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Early-stage innovation report

Treatment of medial tibial stress syndrome using an investigational lower leg brace. A pilot for a randomised controlled trial.

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ABSTRACT

Objective Medial tibial stress syndrome (MTSS) is common and often difficult to treat. The purpose of this study was to examine the effect of a lower leg brace on MTSS symptoms compared to a placebo.

Methods A pilot of a prospective double-blinded randomised placebo-controlled trial conducted in two private sports medicine practices. Included were those with symptomatic MTSS lasting 6 weeks or more. Excluded were those with other lower limb pathologies. Fourteen participants formed the study cohort who wore the brace or placebo. The brace applied counterforce pressure to the musculotendinous junctions of the soleus, compressed periosteum at the distal third of the posteromedial tibia and applied inferomedial torsion to the soleus muscle. Additional treatment modalities were recorded. Participants completed a standardised MTSS Severity Score at 0–6, 8, 12 and 24 weeks and recorded return to full activity.

Results The brace group demonstrated a significantly reduced MTSS severity score from 5 to 24 weeks ($p<0.03$) and had returned to full activity within 5 weeks. MTSS score in the placebo group remained unchanged ($p >0.05$), all participants experienced MTSS recurrence and none returned to full activity over 24 weeks.

Conclusion The lower leg brace demonstrated a reduction in MTSS symptoms from 5 weeks that was sustained over 6 months with a lower rate of MTSS recurrence compared with the placebo. If similar results are seen in a larger cohort, it has potential to benefit patients with MTSS as an adjunct to current treatment modalities. Further investigation regarding efficacy is needed.

WHAT ARE THE NEW FINDINGS

⇒ The use of an investigational lower limb orthosis significantly reduced Medial Tibial Stress Syndrome (MTSS) pain, assisted with an earlier return to sport and was associated with reduced recurrence of disease compared with a placebo in those with established disease.

HOW MIGHT IT IMPACT ON HEALTHCARE IN THE FUTURE

⇒ The use of the investigational lower leg brace as an adjunct in a multimodal management programme for MTSS may assist clinicians to achieve earlier symptom relief, return to full activity and prevention of MTSS recurrence.

Trial registration number ACTRN12620000906954.

INTRODUCTION

Medial Tibial Stress Syndrome (MTSS) is a lower leg injury resulting from stress reactions of the tibia and surrounding musculature in response to repetitive muscle contractions and tibial strain.[1] It affects 4%–20% of the population[1] and has increased prevalence (35%) in athletes and military personnel.[2–4]

The most common complaint is diffuse pain of the lower leg associated with exertion.[5 6] Examination often reveals tenderness of the distal one-third of the posteromedial border of the tibia while the anterior tibia remains non-tender.[7] Patients with mild MTSS experience the worst pain when exercising that can reduce with rest and in more

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severe cases pain symptoms may persist for a number of hours or days later despite adequate rest.[7]

The pathophysiology is believed to be a combination of tendinopathy, periostitis, periosteal remodelling and tibial stress reaction.[4 5 8] Dysfunction of the tibialis posterior, tibialis anterior and soleus muscles are commonly implicated[4 5 8] and these appear to be associated with alterations in tibial loading and bending.[5] Studies have attributed the pain to the disruption of Sharpey's fibres between the medial soleus fascia and its bony insertion.[8] This is consistent with radiography of chronic MTSS showing periosteal and bone marrow oedema and periosteal exostoses.[4 7]

As a result of calf tightening MTSS may also be associated with myofascial pain disorder characterised by the presence of hyperalgesic, firm nodules.[9] One treatment for this disorder is mechanotherapy[10] and allows for earlier commencement of rehabilitation. Similarly, Schulze *et al*[11] applied the fascial distortion model in a case control study showing excellent short term reduction in pain and improved performance with intensive physiotherapy.

Other studies have suggested MTSS develops from repetitive impact forces that eccentrically fatigue the soleus leading to tibial bending and impaired remodeling.[5 12]

Treatment of MTSS is predominantly conservative with few recent advances and limited well-conducted randomised controlled trials (RCTs).[7 13 14] Rest has been shown to be the most effective treatment.[4 5 12 15] For many athletes, however, prolonged rest is not ideal.

