Annals of Internal Medicine ORIGINAL RESEARCH

Efficacy of a Very-Low-Calorie Weight Loss Diet Plus Exercise Compared With Exercise Alone on Hip Osteoarthritis Pain

A Randomized Controlled Trial

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Background: Exercise is recommended to manage hip osteoarthritis, but weight loss recommendations are conflicting.

Objective: To evaluate the efficacy of a weight loss diet added to exercise on change in hip pain.

Design: 2-group superiority randomized trial. (ClinicalTrials.gov: NCT04825483)

Setting: Community.

Participants: 101 adults with hip osteoarthritis and overweight or obesity.

Intervention: Both the exercise only group and very-low-calorie diet (VLCD) plus exercise group were provided with a 6-month home exercise program via 5 telehealth consultations. The VLCD plus exercise group also received a VLCD via 6 telehealth consultations.

Measurements: The primary outcome was 6-month change in hip pain severity (11-point scale; range 0 to 10, with higher scores indicating worse pain; minimum clinically important difference of 1.8). Secondary end points included other measures of hip pain, physical function, quality of life, body weight, body composition, and adverse events.

Results: 99 (98%) and 95 (94%) participants provided 6- and 12-month primary outcomes, respectively. Although VLCD plus exercise lost 8.5% more weight than exercise only, VLCD plus exercise was not more effective for change in hip pain severity (mean difference, −0.6 units [95% CI, −1.5 to 0.3]) at 6 months. Between-group differences for other secondary outcomes at 6 months favored VLCD plus exercise except Hip Disability and Osteoarthritis Outcome Score (HOOS) pain and function. At 12 months, weight, body mass index, HOOS pain and function, and overall hip improvement, but not quality of life and physical activity, favored VLCD plus exercise. There were no serious related adverse events.

Limitation: Participants were unblinded.

Conclusion: Adding a weight loss diet to exercise did not change hip pain but improved most secondary outcomes.

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Hip osteoarthritis is a major public health problem, accounting for 3.85% of osteoarthritis incident cases (1). Osteoarthritis has no cure, and joint replacement is reserved for end-stage disease. Clinical guidelines consistently recommend exercise for hip osteoarthritis (2–6). However, the effects of exercise on pain are modest (7). Additional effective and safe treatments are urgently needed to arrest the escalating demand for costly joint replacement (8), partly due to aging populations and increasing obesity rates (9).

Weight loss could be a potential treatment to reduce joint pain, as having overweight or obesity increases the risk for hip osteoarthritis (9, 10). However, cohort studies conflict as to whether weight loss reduces the risk for hip joint replacement (11, 12). The only clinical trial in hip osteoarthritis evaluated weight loss in those awaiting hip replacement (13). This trial had methodological issues and uncertain symptom effects (13). Hence, there is limited evidence to inform hip osteoarthritis clinical guidelines, leading to inconsistent recommendations. Guidelines from the Osteoarthritis Research Society International do not recommend weight loss (3). In contrast, other guidelines (2, 4–6), including those from the American College of Rheumatology (4), recommend weight loss of at least 5% to 10%, based on evidence from trials in knee osteoarthritis. However, evidence on the efficacy of weight loss is needed in hip osteoarthritis due to concerns about generalizing findings from the knee (14).

There are numerous weight loss dietary interventions, including a very-low-calorie diet (VLCD). Systematic reviews show that VLCD can result in considerable and rapid weight loss (15), with loss maintained up to 2 years

See also:

Editorial comment
Summary for Patients

Web-Only
Supplement

(16). Our pilot study in hip osteoarthritis (17) and clinical trial (18) with nested qualitative studies (19, 20) in knee osteoarthritis have shown feasibility and acceptability of a remotely delivered VLCD intervention that results in around 8% weight loss over 6 months. Thus, our primary aim was to test the hypothesis that weight loss via a VLCD added to exercise would improve hip pain severity at 6 months more than exercise alone in persons with hip osteoarthritis and overweight or obesity. We also aimed to evaluate longer-term effects at 12 months, in addition to effects on other clinical outcomes.

METHODS

Design Overview

This was a prospectively registered (NCT04825483), 2-group, parallel, superiority randomized controlled trial (RCT). The study protocol (available at Annals.org) was published (21), and no amendments were made. Approval was obtained from The University of Melbourne Human Research Ethics Committee. Digital online informed consent was obtained before baseline assessment.

