A systematic review of the evidence base for the Lightning Process

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Abstract

Background

The Lightning Process (LP), a mind-body training programme, has been applied to a range of health problems and disorders. Studies and surveys report a range of outcomes creating a lack of clarity about the efficacy of the intervention.

Objective

This systematic review evaluates the methodological quality of existing studies on the LP and collates and reviews its reported efficacy.

Data sources

Five databases, PsycINFO, PubMed, CINAHL, Embase, ERIC (to September 2018), and Google and Google Scholar were searched for relevant studies.

Study Selection

Studies of the LP in clinical populations published in peer-reviewed journals or in grey literature were selected. Reviews, editorial articles and studies/surveys with un-reported methodology were excluded.

Data extraction

Searches returned 568 records, 21 were retrieved in full text of which 14 fulfilled the inclusion criteria (ten quantitative studies/surveys and four qualitative studies).

Data synthesis and Conclusions

The review identified variance in the quality of studies across time; earlier studies demonstrated a lack of control groups, a lack of clarity of aspects of the methodology and potential sampling bias. Although it found a variance in reported patient outcomes, the review also identified an emerging body of evidence supporting the efficacy of the LP for many participants with fatigue, physical function, pain, anxiety and depression. It concludes that there is a need for more randomised controlled trials to evaluate if these positive outcomes can be replicated and generalised to larger populations.

Keywords

Lightning Process
Systematic review
Patient outcomes

Introduction

The Lightning Process (LP) is a mind-body training programme hypothesised to help individuals to develop a more conscious influence on their neurological function and affect change in physiological processes.[1]
To provide ease of access, the program is delivered via a 4 hr audio home-study program with 1 hr of phone coaching, as preparation for the 3 training seminars (4 hr each) with a registered practitioner, which are delivered face to face or online with 3–8 attendees. It was devised in a similar way to other novel approaches, such as Motivational Interviewing,[2] through an iterative process of practice-based evidence[3] and qualitative inquiries into clients' experience, and its name was suggested by reports of the rapidity of change, as noted subsequently by participants in other studies.[4] It was developed from concepts from Positive Psychology, health education theory, mindfulness, osteopathy, coaching and Neuro-Linguistic Programming (NLP).
It has two phases 1) teaching core concepts and 2) adopting practical tools. In phase 1, participants are presented with relevant theory and research to understand how the mind-body connection can be utilised in order to influence physiology.[5] Particular attention is paid to how language can affect neural pathways[1,6] and the role that patient activation and empowerment,[7,8] chronic stress and response expectancy have on physiology.[9,10] In phase 2 participants learn a set of steps to a) detect disempowering language, negative expectancies

and changes in physiology[11]; b) pause by employing an interruptive ‘stop’ process[12,13] and c) make an active choice to employ a set of self-coaching interventions. The self-coaching includes developing self-compassion[14] and a series of questions designed to identify immediate goals and desired physiological states (to replace those identified in step a). The process is completed by the savouring of positive memories[15] that recall previous experiences of those goals and states, combined with the use of body movements and voice tone and speed,[16,17] congruent with those memories, to encourage improved physiology.

It has been applied to a range of issues, e.g. Multiple Sclerosis, Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME), Complex Regional Pain Syndrome, Chronic Pain and Fibromyalgia, as well as a range of emotional and cognitive issues such as anxiety, depression, dyslexia and dyspraxia.[1,18] It has grown, from its inception in the UK in 1999, to be available in 16 countries and by 2018 had been used by over 23,000 participants.[1]

Early anecdotal reports of positive outcomes from some participants and poor outcomes from others[19] resulted in differing perceptions of the LP´s efficacy. These reports led to a research interest in the approach, although early investigations used a variety of research methods, producing highly varied reports of efficacy and resulting in a lack of clarity amongst stakeholders as to the intervention's value.

The absence of an overview of these studies results and detailed objective commentary on the quality of each study has further contributed to this lack of clarity.

This systematic review aims to resolve this by examining the quality of the evidence base, the studies’ designs and by reviewing the reported efficacy of the intervention. It contextualises and explores the studies’ contribution to understanding the efficacy of the intervention, and using a descriptive narrative[20] provides a synthesis of the research outcomes, its limitations and suggestions for future research.

