPS5 as correlates of CAPS5 at 16 weeks follow up.

Variable ($n = 65$)	Beta, 95% CI [lower, upper]	*p*-value
Therapy adherence	.021 [−.07, .08]	.850
Satisfaction	−.482 [−1.59, −.39]	.002
Therapeutic Alliance Participant Mid-treatment	.235 [−.03, 1.76]	.058
Therapeutic Alliance Participant Post-treatment	−.140 [−1.85, .75]	.399
Therapeutic Alliance Therapist Mid-treatment	.051 [−.90, 1.40]	.667
Therapeutic Alliance Therapist Post-treatment	−.168 [−.41, .07]	.156
Baseline Clinician Administered PTSD Scale for the Diagnostic and Statistical Manual of Mental Disorders Version 5 (CAPS-5)	.355 [.24, .92]	.001

findings elsewhere, including a mean CSQ-8 rating of 28 (SD = 4.8) found in a pilot study of a group guided self-help intervention for low mood and depression (McClay et al., 2015). This is encouraging since satisfaction is an essential determinant of service effectiveness and is a key nationally recommended intervention outcome metric for mental health services in Wales (Withers KLP et al., 2018). Interviewees generally described 'Spring' positively and as a valuable alternative to face-to-face therapy.

Therapist interviewees who had experience of delivering both treatments perceived 'Spring' to be an acceptable alternative to weekly face-to-face therapy, aligning with findings of blended internet-based CBT for depression, where 94% of therapists were overall very or mostly satisfied with it (Mol et al., 2020). Some therapists did note preconceptions that individuals would prefer face-to-face CBT-TF, aligning with therapist views elsewhere in the literature, that internet-based approaches will not be as effective as face-to-face approaches, and that they will fail to meet patient expectations (Thew, 2020). Some therapists reported that their preconceptions had been challenged through experience. This casts doubt on treatment allocation equipoise, at least initially for some therapists. Clinical equipoise is a methodological challenge of the RCT design, a potential bias that is perhaps more likely in cases where a therapist is more experienced in the delivery of one intervention, over the comparator and therefore one that exists across the literature, though arguably largely unavoidable in trials of manualised interventions (Cook & Sheets, 2011).

4.1 Strengths and limitations

The strengths and limitations of the full trial are described in the main paper. Fidelity to treatment delivery was high. Roughly two-thirds of participants identified as female, consistent with the literature reporting a higher female PTSD prevalence (Ditlevsen & Elklit, 2012; Olff, 2017; Pietrzak et al., 2011), and mean age at assessment was in line with the age of onset of PTSD reported elsewhere (Lijster et al., 2016). Roughly two-thirds of participants were educated to '2+ A levels or equivalent', in line with reports that around 64% of people in the UK aged 19–64 years have an education level of National Qualifications Framework (NQF) level 3, or above, equivalent to '2+ A levels or equivalent' (Statistics, 2020). This does however limit the generalisability of the findings to people with a lower education level and the literature suggests education level may be a predictor of engagement with internet-based interventions (Karyotaki et al., 2021). Furthermore, it is also important to note the study excluded individuals who did not have regular access to the internet and those unable to read and write fluently in English.

The pragmatic nature of the trial allowed for the exploration of acceptability in a broad clinical context, albeit with the exception that participants are randomly allocated to treatment (Schwartz & Lellouch, 2009). Qualitative interviews were interpreted with support from public members with lived experience of PTSD (the PAG). Researchers practiced reflexivity around qualitative interviewing and analyses, though we must still acknowledge the potential impact of researcher bias. We cannot generalise the findings of the qualitative interviews. All interviewees had started 'Spring' therefore the findings cannot reflect views from the 10.3% of participants who did not take up the programme. To focus on factors impacting acceptability and implementation, we purposively sampled individuals with different outcomes resulting in over-representation of individuals with poorer outcomes compared to the trial overall. We did not evaluate qualitative interviews from CBT-TF participants, limiting our ability to understand acceptability for the comparison intervention. Furthermore, the therapist interviewees had experience delivering both treatments, whereas the participant interviewees knew only of the 'Spring' treatment. All therapist interviews, and two 'Spring' participant interviews were conducted after the onset of the COVID-19 pandemic, which we know has accelerated the perceived need, provision and use of remote therapies (Wind et al., 2020), an unintended limitation or arguably a strength of the study. Acceptability was not measured beyond 16-week follow-up, limiting our understanding of acceptability to immediately post-treatment. We must acknowledge challenges measuring adherence. Therapy session adherence was determined using a continuous scale, defined *a priori* as the number of sessions attended, as a percentage of the expected number of sessions. The continuum was capped at 100% so that all individuals who attended the expected number of sessions, or more, which was five or more

Table 6. Qualitative interview themes about 'Spring'.

