

## STOPS trial versus Costa *et al*: a more accurate analysis

We thank Travers *et al*<sup>1</sup> for highlighting the results of the Specific Treatment of Problems of the Spine (STOPS) trial.<sup>2</sup> However, a number of their assertions are factually wrong, and we strongly disagree with their interpretation of our results.

Travers *et al* argue that the recovery trajectory of the STOPS comparison group (guideline-based advice) was worse than for participant data from a meta-analysis of cohort studies by Costa *et al*.<sup>3</sup> They propose the reason for this was our advice group receiving a patho-anatomical explanation as a component of the advice intervention, which may have had a negative effect. Travers *et al* conclude that the lower than expected recovery trajectory for the STOPS advice group renders our statistically and likely clinically important results favouring the STOPS primary intervention (individualised physiotherapy) over advice as potentially invalid.

### COMPARING APPLES WITH APPLES

Practitioners<sup>4</sup> and researchers<sup>5</sup> understand that the validity and utility of research for clinical practice are influenced by the complexity of low back disorders (LBD).<sup>6</sup> It is therefore essential that interpretation and comparison of research data are conducted using the

principle of ‘apples for apples’. Travers *et al* suggest that the participants in the Costa *et al* meta-analysis were ‘broadly comparable’ with those in the STOPS trial. A closer analysis reveals that this is not the case.

Travers *et al* compare the Costa *et al* recovery trajectories for ‘acute/subacute’ LBD with the STOPS participants. However, this comparison is based on the authors’ erroneous assertion that the Costa *et al*’s acute group had a symptom duration of 0–12 weeks, when in fact it was 0–6 weeks. This renders the data from Travers *et al* on acute LBD irrelevant given the STOPS trials excluded participants with symptom durations of less than 6 weeks. Only the comparison with the ‘persistent’ LBD group is relevant.

The STOPS trial recruited participants with symptom durations of 6 weeks to 6 months (mean of 15.4 weeks). This seems broadly comparable with the Costa *et al* participants with a persistent symptom duration of greater than 6 weeks. However less than 5% of the participants in their review had a symptom duration of over 12 weeks compared with 198/300 (66%) of participants in the STOPS trial. This means the STOPS participants had a substantially longer symptom duration than participants with persistent pain in Costa *et al*, and consequently a worse prognosis.<sup>7</sup> Other unique characteristics of the STOPS trial participants relative to the

studies in the Costa *et al* meta-analysis include the higher rate of disc herniation with associated radiculopathy (18%) and the low loss to follow-up (7% at 12 months). On this basis the attempted comparison by Travers *et al* between the STOPS trial data and the Costa *et al* recovery trajectories is not ‘apples for apples’.

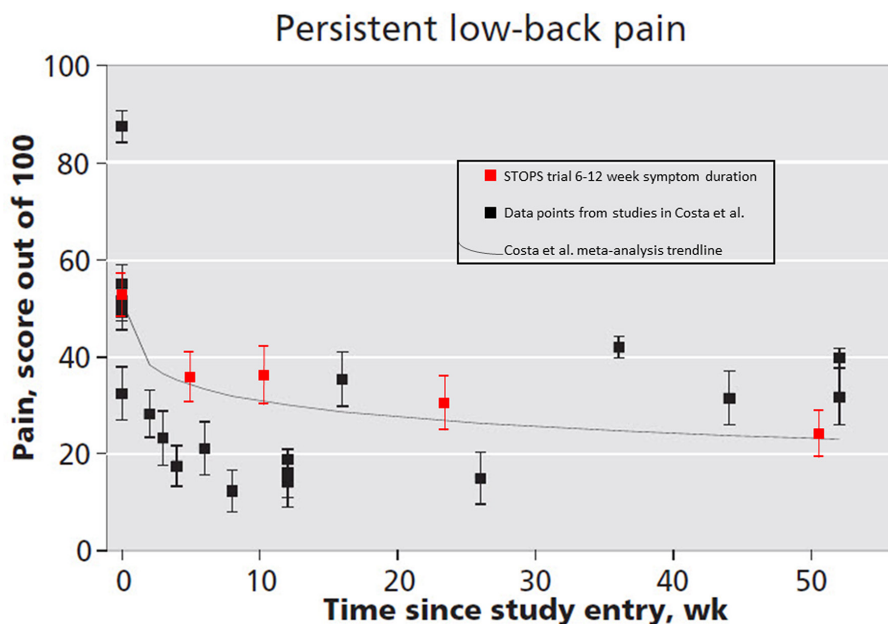
To account for the erroneous assumptions by Travers *et al* regarding duration of symptoms, we extracted the pain data from the STOPS advice group for participants who had a symptom duration of 6–12 weeks and plotted them against the Costa *et al* persistent LBD data (figure 1). When this comparison is made, the trajectory lines between the papers are very similar, with the Costa *et al* trendline falling within the 95% CI of every STOPS trial data point.

In addition, Travers *et al* only included the pain data from Costa *et al* in their comparison. When the disability data from Costa *et al* are compared with the STOPS advice group (again for participants with a symptom duration of 6–12 weeks), the recovery trajectories are very similar. In fact at 1-year follow-up, the STOPS advice group may have had superior outcomes compared with the Costa *et al* participants, given the entire 95% CI for this STOPS data point falls below the Costa *et al* trendline (figure 2).