Methods

The protocol for this review was registered with Prospero[21] reference: CRD42018104336 and this report conforms to the recommendations from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (PRISMA)[22] (see Fig. 1).

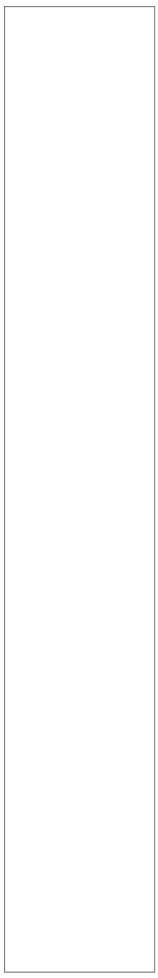

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Fig. 1. PRISMA 2009 Flow Diagram for Systematic Review.

Search strategy

Five electronic reference databases (PsycINFO, PubMed, CINAHL, Embase, ERIC) were searched for the phrase “Lightning Process” in all fields/text. In addition, the authors also conducted manual searches in Google Scholar and Google. The search terms used for this were “Lightning Process” and “Lightning Process” AND ‘study’ OR ‘survey’ OR ‘health’. No date limit was set and articles in all languages were included.

Selection criteria and study selection

The selection criteria are collated in Table 1. Quantitative studies and surveys, including those with cross-sectional designs, qualitative studies and mixed methods studies specific to the Lightning Process intervention published in peer-reviewed journals and grey literature were included. Results were required to

include relevant uses of the phrase ‘Lightning Process’ that referred to studying this intervention and records that did not meet this criterion were excluded (e.g.; Production of perchlorate by laboratory simulated lightning process; the lightning process in thunderstorms).

Table 1. Selection criteria.

P	**Population using the Lightning Process**
I	Lightning Process
C	NA
O	Identify research studying this intervention
S	Cross-sectional designs, qualitative studies and surveys and mixed methods studies published in peer-reviewed journals. Non-peer reviewed articles on surveys or outcome measures studies with a reported methodology.

The Google searches produced over 42,000, mostly non-relevant results, and issue noted by others.[23,24] Therefore, the evaluation was limited to the first 70 results, which provided an adequate buffer to capture key relevant results. Duplicate records were removed and additional records were searched for in the references of the selected records.

Search results

The reference database searches provided a small set of results (PsycINFO = one, PubMed = eight, CINAHL = eight, Embase = eight, ERIC = nine). With the addition of Google and Google Scholar searches a further 560 results were returned.

Six studies were identified from the references of these results and 32 duplicates were removed. This produced a total of 568 records (see Fig. 1) with 21 records identified as potentially eligible and retrieved in full text. Seven studies did not evaluate the LP and were excluded, resulting in a total of 14 studies meeting the inclusion criteria.

Data collection, analysis and quality assessment

Two authors (PP, JA) read and re-read the papers in their entirety and assessed the methodological quality of the selected studies dependent on the study type as suggested by other researchers.[25.], [26.], [27.], [28.], [29.] For evaluating the qualitative studies four review areas (1. Phenomenon studied and context; 2. Ethics; 3 Data collection, analysis and potential researcher bias; 4. Policy and practice implications) suggested by Long and Godfrey[30] were used. The quantitative studies were assessed with the NIH study quality assessment

tools,[31] and the five criteria (1. Clarity of aims and objectives; 2. Appropriateness of research design; 3. Clarity of research process; 4. Relationship of data to results; 5. Appropriateness of method of analysis) identified by Dixon-Woods[25] were used for quantitative surveys.

Any areas identified by these tools as possible sources of bias were evaluated as to their potential effect on the results reported. Following the suggestion by Dixon-Woods[25] to capture the maximum data for review, any rated as 'poor' were to remain within the review but be identified as such in the analysis. Although all 14 studies passed this assessment (see Table 2) potential limitations were identified, which are detailed in the limitations section.

Table 2. Overview of studies.

