



Web-assisted Guided Self-help for Post-Traumatic Stress Disorder: The RAPID Trial



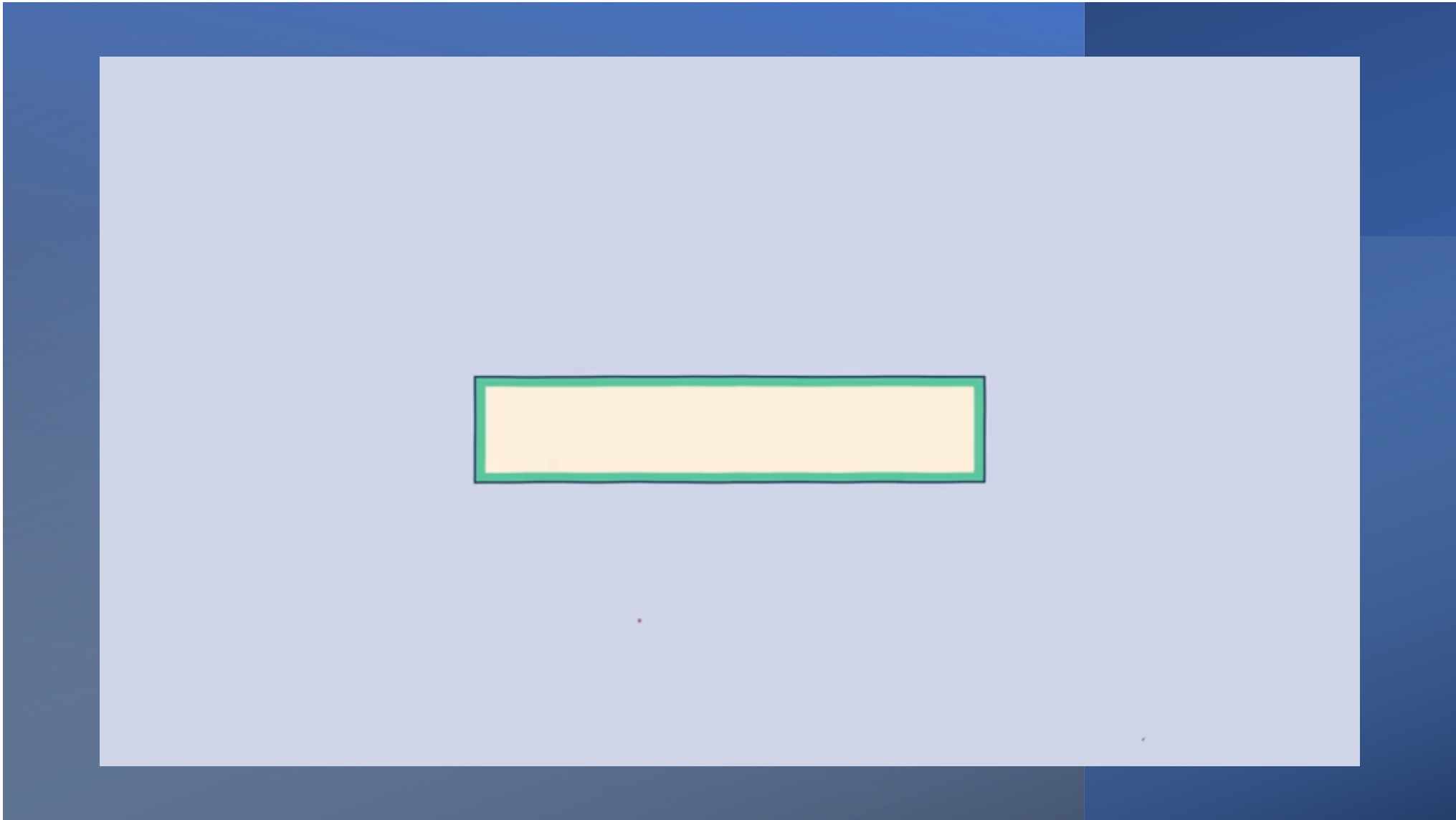
Dr Neil Kitchiner



RAPID Objectives

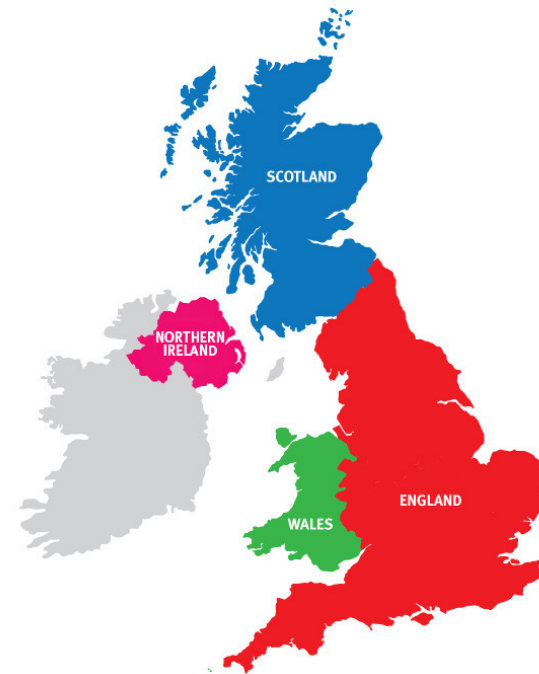
- To determine if GSH using ***Spring*** was at least equivalent in effectiveness (non-inferior) and cost-effective relative to individual face-to-face CBT-TF for people with PTSD
- To describe the experience of receiving GSH using ***Spring*** from the recipient's perspective, and the delivery of GSH using ***Spring*** from the therapist's perspective
- To determine if specific factors may impact effectiveness and successful roll-out of GSH for PTSD in the NHS





Design

- Multi-centre pragmatic randomised controlled non-inferiority trial with nested process evaluation:
 - GSH **not** expected to be more effective than CBT-TF
 - Potential additional benefits, e.g., choice, time, cost and convenience
- Individual randomisation



Eligibility Criteria

- **Inclusion**

- Aged 18 or over
- Primary diagnosis of mild to moderate PTSD to a single event
- Regular internet access
- Ability to read and write fluently in English

