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Research article

Portion perfection and Emotional Freedom Techniques to assist bariatric patients post surgery: A randomised control trial

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ABSTRACT

Background: Although significant health improvements are indicated from weight-loss following bariatric surgery, many individuals are unable to lose weight or maintain their weight-loss. The current study aimed to assess whether post-surgery care comprising Emotional Freedom Techniques (EFT), an emerging energy psychology intervention, combined with a behaviour-based nutrition and portion control eating plan in an online self-guided delivery would aid weight-loss and maintenance in bariatric patients.

Methods: A 6-month randomised controlled parallel-group trial. Participants (N = 343; aged 21–69 years; BMI ≥30 kg/m²) had undergone bariatric surgery (12 + months prior) and were randomly assigned to one of three treatment groups: Portion Perfection for Bariatric Patients (PPBP; n = 109), PPBP combined with an eight-week online self-paced EFT treatment (n = 107), and a treatment as usual (TAU) control (n = 127). Participants completed measures of BMI, emotional eating, uncontrolled eating, food cravings, and self-esteem at 8-week post-treatment (n = 158) and 6-month follow-up (n = 109).

Results: Mixed-design analyses of variances were conducted to examine the effect of the interventions on outcome measures (pre-intervention, 8-week post-intervention, and 6-month follow-up). Emotional eating decreased significantly from pre-intervention to post-intervention for the PPBP and PPBP with EFT groups, and at 6-month follow-up for the TAU group only. There were no statistically significant between-group differences in other outcome variables. However, at 6-months the PPBP with EFT group experienced the greatest improvements in emotional eating (-16.33%), uncontrolled eating (-9.36%), and self-esteem (+4.43%), compared to PPBP only or TAU.

Conclusion: The effect of EFT combined with the eating plan on psychological variables was largely inconsistent with prior research and discussion of how this may be optimised in future trials is discussed.

Clinical trial registration: ACTRN12616001257459.

1. Introduction

In a society where obesity (body mass index [BMI] ≥ 30 kg/m²) is a primary health concern, bariatric surgery has offered successful treatment for weight-loss in the majority of eligible patients, significantly reducing mortality from comorbid diabetes, heart disease, and cancer [1, 2]. Despite the health effects, 20–30% of bariatric patients retain significant weight [3, 4], and three-quarters report weight regain two years post-surgery [5]. While primary post-operative care such as structured diet plans attempt to modify types and volume of food consumed by bariatric patients [6, 7], further help is needed to change dysfunctional eating behaviours [7]. Accordingly, the current study aimed to investigate whether post-bariatric surgery patient outcomes could be enhanced via a standalone behaviour-based treatment, Portion Perfection for Bariatric Patients (PPBP), or by combining PPBP with the emerging energy psychology intervention of Emotional Freedom Techniques (EFT).

1.1. Nutrition and portion control

Based on the idea that vision plays a significant role in food consumption [8], the PPBP kit educates bariatric patients about healthy eating and nutrition using visual aids (e.g., sectioned dinner plate representing appropriate food group portioning) [9, 10]. Since individuals

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lose significantly more weight when using a portion control plate than with dietary teaching alone [11, 12], PPBP is considered an efficacious resource for post-operative bariatric patients.

1.2. Emotional and psychological components of weight

In addition to dietary care post-bariatric surgery, the emotional and psychological aspects of obesity and weight gain appear instrumental in weight-loss management [13, 14]. Psychological factors associated with weight in bariatric patient samples include disinhibited eating [15, 16], binge eating [17], and self-esteem [18]. Eating in response to aversive emotions can significantly influence food consumption for obese individuals [19, 20]; however, there is a paucity of such research in bariatric surgery patients. Therefore, it is important to examine a therapeutic technique that may positively influence psychological outcomes associated with long-term weight management for bariatric patients.