Author/Year	Title	Country	Method	Peer reviewed/ controlled (PR/C)	N	Age group	Quality
Finch, 2010	LP Snapshot Survey of clients' experiences	INTL	Survey	x	1297	Not reported	Fair
ME association, 2010	Managing my M.E	UK	Survey	x	4217	All	Fair
Sussex & Kent ME/CFS Society, 2010	ME/CFS Patients Survey	UK	Survey	x	457	Not reported	Fair
F0nneb0 et al., 2012	Worst Cases Reported to the NAFKAM International Registry of exceptional Courses of disease	Norway	Case report	x	5	Not reported	Good
Sandaunet & Salamonsen, 2012	CFE-/ME-pas i enters ulike erfaringer med Lightning Process.	Norway	Qualitative	PR	22	Adult	Good
Bringsli et al., 2013	The Norwegian ME Association national survey	Norway	Survey	x	1096	All	Fair
Finch, 2013	Outcome measures study	UK	Quantitative	x	205	All	Good
Reme, Archer & Chalder, 2013.	Experiences of young people who have undergone the Lightning Process to treat chronic fatigue syndrome/myalgic encephalomyelitis - a qualitative study.	UK	Qualitative	PR	9	Adolescent	Good
Crawley et al., 2013	The feasibility and acceptability of conducting a trial of specialist medical care and the Lightning Process in children with chronic fatigue syndrome: feasibility randomized controlled trial (SMILE	UK	Qualitative	PR	56	Adolescent	Good

Author/Year	Title	Country	Method	Peer reviewed/ controlled (PR/C)	N	Age group	Quality
	study)						
Finch, 2014	Lightning Process & Multiple Sclerosis: Proof of Concept Study	UK	Proof of Concept	x	11	Adult	Fair
Hagelsteen & Moen Reiten, 2015	Evaluation of a treatment strategy	Norway	Quantitative	x	12	Adolescent	Good
Landmark et al., 2016	Chronic fatigue syndrome and experience with the Lightning Process	Norway	Survey	PR	196	All	Fair
Kristoffersen et al., 2016	Use of complementary and alternative medicine in patients with health complaints attributed to former dental amalgam fillings	Norway	Survey	PR	324	Not reported	Good
Crawley et al., 2017	Clinical and cost-effectiveness of the Lightning Process in addition to specialist medical care for paediatric chronic fatigue syndrome: randomised controlled trial	UK	Randomised Controlled Trial	PR/C	100	Adolescent	Good

Results

Structure of the review

The reviewed studies were categorised as; (1) qualitative studies and case reports; (2) quantitative surveys and (3) quantitative non-survey studies. Guidance on synthesising the results of systematic reviews involving a complex range of un-uniform study designs led to the utilisation of a narrative and a descriptive presentation of the results framed by these categories in chronological order.[20,32]

Studies' design and methodology

All the studies were undertaken in the UK and/or Norway between 2010 and 2018[19,19,33] (Table 2). The sample sizes ranged from five, in the report from Fønnebø, Dragset & Salamonsen[34] to 4217 in the study from the ME Association.[19] Four studies focused on young people/adolescents, four included participants from all age ranges, two studies focused on adults and four did not

specify age ranges. In all of these studies that reported, gender there were more female than male participants. For studies involving CFS/ME the range reported was from 76%[35] to 95%[4] females. This skewed gender representation was also found in the other studies, although to a lesser degree with 71% for the study from Kristoffersen et al.,[36] 67% for the study from Finch[37] and 58% for the study from Hagelsteen & Moen Reiten.[38] Race distribution was not reported in any of the studies, with the exception of those related to the RCT from Crawley et al.,[18] where participants identified themselves as British.

Qualitative studies

Sandaunet & Salamonsen, 2012. A qualitative study of CFS/ME patients' different experiences with Lightning Process recruited participants via the Norwegian National Research in Complementary and Alternative Medicine (NAFKAM) and their Registry of Exceptional Illness (RESF) .[4]
The participants (N = 22, 95% female) self-reported 10–26 months after the LP-course that they had experienced:

1) Significant improvement (n = 13)
2) No response (n = 6)
3) Adverse response (n = 3)