- **Exclusion**

- 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
- Change in psychotropic medication in the past four weeks



Interventions

- **GSH using Spring**

- Initial meeting of one hour
- Four subsequent fortnightly meetings of 30 minutes
- Four brief telephone calls or email contacts between meetings

- **Cognitive Therapy for PTSD**

- Ehlers & Clarke (2000)
- Up to 12 face-to-face, manualised, individual, face-to-face weekly meetings of 60–90 minutes
- Augmented by between meeting assignments

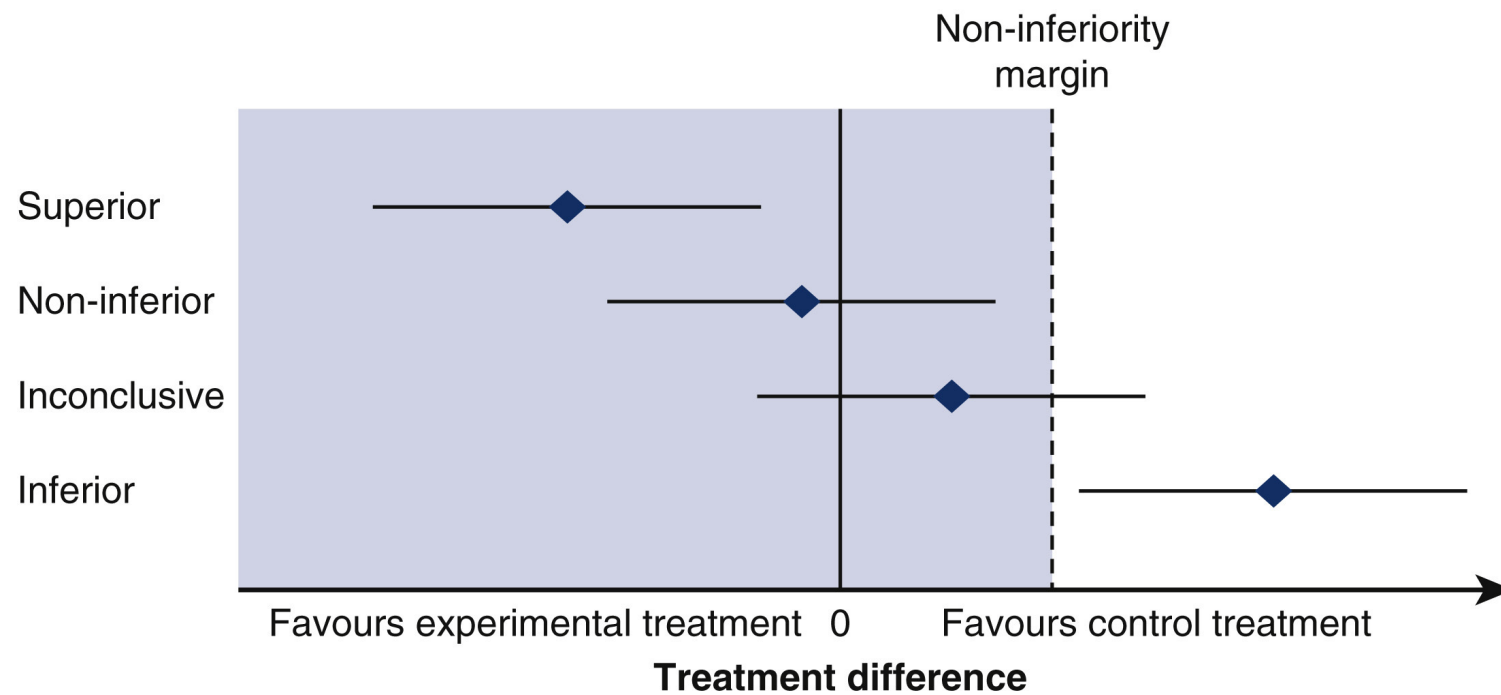


Outcome Measures

- **Primary outcome measure**
 - Clinician Administered PTSD Scale for DSM5
 - Powered to detect a one-sided 95% CI margin of 5 points difference in CAPS-5 scale between the GSH and CBT-TF groups at 16 weeks with 90% power
 - Planned sample size of 192 participants (included an allowance for 20% attrition)
- **Secondary outcome measures**
 - Impact of Event Scale – revised (IES-R)
 - Work and Social Adjustment Scale (WSAS)
 - Patient Health Questionnaire-9 (PHQ9)
 - General Anxiety Disorder-7 (GAD7)
 - AUDIT-O (Alcohol usage)
 - Insomnia Severity Index (ISI)
 - EQ5D-5L (Quality of life)
 - Post-Traumatic Cognitions Inventory (PCTI)
 - General Self-Efficacy Scale (GSES)
 - Multidimensional Scale for Perceived Social Support (MSPSS)
 - The Client Satisfaction Questionnaire (CSQ8)
 - The Agnew Relationship Measure (ARM)