Other treatments include non-steroidal anti-inflammatories, icing[7] and stretching and strengthening of the calf muscles.[2–5 12 15–17] Footwear and orthotics have been shown to reduce the incidence of MTSS[3–5 7 12–15 17 18] and prevent repeat episodes.[5 14]

Some studies have introduced a lower leg brace in military populations,[19–21] however, due to methodological and brace design limitations significant results were not demonstrated. Despite the lack of evidence for leg bracing, this simple, self-directed modality should not be overlooked. The literature demonstrates a multifaceted syndrome and it is hypothesised a brace that addresses bone loading and myofascial aspects may be beneficial.

Study rationale

The purpose of this study was to determine whether current MTSS treatment methods and an adjuvant novel brace are more effective in treating MTSS pain symptoms than current methods.

We hypothesised there would be reduced shin pain, lower recurrence rate and earlier return to full activities when using the brace. A placebo group was used to assess if the brace provided any additional treatment effect.

METHODS

Study design

Following ethics approval (HREC ref no: 2016-07-610), a pilot of a prospective double-blinded RCT was conducted to determine the effect of a lower leg brace on MTSS. Participants were prospectively allocated by a single investigator not involved in data collection or analysis to brace or placebo groups using a computer-generated randomisation code in a 1:1 ratio (Random Allocation Software, Microsoft Basic V.6). Brace fitting, treatment protocol and specific instructions for brace use in each group were performed by an unblinded investigator who was not involved in data collection or analysis. Data were collected and analysed by blinded investigators. Participants were unknown to each other.

Inclusion and exclusion criteria

Patients were reviewed by a blinded clinician and included if they had either bilateral or unilateral symptomatic MTSS for at least 6 weeks with palpable tenderness of the posteromedial tibial border and a history of diffuse, dull shin pain associated with physical exercise.

Exclusion criteria included a previous MRI diagnosis or clinical suspicion of lower limb stress fracture in the past 6 months,[22] plantar fasciitis, compartment syndrome, chronic exertional compartment syndrome, popliteal artery entrapment, complex regional pain syndrome, radicular leg pain, neurological disease affecting the lower leg, coagulopathy, pregnancy, age less than 18 years, individuals with disorders affecting the skin, a body mass index greater than 35, any previous lower limb fracture or surgery, or any condition that increases the risk of lower limb infection.

The investigational brace

The design and function of the brace (Solushin, Australia) was different to any previously studied braces and are described in detail in figure 1. The functional components were designed to produce similar effects seen in lateral epicondylitis counterforce braces.[23] It was hypothesised this brace would unload the soleus and the tibia by dispersing muscular contraction forces across the soleus muscle thereby dampening the forces transmitted through the musculotendinous junctions[6 24 25] with the compressive ellipsoids further enhancing this effect.[26] In addition, soleus inferomedial torsion was used to reduce myofascial traction of the periosteum. Overall these components would optimise soleus function and reduce tibial loading forces. Another study suggested counterforce bracing also improved proprioception and thereby improved associated joint biomechanics and reduced overuse of the muscle.[18] Finally, the rod was designed to compress the distal posteromedial border of the tibia with the aim to reverse the tenting and elevation of Sharpey's fibres seen in MTSS.[2]

The placebo

The placebo appeared visually identical, however, it lacked the functional ellipsoids and rod components of