Setting and Participants

We recruited community-based participants with hip osteoarthritis according to American College of Rheumatology criteria (22) in Melbourne and Sydney, Australia, from online advertisements and our Centre's volunteer database. Initial screening was completed via an electronic survey (Qualtrics), followed by telephone. Potentially eligible participants had an anteroposterior supine hip radiograph, if none within the prior 12 months. Inclusion criteria were age 50 years or older; hip pain for 3 or more months; hip pain of at least 4 on an 11-point numerical rating scale (0 = no pain, 10 = worst pain imaginable) over the past week; pain in the groin or hip on most days of the past month (22); femoral or acetabular osteophytes and joint space narrowing on radiograph (22); access to an internet-enabled device; body mass index (BMI) greater than 27 kg/m^2 based on Royal Australian College of General Practitioners guideline for obesity management (23); able to give informed consent and participate in the study; able to weigh themselves; and medical clearance if indicated by the Exercise and Sports Science Australia stage 1 adult preexercise screening (24). Exclusion criteria are in Table 1 of Supplement 1 (available at Annals.org).

Randomization and Interventions

Three randomization lists were computer-generated by an independent biostatistician. Participants were randomly allocated, first to either exercise only or VLCD plus exercise in a 1:1 ratio using permuted blocks of varying size stratified by site (Melbourne or Sydney) and sex (male or female), then randomly assigned to a physiotherapist (same 8 physiotherapists delivered exercise to both groups) and, if assigned to VLCD plus exercise, randomly assigned to a dietitian. An independent researcher accessed the randomization schedule via a password-protected computer program. Participants were unblinded, thus participant-reported outcomes were unblinded. Dual-energy x-ray absorptiometry outcomes were collected by a blinded assessor. Physiotherapists and dietitians were unblinded. Biostatisticians (F.M. and A.D.S.) were blinded to group names.

Interventions

Eight physiotherapists and 5 dietitians in private practice delivered the interventions. All consultations (45 minutes initial, 30 minutes thereafter) were done via videoconference (Zoom Video Communication) over 6 months. Clinician selection and training procedures are described in the protocol (13). The exercise and VLCD interventions are detailed according to the Template for Intervention Description and Replication guidelines (25) (see Supplement 2, available at Annals.org).

Exercise Only

Exercise was used as the control because it is the core recommended treatment of hip osteoarthritis (2–4, 6). This comprised 5 consultations with a physiotherapist and resources described in Table 2 of Supplement 1 (available at Annals.org). These consults were recommended for weeks 1, 3, 9, 15, and 21. Physiotherapists prescribed a home strengthening exercise program (4 to 6 lower limb exercises performed 3 times per week taking approximately 20 to 30 minutes to complete each session) (Table 3 of Supplement 1, available at Annals.org) and an individualized plan to increase physical activity. Participants were encouraged to continue their program after 6 months.

VLCD Plus Exercise

In addition to the exercise components described earlier (with another 2 arm strengthening exercises to minimize lean mass loss [Table 2 of Supplement 1]), participants had 6 consultations with a dietitian to support them in undertaking a ketogenic VLCD. These consults were recommended for weeks 1, 3, 6, 10, between 14 and 17 weeks, and between 19 and 23 weeks. Participants were provided with Optifast (Nestlé Health Science) or Optislim (OptiPharm) meal replacements for the first 6 months, a portion plate, educational video, hardcopy weight management guide, behavioral support activities, recipe book, and food list pocket guide (Table 2 of Supplement 1). The diet included 3 phases (Table 4 of Supplement 1, available at Annals.org). Phase 1 aimed to reduce body weight by 10% using a ketogenic VLCD (2 meal replacement products daily), consuming 800 kcal or 3280 kJ daily with very low carbohydrate amounts (<50 g) (21). Phase 2 aimed to transition the participant to a longer-term eating plan by reducing meal replacements and reintroducing low glycemic index carbohydrates. Phase 2 commenced once participants reached 10% weight loss or by week 23, whichever came first.

Phase 3 aimed to maintain weight through a healthy diet recommended by the Commonwealth Scientific and Industrial Research Organisation (26). If participants gained 2 kg or more, they were recommended to reinitiate the VLCD for 1 to 2 weeks.

Outcomes and Follow-up

For participants with bilateral eligible hips, the most symptomatic was deemed the study hip. No incentives were given to participants to complete outcomes. The primary outcome was 6-month change in hip pain severity. Participants reported their average overall hip pain severity during the past week via an electronic survey at baseline, 6 months, and 12 months using a validated 11-point numerical rating scale with terminal descriptors of 0 (no pain) and 10 (worst pain possible) (27), which is recommended for osteoarthritis clinical trials (28).