1.3. Emotional Freedom Techniques (EFT)

EFT is a novel intervention that combines aspects of exposure and cognitive therapy with somatic stimulation. Fingers are tapped on specific face and body nerve endings, known as acupoints [21], while the brain attends to cognitions associated with emotional distress. EFT begins with a verbal expression of a setup statement, comprising a negative cognition with a self-acceptance statement. Tapping rounds involve a repeated verbal expression of the set-up statement and focus on a (usually negative) emotion, providing the exposure therapy [22], followed by acupoints stimulation to counter-condition the heightened emotional state. Emotional distress is rated using a subjective unit of distress (SUD) scale [23], and tapping rounds are repeated until the SUD rating is low [24]. For example, if a strong food craving for pavlova was rated a seven, tapping rounds would continue until the food craving intensity decreased to two. Clinical EFT meets the standards set out by Division 12 (Clinical Psychology) of the American Psychological Association (APA) as an evidence-based practice [25]. The psychological and physiological benefits of EFT include the treatment of anxiety, post-traumatic stress, self-esteem, mental well-being [26], weight-loss [27], food cravings [28], and pain [29].

The current study aimed to assess whether a self-guided and online EFT program combined with a behaviour-based nutrition and portion control eating plan would aid weight-loss and maintenance in bariatric patients. The three hypotheses included: that the PPBP with EFT group participants would experience greater reductions in food cravings, emotional eating, and uncontrolled eating and improvement in self-esteem than the PPBP only and TAU participants from pre-intervention to 8-week post-intervention. Secondly, improvement in the psychological outcome variables from pre-intervention to 8-week post-intervention would be maintained over time at 6-month follow-up. Thirdly, at the 6-month follow-up, the PPBP with EFT group would experience greater weight-loss compared to the PPBP and TAU groups.

2. Materials and methods

2.1. Trial design and setting

The current randomised controlled clinical trial employed a mixed within (pre-intervention, post-intervention, 6-month follow-up) and between (control vs PPBP vs PPBP with EFT) subjects design. Participants provided informed consent. Outcome variables assessed via $3 \times 3$ analysis of variance (ANOVA) included BMI, emotional eating, uncontrolled eating, food cravings, and self-esteem. Funding was received from the [edited out for blind review]. Interventions were provided free of charge to participants.

2.2. Participants and procedure

Following study eligibility screening, 357 participants were randomly allocated to one of three groups. The flow of participants throughout the trial is detailed in Figure 1. The final sample (6-month follow-up) consisted of 102 women and six men (aged 21–69 years; $M = 47.35$, $SD = 9.74$). Participants were recruited through social media sites (e.g., Facebook, Instagram) in bariatric patient groups and study-related hashtags. Inclusion criteria included a current BMI $\geq 30$ kg/m$^2$, having undergone bariatric surgery $\geq 12$ months prior as the first weight-loss operation, be residing in the United States of America or Australia, and aged between 18 and 80 years. A computer randomisation generator allocated participants to one of the three conditions: PPBP ($n = 109$), PPBP with EFT ($n = 107$), and treatment as usual (TAU; $n = 127$). A total of 158 participants completed the 8-week post-treatment measures and 109 participants completed 6-month follow-up measures (PPBP ($n = 28$), PPBP with EFT ($n = 43$), and control ($n = 37$)) that were matched to pre-treatment measures via email address. TAU group participants were asked to continue post-surgery dietary care as usual. PPBP group participants were asked to follow a PPBP kit that was mailed to them, while the PPBP with EFT group participants were asked to use the PPBP kit in addition to an eight-week online self-paced EFT treatment.

2.3. Ethical approval statement

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional (the university’s Human Research Ethics Committee) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards [30].

2.4. Informed consent statement

Informed consent was obtained from all participants included in the study.

2.5. Interventions

2.5.1. Portion Perfection for Bariatric Patients (PPBP)

The PPBP kit comprised a PPBP book, 4-week Menu Plan book, Healthy Snack Bible, and portion plate and bowl (see Figure 2), which provided information on nutritional considerations and daily recipes ideas in portion-sizes appropriate for bariatric patients. Additionally, participants had access to a private Facebook group for further support with queries answered by the first author.

2.5.2. PPBP with EFT

Participants were provided with the PPBP kit (as described above) and EFT intervention online over eight weeks, consisting of six hours of videos presented by a Clinical and Health Psychologist trained in EFT. Videos were divided into seven self-paced modules that contained a varying number of lessons (see Table 1). Module topics focused on using EFT for food-related issues such as emotional eating, physical activity, drinks, and mindful eating. Participants were required to complete a brief quiz before access to the ensuing module was permitted. Participants were provided weekly emails and had access to a private Facebook group for further support and information.