Responses were analysed using a grounded theory-based process. Three themes of differentiation emerged; "(a) the response to the theoretical basis and the basic principles of the LP (b) experiences of course leader and (c) the body's response to the LP" .[4(p1)] The study identified that trust and communication were important. Those reporting an initial positive response to the LP expressed that they had a greater insight into their illness, that they could trust their trainer and that the positive physical effect of the LP continued after the seminar. These factors were not seen with the other respondents.
Fønnebø et al., 2012. The NAFKAM institute instigated a protocol in December 2011 to create a warning notice for health authorities if they received three negative reports for an alternative treatment from patients with the same condition.[39] As a result, they reported that three patients with CFS/ME had described how they experienced a strong relapse of their symptoms 6 to 12 months after LP, which they all related to the seminar.[34]

Reme, Archer & Chalder, 2012. A qualitative study evaluated the experiences of nine young people (female = 89%, age range 14–26), who had undergone the LP to treat CFS/ME. [40] The opportunistic sample was recruited through the website Association of Young People with ME (AYME) in the UK and data were collected by semi-structured interviews.
Seven adolescents reporting being satisfied and were much or very much better, and two reported lack of satisfaction and absence of improvement.

Helpful aspects of the approach reported included; the theoretical rationale behind the intervention, the techniques they learned and the practical exercises. Less helpful aspects reported were the short duration and intensity of the LP and little follow-up and, for some, the perceived secrecy surrounding the LP. The study noted how the requirement that participants apply the LP tools as a route to recovery was experienced as a sense of being blamed for lack of change by the two participants who noticed no benefit from the intervention.

Crawley et al., 2013. A pilot randomised trial (N = 56, female = 76.4%, mean age = 14.8 years (SD = 1.6), age range 12–18) was undertaken in the UK to evaluate feasibility and acceptability of the recruitment, randomisation and intervention.[35] The study used an integrated qualitative methodology and found that recruitment, randomisation and interventions were feasible and acceptable. Several changes were suggested by participants to improve the experience and value of taking part in the study. These included more appropriate data collection measures (Chalder Fatigue Scale[41]) and SF-36 physical function subscale,[42] rather than school attendance and data collection by phone calls.

Quantitative surveys

Finch, 2010. A survey, carried out in the UK and Norway, evaluated experiences of the LP intervention at the end of the third day of the seminar[33] (N = 1297, female = 78.5%. Reported issues: ME/CFS 84%, depression 34%, anxiety 56%, low self-esteem 57%, guilt 43%).
Results for the question ‘Did you get the changes you wanted?’ are in Table 3. 0.2% of the respondents reported that they still had issues because the training was ‘not good enough or was inappropriate for their needs’.

Table 3. Did you get the changes you wanted? Score your answer out of 10 (0 = definitely no, 10 = definitely yes).

Score Given	0	1	2	3	4	5	6	7	8	9	10
No. of respondents	0	1	0	11	10	32	39	94	188	223	683

Score Given	0	1	2	3	4	5	6	7	8	9	10
% of 1281 respondents	0%	0.1%	0%	0.9%	0.8%	2.5%	3.0%	7.3%	14.7%	17.4%	53.3%
No. of those with CFS/ME	0	1	0	9	7	26	27	77	145	187	601
% of 1080 respondents	0%	0.1%	0%	0.8%	0.65%	2.4%	2.5%	7.1%	13.4%	17.3%	55.65%

ME Association, 2010. A UK based charity survey (N = 4217, female = 78% age range 11–66), asked respondents about their experiences of managing their ME.[19] Perceptions of using 25 different approaches, including standard approaches, such as Cognitive Behavioural Therapy (CBT) (n = 997), Graded Exercise Therapy (GET) (n = 906) and the LP (which was the third least used of the approaches, n = 101) were rated on a Likert scale.

The survey found that the LP received the highest percentage out of all the 25 approaches for those feeling they had 'greatly improved'. A summary of the reported results is presented in Table 4.

Table 4. Results of ME Association Survey, 2010.