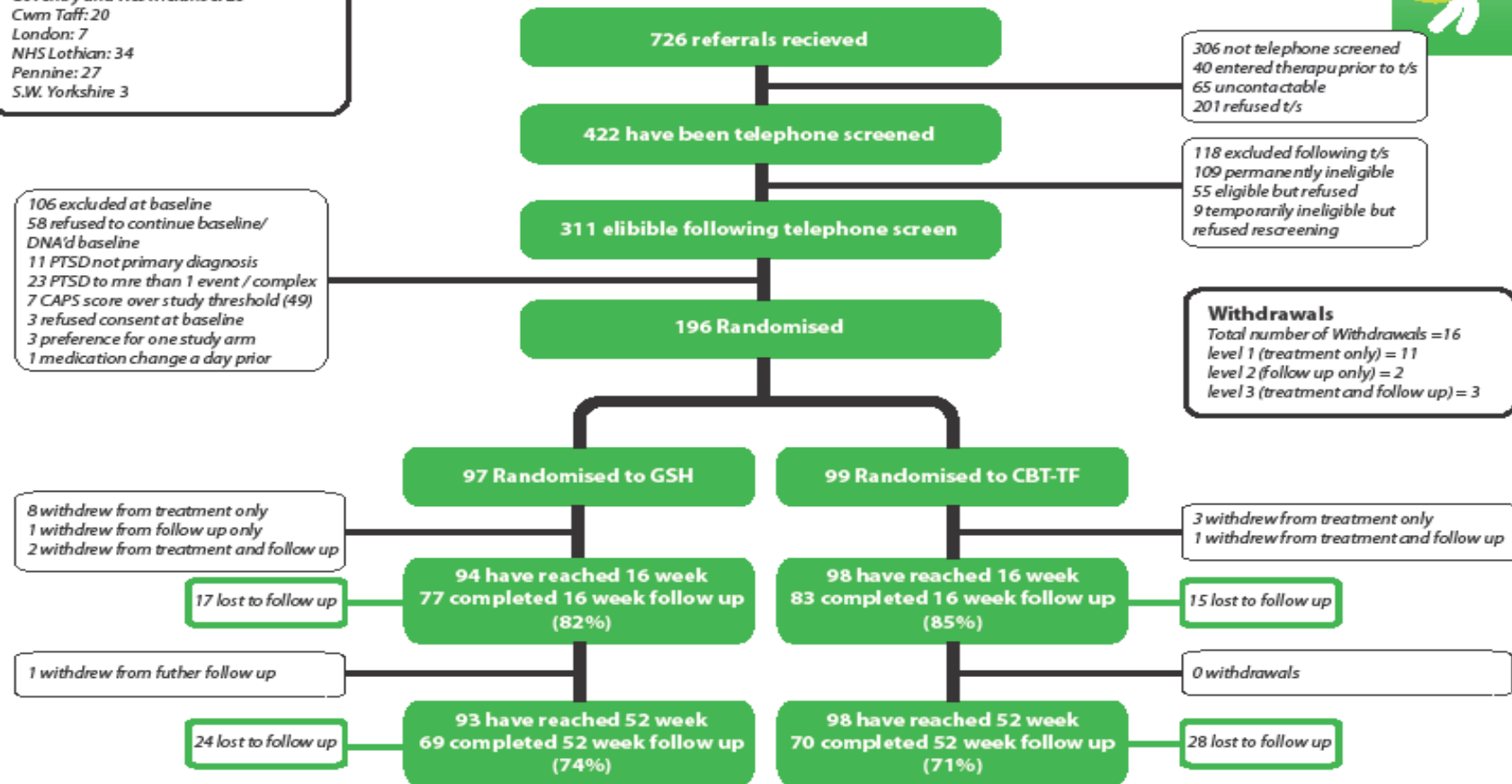


Non-Inferiority Study Design Interpretation

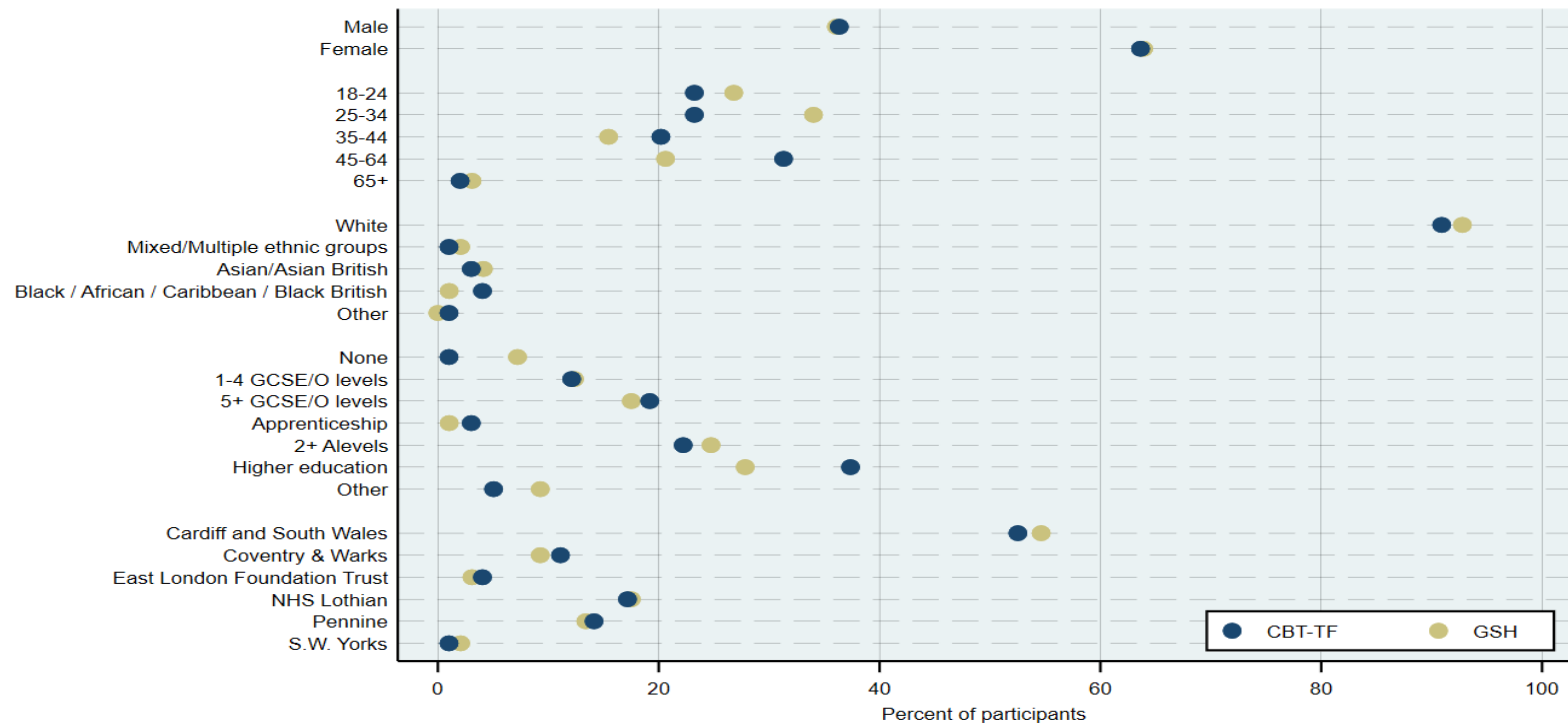


Final Site Recruitment Figures

Cardiff and Vale: 85
Coventry and Warwickshire: 20
Cwm Taff: 20
London: 7
NHS Lothian: 34
Pennine: 27
S.W. Yorkshire: 3

