

Venous haemodynamics of Jet Impulse Technology within a lower limb fibreglass cast: a randomized controlled trial

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Summary

Objectives: We investigated popliteal venous haemodynamics of the Venajet Jet Impulse Technology system within a below-knee fibreglass cast.

Design: Randomized controlled trial.

Participants: Twenty-four healthy participants aged 18–54 had both feet placed within the Jet Impulse Technology system and were randomised for one or other leg to be within a below-knee fibreglass cast.

Setting: Pacific Radiology, Lower Hutt, Wellington

Main outcome measures: The primary outcome variable was peak systolic velocity (cm/s) compared between legs with and without the cast at 60 min (after 10 min Jet Impulse Technology activation), using a mixed linear model and a non-inferiority bound of 4.8 cm/s. Secondary outcome variables were the difference in peak systolic velocity between the casted limb and the non-casted limb at baseline and 40 min after casting, and the difference in mean flow velocity (cm/s), vein diameter (mm), and total volume flow (L/min) between the casted limb and the non-casted limb at baseline, 40 and 60 min.

Results: The mean (standard deviation) peak systolic velocity was 4.6(1.5), 4.8(1.1), 28.8(16.1), and 4.3(1.2), 4.8(1.4) and 29.3(19.0) cm/s at baseline, 40 and 60 min in the casted and non-casted leg, respectively. The difference (95% confidence interval) between cast and no-cast at 60 min was -0.8 (-6.5 to 4.9) cm/s, $P=0.78$. The peak systolic velocity, flow velocity and total volume flow at 40 min were not statistically significantly different from baseline for both casted and non-casted limb.

Conclusion: In healthy volunteers, the popliteal venous haemodynamics of the Jet Impulse Technology system was similar between the legs with and without a below-knee fibreglass cast. In-cast Jet Impulse Technology may provide a non-pharmacological option for venous thromboembolism prophylaxis for lower-limb cast-immobility.

Keywords

venous stasis, below-knee cast, lower limb immobilisation, Jet Impulse Technology, venous thromboembolism, prevention, venous haemodynamics

Introduction

Prolonged cast immobilisation of the lower limb after injury is associated with an increased risk of venous thromboembolism as either or both deep vein thrombosis and pulmonary embolism.^{1–7} In the control groups of studies reviewed in the 2008 Cochrane Review of low-molecular weight heparin for prophylaxis of venous thromboembolism in patients with lower limb immobilisation, the incidence of venous thromboembolism had a wide range, from 4.3 to 40%.³ The majority of venous thromboembolism events in these studies were asymptomatic distal deep vein thrombosis diagnosed by radiological screening. A more recent study reports the incidence of symptomatic venous thromboembolism in 6.3% (95% confidence interval 3.4–10.5) of unselected patients managed with cast immobilisation after an Achilles tendon injury.⁸ This is considerably higher than the estimates for ‘off-prophylaxis’ hip and knee arthroplasty for symptomatic and asymptomatic deep vein thrombosis (1.8%), and pulmonary embolism (1%) estimated by the American College of Chest Physicians.⁹

The main risk of prolonged medication-related prophylaxis, with low-molecular weight heparin, aspirin, an oral thrombin inhibitor, or Factor Xa inhibitor; in relation to venous thromboembolism during lower limb immobilisation, is bleeding.⁹

Intermittent pneumatic compression is an alternative form of prophylaxis that is not associated with increased bleeding risk. It is currently recommended for orthopaedic inpatients either in conjunction with medication-related prophylaxis, or where this is contra-indicated or refused.⁹ The use of intermittent pneumatic compression as a method for venous thromboembolism prophylaxis when cast immobilisation is used for lower leg injuries requires further investigation. It is not known if the performance of

an intermittent pneumatic compression device is adversely affected by being placed within a lower limb cast.

This study examines whether the performance of the VenaJet Jet Impulse Technology using the VenaJet pump and VenaJet undercast pads (specifically designed for use in lower limb immobilisation) is impaired by placement within a lower leg fibreglass cast in healthy volunteers. The Jet Impulse Technology system comprises an in-cast pad that can be placed under a fibreglass or plaster cast and is attached to a pump. The pump mechanism mimics the natural full weight-bearing walking process, rapidly inflating a distal air-cell in the foot cuff to 130 mmHg, which then settles to 52 mmHg, followed by a proximal air-cell 0.3 s later, settling to 48 mmHg. After 6 s of compression at 48–52 mmHg, both air-cells deflate. This cycle is repeated every minute.