Category	Intervention		
	LP (*n* = 101)	CBT (*n* = 997)	GET (*n* = 906)
Greatly Improved	25.7%	2.8%	3.4%
Improved	18.8%	23.1%	18.7%
No Change	34.7%	54.6%	21.4%
Worse	7.9%	11.6%	23.4%
Much	12.9%	7.9%	33.1%

Sussex & Kent ME/CFS Society, 2010. Brighton & Sussex Medical School and the Sussex & Kent ME/CFS Society evaluated the experiences of 457 with CFS (mild 29%, moderate 54%, severe 16%, very severe 1%; female 77%; n surveys sent = 900).[43] Respondents categorised 16 treatments as 'very helpful', 'reasonably helpful' or 'not at all helpful'. The LP received the highest percentage out of all the approaches in the 'very helpful' category and a summary of the reported results is presented in Table 5.

Table 5. Results of Sussex & Kent ME/CFS Society Survey, 2010.

Category	Intervention		
	LP	CBT	GET
Very helpful	44%	24%	12%
Reasonably helpful	36%	50%	51%
Not at all helpful	20%	26%	37%

Bringsli et al., 2013. The Norwegian ME Association surveyed members and visitors to its website (N = 1096, 85% female, age range 11–80+). One question requested the reported effects of 18 interventions,[44] using a Likert scale. A summary of the reported results is presented in Table 6.

Table 6. Results of Norwegian ME Association Survey, 2013.

Category	Intervention		
	LP (*n* = 166)	CBT (*n* = 368)	GET (*n* = 328)
Greatly Improved	8%	2%	1%
Improved	13%	13%	13%
No Change	30%	63%	20%
Worse	22%	14%	41%
Much Worse	27%	8%	25%

Kristoffersen et al., 2016. This study evaluated the 'use of complementary and alternative medicine in those with health complaints attributed to former dental amalgam fillings'[36] using data from the Norwegian Dental Patient Association (NDPA) (N = 324, female = 71.6%) and includes reported responses to the LP (n = 16), with six reporting good effect, seven reporting no change, none reporting a worsening and three non-responders.

Landmark et al., 2016. A call for research[45] published in the Journal of the Norwegian Medical Association reported on a survey evaluation of participants (N = 196, age range 10–76) attending the LP in 2008.[46] Data collected through phone interviews used a structured questionnaire. The majority of participants reported increased activity level (from 3 to 7 on a Likert scale from 1 to 10, where 10 is normal/high level of activity), school and work attendance (from 17% to 60%), time in bed/sofa (from 15 h to 10 h per day) and better life quality (from 3 to 7 on a Likert scale from 1 to 10, where 10 is best). The improvement, compared to baseline, lasted more than a year after the LP. There were no reports of serious adverse effects.

Quantitative studies (non-survey)

Finch, 2013. An interim report was published on an outcome measures, cross-sectional study of LP participants[47] (N = 205, female = 80%, mean age = 37.4 years (SD = 15.6), age range 9–73) using RAND SF-36.[42] The most frequent self-reported reasons for attendance were CFS/ME (64.4%), anxiety/depression disorders (17.1%), Multiple Sclerosis (2.9%) and Fibromyalgia (2.9%). Repeated measures ANOVA using Time of Testing (three levels; pre-test, six weeks, three months) were used to analyse: health change, physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain and general health. The participants reported a significant difference in all sub-scales of RAND SF-36 ($p < .0001$) indicating that the LP is associated with positive change on all dimensions of health tested by RAND SF-36. The significant improvement in

health status persisted in all scales, except the emotion-related measures, at six weeks and three months ($p < .0001$).

Finch, 2014. A proof of concepts study in conjunction with the Multiple Sclerosis Research Council (MSRC) evaluated if the LP could improve outcomes for those with MS.[37] Participants (N = 11, female = 7) were recruited by MSRC in the UK. RAND SF36,[42] Functional Assessment of MS scale (FAMS)[48] and Fatigue Severity Scale (FSS)[49] questionnaires were completed at four time intervals: prior to and six weeks, three and six months after attending the LP seminar. Seven participants remained in the study at the six-month stage, and as a result, missing data were excluded from the analysis. Analysis showed improvements in all sub-scales of the RAND SF-36 at all data collection points, with energy/fatigue levels, general health, role limitations due to emotional problems and emotional well-being showing the greatest change. The MSRC commented that, although the study was of a small scale the results indicated that the LP provides measurable benefits to those with MS.[50]

Hagelsteen & Moen Reiten, 2015. A small-scale treatment evaluation of adolescents (14–18 years) with chronic headaches (N = 12, female = 7) was undertaken in Norway.[38] Pain levels were evaluated using the Visual Analogue Scale[51] and analysis showed that pain was significantly reduced for nine of the participants at three months and this change was maintained at 12 months. The majority also had improved quality of life, were more active and more able to spend time with friends and there was a significant increase in school attendance. The number of participants 'always / almost always in school' had increased from three prior to the LP to eight at one-year post LP.