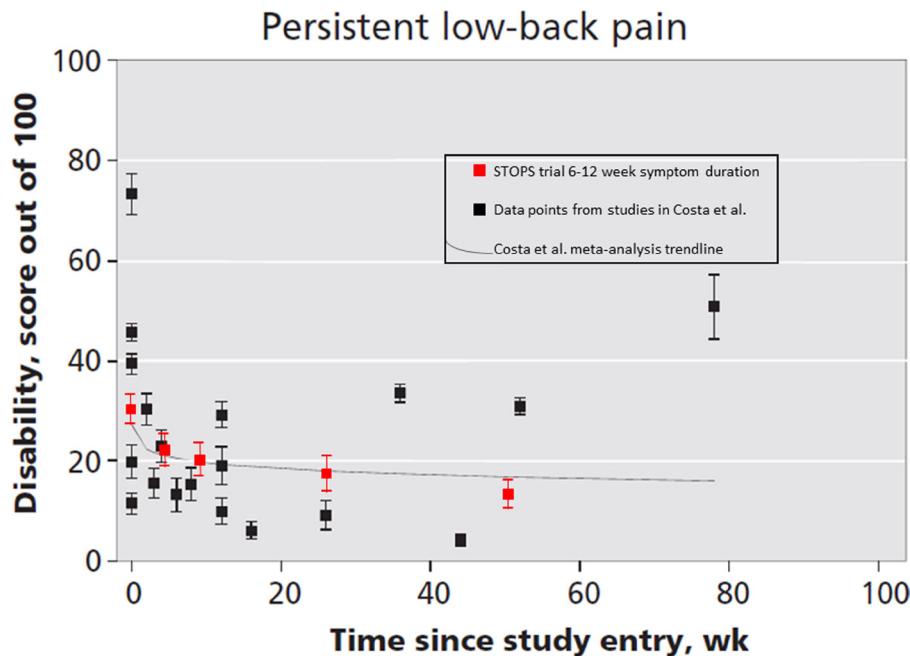
On the basis of a scientifically appropriate and accurate interpretation of the Costa *et al* meta-analysis, it is clear that the proposition that the STOPS recovery trajectories are worse than expected is wrong. Therefore, questioning the conclusions of the STOPS trial on the basis of these data is not appropriate. This demonstrates that comparing randomised controlled trial (RCT) results with other data sets such as the Costa *et al* meta-analysis of cohort studies should only be done with caution and interpreted with care.

### DO WE KNOW THE IMPACT OF ADVICE INCLUDING A PATHOANATOMICAL EXPLANATION?

Travers *et al* suggest it is likely that the pathoanatomical component of the STOPS advice had a negative effect on participant outcomes based on ‘increase(d) perceptions of threat/fragility...exacerbation (of) the pain experience, (and) discouraging early return to normal activities’. Guidelines recommend advice as a primary treatment for acute and subacute LBD<sup>8</sup> despite limited



**Figure 1** Course of pain in patients with persistent low back disorders from Costa *et al*<sup>3</sup> versus the STOPS trial advice participants with 6–12 week symptom duration by Ford *et al*<sup>2</sup> (figure reproduced with permission from the publishers).



**Figure 2** Course of disability in patients with persistent low back disorders from Costa *et al*<sup>3</sup> versus the STOPS trial advice participants with 6-12 week symptom duration by Ford *et al*<sup>2</sup> (figure reproduced with permission from the publishers).

or conflicting evidence.<sup>9</sup> Our sample could be best described as subacute, and in this population the RCT investigating advice with the largest effects included a pathoanatomical explanation.<sup>10</sup> Given this evidence of effectiveness, we based the STOPS advice intervention on the Indahl *et al* protocol.<sup>10</sup>

While it is possible that a pathoanatomical explanation may result in adverse outcomes, data to support this proposition are sparse<sup>11 12</sup> or have a high risk of bias.<sup>13</sup> The outcomes from other trials that have used advice without a pathoanatomical explanation<sup>14</sup> are worse than those reported in the STOPS trial or the original trial by Indahl *et al*. Patients value explanations that include a provisional diagnosis,<sup>15</sup> and our advice intervention was consistent with the biopsychosocial model, incorporating both a biomedical and psychosocial component.<sup>16</sup> The pathoanatomical advice was a small component of the overall advice intervention, with the majority of the consultation time providing reassurance and encouragement to remain active. The STOPS advice intervention was therefore not comparable with studies cited by Travers *et al* that investigated the effect of a pathoanatomical explanation in isolation.<sup>17</sup> To our knowledge there is no evidence that advice combining a pathoanatomical diagnosis with reassurance and encouragement to be active is ineffective. Indeed, this approach is consistent with recent high-quality clinical guidelines.<sup>18</sup>

Finally with our RCT design, we would like to emphasise that both groups received the same advice intervention. Therefore the between-group differences were due to the individualised physiotherapy rather than the advice component. Even if our advice intervention did result in suboptimal outcomes, both groups would have experienced the same degree of negative impact. The important finding of the STOPS trial is that advice was received by both groups, and whatever the effect of this intervention (helpful or otherwise), the superior results in the primary intervention group were attributable to the individualised physiotherapy.

### CONCLUSION

The assertion by Travers *et al* that the results of the STOPS trial should be reconsidered based on the negative impact of advice incorporating a pathoanatomical explanation is not substantiated. Specifically, the recovery trajectory of participants in the STOPS comparison group (guideline-based advice) who were most comparable with the participants in Costa *et al* was very similar to the trajectories depicted in that meta-analysis. Further, our RCT design in which both groups received the same guideline-based advice controls for any effect of that intervention. We therefore stand by the results of the STOPS trial and assert strongly that our trial provides high-quality

evidence that individualised physiotherapy with advice is statistically and likely clinically significantly better than advice alone in improving outcomes for people with LBD.

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