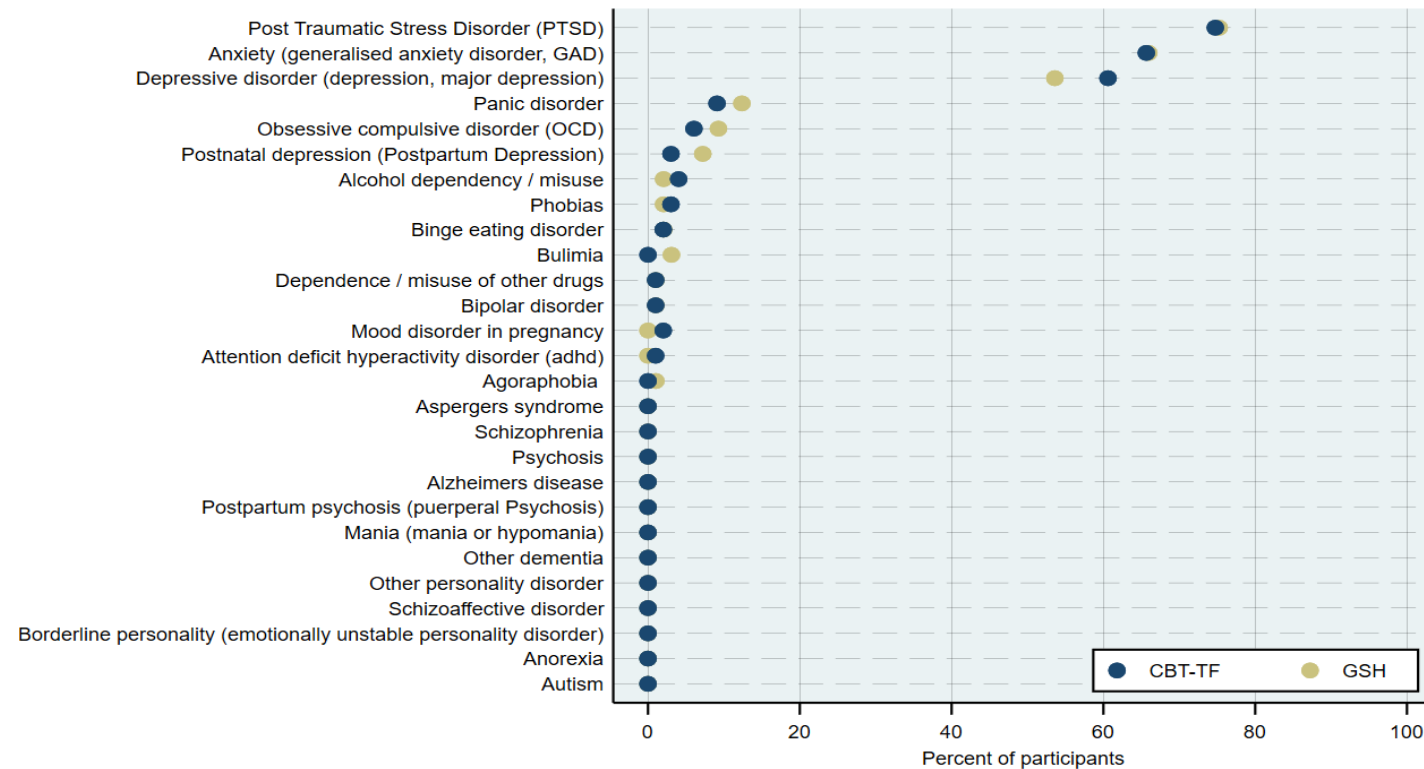
CONSORT Statement for the RAPID Study (ISRCTN 13697710)

Baseline Demographics



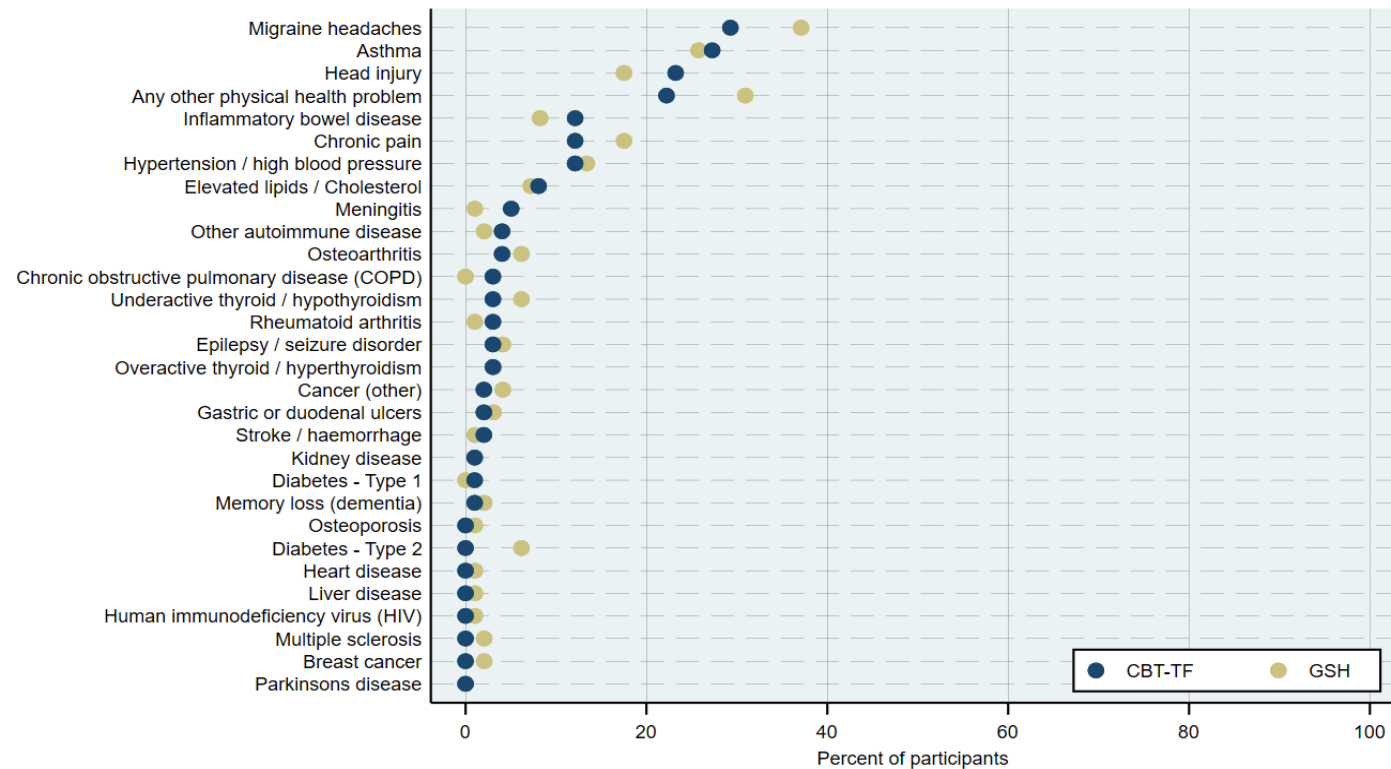
GSH = Guided Self Help; CBT-TF = Cognitive Behavior Therapy - Trauma Focussed.