Secondary outcomes reported by participants and collected via electronic surveys at baseline, 6 months, and 12 months included body weight; BMI; hip pain, physical function and hip-related quality of life subscales of the Hip Disability and Osteoarthritis Outcome Score (29) ([HOOS] 0 to 100, higher indicating better); and health-related quality of life measured via the Assessment of Quality of Life questionnaire (version Assessment of Quality of Life-8 Dimension) (30) (−0.04 to 1.0, higher indicating better). Secondary outcomes also included hip pain severity during the past week at 12 months (27); perceived global change in overall hip problem and in physical activity (7-point Likert scales from "much worse/less" to "much better/more") (21) at 6 and 12 months; proportion of participants reaching the minimum clinically important difference (MCID) of 1.8 (31) for the primary outcome at 6 and 12 months; and visceral and total body fat mass at baseline and 6 months by dual-energy x-ray absorptiometry (GE Lunar iDXA narrow-angle densitometer in Melbourne and iDXA Hologic Apex 5.6.0.7 and Apex 5.6.0.5 in Sydney, Australia).

Adverse events, co-interventions, and other health care were participant-reported at 6 and 12 months. Total body lean mass was assessed using dual-energy x-ray absorptiometry at baseline and 6 months. Use of pain medications; Depression, Anxiety, and Stress Scale (32) (0 to 42, higher worse); Brief Fear of Movement Scale for Osteoarthritis (33) (6 to 24, higher indicating greater fear); and self-efficacy for control for eating via the Weight Efficacy Lifestyle Questionnaire (34) (0 to 180, higher indicating greater self-efficacy) were measured at baseline, 6 months, and 12 months. Questionnaires collected descriptive measures at baseline.

Adherence measures included number of consultations attended; participant-reported number of strengthening exercise sessions performed in the past 2 weeks at 6 months; participant-rated adherence to the physical activity plan (5-point Likert scale from "none of the time" to "all of the time"); and for the VLCD plus exercise group only, adherence to the diet plan (5-point Likert scale from "none of the time" to "all of the time") and total number of weeks meal replacements used in the first 6 months. We also recorded consultation duration and assessed clinician fidelity to the treatment protocols from electronic consultation notes.

