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Efficacy and cost effectiveness of high volume injections with and without corticosteroid compared with sham for midportion Achilles tendinopathy (Inject trial): randomised controlled trial

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ABSTRACT

OBJECTIVE

To test the efficacy and cost effectiveness of high volume injections with and without corticosteroid versus sham injection for midportion Achilles tendinopathy.

DESIGN

Single centred, participant and assessor masked, three arm randomised controlled trial (Inject trial).

SETTING

Community.

PARTICIPANTS

From 5 December 2019 and 24 July 2022, 192 adults (18 years or older) diagnosed with midportion Achilles tendinopathy were randomly assigned (1:1:1) to sham (n=64), high volume injection without corticosteroid (n=63), or high volume injection with corticosteroid (n=65).

INTERVENTIONS

Participants were allocated to sham injection (2-3 mL 0.5% bupivacaine hydrochloride), high volume injection with corticosteroid (50 mL saline and 0.5% bupivacaine with 25 mg hydrocortisone in the first 10 mL), or high volume injection with no corticosteroid (same solution but without hydrocortisone). They received the same exercise programme, education, and activity modification advice.

MAIN OUTCOME MEASURES

The primary clinical outcome was pain and disability using the validated VISA-A and the primary endpoint was at 52 weeks. The economic outcome was cost per quality-adjusted life-years from a societal perspective.

RESULTS

VISA-A data were obtained from 181 (94%) of 192 participants at 12 months. No clear differences were noted between sham and high volume injection either with (-3.5 (98.33% confidence interval -12.0 to 5.0)) or without corticosteroid (4.0 (-4.2 to 12.3)), and between the two injections (-7.5 (-15.3 to 0.3)), at 12 months. The point estimate was closest to the target difference for the comparison between injections and favoured the arm without steroid. The only differences observed on VISA-A at intermediate time points were a benefit for high volume with corticosteroid versus sham at six weeks (9.2 (1.5 to 16.9)) but worse outcomes for high volume injection with corticosteroid versus high volume injection with no corticosteroid at 26 weeks (-8.6 (-16.4 to -0.7)). The health economic analysis found high volume injection with corticosteroid to be less costly than the sham with similar effectiveness based on quality-adjusted life-years (>0.90 probability of being cost effective at $AUD50 000 and $100 000 willingness-to-pay thresholds). No serious trial related adverse events were recorded.

CONCLUSION

High volume injections with or without corticosteroids did not improve pain or disability compared with sham at 12 months. Although high volume injections with corticosteroid showed short term clinical benefit and potential reduction in healthcare costs over a year, they were associated with worse longer term clinical outcomes. The clinical data do not support routine use for high volume injections with corticosteroid for midportion Achilles tendinopathy.

TRIAL REGISTRATION

Australian New Zealand Clinical Trials Registry ACTRN12619001455156

WHAT IS ALREADY KNOWN ON THIS TOPIC

High volume injections with and without corticosteroid are used for Achilles tendinopathy despite limited evidence of efficacy, safety, and cost effectiveness

High volume injection without corticosteroid has shown little clinical benefit up to medium term, while corticosteroid containing injections may provide short term symptom improvement

No trial has previously evaluated the longer term clinical effects and cost effectiveness of high volume injection with or without corticosteroid for Achilles tendinopathy

WHAT THIS STUDY ADDS

High volume injection with or without corticosteroid did not improve pain and disability compared with sham injection at 12 months

High volume injection with corticosteroid provided small, short term improvements at six weeks over sham but worse outcomes than high volume injection without corticosteroid at 26 weeks

High volume injection with corticosteroid had a high probability of cost effectiveness, but the overall clinical findings do not support routine use

Introduction

Achilles tendinopathy is a leading cause of persistent lower limb pain. This disorder affects 6% of the population in their lifetime and disrupts simple daily functions such as walking.[1] Mobility, independence, and quality of life is affected, with 38% of workers reporting reduced work capacity.[2 3] Although exercise based treatment is recommended in clinical guidelines and expert consensus statements,[4-6] up to 44% of people affected do not get better.[7] Almost half (48%) of people with pain and impact on daily activities because

of Achilles tendinopathy pursue additional treatments such as injections.[8]

Injections are commonly used to manage Achilles tendinopathy, despite lacking rigorous evaluation for efficacy, safety, and economic value. High volume injection, typically comprising corticosteroid, local anaesthetic, and 50 mL of saline delivered between the Achilles tendon and Kager's fat pad, is increasingly used worldwide to treat Achilles tendinopathy.[9-14] The proposed mechanisms include mechanical or ischaemic disruption of pain signalling and corticosteroid-mediated anti-inflammatory effects.[9 13] A preliminary trial reported sustained improvements in pain and function with high volume injection containing corticosteroid compared with sham up to 26 weeks.[15] However, two subsequent trials of high volume injection without corticosteroid showed no short term benefit and mixed longer term benefit.[16 17] Whether high volume injections with corticosteroid confer long term harm, as observed in other tendinopathies, is uncertain.[18]

This trial aimed to evaluate the 12 month efficacy and cost effectiveness of high volume injection with and without corticosteroid compared with sham, including potential long term harms.

Methods

Study design

The Inject trial is three arm, parallel group, participant and assessor masked randomised trial included a 12 month follow up and a parallel economic evaluation. Conducted at a radiology clinic in Melbourne, Australia (Imaging at Olympic Park), the study was approved by the Monash University Human Ethics Committee (13138) and was prospectively registered with the ANZCTR (ACTRN12619001455156). Our methods followed the published protocol.[19]

Participants

We included adults (≥18 years) who had Achilles tendinopathy (gradual onset mid-portion pain during or after tendon loading activities, such as walking or running) diagnosed clinically and by ultrasound (hypoechoic regions or Doppler signal, or both[19]) and who had pain for at least three months. To be eligible, participants needed to have a Victorian Institute of Sport Assessment-Achilles (VISA-A) score of less than 75 (0-100, 0 is worst pain and disability)[20] and had not responded to prior treatment. Our exclusion criteria included prior rupture or surgery, injection treatment in the past three months, or medical conditions precluding participation. For the full list of inclusion and exclusion criteria, see the protocol.[19] Eligibility was confirmed by teleconference assessment, and participants provided written consent and completed online baseline assessments before randomisation. Recruitment was from paid social media advertising and direct referrals from local physicians and physiotherapists.