Methods

In this randomized controlled trial, 24 healthy volunteers aged between 18 and 65 y were recruited after attending a screening visit at the research office for review of inclusion and exclusion criteria and provision of informed consent. Potential participants were excluded if they had a history of previous or current deep vein thrombosis, were pregnant, or had clinical features of peripheral vascular disease, peripheral neuropathy, scleroderma, lymphoedema, or joint deformity from inflammatory arthritis. Participants who met all the inclusion and exclusion criteria were given appointments to attend a second visit for the study procedures.

At the second visit, each participant was initially seated quietly for 10 min on the edge of an examination couch with both legs hanging dependent, as they would normally be seated to have their lower limb placed in an equinus lower limb cast. Baseline popliteal venous flow was measured at this time. Participants then had the Jet Impulse Technology systems (Vena Jet, Germany) placed on BOTH feet and were randomised to have either their left or right leg placed in a fibreglass below-knee equinus cast which also encased the Jet Impulse Technology system on that limb. Initially, we intended that participants would remain in the initial position for the remainder of the study, but baseline popliteal venous flow measures were found to be very slow, and static in one participant, so participants were moved onto seats where they could rest at least part of their feet on the ground with the angle between the thigh and the lower leg at 120°. Participants were asked to sit forward enough on the chair that measurements with duplex ultrasonography could be performed without

participants needing to move for the remainder of the study. Popliteal venous flow in this sitting position was re-measured 40 min after the randomised lower limb was placed in a cast. Then, 50 min after the limb was placed in a cast the Jet Impulse Technology systems on both legs were activated to inflate to 130 mmHg every minute using the Vena Jet pump (VADOPlex, Germany). After 60 min, 10 min after Jet Impulse Technology activation, popliteal venous flow was measured again and then the cast and Jet Impulse Technology devices were removed.

Imaging used a broadband linear ultrasound transducer (Philips IU22, Royal Philips, Eindhoven, The Netherlands) capable of both colour and pulsed Doppler. With a bandwidth of 3–9 MHz, pulsed Doppler imaging was acquired with a frequency of 3.5 MHz. The incident pulsed Doppler was beam steered to ensure a Doppler angle of less than 60° to reduce errors in velocity calculation. The pulsed Doppler wall filter was reduced to capture low-velocity flow. The sample volume was adjusted to encompass the entire diameter of the vein under investigation. Using triplex mode (live B-mode, colour, and pulsed Doppler), the popliteal vein was sampled for flow. Auto-calculation measurements were made over a 2-s interval with phase being predominantly towards the heart. Cine-loop review allowed for vein diameter measurement (used to calculate volume flow) with good temporal resolution. Two sonographers were involved in the study, each measuring 12 participants in total. All measures of popliteal vein flow at each time point were undertaken twice in each limb, with the left limb measured first, and the mean of both measurements used in statistical analysis.

The primary outcome variable was the difference in peak systolic velocity (cm/s), in the popliteal vein between the casted limb and the non-casted limb after 60 min, at which time the Jet Impulse Technology system had been running for 10 min. Secondary outcome variables were the difference in peak systolic velocity between the casted limb and the non-casted limb at baseline and 40 min after casting, and the difference in mean flow velocity (cm/s), vein diameter (mm), and total volume flow (L/min) between the casted limb and the non-casted limb at baseline, 40 min after casting and at 60 min.

The sample size was designed to rule out a paired difference in peak systolic flow of less than 4.8 cm/s. This non-inferiority bound is based on a past haemodynamic study where the mean maximum peak systolic velocity achieved with an intermittent pneumatic compression outside of a fibreglass cast was 20.1 cm/s with a paired standard deviation for peak systolic velocity of 6.8 cm/s.¹⁰ The chosen non-inferiority bound

of 4.8 cm/s is 25% of the mean maximum peak systolic velocity found in the past study. A sample size of 24 has 90% power with an alpha of 5% to rule out the nominated non-inferiority bound.

Participants were randomised to have a cast on one or other leg using a computer random-number based schedule developed by a biostatistician. The randomisation schedule was provided directly to a non-investigator, who prepared opaque envelopes for each study participant. The envelopes were opened by each participant immediately prior to the placement of the Jet Impulse Technology systems and equinus cast.