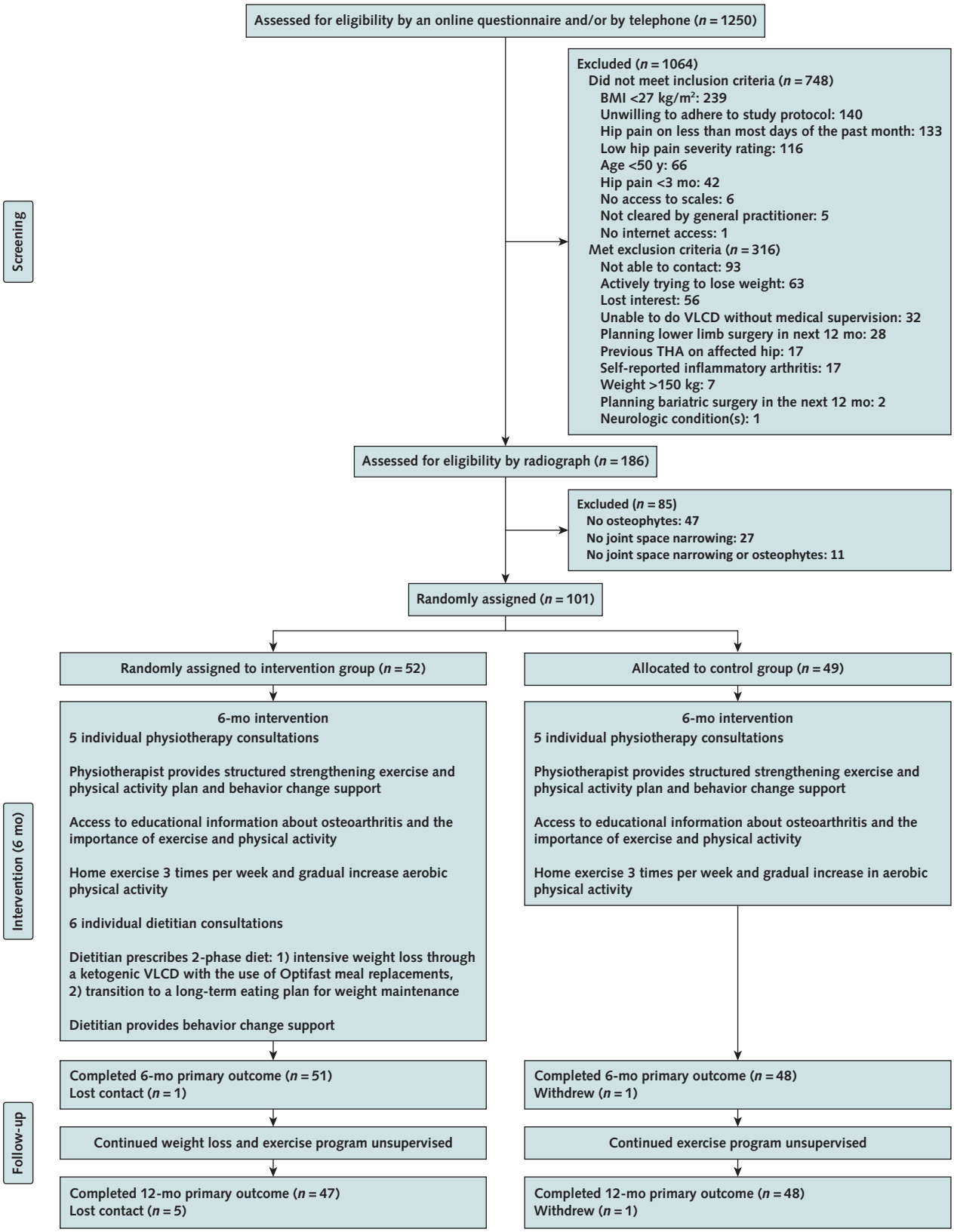
Statistical Analysis

The trial was powered to detect an MCID of 1.8 points (31) on the numerical rating scale in the between-group difference in 6-month change in hip pain severity. The MCID was extrapolated from the most conservative 17.5-mm MCID on a 0- to 100-mm visual analogue scale determined by expert consensus (31). Assuming a 2.5-point SD at baseline across all participants, a 0.25 correlation between baseline and 6-month scores (35), an intracluster correlation of 0.05, and 5 dietitians treating approximately 8 participants each, for 80% power at a 2-sided significance level of 0.05, and allowing for a 20% loss to follow-up, 50 participants per group were required.

We published a statistical analysis plan while blinded (available at Annals.org) and provide additional details in **Supplement 1** (p. 10-11). Comparative analyses between groups used all randomized participants based on intention to treat. The primary outcome was compared between groups using a mixed-effects linear regression model including all data from 6 and 12 months for each participant, adjusted for baseline scores and stratifying variables of site and sex, with random effects for participants, and accounting for clustering by the physiotherapist and dietitian. Mean differences with 2-sided 95% CI and *P* values were obtained. Continuous secondary outcomes were analyzed similarly, with no random effects for participants in models for outcomes measured only at baseline and 6 months. Binary secondary outcomes were compared between groups using logistic regression, with models adjusted for the stratifying variables, and fit using generalized estimating equations to account for clustering by the physiotherapist. Risk differences and risk ratios were estimated with 2-sided 95% CIs.

Prespecified exploratory moderator analyses for the primary outcome at 6 months were done for sex (male vs. female) and baseline BMI, while post hoc moderation of the primary outcome at 6 months by radiographic disease severity (grade 2 vs. grades 3 and 4) and the expected treatment effect (large improvement or complete recovery vs. no effect, minimal improvement, or moderate improvement) was explored (different to our planned approach of benefit vs. no benefit because only 1 VLCD plus exercise participant expected no benefit). Analyses were done using the primary outcome regression model by including an interaction term between the randomized group and potential moderator. The relationship between 6-month weight loss and 6-month change in hip pain severity was explored by including 6-month weight loss, baseline weight, and age in the primary outcome regression

Figure 1. Flow of participants through the trial.



BMI = body mass index; THA = total hip arthroplasty; VLCD = very-low-calorie diet.