Crawley et al., 2017. The Specialist Medical Intervention and Lightning Evaluation (SMILE) RCT (N = 100) run by the UK's NHS and University of Bristol compared Specialist Medical Care (SMC) (n = 49) to SMC plus LP (n = 51).[18] SMC comprised a range of approaches including sleep and activity management, CBT for anxiety and low mood and GET. 12–18 year olds (mean age = 14, 76% female) with mild/moderate CFS/ME were recruited for the study. The study found those receiving SMC plus LP had improved physical function at six months compared to those receiving SMC, with an adjusted difference in means 12.5 [95% CI 4.5, 20.5], $p = .003$), and at 12 months this had increased to 15.1 (95% CI 5.8, 24.4, $p = .002$). Those in the SMC plus LP had a greater reduction of anxiety symptoms measured by both the Hospital Anxiety and Depression Scale (HADS)[52] (−3.3, [95% CI −5.6, −1.0], $p = .005$) and the Spence Children's Anxiety Scale (SCAS)[53] (−8.7, [95% CI −16.9, −0.5], $p = .039$)

at six months, and that continued at 12 months. Results also showed a reduction in depression in participants in the SMC plus LP arm compared to those in the SMC arm at 12 months (adjusted difference in means in HADS depression score −1.7 [95% CI −3·3, −0·2] p = .030). Pain scores were reduced in participants receiving SMC plus LP compared with those receiving SMC at both six and 12 months, but confidence intervals were wide and unreported. Those in the SMC plus LP arm had improved school attendance at 12 months compared to those receiving SMC (adjusted difference in means 0.9 days of school per week [95% CI 0.2, 1.6] p = .018). Additionally, it reported evidence that combining SMC with LP was more cost-effective than delivering SMC on its own. This considered the reduced costs of using the NHS as a result of improvement (which was not shown by the study) and increase in health-related quality of life (which was shown by the study), measured by QALYs, derived from the EQ-5D-Y.[54] Although nine participants reported a worsening of symptoms at six months (eight in SMC arm, one in SMC + LP arm), five of these nine had deterioration of ≤10 on the SF-36 physical function subscale (range 0–100) which is considered to be less than the minimal clinically important difference. Notability none of the participants in the SMILE trial had any serious adverse events attributable to receiving either SMC or SCM plus LP, which is a valuable finding for assessing benefits to risk ratios.

In January 2018 the journal editors were contacted with concerns that the paper 'lacked sufficient detail and clarity for readers to fully understand the study as conducted.'[55] An extensive clarification process was undertaken with the authors to address these concerns. This resulted in the publication of a revised version of the paper with 'extensive clarifications to the study's timeline and methods'[55] which, the editors concluded, addressed the criticisms raised.

Discussion

This is the first systematic review to evaluate the quality of the evidence base and collate and review the research on the LP. It presents a timeline of the research as the approach moved from one of practice base evidence, through anecdotal case reports to surveys and finally to peer-reviewed studies, culminating in a well-conducted RCT. There are a number of findings that can be drawn from this review; first, the evidence base is in its early stages, with the first studies appearing in 2010. Second, the quality of the studies has developed with time, with earlier studies being mainly uncontrolled surveys, with potential

issues of bias and the later studies being of higher quality, with clearer methodology, and in the case of the RCT, randomisation and controlling elements.

Limitations

The following limitations are recognised in this review. Several databases were searched, however, others that might have been valuable to include, such as Amed, were not included. Although this had the potential to exclude relevant studies, it was considered that the Google and Google Scholar searches would provide adequate access to studies in journals represented by Amed.