2.6. Measures

2.6.1. Body mass index (BMI)

BMI was calculated using self-reported weight and height measurements. BMI is defined as weight in kilograms divided by height in metres squared (kg/m$^2$).
2.6.2. Emotional eating

The Three-Factor Eating Questionnaire-Revised 18 (TFEQ-R18) [31] assessed emotional eating (i.e., consumption of food in response to emotional distress), cognitive restraint (i.e., deliberate restriction of food), and uncontrolled eating (tendency to lose eating control and consume excess food). The TFEQ-R18 has good construct validity, supporting its use as a measure of eating behaviours [32]. In the current study, Cronbach’s alphas for emotional and uncontrolled eating were .81 and .87 respectively.

2.6.3. Food cravings

The Food Craving Inventory (FCI) [33] is a 37-item scale that assesses food craving intensity for different food types. The scale provides sub-scale scores for high fats, sweets, carbohydrates, and fast food fats, in addition to a global measure of food cravings. Items are scored on a 5-point Likert-type scale ranging from 1 (Never) to 5 (Always/Almost Every Day), with higher scores reflecting greater cravings. In the present study, Cronbach’s alpha (.88) for total FCI scores indicated good internal consistency.
Five 3 × 3 mixed design ANOVAs examined the main effects of treatment group (TAU vs. portion perfection group vs. EFT & portion perfection group) and time (pre vs. post-intervention vs. 6-month follow-up), in addition to the interaction of treatment group and time for BMI, emotional eating, uncontrolled eating, food cravings, and self-esteem. Descriptive statistics for outcome variables are displayed in Table 3.

3.1. BMI

There was significant main effect for time, \( F(2, 210) = 3.341, p = .050 \), partial \( \eta^2 = .031 \). Pairwise comparisons indicated BMI post-intervention (\( M = 36.40, SD = 6.12 \)) was significantly lower than pre-intervention (\( M = 36.99, SD = 6.08 \)), \( p = .040 \). BMI at 6-month follow-up (\( M = 36.77, SD = 6.08 \)) was not significantly different from BMI at pre-intervention or BMI post-intervention. There was no significant difference in BMI between groups, \( F(2, 105) = .518, p = .597 \), partial \( \eta^2 = .010 \), or for the time × group interaction, \( F(4, 210) = .178, p = .917 \), partial \( \eta^2 = .003 \).

3.1.2. Emotional eating

While emotional eating did not significantly differ between groups, the group × time effect was significant, \( F(2, 210) = 34.848, p = .001 \), partial \( \eta^2 = .249 \). Simple effects analyses revealed differences in emotional eating across all groups: PPBP group, \( F(2, 54) = 10.403, p < .001 \), partial \( \eta^2 = .278 \); PPBP with EFT group, \( F(2, 84) = 24.804, p < .001 \), partial \( \eta^2 = .371 \), and TAU group, \( F(2, 72) = 4.422, p < .015 \), partial \( \eta^2 = .109 \). Decreases in emotional eating from pre-intervention to post-intervention and from pre-intervention to 6-month follow-up were found in the PPBP and PPBP with EFT groups, but only from pre-intervention to 6-month follow-up in TAU participants.

3.1.3. Uncontrolled eating

A significant main effect for time was obtained \( F(2, 210) = 22.345, p = .001 \), partial \( \eta^2 = .175 \). Pairwise comparisons showed significant decreases from pre-intervention (\( M = 22.93, SD = 5.25 \)) to post-intervention (\( M = 20.73, SD = 6.09 \)), \( p = .001 \), and pre-intervention to 6-month follow-up (\( M = 20.27, SD = 5.81 \)), \( p = .001 \) only. There was no difference in uncontrolled eating between groups, \( F(2, 105) = 1.341, p = .262 \), partial \( \eta^2 = .010 \). There was no significant difference between groups, \( F(2, 105) = .262, p = .774 \), partial \( \eta^2 = .010 \), or for the time × group interaction, \( F(4, 210) = .955, p = .425 \), partial \( \eta^2 = .018 \).