'Spring' theme 1
Calming, containing, empowering, essential, progressive and structured
'I think it was … a very great and, and progressive method of doing this and ironically as the year's gone on with COVID I think you know, something like that is more and more essential … ' (participant, Emma).
'that variation for the therapist helps … guiding them along their journey … there were parts that kind of felt more, erm, therapeutic … but … yeah, it's a lot less intensive for the therapists'. (therapist, Annabel).
'it was so structured, it also helped me to try and also maintain a structure, and the other people as well. Especially if … they're prone to going off at a tangent … it helped them as well'.
(therapist, Gavin).
'Spring' theme 2
A mixture of views about its pace, length, and flexibility
'it was nice to just do half an hour every day … just perfect for me'.
(participant, Luke).
'I honestly don't think that eight weeks, in my situation … it's not long enough'.
(participant, Mike).
'luckily it fit in around work … '
(participant, Stewart)
'people can do it in their own homes if they felt a bit nervous about talking to somebody'.
(participant, Becky)
'factoring in something that was self-driven myself, at home when I had a new born and … suffering from trauma was very difficult to do … '
(participant, Emma)
'Spring' theme 3
A mixture of views about 'Spring' therapeutic alliance
'I had a little bit of a dip where … it sort of gets worse before it gets better when you're confronting it … So she [therapist] … made me do it [trauma narrative exercise] there with her … Someone's sort of picking you up as you're going along'.
(participant, Ellen)
Participant Becky described the sessions as, 'very administrative'
'I noticed … a much stronger therapeutic alliance with the patients I was doing the face-to-face sessions with'.
(therapist, William)
'the thoughts work and the updates to the memory … felt a lot more therapeutic … I think rapport was built quite well and I think that first face to face appointment makes a big difference … '
(therapist, Annabel).
'Spring' theme 4
Benefits and drawbacks of 'Spring' treatment components
'breathing exercises and stuff like that, so if I ever felt anxious … I would log on … it was a comfort for me … I felt grounded'.
(participant, Luke)
Ellen described the trauma narrative exercise as a turning point, 'where I went over the hill and it got it a lot easier … I think it's acceptance of what has happened … essentially getting it out'.
'thinking about them having to go through that [exposure/reliving] on their own … I was … happy to do that in the session, together if we needed to, you're kind of there to really sort of help that process'.
(therapist, Jenny)
'Spring' theme 5
Potential limitations of 'Spring' for individuals with PTSD symptoms to a specific trauma, or with complexity
'delivering the programme when somebody had … lost a loved one I found that a little bit challenging … the grieving is going on as well … people probably benefit more from one to one … '
(therapist, Jenny)
In relation to themes of shame and guilt, Laura shared, 'they could be addressed through guided self-help but I just felt that it needed more of a personal component to it from the therapist'.
'Spring' theme 6
Preconceptions of 'Spring' had been challenged through experience
' … the bias I entered into was that the … cognitive therapy for PTSD [face-to-face therapy] … was going to be superior over the online version … But very quickly that's challenged'.
(therapist, Meg)
'I think it's slightly surprising because people weren't as shocked as you think about only offering them … the guided self-help'.
(therapist, Laura)
'I've become more … relaxed about using online … '
(therapist, Gavin)
'Spring' theme 7
Widening and diversifying treatment access
'you need the influencers … people with the power to commission … people that can see the value in it … in psychotherapies and mental health and … policy makers and Government'.
(therapist, Christian)
'Spring' theme 8
Good outcomes from 'Spring'
'I just didn't wanna be around anyone cos I just felt angry all the time for no reason … but it kinda helped me realise that it's normal and I can stop being angry … I did then start making more of an effort to see my friends again'.
(participant, Becky)

in the case of 'Spring', or twelve or more for CBT-TF, were interpreted as adhering at 100%. Our findings do not therefore account for the individuals who received more than the total number of sessions.

Measuring and interpreting internet-based intervention adherence is particularly challenging (Beintner et al., 2019; Eysenbach, 2011). There was a surprising discrepancy between findings of 'Spring' therapy session adherence and programme usage. Seventy-eight participants adhered fully to therapy sessions, whilst only 39 fully completed all eight of the programme steps. It is possible that participants more readily engaged with 'Spring' therapy sessions than with completion of the online programme.

Alternatively, the *a priori* definitions for 'Spring' therapy adherence and online programme usage may not be as useful as we might have expected. For example, the 'Spring' programme indicated that steps were not complete if the individual had chosen not to take the non-mandatory quiz at the end of the step, even where the individual had exposed themselves to all the content of the step and entered information into this step. Similarly, the range of 'Spring' usage in the category of partial completers was very large, ranging from an individual starting just step one, to an individual completing steps one to seven but only starting step eight. Furthermore, some individuals shown to have completed some steps, may not have meaningfully engaged with those steps. Interpreting online engagement is therefore challenging.