Table 1. Baseline Characteristics

Baseline Characteristic	Exercise Only ($n = 49$)	VLCD Plus Exercise ($n = 52$)
Mean age (SD), *y*	61.0 (5.5)	62.6 (6.3)
Sex, *n* (%)		
Female	35 (71)	36 (69)
Male	14 (29)	16 (31)
Mean height (SD), *m*	1.7 (0.1)	1.7 (0.1)
Median hip symptom duration (IQR), *y*	3 (1–6)	2 (1–5)
Unilateral symptoms, *n* (%)	34 (69)	35 (67)
Geographic location, *n* (%)*		
Major city	43 (88)	48 (92)
Inner regional	5 (10)	3 (6)
Outer regional	1 (2)	1 (2)
Remote	0 (0)	0 (0)
Very remote	0 (0)	0 (0)
Education level, *n* (%)		
<3 y of high school	0 (0)	2 (4)
≥3 y of high school	5 (10)	3 (6)
Some education beyond high school	10 (20)	12 (23)
Completed tertiary or higher education	34 (69)	35 (67)
Current employment status, *n* (%)		
Currently employed	31 (63)	33 (63)
Unable to work due to health reasons	2 (4)	0 (0)
Retired (not due to health reasons)	13 (27)	17 (33)
Unemployed/student	0 (0)	1 (2)
Homemaker	3 (6)	1 (2)
Kellgren-Lawrence grade of radiographic severity, *n* (%)†		
Grade 2	32 (65)	33 (63)
Grade 3	13 (27)	15 (29)
Grade 4	4 (8)	4 (8)
Comorbid conditions, *n* (%)‡		
≥1 comorbid condition	38 (78)	44 (85)
Heart disease	3 (6)	5 (10)
High blood pressure	15 (31)	22 (42)
Depression	5 (10)	4 (8)
Anemia or other blood disease	0 (0)	0 (0)
Ulcer or stomach disease	3 (6)	2 (4)
Rheumatoid arthritis	0 (0)	0 (0)
Diabetes	2 (4)	1 (2)
Lung disease	3 (6)	1 (2)
Cancer	1 (2)	3 (6)
Back pain	23 (47)	25 (48)
Kidney disease	1 (2)	1 (2)
Liver disease	1 (2)	0 (0)
Other	18 (37)	14 (27)
Current pain medication use, *n* (%)§		
≥1 medication used	42 (86)	43 (83)
Acetaminophen alone or in combined formulations	37 (76)	38 (73)
Topical anti-inflammatory drugs	12 (24)	17 (33)
Oral nonsteroidal anti-inflammatory drugs	25 (51)	26 (50)
Oral corticosteroids	0 (0)	2 (4)
Oral opioids	0 (0)	2 (4)
Expectation of treatment outcome, *n* (%)‖		
No effect at all	1 (2)	0 (0)
Minimal improvement	5 (10)	1 (2)
Moderate improvement	24 (49)	14 (27)
Large improvement	17 (35)	36 (69)
Complete recovery	2 (4)	1 (2)
Problem in other joint, *n* (%)¶		
≥1 problem in other joint	42 (86)	47 (90)
Hand/wrist	17 (35)	21 (40)
Neck	16 (33)	16 (31)
Back	22 (45)	24 (46)
Knee	32 (65)	30 (58)
Foot/ankle	19 (39)	17 (33)
Shoulder	15 (31)	18 (35)
Elbow	3 (6)	2 (4)

Continued on next column

Table 1–Continued

VLCD = very-low-calorie diet.

* Based on residential postcode, in accordance with Australian Statistical Geography Standard.

† The Kellgren–Lawrence system grades radiographic osteoarthritis disease severity from 0 to 4. Grade 2 indicates presence of osteophytes and possible joint space narrowing. Grade 3 indicates multiple osteophytes, definite joint space narrowing, sclerosis, and possible bony deformity. Grade 4 indicates large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bony ends.

‡ Comorbid conditions assessed using the Self-Administered Comorbidity Questionnaire.

§ Defined as ≥1 time per week over the past month.

‖ Treatment expectation was assessed by a 5-point Likert scale with participants asked "What effect do you think your exercise (and weight loss, if VLCD plus exercise group) program in this study will have on your hip problem(s)?" Score range is 0 (no effect at all) to 4 (complete recovery).

¶ In response to the question "Do you suffer from any problems (e.g., pain, aching, discomfort, or stiffness) around the following joints in your body?"

model. The mean (95% CI) change in pain was estimated for each percentage point increase in weight lost from baseline to 6 months. Intervention costs included consultations and participant materials and resources.

Role of the Funding Source

The National Health and Medical Research Council of Australia funded the study but played no role in the study design or conduct, statistical analysis, or the decision to publish the manuscript.

RESULTS

Sample Characteristics

A total of 101 participants were enrolled from 1250 persons screened between June 2021 and January 2023, with follow-up completed in January 2024 (**Figure 1**). Participant characteristics were generally similar between groups (**Table 1**), although the median symptom duration was higher in the exercise only group and a higher proportion of the VLCD plus exercise group expected a large treatment effect. The primary outcome was provided by 99 of 101 (98%) participants at 6 months and 95 of 101 (94%) at 12 months. Thus, available case analyses were conducted.