Randomisation and masking

Participants were randomly assigned (1:1:1) via a third party web based service (hosted by Griffith University, QLD, Australia) using computer generated randomised permuted blocks (sizes 4, 8, 12). To ensure allocation concealment, randomisation occurred only after all baseline data were collected. An unmasked radiology nurse undertook randomisation and prepared the injections. They were instructed to not discuss the procedure with participants (this was the responsibility of the radiologist). Participant masking was maintained by use of identical injection procedures (five 10 mL syringes) and syringe tape to conceal the fluid colour. For sham injections, fluid was diverted to a hidden bag via a three way stopcock. Radiologists were aware of whether the injection was active or sham but were masked to whether the active injection contained corticosteroid. All clinicians providing care after treatment were unaware of participants' randomisation status. Outcome assessors and statisticians were fully masked. Participant masking was checked immediately after the injection by asking them to guess their allocation (ie, intervention, sham, or not sure).[21]

Procedure

Study treatments

All participants received a single injection administered by a musculoskeletal radiologist while lying prone. In cases of bilateral symptoms, the side that the participant reported as the most symptomatic was injected (or on the right side if they could not decide).

The radiologist delivered the high volume injection into the interface between Kager's fat pad and the Achilles tendon. This intervention comprised five 10 mL syringes: the first contained 10 mL of 0.5% bupivacaine hydrochloride with 25 mg hydrocortisone, followed by four syringes of 10 mL normal saline. By use of a connecting tube, the anaesthetic and corticosteroid were injected first, followed by the saline. The needle position was continuously monitored via ultrasound and gently moved along the interface between Kager's fat and the tendon to ensure an even distribution over the pathological area.

This injection was identical to the high volume injection with corticosteroid, but the first syringe contained only 10 mL of 0.5% bupivacaine hydrochloride (ie, no corticosteroid).

The sham injection, delivered under identical conditions to the high volume injections, involved 2-3 mL of 0.5% bupivacaine hydrochloride injected at least 10 mm more anterior from Kager's fat-Achilles tendon interface (unlikely to be therapeutic due to suboptimal placement and transient effects). This injection produced a similar numbing effect to the high volume injections.

Immediately after injection, all participants received identical care from a physiotherapist.[9] To maintain masking, participants wore a sleeve over the Achilles region to conceal potential swelling from high volume injection. Care included a progressive,

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evidence based Achilles tendon exercise programme targeting the calf and Achilles tendon,[22 23] education on activity modification and progression using a pain monitoring model,[22 23] and information about pathology, prognosis, treatment options, and recovery timelines. We requested participants refrain from concurrent treatment and highlighted the importance of completing the prescribed exercise for the 12 week period, even if symptoms improved. Education materials, exercise video links, and an exercise progression framework were provided (appendix, p 2). Follow up included a phone check-in one week after injection, a teleconference at two weeks, an in-person session to adjust exercises at six weeks, and a review at 12 weeks to guide long term exercise continuation. Participants saw the same physiotherapists at weeks 26 and 52 and could ask questions and receive advice if needed. Physiotherapists were available by phone or email throughout the 12 month trial. Participants were asked to avoid other treatments during the first 12 weeks but could use paracetamol (up to 4 g/day) for pain relief.

Radiologist and physiotherapist training and fidelity assessment

Three experienced radiologists (≥5 years' experience) administered the injections. To ensure fidelity to the original high volume injection procedure, the technique's originator conducted three hour in-person training at the trial site, including a demonstration and the development of a checklist (appendix, p 8). Each radiologist then practised on at least three patients until they met the checklist criteria, assessed by a trained researcher (PM). During the trial, 21 injections (11%) were randomly observed and assessed by the same researcher (PM) for fidelity using the checklist.

Four qualified physiotherapists delivered the after care. The first two managed the initial 43 participants until recruitment was paused on 10 July 2020 due to covid-19; both resigned during this period. Two new physiotherapists were trained and resumed enrolment in July 2021. Training included a three hour session with instruction, modelling, simulated practice with feedback, and a review of patient facing materials. Delivery fidelity of the second physiotherapist pair was assessed at three timepoints (after about 15, 35, and 75 baseline sessions had been delivered) and has been reported elsewhere.[24]

Outcomes

Participants self-reported outcomes or the masked physiotherapists delivering the post-injection intervention assessed the outcomes. The primary clinical outcome was self-reported pain and disability using the Victoria Institute of Sport Assessment-Achilles (VISA-A) (0-100, where 0 is worst pain and disability) at 52 weeks.[20] The VISA-A is endorsed in the most recent core outcome set for assessing disability in Achilles tendinopathy, supported by evidence of its reliability and validity.[25]

Secondary clinical outcomes included: (1) VISA-A at weeks six, 12, and 26; (2) global rating of change (11-point Likert, where 0 indicates not change)[26]; (3) overall pain intensity (0-100, where 100 is worse)[27]; (4) health-related quality of life (EQ-5D-5L: utility score 0-1, where 1 represents full health, and health rating 0-100, where 0 is worse)[28]; (5) physical activity (7 day recall, by metabolic equivalent)[29]; (6) kinesiophobia (Tampa Scale for Kinesiophobia-11, 0-44, where 44 indicates severe fear of movement)[30]; (7) catastrophising (pain catastrophising scale, 0-52, where 52 represents most severe pain catastrophising)[27]; (8) pain self-efficacy (pain self-efficacy questionnaire, 0-60, higher scores indicate higher confidence in daily ability)[31]; (9) ankle plantarflexor strength (maximal isometric force/bodyweight);[32] and (10) Achilles tendon Doppler signal area (mm^2) and thickness (mm) via ultrasound.[33 34] Outcomes were assessed at baseline and at weeks six, 12, 26 and 52, aside from global rating of change, which was not assessed at baseline. Knowledge of imaging could have affected self-reported outcomes so we collected self-reported outcomes at baseline, prior to imaging.