The analysis used a mixed linear model to estimate the overall difference between the Jet Impulse Technology system within a cast and on the other leg, as the control intervention. The baseline measurement is used as a continuous covariate, and the order of treatment, randomised leg, and sonographer as the other fixed effects, and the individual participants as random effects, to account for the paired design.

SAS version 9.3 was used for statistical analysis

Ethics approval was obtained from the New Zealand Health and Disability Ethics Committee, ref

14/STH/82 20394, dated 3 July 2014 and the trial was prospectively registered with the Australia New Zealand Clinical Trials Registry: ANZCTR 12614000730606.

Results

The flow of participants is shown in Figure 1. The age range for the participants was 18–54 years and 17 (71%) were women. Mean (range) body mass index was 25.9 (19–36) kg/m². One participant had no measurable blood flow in the leg randomised to be placed in a cast while in the baseline sitting position was withdrawn from further participation in the study, although the baseline measurements in the leg without the cast were able to be used for analysis.

Table 1 shows summaries of popliteal vein blood flow. The mean (standard deviation) peak systolic velocity after 60 min, when the Jet Impulse Technology system had been running for 10 min, was 28.8 (16.1) cm/s and 29.3 (19.0) cm/s in the legs with and without the cast, respectively, representing a 6.3- and 6.8-fold increase from baseline (Figure 2). Mean Flow Velocity and Total

Figure 1. Flow of participants through study.