Table 2. Change in Continuous Outcomes Within and Between Groups*

Outcome	Mean Change Within Groups (6 Months Minus Baseline) (SD)		Mean Difference in Change Between Groups at 6 Months (VLCD Plus Exercise vs. Exercise Only) (95% CI)	Mean Change Within Groups (12 Months Minus Baseline) (SD)		Mean Difference in Change Between Groups at 12 Months (VLCD Plus Exercise vs. Exercise Only) (95% CI)
	Exercise Only ($n = 48$)†	VLCD Plus Exercise ($n = 51$)‡		Exercise Only ($n = 48$)§	VLCD Plus Exercise ($n = 47$)‖	
Primary outcome						
Hip pain severity¶**††	−2.0 (2.2)	−2.8 (2.2)	−0.6 (−1.5 to 0.3)	−1.8 (2.6)	−2.5 (2.3)	−0.5 (−1.4 to 0.3)
Secondary outcomes						
HOOS¶‡‡§§						
Pain	9.9 (16.0)	18.0 (17.6)	6.0 (−0.7 to 12.7)	11.5 (20.4)	20.1 (21.3)	7.1 (0.4 to 13.8)
Physical function	9.4 (14.7)	16.1 (19.1)	5.2 (−1.1 to 11.5)	10.1 (19.4)	17.9 (21.4)	6.7 (0.4 to 13.0)
Hip-related quality of life	9.9 (19.4)	19.4 (20.8)	8.6 (0.3 to 16.8)	16.1 (24.8)	21.0 (21.0)	4.7 (−3.5 to 12.9)
Assessment of Quality of Life-8 Dimension score¶§§‖‖‖	0.04 (0.12)	0.10 (0.15)	0.06 (0.01 to 0.12)	0.06 (0.15)	0.11 (0.14)	0.06 (0.01 to 0.11)
Body weight, *kg*¶††	−1.1 (3.1)	−10.3 (6.5)	−8.8 (−11.1 to −6.4)	−2.9 (4.0)	−8.8 (7.7)	−5.4 (−7.7 to −3.1)
BMI, kg/m^2¶††¶¶	−0.4 (1.2)	−3.7 (2.3)	−3.2 (−4.0 to −2.3)	−1.1 (1.4)	−3.1 (2.7)	−1.9 (−2.8 to −1.1)
Visceral fat mass, *g*†† ***	−73 (241)	−524 (461)	−402 (−539 to −266)	NA	NA	NA
Total body fat mass, *g*††***	−709 (2701)	−8283 (5626)	−7386 (−9239 to −5532)	NA	NA	NA

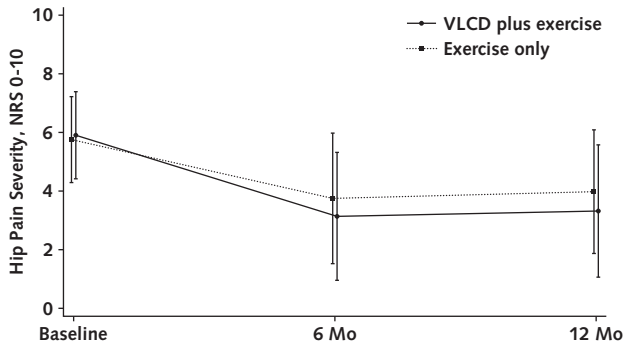
BMI = body mass index; HOOS = Hip Disability and Osteoarthritis Outcome Score; NA = not available; VLCD = very-low-calorie diet.
* Data presented are available cases, as multiple imputation was not done given <5% missing primary outcome data.
† Exercise only: HOOS pain ($n = 45$); HOOS physical function ($n = 45$); HOOS hip-related quality of life ($n = 45$); Assessment of Quality of Life-8 Dimension score ($n = 45$); body weight ($n = 45$); BMI ($n = 45$); visceral fat mass ($n = 41$); total body fat mass ($n = 41$). Exercise only correlations between baseline and 6-mo timepoints: hip pain severity (0.35); HOOS pain (0.33); HOOS physical function (0.54); HOOS hip-related quality of life (0.58); Assessment of Quality of Life-8 Dimension score (0.72); body weight (0.98); BMI (0.97); visceral fat mass (0.96); total body fat mass (0.96).
‡ VLCD plus exercise: HOOS pain ($n = 50$); HOOS physical function ($n = 50$); HOOS hip-related quality of life ($n = 50$); Assessment of Quality of Life-8 Dimension score ($n = 50$); body weight ($n = 50$); BMI ($n = 50$); visceral fat mass ($n = 46$); total body fat mass ($n = 46$). VLCD plus exercise correlations between baseline and 6-mo timepoints: hip pain severity (0.35); body weight (0.91); BMI (0.89); HOOS pain (0.32); HOOS physical function (0.35); HOOS hip-related quality of life (0.41); Assessment of Quality of Life-8 Dimension score (0.60); body weight (0.91); BMI (0.89); visceral fat mass (0.86); total body fat mass (0.84).
§ Exercise only: HOOS pain ($n = 47$); HOOS physical function ($n = 47$); HOOS hip-related quality of life ($n = 47$); utility score for Assessment of Quality of Life-8 Dimension ($n = 47$). Exercise only correlations between baseline and 12-mo timepoints: hip pain severity (−0.03); HOOS pain (0.07); HOOS physical function (0.27); HOOS hip-related quality of life (0.22); Assessment of Quality of Life-8 Dimension score (0.61); body weight (0.96); BMI (0.95).
‖ VLCD plus exercise correlations between baseline and 12-mo timepoints: hip pain severity (0.31); HOOS pain (0.17); HOOS physical function (0.20); HOOS hip-related quality of life (0.46); Assessment of Quality of Life-8 Dimension score (0.56); body weight (0.88); BMI (0.86).
¶ Adjusted for baseline value of the outcome, stratifying variables (site and sex), with random effects for participants, and accounting for clustering by physiotherapist and dietitian as appropriate.
** Measured on an 11-point numerical rating scale for overall average hip pain severity in the past week. Score range is 0 (no pain) to 10 (worst pain possible); higher score indicates worse pain. Minimum clinically important difference is 1.8 points.
†† For change within groups, negative changes indicate improvement. For difference in change between groups, negative differences favor VLCD plus exercise.
‡‡ HOOS is a hip-specific questionnaire with different subscales, pain (12 items), activities of daily living (physical function) (17 items), and hip-related quality of life (4 items). Total subscale scores range from 0 to 100, with 0 indicating extreme problems and 100 indicating no problems. Minimal clinical important change/difference: pain (range, 9 to 36), physical function (range, 9 to 29), hip-related quality of life (range, 9 to 27).
§§ For change within groups, positive changes indicate improvement. For difference in change between groups, positive differences favor VLCD plus exercise.
‖‖‖ The Assessment of Quality of Life-8 Dimension is a 35-item questionnaire regarding health-related quality of life. The score range is −0.04 to 1.0; higher scores indicate better quality of life. Minimum clinically important difference is 0.06 units.
¶¶ Calculated as weight in kilograms divided by height in meters squared.
*** Adjusted for the outcome at baseline and the stratifying variables (site and sex), as well as accounting for clustering by physiotherapist and dietitian as appropriate.