We also report exercise adherence (average sessions per week (0, 1, 2, ≥3); proportion meeting ≥2 per week) and number of adverse events (serious and other).

For the trial based cost-utility analysis (societal perspective), we assessed direct health costs (from Australian Government datasets), other direct costs (eg, admission to hospital and travel), via patient questionnaires and indirect costs (eg, absenteeism, presenteeism, and unpaid labour) via the Institute of Medical Technology Assessment (iMTA) productivity cost questionnaire.[35]

Statistical analysis

The trial was powered to detect a 10 point difference on the VISA-A scale for any pairwise comparison among the three groups. The 10 point difference is consistent with previous studies[36 37] and with Cochrane recommendations to target a difference of approximately 10% of the scale range when an established target difference is unavailable.[38] To gain 80% power at a significance level of less than 0.0167, which allows for multiple comparisons assuming a standard deviation of 15.6 (from preliminary data[16]), we required data from 51 participants in each group. Allowing for a 20% loss to follow up, our target sample size was 192. We prospectively published (prior to any analyses starting) the full statistical analysis plan on the Open Science Framework[39]; a summary is provided below. A masked statistician (AF) and researcher (TPH) conducted analyses by intention to treat (except for safety outcomes).

We assessed between-group differences in primary and secondary outcomes at weeks six, 12, 26, and 52. We analysed continuous outcomes using linear mixed models with unstructured covariance and robust standard errors, including terms for treatment group, time, their interaction, and baseline values (where available). We estimated between-group differences in

follow-up scores adjusted for baseline. For the global rating of change (no baseline), groups were compared at each timepoint. Dichotomous outcomes (adherence to ≥2 sessions per week and serious and other adverse events) were analysed using generalised estimating equations with robust standard errors and both log and identity links to estimate marginal risk ratios.

We conducted secondary per protocol analyses by: (1) excluding participants who did not receive their allocated injection, and (2) excluding people who averaged less than two exercise sessions a week during the monitored 12 week period. Where appropriate, 98.33% confidence intervals and p values (<0.0167) were reported alongside point estimates. The primary outcome for each comparison was also analysed with alpha set at 0.05 in a supplemental file to support future systematic reviews. Multiple imputation using chained equations was applied for outcomes with more than 5% missing data. A data management committee, including two biostatisticians and clinical experts, monitored trial safety and compliance. We used STATA v17 (StataCorp, TX) for analyses.

For the incremental cost-utility analysis, we adopted a societal perspective in the base case (primary analysis), incorporating valuation of drugs and other inputs by opportunity costs, inclusion of productivity gains and losses, and use of community preferences to estimate the utility of health states (appendix, p 24).[40] We estimated productivity losses using the human capital approach. Sensitivity analyses were conducted by varying the calculation of key cost inputs (eg. use of friction method to estimate productively losses) and by varying the perspective of the analyses.

The approach for imputation of missing data is outlined in the appendix (p 32). Bootstrap resampling (20 000 replications per analysis) was used to generate a 95% confidence interval ellipse for incremental cost-utility estimates.[41] An area-under-the-curve approach was used to extrapolate values across timepoints, and costs were pro-rated to cover the full intervals between assessments (baseline and weeks six, 12, 26, and 52).[40] If no participant data were collected during these periods, the data were treated as missing at the end timepoint, and multiple imputation was used to address this. All costs were calculated using a 2019-20 financial base year. Pseudonyms were used to conceal group identity for the economic analysis.

Deviations to the protocol

Due to covid-19, we made some deviations to the protocol. Imaging outcomes (anteroposterior diameter and Doppler pixels) were collected at three timepoints (baseline and weeks six and 52), omitting weeks 12 and 26. Physiotherapists provided participants with their phone contact and limited follow-up calls to one week after injection, instead of the originally planned check-ins at weeks one, four, eight, and 10. To reduce participant burden: the original validated VISA-A was used as the sole primary outcome measure, instead of both original and modified versions as initially planned. Additionally, we collected self-reported data for adverse events, adherence, productivity, and healthcare use every six weeks (rather than every four weeks). We did not assess the rate of force development because most participants were unable to perform the rapid effort required. We reported exercise adherence as average sessions per week and the proportion of participants who did at least two sessions per week over 12 weeks, rather than in quartiles, due to missing data for the first quartile.

Patient and public involvement

Patients or the public were not involved in the design of this trial, but they did assist in developing patient facing materials and they will be involved in development of patient facing dissemination materials.

Results

Between 5 December 2019 and 24 July 2022, we screened 1116 individuals; 321 declined and 603 were ineligible (appendix, p 9). We randomly assigned 192 participants: 64 (33%) to sham, 63 (32%) to high volume injection with no corticosteroid, and 65 (34%) to high volume injection with corticosteroid (fig 1). At 52 weeks (primary timepoint), 181 (94%) completed the primary outcome: 58 (91%) in the sham group, 60 (95%) in the high volume injection with no corticosteroid group, and 63 (97%) in the high volume injection with corticosteroid group (fig 1; appendix, p 10). Missing data for physical outcomes (Doppler signal, tendon thickness, and plantarflexor strength) were more frequent than planned due to covid-19-related site access restrictions.

At baseline, participants reported moderate to high pain and disability (mean VISA-A: 48.7 (standard deviation (SD) 15.6), scale 0-100, where 100 is no pain/disability) and a median symptom duration of two years (interquartile range 0.8-6). Of the 192 participants, 105 (55%) were men and 86 (45%) were women, with a mean age of 48.7 years (SD 10.8, range 19-75). Sixty four (33%) were obese, and 97 (51%) had bilateral Achilles tendinopathy symptoms (table 1).

Immediately after injection, most participants were not sure of their allocation (sham: 42/63 (67%); HVI with no corticosteroid: 43/59 (73%); HVI with corticosteroid: 43/62 (69%)). A similar proportion believed that they had received an active injection (14/63 (22%), 13/59 (22%), and 15/62 (24%), respectively) (appendix, p 11). Only minor issues with injection procedure fidelity were observed (eg, not recording images and not checking needle placement in both transverse and longitudinal planes) with feedback provided as needed. Exercise delivery fidelity has been reported elsewhere.[24] Over 80% of checklist items were delivered as intended for 7, 9, and 10 of the 10 components at timepoints 1, 2, and 3, respectively, and has been reported elsewhere.