Baseline Mental Health Issues



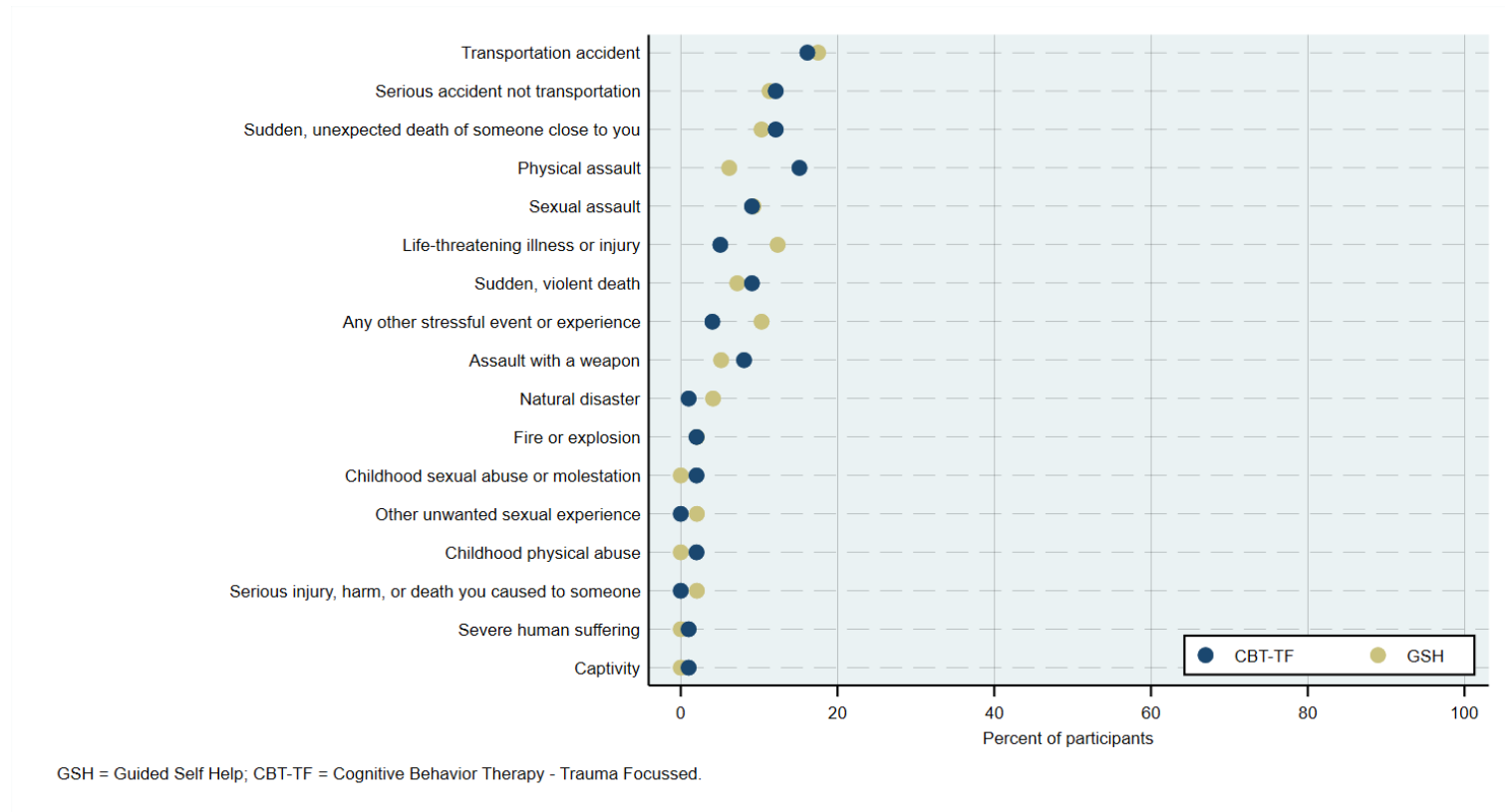
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Baseline Physical Comorbidities