Table 1. Outline of the online EFT sessions.

<table>
<thead>
<tr>
<th>Session</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Introduction to EFT</td>
<td>• EFT treatment overview.</td>
</tr>
<tr>
<td>(2) Tapping on less healthy foods</td>
<td>• Food cravings (e.g., intense emotional urges to eat) and their relationship to binge-eating episodes.</td>
</tr>
<tr>
<td></td>
<td>• EFT demonstrations to reduce food cravings.</td>
</tr>
<tr>
<td>(3) Tapping on healthier foods</td>
<td>• EFT and healthier food choices.</td>
</tr>
<tr>
<td>(4) Tapping on emotions</td>
<td>• EFT and emotions.</td>
</tr>
<tr>
<td>(5) Tapping on emotional eating</td>
<td>• EFT and links between primary emotions (i.e., anger, guilt, shame) and emotional eating and food cravings.</td>
</tr>
<tr>
<td>(6) Tapping on increasing the desire for physical activity</td>
<td>• EFT and motivation for exercise.</td>
</tr>
<tr>
<td>(7) Tapping on drinks</td>
<td>• EFT and healthier drink choices.</td>
</tr>
<tr>
<td>(8) Tapping into mindful-intuitive eating</td>
<td>• Stress, emotional eating and cravings, and mindful-intuitive eating</td>
</tr>
</tbody>
</table>

Table 2. Results from one-way ANOVAs to assess variables at pre-intervention.

<table>
<thead>
<tr>
<th>Variable</th>
<th>( F )</th>
<th>( df )</th>
<th>( p )</th>
<th>( SE )</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI</td>
<td>0.541</td>
<td>2</td>
<td>.004</td>
<td>0.59</td>
<td>33.83</td>
<td>38.15</td>
</tr>
<tr>
<td>Emotional Eating</td>
<td>0.906</td>
<td>2</td>
<td>.007</td>
<td>0.19</td>
<td>9.85</td>
<td>10.59</td>
</tr>
<tr>
<td>Uncontrolled Eating</td>
<td>0.133</td>
<td>2</td>
<td>.05</td>
<td>0.50</td>
<td>21.93</td>
<td>23.93</td>
</tr>
<tr>
<td>Food Craving</td>
<td>1.391</td>
<td>2</td>
<td>.253</td>
<td>1.50</td>
<td>59.15</td>
<td>64.94</td>
</tr>
<tr>
<td>Self-esteem</td>
<td>2.591</td>
<td>2</td>
<td>.080</td>
<td>0.54</td>
<td>25.31</td>
<td>27.44</td>
</tr>
</tbody>
</table>

Note. SE = Standard Error Difference. CI = Confidence Interval for Mean.
and maintenance for individuals (BMI with Emotional Freedom Techniques (EFT) could improve weight-loss treatment, Portion Perfection for Bariatric Patients (PPBP), combined

4. Discussion

A significant main effect for time was obtained $F(2, 210) = 29.993, p = .001$, partial $\eta^2 = .222$. Pairwise comparisons indicated decreases in food cravings from pre-intervention ($M = 62.05, SD = 15.161$) to post-intervention ($M = 53.77, SD = 13.61$), $p = .001$, and pre-intervention to 6-month follow-up ($M = 54.43, SD = 13.58$), $p = .001$. No significant differences were found in food craving between groups, $F(2, 105) = 1.742, p = .180$, partial $\eta^2 = .032$, or between time and group intervention, $F(4, 210) = 1.162, p = .328$, partial $\eta^2 = .022$.

3.1.5. Self-esteem

A significant main effect for time was obtained $F(2, 210) = 7.710, p = .001$, partial $\eta^2 = .068$. Pairwise comparisons indicated decreases in self-esteem pre-intervention ($M = 26.38, SD = 5.58$) to post-intervention ($M = 27.69, SD = 5.97$), $p = .011$, and pre-intervention to 6-month follow-up ($M = 27.83, SD = 6.03$), $p = .002$. There was no difference in self-esteem between groups $F(2, 105) = 2.751, p = .068$, partial $\eta^2 = .050$, or between and no differences in time x group intervention, $F(4, 210) = 2.183, p = .072$, partial $\eta^2 = .040$.