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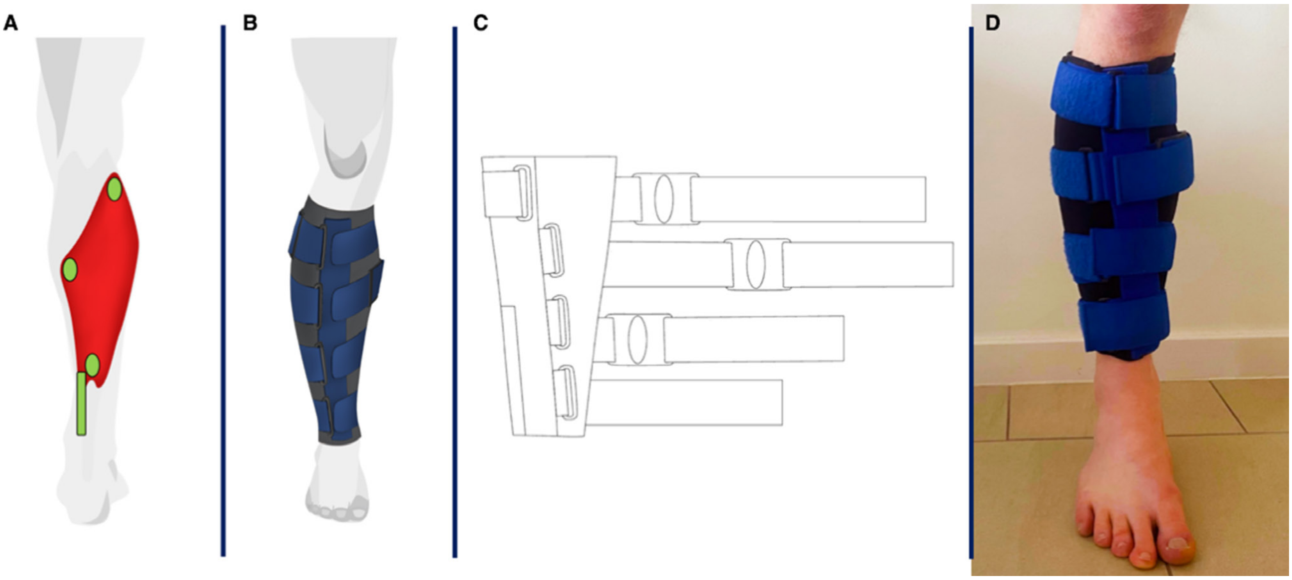

Figure 1 Diagrammatic representation of (A) The anatomical locations of the three compressive rubber ellipsoids (green) that were applied to the musculotendinous junctions of the soleus muscle (posterior to fibular head, mid-diaphysis of posteromedial tibia, Achilles tendon) and the compressive 10 cm semirigid rod at the posteromedial distal one-third of the tibia. These were secured with circumferential elastic strapping. (B) The investigational brace when applied to the leg. (C) The investigational brace layout comprising of a pocket for the compressive rod, four circumferential straps with loops allowing for adjustment of rubber ellipsoids and compression all components and a sleeve by which the functional components were secured. (D) Photographs taken of the investigational lower leg brace in use from the anterior view.

the brace. Therefore, it consisted of a spandex sleeve with four circumferential elastic straps that were tightened to apply firm pressure. This was an ideal placebo as previous research has demonstrated no clinical benefit of compressive garments for MTSS.[27]

Brace fitting and use

All eligible participants were fitted bilaterally with placebo or investigational braces by a single investigator, tested for comfort and instructed on self-application. Participants were instructed to wear their braces for up to 2 hours before and after exercise. Brace use during exercise was not permitted. On rest days participants were instructed to wear their braces for up to 2 hours in two separate sessions. This regimen was established after early prototype testing indicated use between 30 min and 2 hours once or twice daily achieved the desired effect. Participants followed these instructions for 6 months, continuing this regimen even if their pain resolved. The mean use-to-exercise ratio (days used/exercise sessions per week) was calculated to quantify adherence to brace or placebo use.

MTSS severity assessment

Participants completed a standardised MTSS severity questionnaire[28] prior to the study and from weeks 1–6, 8, 12 and 24 weeks, which appraised activity levels and pain, and formed a score out of 10. A score less than 2 was considered a clinically significant improvement whereby an individual was able to complete all activities with minimal pain. Return to full time activity was defined as an MTSS score less than 2. Recurrence of MTSS was defined as any reduction in activity due to MTSS. In addition to the MTSS score, participants completed questions detailing exercise volume, duration, rest days, brace use and any concurrent treatments they were receiving. Participants were allowed to receive concurrent treatments as suggested by their treating clinician including physiotherapy, stretching and strengthening exercises, acupuncture, icing, massage, and orthotic use.