Primary Outcome and Moderator Analysis

For the primary outcome at 6 months, there was no evidence of a between-group difference (mean, -0.6 units [95% CI, -1.5 to 0.3] $P = 0.20$) (Table 2 and Figure 2), with the CIs indicating that a clinically important benefit with VLCD plus exercise is unlikely. Both groups showed reductions in hip pain severity (Table 5 of Supplement 1, available at Annals.org). Similar results were found at 12 months (Table 2, Table 5 of Supplement 1, and Figure 2). However, more VLCD plus exercise participants had a clinically relevant reduction in hip pain severity than exercise only participants at 6 months but not at 12 months (Table 3).

Moderator analyses showed that the effects of VLCD plus exercise compared with exercise only on 6-month change in hip pain severity were similar between sexes, radiographic disease severity (grade 2 vs. grade 3 and 4), and treatment expectation (large improvement or complete recovery vs. no effect,

Figure 2. Group summary of mean (SD) hip pain severity (NRS: 0 to 10; higher is worse) over time.



NRS = numerical rating scale; VLCD = very-low-calorie diet.

minimal improvement, or moderate improvement), and with 1 kg/m^2 increments in BMI (**Tables 6 and 7 of Supplement 1**, available at Annals.org).

Secondary and Other Outcomes

Results of secondary outcomes are shown in **Tables 2** (continuous) and **3** (binary) and **Tables 5 and 8 of Supplement 1** (available at Annals.org). All secondary outcomes at 6 months favored VLCD plus exercise compared with exercise only, with the exception of HOOS pain and function. At 12 months, benefits of VLCD plus exercise compared with exercise only persisted for health-related quality of life, body weight, BMI, and overall hip improvement but not for HOOS hip-related quality of life or physical activity improvement. Benefits of VLCD plus exercise became apparent for HOOS pain and function.

The VLCD plus exercise group lost 8.5% more body weight than exercise only, with 82% of VLCD plus exercise participants achieving greater than 5% body weight loss versus 16% in exercise only. There was no evidence of a clinically meaningful relationship between the amount of weight lost and change in hip pain severity at 6 months (**Table 9 of Supplement 1**, available at Annals.org).

Other measures are reported in **Tables 10 and 11 of Supplement 1** (available at Annals.org). At 6 months, the VLCD plus exercise group showed greater improvements in depression, fear of movement, and self-efficacy for eating control than exercise only, with these sustained at 12 months. There was a between-group difference in the 6-month change in total body lean mass, driven by a loss of lean mass in the VLCD plus exercise group.