Percentage changes in psychological symptoms from pre to post-intervention and from pre to 6-month follow-up are displayed in Table 4.

4. Discussion

The current study aimed to investigate whether a behaviour-based treatment, Portion Perfection for Bariatric Patients (PPBP), combined with Emotional Freedom Techniques (EFT) could improve weight-loss and maintenance for individuals (BMI $\geq 30$ kg/m²) following bariatric surgery. The effects of PPBP with EFT on BMI and four psychological variables (emotional eating, uncontrolled eating, food cravings, and self-esteem) were examined.

Although not statistically significant, percentage changes in psychological symptoms were found (pre-intervention to 8-week post-intervention, and pre-intervention to 6-month). Overall, reductions were found in BMI, emotional eating, uncontrolled eating, while self-esteem improved in all participants groups, and except for food cravings. Food cravings improved most in the EFT with PPBP group compared to the PPBP only and TAU. Emotional eating significantly decreased in the PPBP with EFT and PPBP groups (from pre-intervention to 8-week post-intervention and from pre-intervention to 6-month follow-up), and in the TAU group (pre-intervention to 6-month follow-up). This result suggests that both the PPBP and PPBP with EFT interventions accelerated emotional eating reductions between pre-intervention and 8-week post-intervention. However, EFT may not have impacted emotional eating since no between-group differences were observed. Therefore, in contrast with hypothesis one, results suggested that PPBP with EFT was no more effective at reducing food cravings or uncontrolled eating in bariatric patients than the PPBP or treatment as usual (control). This result was inconsistent with previous findings in which EFT was more efficacious in reducing food cravings than waitlist controls [28] and cognitive behavioural therapy (CBT) [37]. Additionally, inconsistent with prior work in which self-esteem improvements were found following EFT exposure [26], self-esteem did not differ between groups or across time in the current study.

In contrast with the second hypothesis, changes in psychological outcome variables were not significant over time. Measures of uncontrolled eating, food cravings, and self-esteem were not statistically significant at 6-months for the PPBP with EFT group participants. Similarly, results did not support the third hypothesis, with no significant differences in BMI observed between groups from pre-intervention to 6-month follow-up. Mean BMI for all groups increased following the intervention phase, which is inconsistent with previous research conducted by Stapleton et al. [28], and other work that has found EFT a psychological therapy beneficial for weight reduction and management [27].

Current results were largely inconsistent with previous findings. It is important to note that participant attrition in the study was extremely high. Less than one third of participants completed the 6-month follow-up measures. This lack of response may be attributed to several issues. The first may relate to poor participant adherence to EFT treatment. By the 6-month follow-up, only 23.8% of group participants reported using EFT occasionally, while 76.2% had ceased the EFT intervention altogether. Additionally, obesity has links to an external locus of control [38], with externally motivated individuals found to achieve less successful weight-loss endeavours [39]. Current PPBP with EFT group participants may have lacked the self-motivation to independently commit to the eight-week online self-guided modules, despite the social support group offered through a Facebook group. Research has also indicated

### Table 4. Changes in symptoms (%) from pre-intervention to 8-week post-intervention and pre-intervention to 6-month follow-up.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Treatment as Usual (n = 37)</th>
<th>Portion Perfection (n = 28)</th>
<th>Portion Perfection with EFT (n = 43)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pre-8-week post % change</td>
<td>pre-6-month % change</td>
<td>pre-8-week post % change</td>
</tr>
<tr>
<td>BMI</td>
<td>-1.46</td>
<td>-1.06</td>
<td>-1.50</td>
</tr>
<tr>
<td>Emotional Eating</td>
<td>-5.67</td>
<td>-7.67</td>
<td>-12.17</td>
</tr>
<tr>
<td>Uncontrolled Eating</td>
<td>-1.94</td>
<td>-4.28</td>
<td>-8.25</td>
</tr>
<tr>
<td>Food Cravings</td>
<td>-4.07</td>
<td>-5.89</td>
<td>-6.62</td>
</tr>
<tr>
<td>Self-esteem</td>
<td>6.63</td>
<td>3.80</td>
<td>1.15</td>
</tr>
</tbody>
</table>

$p = .266$, partial $\eta^2 = .025$, or in time x group intervention, $F(4, 210) = 1.825, p = .130$, partial $\eta^2 = .034$.