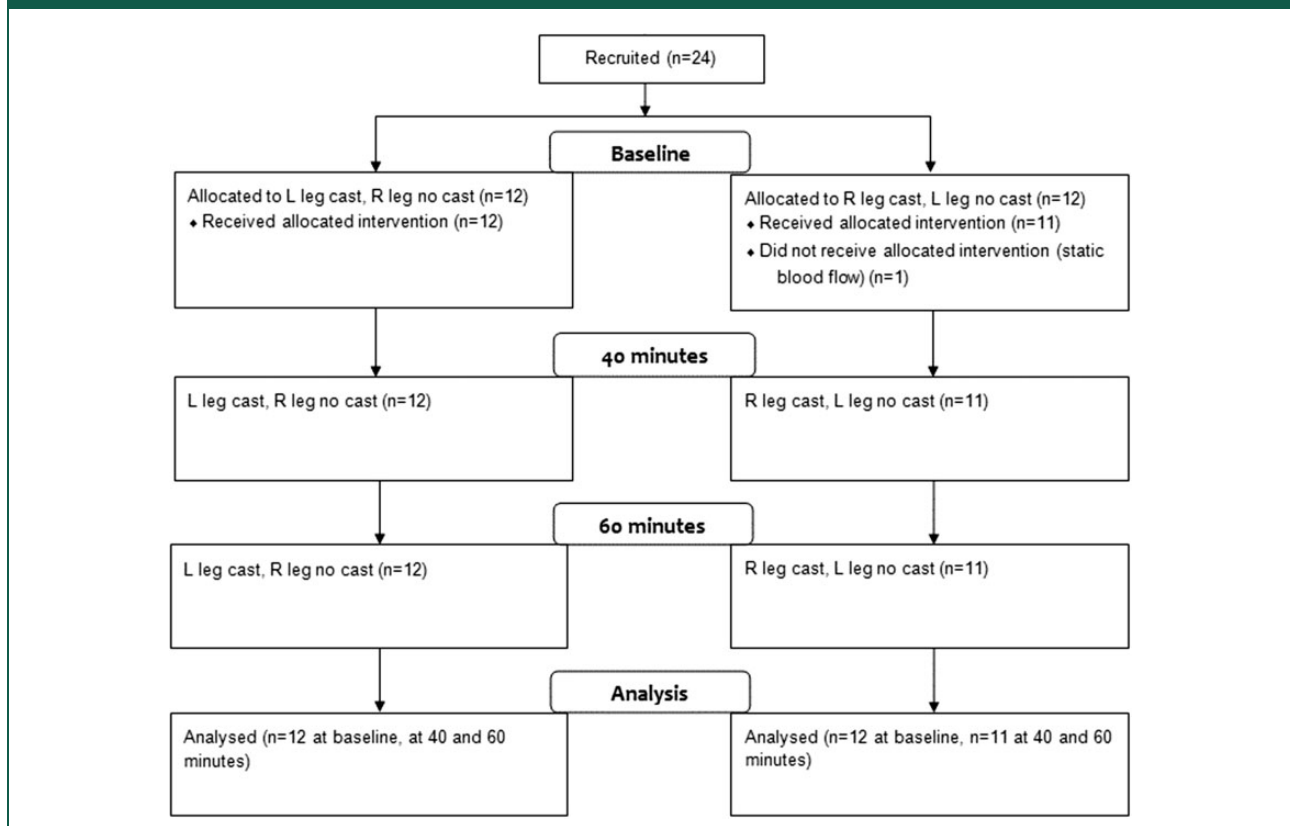
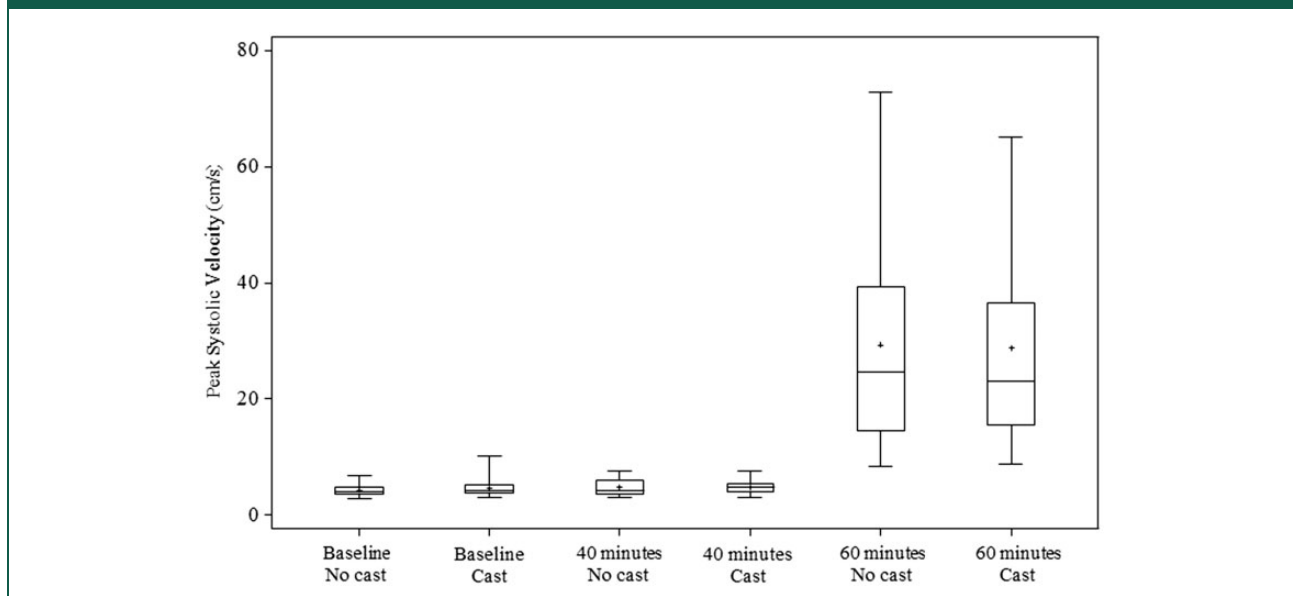


Table 1. Popliteal vein blood flow measurements assessed by duplex ultrasonography.

	Mean (standard deviation) (range)					
	Leg in cast			Leg not in cast		
	Baseline (n = 23) ^a	40 min (n = 23) ^a	60 min (n = 23) ^a	Baseline (n = 24)	40 min (n = 23) ^a	60 min (n = 23) ^a
Peak systolic velocity (cm/s)	4.6 (1.5) (3.1–10.1)	4.8 (1.1) (3.1–7.7)	28.8 (16.1) (8.6–65.2)	4.3 (1.2) (2.8–6.8)	4.8 (1.4) (3.0–7.6)	29.3 (19.0) (8.4–72.8)
Mean flow velocity (cm/s)	1.4 (0.7) (0.4–3.1)	1.8 (0.7) (0.4–3.5)	4.8 (3.3) (1.6–14.7)	1.4 (0.7) (0.3–2.8)	1.7 (0.9) (0.4–3.2)	3.8 (2.4) (0.9–9.6)
Total volume flow (L/min)	.048 (.027) (.015–.108)	.060 (.025) (.014–.106)	.172 (.140) (.031–.598)	.044 (.023) (.009–.104)	.053 (.033) (.008–.128)	.133 (.095) (.027–.411)
Vein diameter (cm)	0.85 (0.13) (0.57–1.06)	0.85 (0.12) (0.60–1.04)	0.85 (0.13) (0.61–1.06)	0.83 (0.11) (0.63–1.00)	0.82 (0.15) (0.51–1.03)	0.85 (0.14) (0.57–1.21)