Sham versus high volume injection with corticosteroid

At 52 weeks, a small, non-significant difference was noted that favoured sham over high volume

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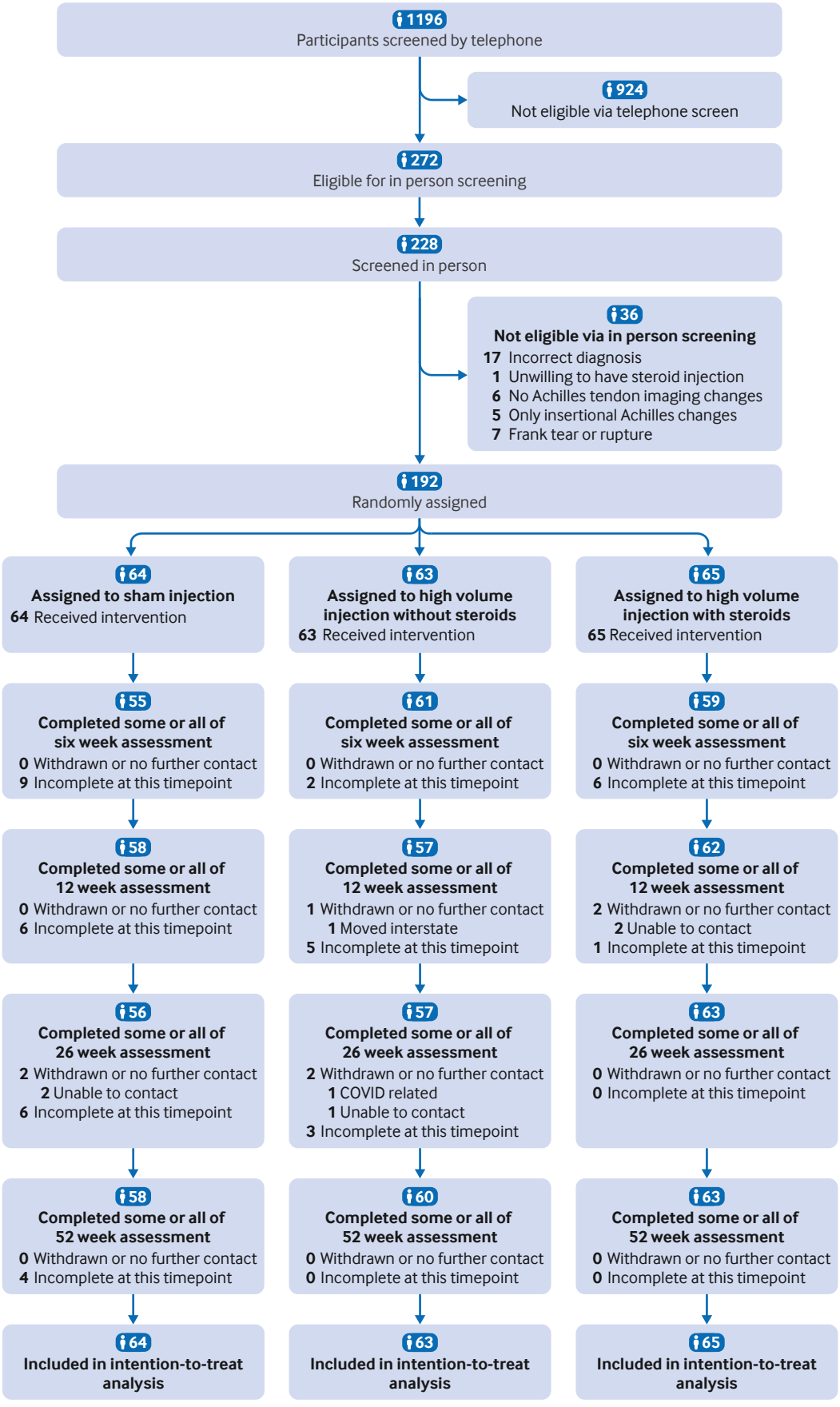


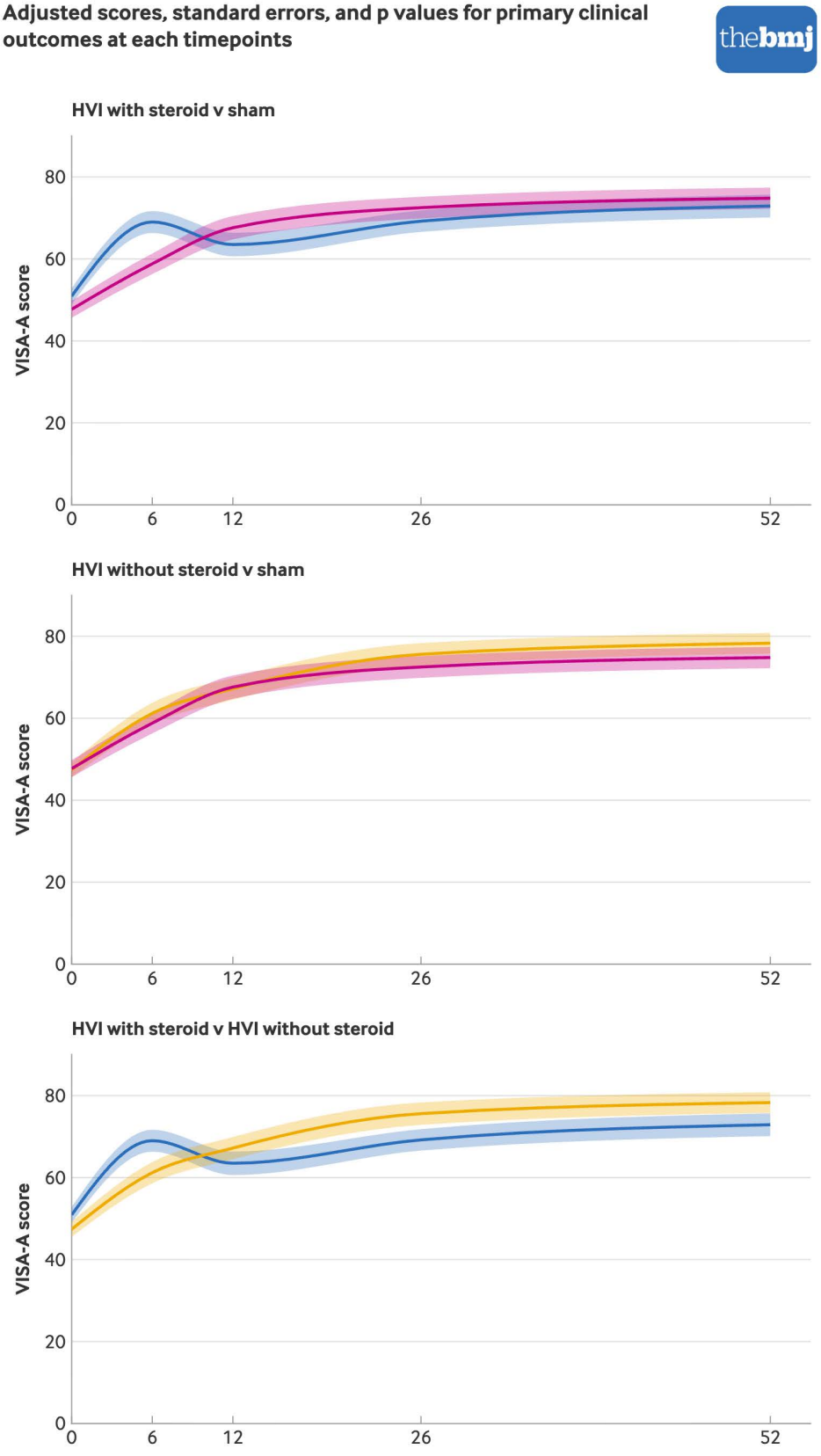
Fig 1 | Trial profile (HVI=high volume injection)