Return to full activity programme

Despite evidence that loading is a risk factor for MTSS and evidence that gait retraining can be effective,[29] currently, there are no published loading programme protocols available. However, as this was a potential effect modifier we developed a programme to control loading that was given to participants at commencement of the study that detailed an 11-stage return to activity programme.[30] Participants began at the stage that did not elicit pain and were progressed every 3 days if pain-free. If they experienced pain during or after activity they were given 24 hours relative rest then they continued from the preceding stage. For participants whose loading capabilities were beyond the scope of the programme, the researchers developed a tailored equivalent whereby the first stage reflected a level of exercise that was painless for the participant. Time to return to full activity was defined as time taken to reach an MTSS score less than 2.

Statistical analysis

Comparisons were made within groups using Wilcoxon signed-rank tests for categorical data and between

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Table 1 Cohort demographics of placebo and brace groups

Demographic	Placebo group (n=7)	Brace group (n=7)
Age (mean±SEM)	28±2.3 years (range 20–37 years)	26±1.8 years (range 22–32 years)
Male/female	4 male, 3 female	2 male, 5 female
Height (mean±SEM)	172 cm±3.7 cm; range 160–185 cm	172 cm±3.6 cm; range 160–190 cm
Weight (mean±SEM)	67 kg±3 kg	65 kg±3.2 kg
BMI (mean±SEM)	22.42±0.44	21.95±0.66
Duration of symptoms (mean±SEM)	23±9 months (range 2–52 months)	29±14 months (range 2.5–104 months)
Affected leg(s)	Left (1), right (0), both (6)	Left (1), right (1), both (5)
Previous history of MTSS	Yes (71%), no (29%)	Yes (43%), no (57%)
Highest level of sport achieved	Hobby (1), club (3), state (2), national (1)	Hobby (0), club (2), state (3), national (2)
Current level of sport	Hobby (3), club (3), tate (1), national (0)	Hobby (2), club (2), state (2), national (1)
Previous surgeries	Nil	Nil
Concurrent treatment	Nil (1), physiotherapy (2), orthotics (3), acupuncture (1)	Nil (1), physiotherapy (2), orthotics (3), stretching (1)

BMI, body mass index; MTSS, Medial Tibial Stress Syndrome.

groups using Mann-Whitney rank-sum tests for categorical data and Student's t-test for continuous data. Statistical significance was set at $p<0.05$.

Patient and public involvement statement

Participants were not involved in the design, conduct, reporting or dissemination of the research findings. Participants were provided with informed consent regarding intervention burden and time commitment of the intervention.

RESULTS

Study group

Between June 2017 and December 2018, 20 individuals presented with shin pain. Three were excluded for stress fracture, one for plantar fasciitis and two were unwilling to commit to the study period. The remaining 14 participants formed the study cohort. There were no withdrawals from the study, however, one participant in the brace group had incomplete data at 3 and 6 months.

Cohort demographics

The study cohort was randomised to placebo and brace groups. Table 1 summarises the relevant demographic data of each group. There were no statistically significant differences between groups ($p>0.05$).

Protocol modifications

There were several minor changes from the study protocol.[30] The sample size was 14 instead of 46 as suggested by the power analysis. Due to resource constraints, an interim analysis for a pilot study was performed at a sample size of 14 and was found to reach statistical and clinical significance. Knee to wall testing was excluded from the study as it required in-person clinical assessment that most participants were unable to attend.

Brace usage

Over 6 months the mean weekly usage for the placebo was 116 (left) and 119 (right) min daily for 5.18±0.3 days (range 4.8–5.8 days). The mean weekly usage for the brace was 100 (left) and 104 (right) min each day for 3.66±0.4 days (range 3.1–4.2 days) per week. Comparison between groups at each time point did not identify any statistically significant differences in usage time ($p>0.05$). Total usage for the placebo demonstrated significantly greater usage time compared with the brace (placebo 609±91 (left) and 618±84 (right) min/week; brace 364±73 (left) and 378±66 (right) min/week) ($p<0.05$). Total usage remained consistent within groups throughout the study period ($p>0.05$). The mean use-to-exercise ratio for the placebo (1.7±0.3 days/session) was greater than the brace (1.1±0.2 days/session) at a statistically significant level ($t_{16}=5.7$, $p<0.001$, 95% CI 0.4 to 0.9).