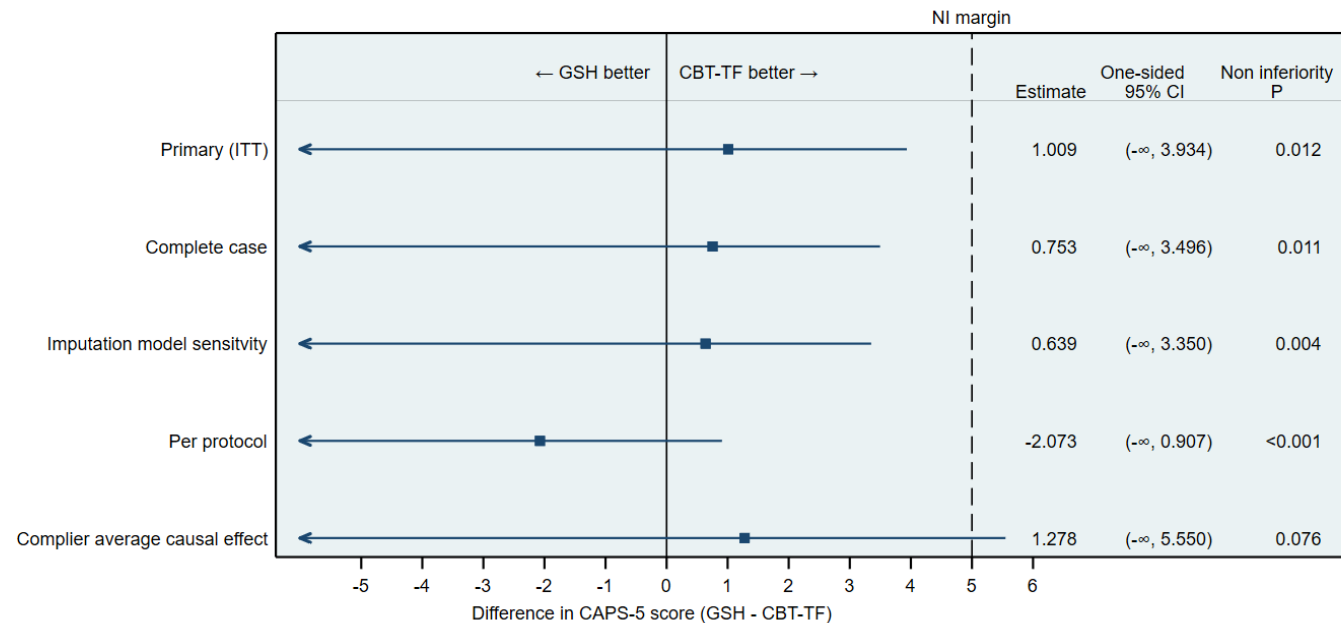


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Worst Traumatic Event Experienced



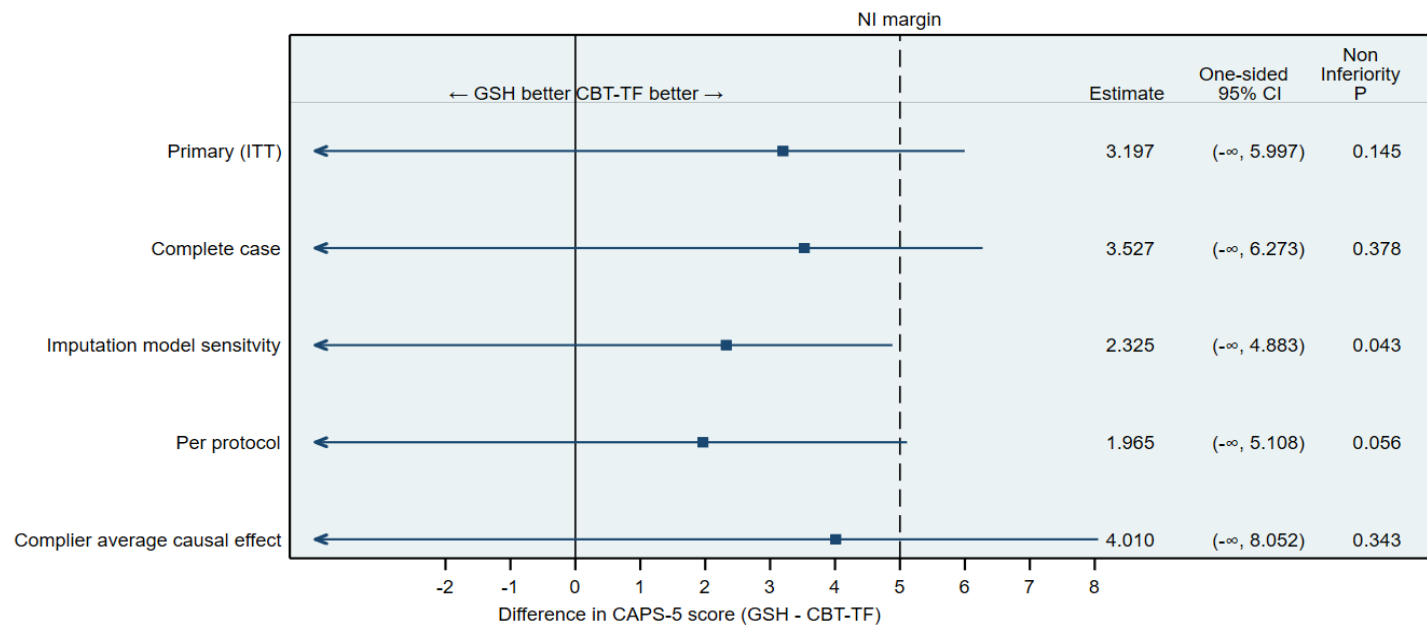
Primary Analysis: CAPS-5 16 Weeks



Note: NI = non inferiority; CI = confidence interval; CAPS-5 = Clinician-Administered PTSD Scale for DSM-5; GSH = Guided Self Help; CBT-TF = Cognitive Behavior Therapy - Trauma Focussed.
Analysis adjusted for the following variables at baseline: CAPS-5 score, gender, research centre, co-morbid depression (baseline PHQ-9) and time since trauma (months).



