Pragmatic randomised controlled trial of guided self-help versus individual cognitive behavioural therapy with a trauma focus for post-traumatic stress disorder (RAPID)

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Scientific summary

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Scientific summary

Background

Post-traumatic stress disorder (PTSD) is a common mental health condition that may develop following exposure to traumatic events that involve threatened or actual death, serious injury or sexual violence. PTSD causes significant distress to those affected by it, often co-occurs with other physical and mental health conditions and is associated with a large economic burden. Face-to-face, trauma-focused psychological treatments (TFPT) have been found to be the most effective currently available treatments for PTSD and are recommended first line by treatment guidelines across the world.

Unfortunately, the limited number of suitably trained therapists available to deliver TFPT in the National Health Service often prevents timely access to treatment and some people find accessing and fully engaging with face-to-face TFPT difficult for other reasons, including work commitments, travel and childcare. Guided self-help (GSH) provides an alternative approach to the delivery of treatment by combining the use of self-help materials with regular guidance from a trained professional and requires less therapist time than recommended face-to-face TFPT. GSH has been shown to be effective for other mental conditions and, if effective for PTSD, GSH would offer a time-efficient and accessible treatment option, with the potential to reduce waiting times and intervention costs.

Objectives

The main aim of the RAPID trial was to determine the likely clinical and cost-effectiveness of GSH using *Spring*, an internet-based programme based on cognitive behavioural therapies with a trauma focus (CBT-TF), for mild to moderate PTSD. RAPID also aimed to describe the experience of receiving GSH using *Spring* from the recipient's perspective, and the delivery of GSH using *Spring* from the therapist's perspective.

The objectives were to determine if:

1. GSH using *Spring* was at least equivalent in effectiveness and cost-effective relative to individual face-to-face CBT-TF for people with PTSD, as judged by reduced symptoms of PTSD and improved quality of life.
2. GSH using *Spring* improved functioning and reduced symptoms of depression, symptoms of anxiety, alcohol use and perceived social support.
3. Specific factors may impact effectiveness and successful roll-out of GSH for PTSD in the NHS.

Methods

RAPID was a multicentre pragmatic randomised controlled non-inferiority trial with assessors masked to treatment allocation. Individual randomisation was used. Economic evaluation was undertaken to determine cost-effectiveness and nested process evaluation to assess fidelity and adherence, dose and factors that may influence outcome (including context, acceptability, and facilitators and barriers, measured qualitatively). GSH using *Spring* was not expected to be more effective than face-to-face CBT-TF, and therefore, a non-inferiority design was chosen.

Participants were recruited from NHS Improving Access to Psychological Therapy services based in primary care in England, and NHS psychological treatment settings based in primary and secondary care in Scotland and Wales. Wide eligibility criteria were used to ensure good external validity. Participants

were aged 18 or over, had mild to moderate PTSD as their primary diagnosis, had regular access to the internet and gave informed consent to take part. Exclusion criteria were inability to read and write fluently in English, previous completion of a course of TFPT for PTSD, current PTSD symptoms to more than one traumatic event, current engagement in psychological therapy, psychosis, substance dependence, active suicide risk and change in psychotropic medication in the past 4 weeks.

Participants were randomised to receive up to 12 face-to-face, manualised, individual CBT-TF sessions, each lasting 60–90 minutes, or to GSH using *Spring*. *Spring is* a manualised, eight-step online GSH programme based on CBT-TF. An initial meeting of 1 hour between the therapist and the person with PTSD is followed by four subsequent fortnightly meetings of 30 minutes, with four brief telephone calls or e-mail contacts between sessions.

The primary outcome was the severity of symptoms of PTSD over the previous week as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) at 16 weeks post-randomisation. Secondary outcomes included severity of PTSD symptoms at 52 weeks, and functioning, symptoms of depression, symptoms of anxiety, alcohol use, and perceived social support at both 16 and 52 weeks post-randomisation. Resource use was also collected to support the health economic evaluation.