MTSS severity score

Comparisons were made between groups and within groups comparing progression over time (figure 2). There was no difference in MTSS severity score between groups from weeks 0 to 4 ($p>0.05$). However, from weeks 5 to 24, the brace group demonstrated a lower score compared with the placebo that was clinically and statistically significant ($p<0.03$).

Comparison within the placebo group demonstrated a consistently poor severity score throughout the study period ($p>0.05$). Comparison within the brace group yielded a statistically and clinically significant reduction in MTSS severity from 0 to 5, 6, 8, 12 and 24 weeks ($p<0.03$). At 5 weeks, the brace group had returned to full activity with a mean score less than 2. Two participants in the brace group experienced recurrence of symptoms. One participant was forced to reduce their activity volume from weeks 6–8 and the other was forced to do alternative activities from weeks 4, 5 and 8.

All participants with the placebo experienced recurrence of symptoms. Three participants were forced to reduce their activity volume only (weeks 6–8; 3 and 12; 1–5, 12–24), and four participants were forced to engage in alternative activities (weeks 3–5, 8 and 12; 2 and 6; 5, 6 and 8; 2, 3, 5 and 6). In addition, three participants were unable to return to full activities.

Exercise session frequency

The mean weekly sessions for the placebo group were 3.7±0.2(range 2.9–4.3) and 4.2±0.2 (range 3.7–5.3) for the brace group. There was no statistically significant difference in session frequency in the first 5 weeks

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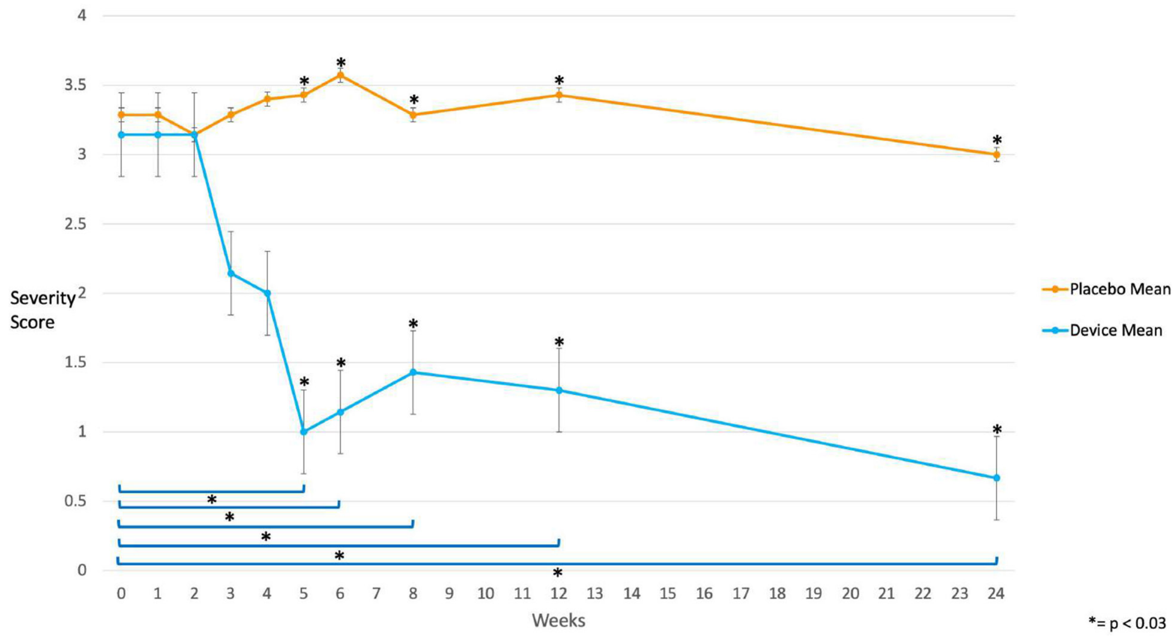

Figure 2 Comparison of MTSS severity score between brace and placebo groups from study commencement to 6 months postintervention showing a statistically significant difference between groups from 5 weeks that was sustained until 6 months. The placebo group demonstrated a consistently poor severity score (p>0.05). The brace group yielded a statistically significant reduction in MTSS severity from 0 to 5 weeks, 0 to 6 weeks, 0 to 8 weeks, 0 to 12 weeks and 0 to 24 weeks (p<0.03). MTSS, Medial Tibial Stress Syndrome.