Table 1 | Baseline characteristics of study participants. Data are number (%), mean (standard deviation), and median (interquartile range), unless otherwise specified.

Characteristics	Sham (n=64)	HVI without steroid (n=63)	HVI with steroid (n=65)
Gender (%):			
Women	30 (47)	28 (44)	28 (43)
Men	34 (53)	35 (56)	36 (55)
Non-binary	0 (0)	0 (0)	0 (0)
Prefer not to say	0 (0)	0 (0)	1 (2)
Age, years	50.1 (12.2)	48.1 (10.9)	47.9 (9.3)
University education (%)	38 (59)	39 (62)	32 (49)
Ethnic group on ABS classification (%)*:			
Australian	19 (48)	23 (45)	20 (41)
Indigenous Australian	0	0	0
New Zealander	0	3 (6)	0
European	15 (38)	22 (43)	25 (51)
Middle Eastern†	0	0	2 (4)
Asian	1 (3)	1 (2)	2 (4)
Africa	2 (5)	0	0
American	3 (8)	2 (4)	0
Employed or self-employed	46 (72)	55 (87)	57 (88)
Comorbidities (%):			
Type 2 diabetes	3 (5)	0	0
Elevated cholesterol	8 (13)	10 (16)	11 (17)
Hypertension	8 (13)	9 (14)	8 (12)
Obesity	20 (31)	25 (40)	19 (29)
Coronary artery disease	1 (2)	1 (2)	1 (2)
History of cancer	1 (2)	4 (6)	3 (5)
Weight, kg	86.0 (14.4)	84.5 (17.5)	85.1 (17.3)
Height, cm	173.6 (9.3)	172.3 (8.7)	173.2 (9.3)
BMI	28.6 (5.0)	28.5 (5.2)	28.4 (5.9)
Pressure pain threshold, kg	16.8 (8.9)	13.9 (8.0)	14.7 (8.9)
Achilles tendon pain pixels, ^{m}m2	420 (261)	458 (423)	441 (320)
Median duration of current episode, years (IQR)	2.3 (0.5 to 10.0)	2.0 (1.0 to 5.0)	2.0 (0.8 to 6.5)
Bilateral Achilles tendinopathy (%)	33 (52)	33 (52)	31 (48)
Neuropathic pain (%)‡	5 (8)	8 (13)	5 (8)
VISA-A (0-100, 0 is worst)	47.7 (16.5)	47.4 (14.7)	50.9 (15.5)
Anteroposterior diameter (mm)	8.7 (2.3)	8.7 (1.9)	8.7 (2.6)
Doppler pixels (mm^2)	3.3 (0.6 to 10.3)	4.1 (0.7 to 10.0)	3.6 (1.5 to 13.5)
Worst pain, past 7 days (0-100, 100 is worst)	50.3 (23.8)	50.1 (21.9)	49.8 (23.1)
EQ-5D-5L (utility)	0.83 (0.15)	0.85 (0.14)	0.83 (0.20)
EQ-5D (vas) (0-100, 0 is worst)	73.9 (17.1)	67.1 (17.6)	72.4 (16.4)
7-day activity recall, MET	272.3 (51.5)	271.4 (49.0)	277.1 (80.4)
TSK-11 (11-44, 44 is worst)	25.4 (5.3)	26.2 (4.6)	25.3 (5.5)
PCQ (0-52, 52 is worst)	11.3 (9.1)	11.2 (9.6)	11.8 (11.0)
PSEQ (0-60, 0 is worst)	47.7 (11.6)	46.3 (10.1)	49.5 (9.8)
Plantarflexor MVIC, force/body weight	0.84 (0.35)	0.79 (0.30)	0.82 (0.32)
Past treatment (%):			
Exercise	51 (80)	50 (79)	51 (79)
Activity modification or rest	51 (80)	49 (78)	56 (86)
Medication	20 (31)	18 (29)	24 (37)
Injection	5 (8)	12 (19)	9 (14)
Other§	63 (99)	63 (100)	61 (94)
Consulted professional	62 (99)	62 (99)	61 (94)
CEQ:			
Credibility	19.7 (5.4)	19.9 (4,1)	19.8 (3.9)
Expectancy	17.4 (5.3)	17.7 (4.8)	16.8 (4.1)