To increase the quality of the review, opinion pieces, forum and blog posts, books, newspapers and magazine articles were excluded,[56,57] but it could be argued that the addition of non-peer-reviewed studies in this review has the potential to lower the quality of the findings. Issues arose from potential bias in selection of participants, which were acknowledged particularly by the authors of the surveys from the ME charities.[19,43,44] Sample sizes, a lack of detail of power calculations and statistical analysis were of concern in selected papers, including the small sample size of three respondents in the NAFKAM report,[34] issues of comparing interventions when the samples sizes for each intervention were different[19,44,58] and from high attrition levels, such as Finch's 2014 MS study. The surveys reported participants' experiences at one time point, Finch's 2010 survey, for example, being undertaken shortly after attending the LP, and are thus limited in assessing longevity of effects. Additionally, limitations common to surveys, concerning self-report and lack of information about clarity of diagnosis,[59,60] an issue that is the cause of strong debate in CFS/ME studies,[61,62] may affect the quality of the included studies.
In the qualitative studies, the positive or negative outcomes were described, as is usual practice, by self-report. As a result, these naturally lack confirmation through validated measures and have the potential to ascribe cause and effect where it may not be appropriate, particularly where the effect is reported 6–12 months after receiving an intervention.[4,34] However, it was decided that maintaining an awareness of, and commenting on the research quality, justified their inclusion and in turn increased the comprehensiveness of this review. As with other studies reporting one author (PP) as the originator of the intervention central to the studies being reviewed, the potential for bias was recognised and

a series of reflexivity procedures as suggested by researchers[63,64] were implemented by the authoring group during all phases of the study to ameliorate this.[65]

Outcomes of the LP

The studies showed that there was a range of participant's responses to the LP. However, the most robust study reported here, the RCT,[18] and the non-survey quantitative studies, reported significant outcomes in a range of measures. Additionally, all the studies and surveys in the review identified a level of benefit from the intervention. Given the range of conditions participants presented with, this suggests that the LP has a broad degree of applicability.
The studies also suggest that positive outcomes were not experienced by all, and in the qualitative studies and earlier surveys, a worsening was reported by some.[4,34,40] However, the RCT[18] did not find any adverse events attributed to either the SMC or SMC +LP arm of the trial. Although reports of worsening after treatment is a finding seen in studies on other interventions for CFS/ME,[19,34,66] these reports highlight issues for the LP organisation to reflect on and learn from. These include the reports of issues of practitioner communication, with some participants reporting feeling blamed or instructed to ignore symptoms,[4,34,40] although a language barrier might be an issue in these two 2012 Norwegian studies, where the seminars were delivered in English to Norwegian speakers. While this sense of blame is counter to published materials on the LP approach,[1,8,67] it raises issues with communication, or understanding, of the core concepts, which the organisation and practitioners have reportedly have begun,[68] to take action to address. This variability in responses raises important research questions as to why the LP is reported to have a statistically significant effect in a variety of standardised measurements and no change for others.

Clarity about the LP

The review also notes the variance and accuracy of reporting of the mechanics and aims of the process.[4,40,45,69] It is anticipated that the recent paper on the LP hypothesis[1] and the publication of this review will encourage discussion between researchers and those directly involved in the LP to ensure more clarity of description for future studies.

Conclusion

In conclusion, this review identified that there is a developing body of evidence supporting the efficacy of the LP for many participants, although it found a range of reported outcomes to the intervention and a variance in the reported descriptions of the mechanics of the approach. There is a variance in the design and quality of the studies, with the more recent studies being of higher quality and better designed than earlier, non-peer-reviewed ones.

Research to date points to the LP as a developing field of interest which potentially provides additional solutions to a range of illnesses with currently poor treatment outcomes. It is also clear that more research is needed with larger populations to 1) identify who would most benefit from the approach, 2) further evaluate its efficacy, ideally by comparing the LP to a single intervention, to identify if the results of the RCT can be replicated on a larger scale and with adult populations and 3) explore the accuracy of its hypothesised mechanisms with a range of biochemical and functional imaging investigations.

Declaration of Competing Interest

PP declares an interest in the intervention The Lightning Process as its originator; JA declares an historical interest in the Lightning Process as a former practitioner; LDR declares no interest in the subject under study.

Appendix. Supplementary materials

Download : **Download spreadsheet (10KB)**

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