Semistructured interviews were conducted with 19 participants and 10 therapists as part of the process evaluation, to gather perspectives of receiving and delivering the interventions, to examine underlying mechanisms and factors influencing future implementation.

Results

One hundred and ninety-six participants were randomised with 82% retention at 16 weeks and 71% at 52 weeks. There were no serious imbalances observed in the baseline data between the two groups. Non-inferiority (margin of 5 points) was demonstrated at the primary endpoint of 16 weeks on the CAPS-5 using the intention to treat principle [mean difference 1.0, 95% one-sided confidence interval (CI) (−∞, 3.9, non-inferiority $p = 0.012$)]. This was also the case for all secondary outcomes at this time point, except for client satisfaction that was inconclusive but in favour of CBT-TF. At 52 weeks post-randomisation, non-inferiority was shown for Multidimensional Scale for Perceived Social Support (MSPSS), Alcohol Use Disorders Test and GSES; non-inferiority was not shown for the other outcomes but the results, which were inconclusive, were in favour of CBT-TF.

Further examination of the Impact of Event Scale-Revised (IES-R) longitudinal measurements indicated that while the GSH group maintained their reduction (improvement) in IES-R scores between the 16- and 52-week assessments, the CBT-TF group continued to improve at a slow rate over the same period. There were no subgroup effects that showed any evidence of difference between the interventions including gender (pre-specified), mode of data collection or assessments conducted after the introduction of the COVID-19 lockdown.

Spring was cheaper to deliver than face-to-face CBT TF [£277 (95% CI £253 to £301) vs. £729 (95% CI £671 to £788)]. When total costs were included, *Spring* was £572 (95% CI £64.96 to £1080.14) cheaper and produced but derived fewer quality-adjusted life-years (QALYs) compared to CBT-TF, −0.04 (95% CI −0.10 to 0.01). At a willingness-to-pay threshold of £30,000 per QALY gained, the probability of GSH being cost-effective was 29.74%. The process data provided evidence of acceptability of the overall trial methodology, although key points were identified for consideration in future randomised controlled design, especially concerning burden and impact of outcome measures on participants and how they are delivered and explained.

Intervention acceptability was indicated for both GSH and CBT-TF interventions, although there was a preference for face-to-face treatment. Therapeutic relationship was an important factor highlighted in

the acceptability of the interventions. Flexibility identified with GSH was seen as positive and some activities within *Spring* were described as more helpful than others.

Conclusions

Implications for health care

- GSH using *Spring* was found to be non-inferior to face-to-face CBT-TF at treating people with mild to moderate PTSD. Significant gains were maintained in the GSH using *Spring* group at 52 weeks but some ongoing improvements in the CBT-TF group appeared to result in largely inconclusive findings with respect to non-inferiority at 52 weeks.
- The additional benefits of GSH using *Spring* with respect to time, cost and convenience, and having another evidence-based treatment option could be argued as outweighing what appear to be minor differences at 52 weeks.
- The results of the RAPID trial should herald a step change in the approach of services to the provision of evidence-based treatment to people with mild to moderate PTSD. There is now an urgent need to make GSH using *Spring* available as a low-intensity treatment option for people with PTSD.

Future research implications

- How best to effectively disseminate and implement GSH using *Spring* at scale, to maximise its impact, is a key research question. This includes identification of the specific skill set and competencies required by a guiding clinician to foster effective alliance and engagement, and the optimal level of training and supervision required for the provision of GSH using *Spring*.
- The optimal amount of guidance is unclear. The quantitative and qualitative results strongly suggest that the current number of facilitation sessions is right for most people but that some people could probably benefit with more. Research into the impact of increased flexibility in delivery and more personalised adaptations is desirable.
- Research is also required to understand the extent to which individuals may or may not be excluded from internet-based treatments due to language and literacy issues, and online access issues, and how best to address these.

Trial registration

This trial is registered as ISRCTN13697710.

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