^aOne participant had static blood flow in leg randomised to be placed in a cast and they were withdrawn from the study. Baseline measures for their non-casted leg were used in the analysis (n = 24), but no other measures were analysed ((n = 23) for remaining time points).

Figure 2. Box-plot of peak systolic velocity in casted and non-casted leg at each time point. The horizontal lines are the 25th, median, and 75th percentile, the symbol is the mean and the whiskers are the minimum to maximum.

Volume Flow were increased after 60 min compared to baseline while Vein Diameter remained unchanged.

The mean (standard deviation) and range peak systolic velocity after 40 min was 4.8 (1.1), 3.1–7.7 cm/s; and 4.8 (1.4), 3.0–7.6 cm/s in the legs with and without the cast, respectively. These measurements as well as the mean flow velocity and total volume flow were not statistically significantly different from baseline.

Differences in popliteal vein blood flow between the legs with and without the cast are shown in Table 2. There was no statistically significant difference between the legs with and without the cast for any measurement at any time point.

Discussion

This study found that the effect of the Jet Impulse Technology system on popliteal venous

Table 2. Differences in popliteal vein blood flow between casted leg and non-casted leg at each time point.

	Mean (standard deviation)		
	Cast minus no cast	Change from baseline: cast minus no cast	Estimate (95% confidence interval) of cast minus no cast, <i>p</i> value
40 min			
Peak systolic velocity (cm/s)	0.004 (1.3)	−0.2 (2.1)	−0.04 (−0.66 to 0.59) 0.91
Mean flow velocity (cm/s)	0.1 (0.8)	0.1 (1.0)	0.12 (−0.26 to 0.49) 0.53
Total volume flow (L/min)	0.067 (0.029)	0.042 (0.043)	0.062 (−0.076 to 0.201) 0.36
Vein diameter (cm)	0.03 (0.09)	0.02 (0.12)	0.02 (−0.02 to 0.07) 0.28
60 min			
Peak systolic velocity (cm/s)	−0.4 (12.7)	−0.6 (12.7)	−0.8 (−6.5 to 4.9) 0.78
Mean flow velocity (cm/s)	1.0 (2.6)	1.0 (2.6)	0.96 (−0.17 to 2.1) 0.09
Total volume flow (L/min)	0.386 (0.121)	0.362 (0.117)	0.365 (−0.147 to 0.876) 0.15
Vein diameter (cm)	−0.005 (0.13)	−0.02 (0.14)	−0.01 (−0.07 to 0.04) 0.67

haemodynamics was not impaired by its use within a fibreglass below-knee cast. There was no statistically significant difference between the primary outcome of the peak systolic velocity measured in the Jet Impulse Technology system in legs with and without the cast after it was operating for 10 min, although the confidence interval for the Jet Impulse Technology system peak systolic velocity difference (−6.5 to 4.9 cm/s) just included the non-inferiority bound of 4.8. The lack of statistical power to exclude non-inferiority of the system within the cast was because the standard deviation of the measurements was double that anticipated based on our past research; 12.1 cm/s compared to the anticipated standard deviation of 6.8 cm/s. The peak systolic velocity of 28.8 cm/s measured in the leg with the cast and the Jet Impulse Technology system represents a large (sixfold) change from baseline.

A number of methodological issues are relevant to the interpretation of the study findings. Venous haemodynamics were measured by Doppler ultrasound which is a non-invasive method of measuring lower limb blood flow that is sensitive, specific, and

reproducible.^{11,12} Peak systolic velocity was chosen as the primary outcome variable because it is the most consistent non-artefactual wave form detected by ultrasound.¹¹ Although it is known that the right and left legs have similar venous haemodynamics with research participants,¹³ we randomised participants to have the Jet Impulse Technology system placed on either the right or left leg to avoid any possibility of bias related to selection of the leg for casting, such as perceived discomfort which could be indirectly related to venous blood flow. Although it was not possible to blind the sonographers to the intervention allocation we feel this is unlikely to have resulted in biased assessment of blood flow.