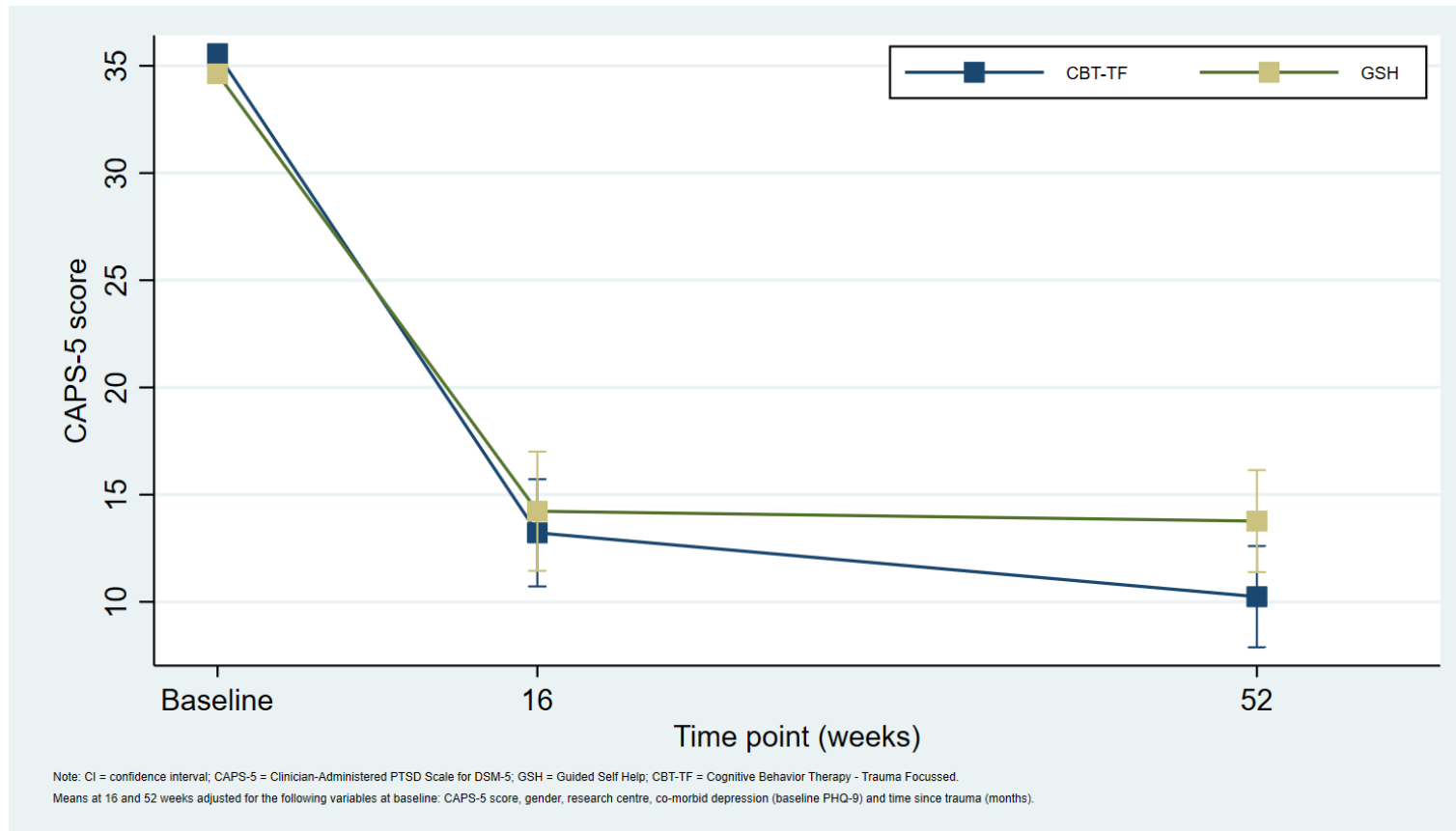
Secondary Analysis: CAPS-5 52 Weeks



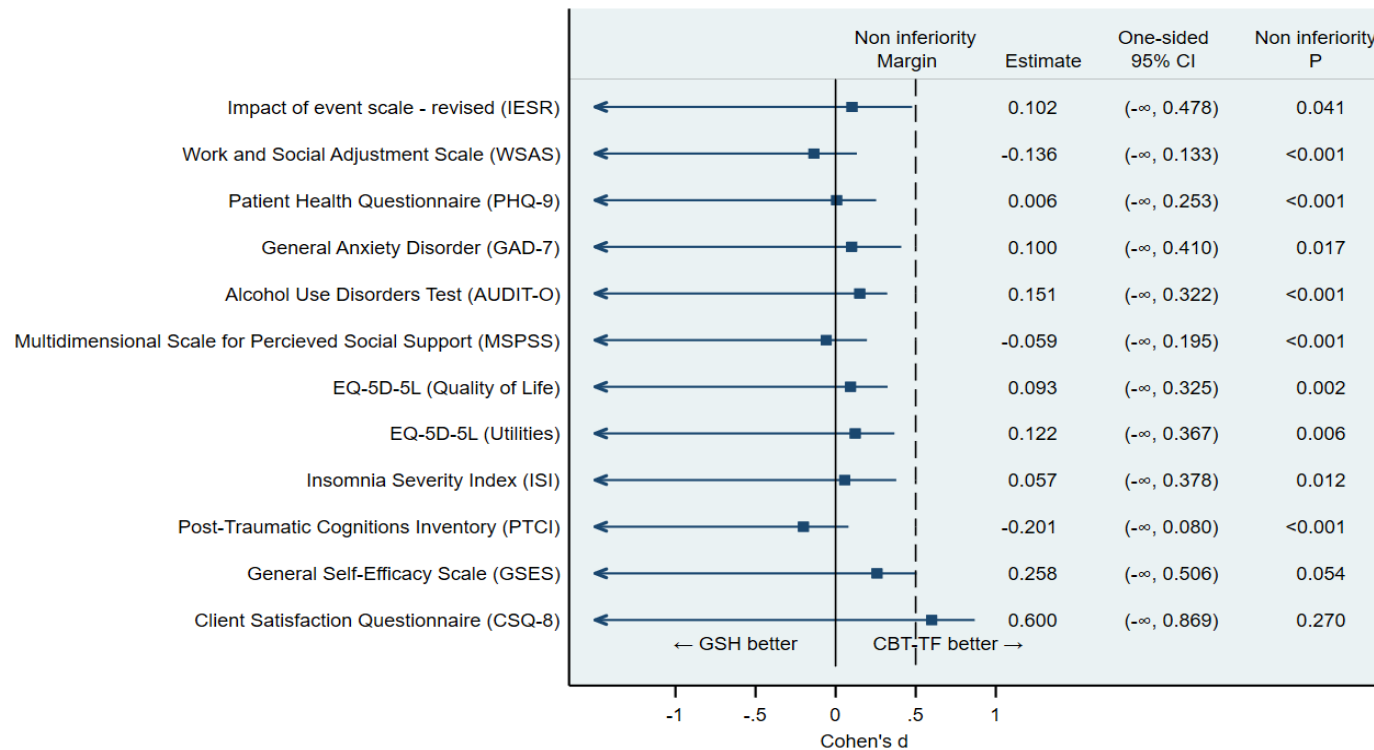
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Adjusted Mean CAPS-5 Scores Over Time



