Overview of the SMILE results
By Phil Parker, designer of the Lightning Process and Psychology of Health Researcher, London Metropolitan University

Clinical and cost-effectiveness of the Lightning Process in addition to Specialist Medical care for pediatric Chronic Fatigue Syndrome: randomized controlled trial.
School of Social and Community Medicine, University of Bristol and School of Medicine

This important research, which utilised a Randomised Controlled Trial (RCT - the gold standard of research) to investigate the effectiveness and cost-effectiveness of the Lightning Process in addition to Specialist Medical Care (SMC) compared to SMC alone, for children with CFS/ME, adds considerably to the evidence base into the LP.

It concludes stating 'The **Lightning Process is effective** and **is probably cost-effective** when provided in addition to specialist medical care for **mild/moderately affected adolescents with CFS/ME**.'

Setting and Diagnosis
The study was run by Bristol University in an NHS CFS/ME specialist service, which ensured accuracy of diagnosis of the condition.

Participants
100 participants were randomised to one of two groups, with 49 receiving SMC and 51 receiving SMC+LP (average age was 14, 76% were female).

Measures
The research used a number of standard measures to assess, at baseline, 3,6 & 12 months:

1. Physical function (SF-36 physical function subscale)
2. Fatigue (Chalder Fatigue scale)
3. Days attended at school
4. Anxiety, Depression (Hospital Anxiety and Depression Scale and the Spence Children's Anxiety Scale)
5. Pain (Visual analogue pain scale) (measured at baseline and 6 months)
6. Quality-adjusted life years (QALYs, derived from the EQ-5D-Y)
7. General health and cost effectiveness (adapted 4 item Work Productivity and Activity Impairment: General Health V2.0 and a resource use questionnaire assessing their child's health service use (e.g. GP or specialist care), educational service use (e.g. school counsellor), health related travel and other family costs.)

Results
1. Physical function (SF-36 physical function subscale)
   Mean SF-36 physical function improved more over time in participants allocated to SMC+LP than in those allocated to SMC.
   Participants allocated to SMC+LP had better physical function at six months than those allocated to SMC with an adjusted difference in means 12.5 [95% CI 4.5, 20.5], p=0.003).
   This difference increased to 15.1 (95% CI 5.8, 24.4, p=0.002) at 12 months.

2. Fatigue (Chalder Fatigue scale)
   Participants in the SMC+LP arm had less fatigue (adjusted difference in means -4.7 [95% CI -7.9, -1.6], p=0.003) than those allocated to SMC; this continued at 12 months, although was somewhat smaller (-3.2 [95% CI -6·3, -0·1].

3. Days attended at school
   Participants allocated to SMC+LP had better school attendance at 12 months than those allocated to SMC (adjusted difference in means 0.9 days of school per week [95% CI 0.2, 1.6] p=0.018).

4. Anxiety, Depression (Hospital Anxiety and Depression Scale and the Spence Children's Anxiety Scale)
   Participants in the SMC+LP arm had a greater improvement in anxiety symptoms measured by both the HADS (-3.3, [95% CI -5.6, -1.0], p=0.005) and the SCAS (-8.7, [95% CI -16.9, -0.5], p=0.039) scores at six months. This continued at 12 months, although the different between the two groups was somewhat smaller -2·8 [-4·7, -0·8]. However, the difference in means in SCAS anxiety was greater at 12 months (-12·1 [95% CI -20·1, -4·1] and there was evidence that there was less depression among participants allocated to SMC+LP than those allocated to SMC at 12 months (adjusted difference in means in HADS depression score -1.7 [95% CI -3·3, -0·2] p=0.030).

5. Pain (Visual analogue pain scale) (measured at baseline and 6 months)
   Pain scores were lower in participants allocated to SMC+LP compared with those allocated to SMC at both six and 12 months, but confidence intervals were wide. (This means the results were positive but statistically this was less significant than some of the other findings.)

6. Quality-adjusted life years (QALYs, derived from the EQ-5D-Y)

7. General health and cost effectiveness
   There was good evidence that SMC+LP was probably more cost-effective than SMC alone. This considered two measurements - the reduced costs of using the NHS as a result of improvement (this was not found by the study) and improvement in health related quality of life (this was found by the study). As a result of looking at these two figures, the researchers felt it was, on balance, probably more cost effective.

8. Participants in the SMILE trial **did not have any serious adverse events** attributable to either treatment arm. The lack of serious adverse events is consistent with other treatment trials in CFS/ME. 9 experienced a deterioration in physical function and the majority of these had a deterioration of ≤ 10 on the SF-36 physical function subscale (8 of these were in the SMC arm and 1 in the SMC+LP arm), which is considered to be less than the Minimal Clinically Important Difference (MCID).

Comments/Limitations

Due to the structure of the trial, where the two arms compared were SMC or SMC+LP **the study can only comment that LP is effective in addition to specialist medical care and not whether it is effective on its own.** However, we recognise that most of those attending LP (outside of this study) continue to seek SMC at the same time.

The study only recruited children aged 12 and over who were not housebound and who spoke English. **It can therefore not report on whether LP is effective, acceptable or feasible for those who are severely affected, less than 12 years old or do not speak English**.

The results of the SMC were similar to adults receiving GET or CBT; in the SMC+LP the results are **similar to paediatric trials of those getting CBT**, however in those trials results

were not maintained at 6 and 12 months, whilst **participants in the SMC+LP arm maintained or increased improvements compared to SMC alone at 12 months.**

Further research is needed to understand why LP improves outcomes at 6 and 12 months and which aspects of the LP contribute to its effectiveness.

These results support what LP practitioners and participants have found in clinical practice and show that the LP enhances medical care for this client group, improving results for fatigue, anxiety, pain, depression, school attendance and shows no adverse effects. It also suggests it is probably a cost effective approach.