ABD=Australian bureau of statistics; CEQ=credibility and expectancy questionnaire; EQ-5D-5L=EuroQol 5 Dimensions, 5 Levels; IQR=interquartile range; MET=metabolic equivalent; MVIC=maximal voluntary isometric contraction; PCS=pain catastrophising scale; PSEQ=pain self-efficacy questionnaire; TSK-11=Tampa scale of kinesiophobia 11-item version; VISA-A=Victorian Institute of Sport Assessment-Achilles.
*140 (73%) responded (n=40 sham; n=51 HVI without steroid; n=49 HVI with steroid).
†Includes people identifying as Arab, Jewish, Peoples of the Sudan, other North African and Middle Eastern.
‡Based on painDETECT classification.
§Including extracorporeal shockwave therapy, oral steroid, weight loss.

injection with corticosteroid (-3.5 (98.33% CI -12.0 to 5.0)) (fig 2, appendix, p 12). However, at six weeks, a statistically significant benefit that was less than the target difference of 10 points showed favouring of high volume injection with corticosteroid over sham (9.2 (1.8 to 16.9)) (fig 2, appendix, p 12). For secondary outcomes, a greater global rating of change was observed at six weeks in the corticosteroid group compared with sham (0.9 (0.1 to 1.7)) (appendix, p 13).



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HVI=High volume injection; VISA-A=Victorian Institute of Sport Assessment-Achilles

Fig 2 | Adjusted scores, standard errors, and p values for primary clinical outcomes at each timepoint. HVI=High volume injection; VISA-A=Victorian Institute of Sport Assessment-Achilles

Sham versus high volume injection without corticosteroid

VISA-A scores at 52 weeks showed a small, non-significant difference, favouring high volume injection without corticosteroid compared with sham (4.0 (98.33% CI -4.2 to 12.3)) (fig 2, appendix, p 12). Differences at other timepoints were also small and non-significant (all favoured the high volume injection without corticosteroid), and no differences in secondary clinical outcomes reached statistical significance (appendix, p 14).

High volume injection with versus without corticosteroid

VISA-A scores showed small differences favouring high volume injection without corticosteroid at weeks 26 and 52 when compared with sham. At 26 weeks, the difference was -8.6 (98.33% CI -16.4 to -0.7), whereas at 52 weeks the estimate was of a similar size but was not statistically significant (-7.5 (-15.3 to 0.3)). (fig 2, appendix, p 12). In both cases, the observed effects size was less than our target difference of 10. For secondary outcomes, a small reduction in tendon thickness was noted at six weeks in the corticosteroid group (-0.5mm (-0.9 to -0.1)), while worst pain over the past 7 days at was significantly higher in the group with corticosteroid at 26 weeks (11.3 (2.2 to 20.3)) (appendix, p 15).

Sensitivity analyses for missing data showed small benefits for high volume injection without corticosteroid versus high volume injection with corticosteroid on VISA-A at 26 weeks and pain at 12 weeks. However, differences for high volume injection with corticosteroid versus sham (VISA-A and global rating of change at six weeks) and for high volume injection with corticosteroid versus high volume injection without corticosteroid (tendon thickness at six weeks) were not significant (appendix, p 16).

No participants experienced Achilles tendon ruptures. Six participants had serious adverse events (none related to the trial): two (3%) in each of the three groups (appendix, p 20). Eighty non-serious adverse events were recorded, mostly for Achilles or other musculoskeletal pain, with similar proportions across groups: 34/64 (53%) in sham, 24/63 (38%) in high volume injection without corticosteroid, and 32/65 (49%) in high volume injection with corticosteroid (appendix, p 20). Only one non-serious adverse event (injection site pain) was related to the injection (HVI with corticosteroid) (table 2).

Between-group differences in weekly exercise sessions and the proportion of participants meeting the minimum frequency of at least two sessions per week (91.4% to 94.7% across the groups) were small and non-significant (appendix, p 21). Exclusion of participants who did not meet the minimum exercise frequency did not change the primary findings, except for an additional benefit for high volume injection without versus with corticosteroid on VISA-A at 52 weeks and EQ-5D at 12 weeks (appendix, p 22). As all participants received their allocated injection, the first per protocol analysis was not conducted.

In the base case and in all health economic analyses, participants allocated to high volume injection with corticosteroid had similar quality-adjusted life years (marginally favouring high volume injection with corticosteroid) and lower costs than sham (appendix, p 42). Cost effectiveness acceptability curves showed a more than 90% probability of cost effectiveness at both AUS$50 000 and $100 000 willingness-to-pay thresholds (fig 3). By contrast, high volume injection without corticosteroid had a low probability of cost effectiveness (<60%) across all plausible willingness-to-pay thresholds considered (fig 3).

Discussion

Principal findings

Among people with Achilles tendinopathy, high volume injections with or without corticosteroid did not result in better pain or disability outcomes (primary outcome)

Table 2 | Adverse events over the 12 month trial period

	Sham (n=64)	HVI without steroid (n=63)	HVI with steroid (n=65)
Serious adverse events (none were potentially trial related)			
Participants reporting one or more serious adverse events (%)	2 (3)	2 (3)	2 (3)
Unrelated surgery requiring admission to hospital	2 (3)	1 (2)	2 (3)
Transient ischaemic attack requiring admission to hospital	—	1 (2)	—
Motor vehicle accident requiring admission to hospital	—	—	1 (2)
Non-serious adverse events			
Participants reporting one or more non-serious adverse events (%)	34 (53)	24 (38)	32 (49)
Potentially trial related (%)			
Reaction to trial injections	—	—	1 (2)
Aggravated Achilles pain	18 (28)	10 (16)	16 (25)
Delayed onset calf muscle soreness	1 (2)	2 (3)	1 (2)
Other non-serious adverse events (%)			
Musculoskeletal pain condition	9 (14)	9 (14)	11 (17)
Non-trial related surgery	1 (2)	—	1 (2)
Covid-19 infection or other infection	4 (6)	3 (5)	2 (3)
Fracture	1 (2)	—	—

Serious adverse events were defined as an event related or not related to the interventions that results in death, life threatening complication, hospital admission, surgery, permanent or temporary physical disability, or congenital abnormalities. Non-serious adverse events were defined as any other unfavourable or unintended diagnosis, sign, symptom, or disease that may or may not be related to the intervention (eg, low back pain) that lasts for seven consecutive days.