### Table 3. Means and Standard Deviations of BMI, Emotional Eating, Uncontrolled Eating, Food Craving, and Self-esteem for each Treatment Group at Pre, Post, and Follow-up.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control (n = 37)</th>
<th>Portion Perfection (n = 28)</th>
<th>Portion Perfection with EFT (n = 43)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre M(SD)</td>
<td>Post M(SD)</td>
<td>Follow-up M(SD)</td>
</tr>
<tr>
<td></td>
<td>Post M(SD)</td>
<td>Follow-up M(SD)</td>
<td>Post M(SD)</td>
</tr>
<tr>
<td>BMI</td>
<td>37.58 (7.20)</td>
<td>37.03 (7.14)</td>
<td>37.18 (7.38)</td>
</tr>
<tr>
<td>Emotional Eating</td>
<td>9.92 (2.02)</td>
<td>9.24 (2.78)</td>
<td>9.00 (2.68)</td>
</tr>
<tr>
<td>Uncontrolled Eating</td>
<td>23.11 (5.50)</td>
<td>22.41 (6.93)</td>
<td>21.57 (6.09)</td>
</tr>
<tr>
<td>Food Craving</td>
<td>61.46 (13.55)</td>
<td>55.76 (16.33)</td>
<td>53.22 (13.13)</td>
</tr>
<tr>
<td>Self-esteem</td>
<td>25.43 (5.47)</td>
<td>28.08 (6.51)</td>
<td>26.95 (5.71)</td>
</tr>
</tbody>
</table>
that individuals with an external locus of control may benefit more from seeking assistance from a health care professional [40]. Future research is suggested to examine the locus of control of bariatric patients, and to compare the efficacy of EFT delivery in-person versus online. It is also important to note that treatment adherence in the current study may have been impacted by the participant effort required to comply simultaneously with the PPBP kit and online EFT program. As such, current results may not provide an accurate assessment of the efficacy of EFT on assessed variables.

5. Limitations

Although EFT has been previously shown to be effective when delivered in online programs [41] with long term follow-up [42]; it is also well known that bariatric patients have psychiatric comorbidities post-surgery and the current study only had passive and online therapist guidance and support. The lack of adherence to EFT intervention within the PPBP with EFT group may reflect this and future trials would benefit from comprehensive psychological pre-assessment and preferably in person therapeutic intervention with this population. The small representation of men in the sample limited the generalisability of findings to the bariatric patient population and the exclusive use of self-report questionnaires including self-reported weight inaccuracies may have confounded outcome variables, which could be addressed through in-person measurement in future studies. As noted in the introduction, time of surgery may interfere with research outcomes and this was not accounted for the results and may have resulted in bias. Finally, the socio-economic status of the participants may have also influenced the outcomes of the study.

6. Conclusion

This parallel-group randomised control trial examined the impact of EFT intervention together with a nutritional eating plan on psychological and emotional components of weight-loss in post-surgery bariatric patients. Current findings are largely inconsistent with prior studies in which EFT was an efficacious treatment for food cravings and eating behaviours. Due to high participant attrition and poor treatment adherence by PPBP with EFT group participants, results have not provided a reliable assessment of EFT intervention on weight-loss and cognitive components of obesity in bariatric patients. Further research addressing psychological characteristics of bariatric patients, such as locus of control, is recommended, together additional randomised control trials to investigate differences between online and in-person delivery of EFT in the bariatric client population.

Declarations

Author contribution statement

P. Stapleton: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper. A. Clark: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data. D. Sabot and B. Carter: Analyzed and interpreted the data; Wrote the paper.

K. Leech: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

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Competing interest statement

The authors declare the following conflict of interests: P. Stapleton declares they may be paid for keynote and conference presentations on the topic being investigated. A. Clark declares they may earn income from the product being investigated.

Additional information

The clinical trial described in this paper was registered at Australian and New Zealand Clinical Trial Registry under the registration number ACTRN12616001257459.

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