The multi-faceted construct of acceptability was demonstrated as sound and explained 45.0% of the variance in treatment outcome across groups. This builds on previous work proposing acceptability as multi-faceted, and reflecting the views of patients and providers (Sekhon et al., 2017). We did not however have data from participants who had officially withdrawn or had become lost to follow-up, and several therapist record sheets and ARM-5 measures were missing, resulting in the exclusion of almost two-thirds of participants in the multi-component analysis, which may therefore be under powered. We also acknowledge the potential for false positives from other ad-hoc quantitative analyses due to the multiplicity of statistical testing.

4.2 Research implications

Several patient-specific factors appear to be important for engagement and acceptability, including baseline PTSD symptoms and depression. Future research is needed to examine the interaction of facets of acceptability and moderators and mediators, to understand for whom guided internet-based therapies will be most appropriate (Rozental et al., 2019). Research must address common methodological challenges that have been highlighted, including measuring internet-based intervention adherence. Standardised methodology is required to draw meaningful comparisons across studies. Online intervention reporting guidelines are available (Eysenbach, 2011). Measures specific to digital health interventions are available including a version of the ARM (Berry et al., 2016).

These findings contribute to evidence that guided internet-based therapies are suitable for mild to moderate disorders (Stephen et al., 2011; Topooco et al., 2017). The mixture of views collected through qualitative interviews, sometimes opposing, suggests the importance of personalising guided self-help, depending on an individual's presentation, treatment formulation, and preferences. Further research is now required to understand the impact of adapting guided self-help. For example, adapting programmes to be available in a service user's mother tongue, or changing the gender of the voice over (Peck, 2008), or delivering the intervention entirely remotely (Ashwick et al., 2019; Wild et al., 2020). Adaptations might include changes to the pace or time allocated to treatment components, which may be evaluated in routine clinical practice, for example 'Plan-Do-Study-Act' quality improvement (QI) initiatives (Knudsen et al., 2019). A QI project is currently examining 'Spring' delivered entirely remotely, in the context of routine NHS Wales practice.

The therapists of the RAPID trial were all experienced trauma psychological therapists, with prior experience delivering CBT-TF, casting some doubt on the level of equipoise. We need to understand the competencies required by guiding clinicians to facilitate guided self-help engagement and to enable individuals to feel safe to disclose trauma information and engage in remote trauma based processing (Capaldi et al., 2016; Kehle-Forbes & Kimerling, 2017), as well as understanding the optimal model of training and supervision required, in line with findings elsewhere (Simon et al., 2021a). Research should explore the extent to which guided internet-based therapies may be able to play a part in the treatment of people with severe PTSD, people with PTSD to multiple and prolonged traumas, and people with more complex needs (Ashwick et al., 2019; Olff et al., 2019).

4.3 Clinical implications

Guided self-help may increase availability and equitable resources for mental health care globally, potentially addressing unmet needs in many settings where evidence-based psychological interventions are currently inaccessible (Olff, 2015). Guided self-help may however exclude some people if easy read versions or modifiable programmes are not available, and if equipment and mobile network data cannot be provided. Shared decision making would consider an individual's readiness to engage with trauma-focused psychological therapies, holding in mind that some may choose not to engage with internet-based approaches (Ennis et al., 2012). Clinicians may draw on literature identifying opportunities and barriers to working with and rolling out guided internet-based treatments for PTSD (Simon et al., 2021a). For example, a lack of supervision and training have been identified as barriers (Finch et al., 2020), therefore protection of time and resources may be beneficial (Sarre et al., 2018).

Acknowledgements

We thank the trial therapists and fidelity assessors, and CTR trial data managers and database designers, members of the

public advisory group, trial steering committee, independent data monitoring committee, and staff at Healthcare Learning for their technical support. We thank the people who took part in this study for their time and contributions.

Disclosure statement

The 'Spring' programme was developed by and is owned by Cardiff University and, if commercialised, Cardiff University would benefit, as would authors JIB, NK, CL, and NPR.

Funding

This project was funded by the UK National Institute for Health Technology Assessment (NIHR HTA) programme; project No 14/192/97, and has been published in full in the NIHR Health Technology Assessment journal (further information available at www.journalslibrary.nihr.ac.uk/programmes/hta/1419297#/); the NHS costs of the study were funded by the Welsh Government, through Health and Care Research Wales. The funders had no role in considering the study design or in the collection, analysis, interpretation of data, writing of the report, or decision to submit the article for publication. This report presents independent research commissioned by the NIHR. The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, NIHR, Medical Research Council, NIHR Central Commissioning Facility, NIHR Evaluation, Trials, and Studies Coordinating Centre (NETSCC), the HTA programme, or the Department of Health.

Data availability

The dataset is available from the corresponding author.

Statement of ethics

The trial was granted a favourable ethical opinion by the South East Wales Research Ethics Committee (17/WA/0008).

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