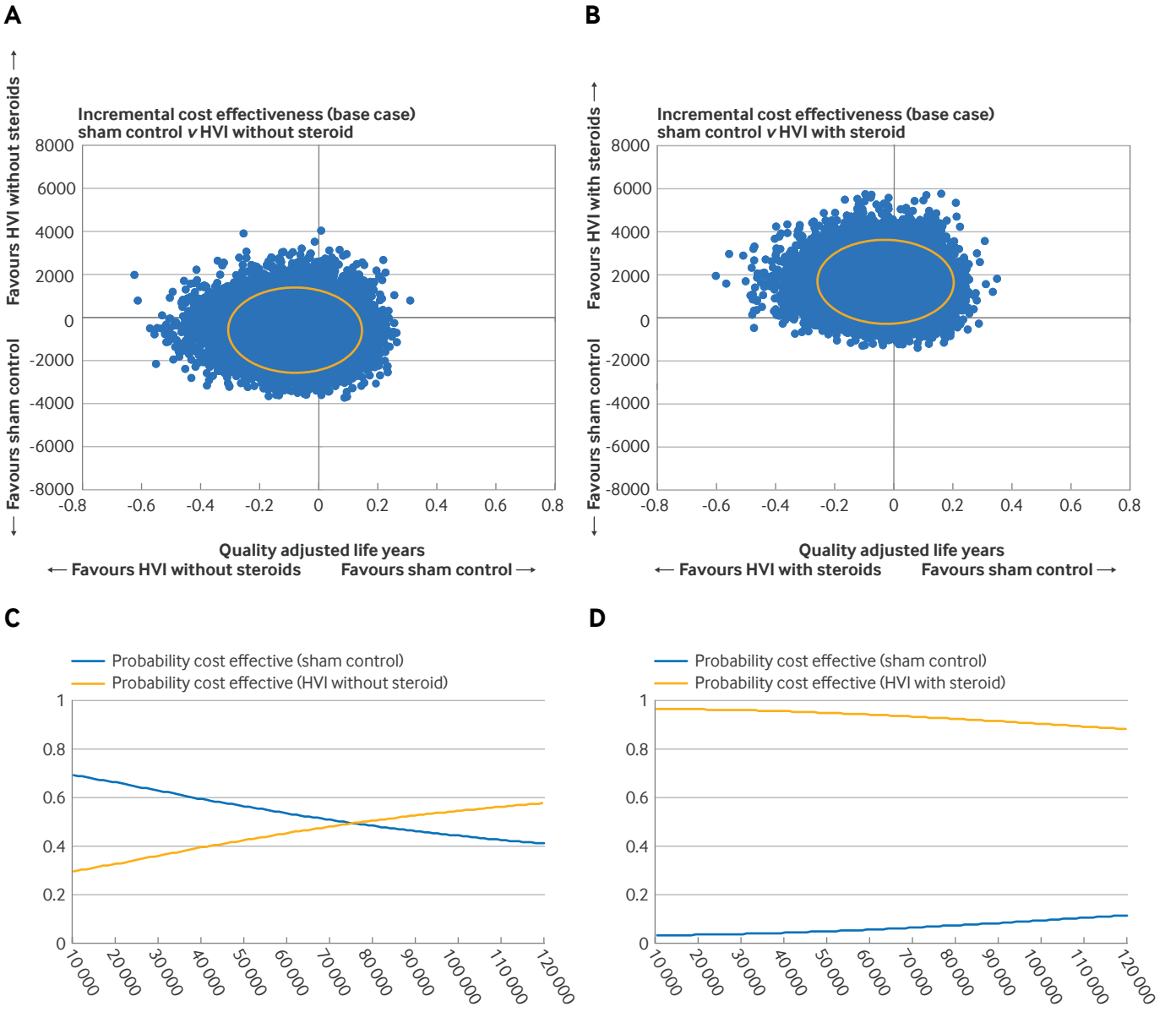


Fig 3 | Cost effectiveness planes (A and B) and acceptability curves (C and D) for paired comparisons of treatment groups, based on 20 000 bootstrapped cost effect pairs. Costs are shown in AUS$. HVI=high volume injection; QALYs=quality-adjusted life years

compared with sham at the 12 month primary endpoint. Most participants (almost 80%) had previously undertaken exercise based treatment and had, on average, moderate severity based on VISA-A scores. High volume injection with no corticosteroid showed no benefit over sham at any timepoint. For the primary outcome, high volume injection with corticosteroid provided small short term improvements at six weeks over sham but worse outcomes than high volume injection with no corticosteroid at 26 weeks (with the same trend but slightly smaller size at 52 weeks). Early benefit is unlikely to be clinically meaningful (mean benefit was less than our target difference of 10 points, but the upper limit of the confidence interval does not exclude a meaningful effect). Secondary outcomes mirrored a shorter term benefit of high volume with corticosteroid versus sham (global rating of change at six weeks) but a longer term harm for injection with versus without corticosteroid (pain at 12 weeks). While an observed short term benefit from corticosteroids is biologically plausible, and consistent with studies in other clinical areas, this effect might be no more than random chance. The overall evidence suggests that this modest short term benefit is outweighed by the longer term disadvantages with high volume injection with corticosteroid. However, desire for short term relief might reasonably affect decisions in some situations. For example, a person who is self-employed and under financial pressure might need to be relatively pain-free to continue working.

Despite modest and short lived symptom relief, high volume injection with corticosteroid was the most economically efficient option, suggesting limited clinical, but potentially important, economic benefits. To our knowledge, this trial is the first to assess cost effectiveness alongside clinical outcomes for an injection treatment in Achilles tendinopathy. High volume injection with corticosteroid was both more effective (QALYs gained) and less costly than sham, with findings consistent across all sensitivity analyses. Economic benefit was driven by reduced absenteeism in the first 12 weeks and lower healthcare costs in the final six months. Reduced absenteeism aligns with broader evidence that productivity losses are a major cost driver in musculoskeletal conditions.[42] A possible explanation is that the short term symptom relief that we observed contributed to improved productivity gains and economic value from a societal perspective. However, given the very small QALY differences, this conclusion should be interpreted cautiously because the health benefit is negligible.