(p>0.05). At 6 weeks, session frequency was similar between groups (brace 4.7±0.6 sessions (range 2–7); placebo 4.1±0.9 (range 2–9); p>0.05). At 3 months, the brace group completed a significantly greater number of sessions compared with the placebo (brace 4.8±0.7 (range 2–7); placebo 2.9±0.5 (range 1–4); p<0.05). This difference continued at 6 months at a statistically significant level (brace 5.3±0.9 (range 1–7); placebo 3±0.3 (range 2–4); p<0.05).

DISCUSSION

This pilot study demonstrated feasibility of the methodology and showed participants who wore the brace had reduced pain and improved function from 5 weeks. This effect was sustained until 6 months postintervention with a lower rate of recurrence compared with the placebo.

To our knowledge, this is the first study to demonstrate an improvement in MTSS symptoms when using a lower limb brace. Participants with symptomatic MTSS who wore the brace achieved a reduction in pain and improvement in function from 5 weeks to 6 months with a low rate of MTSS recurrence. This was compared with a placebo group whose symptoms and function remained similar throughout the study. As a pilot, these findings may reflect a statistically and clinically significant difference that may be seen in a larger study or may be due to chance.

Several studies have investigated the use of a lower limb brace in the treatment of MTSS.[19–21] One study showed no benefit of a rigid rod spanning the length of the posteromedial tibia.[31] Another study investigated a pneumatic brace commonly used for tibial stress fractures, however, this did not demonstrate efficacy.[21] Finally, some studies have examined the use of calf compression sleeves and, despite their popularity, there was no benefit.[27] In comparison, our study used a compression sleeve as a placebo compared with the brace with a low withdrawal rate and good compliance. This may be attributed to having a small group of highly motivated participants and regular follow-up.

Initially, we observed exercise session frequency was similar between groups, however, at 3 and 6 months the brace group completed ~2 more sessions per week compared with the placebo group suggesting the brace assisted participants to better manage load and maintain consistency with their exercise. Furthermore, this usage data may help clinicians to establish a realistic treatment regimen for their patients and aid planning of future studies.

The strengths of this pilot study are the randomised, double-blinded design with prospectively collected data, compliance with brace use and the use of a verified placebo.[27] The use of the MTSS severity score was a reliable method of assessing MTSS severity and tracking progress.[28] A future RCT using this study design with a larger sample size is feasible and would help determine if the findings of this study are statistically and clinically significant.

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A major limitation of this study was sample size. In comparison to other studies investigating a lower limb orthosis for the treatment of MTSS, this study has a similar sample size and reflects the challenges of participant recruitment in sports medicine research.[19 20 27] We acknowledge that we did not reach the sample size required to reach appropriate power for the study, however, as a pilot it demonstrated feasibility of the study design and promising early findings. We also noted that participants wore the placebo ~15 min longer each day compared with those with the brace. In a larger cohort, this difference would reach statistical significance. Participants may have been more comfortable in a softer compressive sleeve, or they may have extended their use while striving for a clinical benefit. Given the sufficient duration of brace use and the previously established placebo,[27] increased placebo use is unlikely to have affected the outcome but is an important consideration for future studies. Finally, this study was conducted over a relatively short-to-medium term and may not have accounted for recurrence of symptoms in the long term.

In conclusion, this pilot RCT demonstrated the lower leg brace reduced MTSS pain symptoms and recurrence, and it facilitated earlier return to full activities and provided symptom relief up to 6 months. These results are promising and provides clear implications for a future RCT with a larger sample size that would have greater power, and closely scrutinise clinical significance. Future investigation into cost-effectiveness of the intervention is also necessary.

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Competing interests The corresponding author is the inventor of the investigational lower leg brace, owns a patent for its design and has shares in the associated company (Solushin, Australia). Currently, the corresponding author does not receive any financial benefits as the brace is yet to generate revenue. All other authors do not have any interests to disclose.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Bellberry LtdID: HREC ref no: 2016-07-610. Participants gave informed consent to participate in the study before taking part.

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