Secondary Outcomes (16 Weeks)

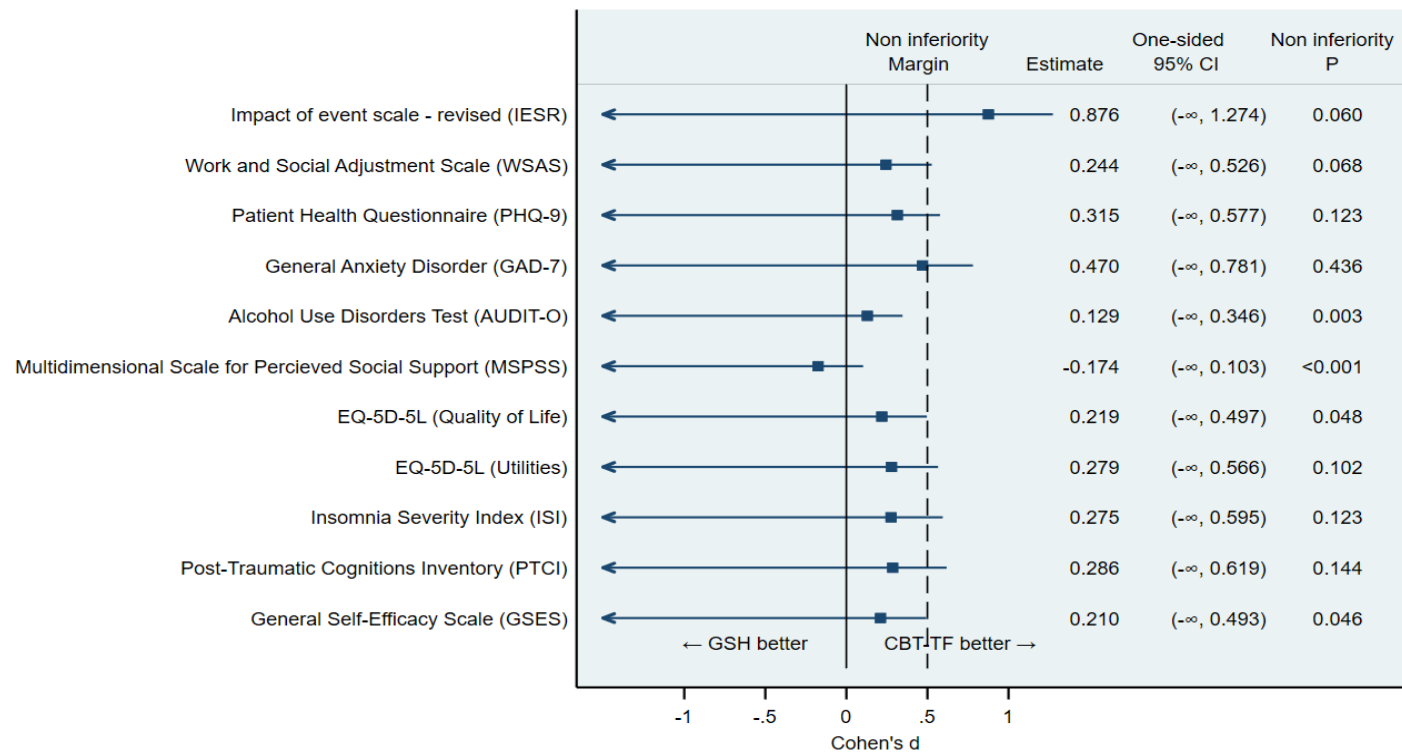


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Secondary Outcomes (52 Weeks)



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Health Economic Evaluation

- Face-to-face therapy appointments

| | <i>Spring</i> GSH | Face-to-face CBT-TF |
|---------------------|-----------------------|------------------------|
| Mean N appointments | 3.9 | 8.6 |
| Mean total time | 208 minutes (SD 69.3) | 767 minutes (SD 278.2) |

- The cost of therapy was calculated as time in face-to-face sessions, phone calls, and non-contact time for note taking.

| | <i>Spring</i> GSH | Face-to-face CBT-TF |
|----------------------|-------------------|---------------------|
| Mean cost of therapy | £277 | £729 |



Summary

- GSH, based on CBT-TF using the *Spring* programme, was non-inferior to face-to-face CBT-TF at reducing PTSD symptoms at the primary endpoint, 16 weeks post-randomisation
- This was also the case for all secondary outcomes at 16 weeks, except for client satisfaction that was inconclusive but in favour of CBT-TF
- Very clinically significant improvements were maintained at 52 weeks post-randomisation, when most results were inconclusive but in favour of CBT-TF
- GSH using *Spring* was not shown to be more cost-effective than face-to-face CBT-TF but was significantly cheaper to deliver and appeared to be well-tolerated



Conclusions

- The RAPID trial showed GSH using ***Spring*** to be a clinically effective, cheaper, well-tolerated and non-inferior treatment to face-to-face CBT-TF for people with mild to moderate PTSD to a single traumatic event
- The results should provide more choice and facilitate improvements to current care pathways for people with PTSD, that result in improved health and wellbeing