Comparison to the literature

Whether corticosteroid injections increase the risk of tendon rupture or contribute to long term symptom recurrence in tendinopathy is debatable. While intratendinous injections have been linked to Achilles ruptures,[43] our study and others using peritendinous corticosteroid injections reported no ruptures over 6-24 months.[16 44] Our findings align with a pattern of short term benefit followed by a longer term disadvantage, as noted in a 2010 review,[18] which mainly investigated corticosteroid as monotherapy for lateral elbow tendinopathy. Nevertheless, our trial found possible disbenefit versus the injection without corticosteroid as opposed to sham. More recently, Johannsen and colleagues (n=100) compared up to three corticosteroid injections versus sham injections (lipid emulsion and saline) as an addition to Achilles tendon exercise and found benefit for corticosteroid at each timepoint up to 6 months but not at 12-months.[44] The lack of a between-group difference at 12 months suggests that corticosteroid benefit may not be sustained, consistent with our findings, but occurring later, potentially reflecting the use of repeated injections over a three month period. The long term harms from repeated corticosteroid injections are unknown. Boesen and colleagues (n=28) reported sustained benefit when comparing high volume injection with and without corticosteroid up to six months when added to Achilles tendon exercise; however, the use of saline as sham may have compromised masking, and the small sample size raises concerns of effect overestimation.[16] Overall, adding a corticosteroid intervention with an Achilles tendon exercise seems to provide no long term benefit. Consistent with the wider musculoskeletal literature, some short term benefits have been shown from corticosteroid injections when used for Achilles tendinopathy. We have observed a small disbenefit in the medium term when compared with HVI alone, which may be reason enough not to administer steroid in an HVI.

Our findings, alongside those of van der Vlist and colleagues,[17] provide compelling evidence that high volume injection with no corticosteroid results in no meaningful clinical benefit over sham. Both trials consistently showed no significant differences in symptoms or functional outcomes between high volume injection with no corticosteroid and sham at weeks six, 12, or 26, with our study further extending this conclusion to 52 weeks and including a broader range of outcomes. Our imaging data support these clinical findings: no differences in Doppler signal or Achilles tendon thickness were detected between the group receiving high volume injection without corticosteroid and sham. These results are in contrast to the Achilles tendon thickness improvements seen with corticosteroid containing injections versus high volume injection without corticosteroids at six weeks. Collectively, these findings suggest that simply injecting fluid volume does not affect tendon pathology or improve clinical outcomes in Achilles tendinopathy.

Strengths and limitations of this study

The strengths of this study include high fidelity in both the intervention delivery (injections) and exercise implementation, broad eligibility criteria that improves generalisability, inclusion of a well designed and effective sham injection, prospective registration and adherence to the planned outcome measures, and low loss to follow-up. Additionally, adverse events were reported in detail, and the study incorporated a broad range of outcomes, including six of the nine recommended core outcome domains for tendinopathy from Vicenzino and colleagues.[45] The findings should also be considered in the context of study limitations. We only included one of the four (VISA-A) recommended outcome instruments from the Achilles tendinopathy core outcome set, developed after the trial commenced by de Vos and colleagues.[25] Missing data increased over time for self-reported economic data aside from EQ-5D-5L, and the probability of declining consent to access medicare benefits schedule and pharmaceutical benefits scheme data were higher in the high volume injection without corticosteroid group than in the sham group. Additionally, while the participants, physiotherapy providers, and statisticians were masked to treatment group allocation, the nurse and radiologist providing the injection could not be masked. Not masking these caregivers was mitigated by ensuring that they followed a scripted protocol, which minimised any discussions about the injection or its likely outcomes. In participants with bilateral Achilles symptoms, only the most affected side was injected. Although contralateral symptoms may have influenced perceived outcomes, this effect was mitigated by reminding participants at each assessment to report outcomes for the injected side only. Another limitation was the recruitment method; participants were recruited primarily via social media, meaning that the sample may not represent the broader population seeking care in hospital or clinical settings. To minimise participant burden, self-reported adverse

events, adherence, productivity, and healthcare use were assessed at six week intervals, which, although commonly used in clinical trials, may be susceptible to recall bias. Given the large number of outcomes assessed across multiple timepoints, some observed effects could reflect chance findings rather than true treatment effects.

Policy and practice implications

This trial explores 12 month effects of high volume injection with corticosteroid. These findings are timely because high volume injections, both with and without corticosteroid, are already in clinical use. They have been thought to have a different clinical trajectory than corticosteroid alone because of the added volume of saline.[9] However, our results show that there is no difference. The clinical course with high volume injection with corticosteroid mirrors that observed with corticosteroid injections (ie, short lived benefit, with no sustained improvement and possible longer term harm). This evidence should prompt clinicians to reconsider the rationale for using these injections in people with Achilles tendinopathy.

Conclusion

High volume injections with or without corticosteroids did not improve pain or disability compared with sham at 12 months. Although high volume injections with corticosteroid showed short term clinical benefit and potential reduction in healthcare costs over a year, they were associated with worse longer term clinical outcomes. The clinical data do not support routine use for midportion Achilles tendinopathy.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/disclosure-of-interest and declare: one author (DC) is an interventional radiologist who works in a clinic where high volume injections are offered for Achilles tendinopathy and a further two authors (PM, DM) work as physiotherapists and have recommended the high volume injection in the past; support a project grant from the National Health and Medical Research Council of Australia (NHMRC); no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work..

Ethical approval: The study was approved by the Monash University Human Ethics Committee (13138).

Data sharing: The code used to analyse the data and the data underlying the findings in this paper are openly and publicly available and can be found here: https://doi.org/10.26180/c.8671176. If you encounter problems accessing the data, please contact the corresponding author.

Transparency: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: Results will be shared with participants through co-developed patient-friendly summaries. These summaries will also be disseminated more broadly through Monash media channels and links shared with relevant patient advocacy and community groups.

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Supplementary information