The original research protocol was that all participants remained in the baseline position, with feet hanging dependent off the edge of the examination couch, for the duration of the study. This would have allowed the ultrasonographer access to the popliteal vein, and placement of the equinus cast without having to move participants during the study. Unexpectedly, there was very poor blood flow in this position, which in fact resulted in withdrawal of

one participant. We therefore modified the protocol so that all participants were moved onto chairs so their feet could rest on the floor in order to relieve some of the compression of the femoral vein at the adductor hiatus. While every effort was made to ensure that the participants remained as still as possible after being moved from their baseline position, it cannot be guaranteed that this was achieved at all times. This may have resulted in the unexpectedly large standard deviation seen in the study. This improves the generalisability of the study however as patients with injuries who are immobilised with a lower limb cast are unlikely to remain in a seated position without moving for prolonged periods of time.

We chose to investigate the Jet Impulse Technology system in this trial as it is designed to be used within an already existing lower limb immobilisation system, and it delivers an inflation pressure (130 mmHg) consistent with those delivered by foot intermittent pneumatic compression devices.¹⁴ While this pressure is at the lower end of the spectrum of previously studied foot intermittent pneumatic compression devices, this is likely to make the Jet Impulse Technology system more tolerable when confined within a lower limb cast for between six and eight weeks. Past research also shows limited increases in peak systolic velocity with increasing pressures delivered by foot intermittent pneumatic compression devices outside of a lower limb cast, so a higher pressure system may have produced little further clinical benefit.¹⁴ Use of a calf or calf and foot intermittent pneumatic compression within a cast is likely to be

technically difficult and result in cast integrity issues over time.

The study was of 60 min duration, insufficient to measure any effect of the Jet Impulse Technology system on the integrity of the cast over a protracted period of time. Now that we have shown the Jet Impulse Technology system works at initial casting, further studies are indicated to assess the longer term effects and tolerability of constant Jet Impulse Technology activation within a lower limb cast over periods of time reflective of those between orthopaedic outpatient visits.

While we have shown that peak systolic velocity is significantly increased by using the Jet Impulse Technology system within a cast, consideration needs to be given to those issues that might limit its use in the clinical setting. These include skin and cast integrity, patient adherence to treatment, other aspects of tolerability, and cost. These concerns may provide the focus of a future feasibility study assessing the longer term use of the Jet Impulse Technology system within lower limb casts.

This study shows that in a sample of healthy volunteers with their leg placed in a below-knee fibreglass cast, the Jet Impulse Technology system substantially increases peak systolic velocity in the popliteal vein, and this is similar to the peak systolic velocity of the same system outside of a lower limb cast. Further studies are indicated to address other issues such as skin and cast integrity with prolonged use, patient tolerability and adherence to treatment in a clinical sample of patients with injuries requiring prolonged lower limb immobilisation.

CONSORT 2010 checklist of information to include when reporting a randomised trial.*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	5–6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/a

(continued)

Continued.

Section/Topic	Item No	Checklist item	Reported on page No
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7–8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6–9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	10 and Fig 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	11 / Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10

(continued)

Continued.

Section/Topic	Item No	Checklist item	Reported on page No
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	10–12
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13–15
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	13–15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13–15
Other information			
Registration	23	Registration number and name of trial registry	Title and 16
Protocol	24	Where the full trial protocol can be accessed, if available	Uploaded
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Title and 16

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming; for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Declarations

Competing Interests: None declared.

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Ethical Approval: It was obtained from the New Zealand Health and Disability Ethics Committee, ref 14/STH/82 20394, dated 03/07/2014 and the trial was prospectively registered with the Australia New Zealand Clinical Trials Registry: ANZCTR 12614000730606.

Guarantor: IB is the guarantor for this article, had full access to the data and takes responsibility for the integrity and accuracy of the data analysis. MW undertook the statistical analysis.

Contributorship: Concept and design: RB, IB, and MW; Data acquisition: IB, SM, SB, AM, KS, and BdR; Data integrity: IB and TM; Statistical analysis: MW; Figures: IB and MW; Data

interpretation: RB, IB, SM, and MW; Manuscript draft and review: IB, SM, SB, AM, KS, BDR, MW, and RB.

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Provenance: Not commissioned; peer-reviewed by Julia Phillips.

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