Adherence to Interventions and Co-interventions

As shown in **Table 12 of Supplement 1** (available at Annals.org): 90% of VLCD plus exercise participants attended all 6 dietitian consultations; more participants attended all 5 exercise sessions in the VLCD plus exercise group (43 of 52) than the exercise only group (32 of 49); and consultation durations were similar across groups. Dietitian (**Tables 13 and 14 of Supplement 1**, available at Annals.org) and physiotherapist (**Table 15 of Supplement 1**, available at Annals.org) fidelity to the protocol was excellent.

Co-interventions used were generally similar between groups at 6 months, but the rate was lower in the VLCD plus exercise group at 12 months (15 of 47 vs. 29 of 48) (**Table 16 of Supplement 1**, available at Annals.org). For pain medication use, fewer VLCD plus exercise participants reported taking acetaminophen at 6 and 12 months and oral anti-inflammatory drugs at 6 months (**Table 17 of Supplement 1**, available at Annals.org), and although more reported using them less often at 6 months (**Table 17 of Supplement 1**) than in exercise only, numbers were small.

Adverse Events and Intervention Costs

There were no serious related adverse events. Six participants ($n = 5$ in VLCD plus exercise) reported nonserious related adverse events (**Table 16 of Supplement 1**). Direct intervention costs were A$3243 (SD, A$171) for VLCD plus exercise and A$1112 (SD, A$247) for exercise only, with a between-group difference of A$2131 (CI, A$2214 to A$2047).

DISCUSSION

Our study investigated the effects of dietary weight loss in hip osteoarthritis. The VLCD plus exercise group lost a mean 8.8 kg (8.5%) more body weight than exercise only, an amount consistent with guideline recommendations of 5% to 10% (4). Despite this, and contrary to our hypothesis, there was no clinically meaningful effect of the VLCD on the primary outcome of change in hip pain severity. However, most secondary outcomes favored the VLCD plus exercise group at either 6 and/or 12 months.

The VCLD had no effect on the primary pain outcome, with a small between-group difference and CIs that excluded our prespecified MCID of 1.8 units. However, we acknowledge that smaller MCIDs have been reported (36) and as such we cannot fully exclude the possibility that weight loss might provide a clinically relevant pain relieving effect. This possibility is supported by the improvement in our secondary HOOS pain outcome, which may be capturing different aspects of pain given its complex nature (37), and the greater proportion that achieved the MCID on the primary outcome in the VLCD plus exercise group. Other secondary outcomes of function, hip- and health-related quality of life, overall hip change, and physical activity also improved more with the addition of the VLCD. Although the mechanisms underpinning these benefits are unknown, postulated mechanisms include reduced joint loading, lowered systemic inflammation, and improved psychological status (17, 38).

Our study extends prior research on weight loss in osteoarthritis, which has primarily focused on the knee.

Table 3. MCID in Hip Pain Severity and Global Improvement

Outcomes	Exercise Only, *n/Total n* (%)*	VLCD Plus Exercise, *n/Total n* (%)*	Relative Risk (95% CI)*†	Risk Difference (95% CI)*†
6 mo				
Achieve MCID‡ for hip pain severity§‖	24/48 (50.0)	35/51 (68.6)	1.36 (1.12 to 1.66)	0.18 (0.08 to 0.28)
Global improvement‖				
Overall hip problem¶	25/46 (54.3)	38/50 (76.0)	1.40 (1.07 to 1.81)	0.22 (0.05 to 0.38)
Physical activity**	21/46 (45.7)	36/50 (72.0)	1.61 (1.15 to 2.27)	0.27 (0.11 to 0.44)
12 mo				
Achieve MCID‡ for average hip pain severity§‖	27/48 (56.2)	30/47 (63.8)	1.13 (0.87 to 1.48)	0.08 (−0.08 to 0.23)
Global improvement‖				
Overall hip problem¶	21/48 (43.8)	32/47 (68.1)	1.56 (1.11 to 2.18)	0.24 (0.07 to 0.42)
Physical activity**	23/48 (47.9)	25/47 (53.2)	1.14 (0.72 to 1.79)	0.06 (−0.16 to 0.29)

MCID = minimum clinically important difference; VLCD = very-low-calorie diet.
* Count and proportions; relative risk and risk differences are based on the available (observed) data.
† Relative risks >1 and risk differences >0 favor VLCD plus exercise group.
‡ MCID is 1.8 numerical rating scale points.
§ Measured on an 11-point numerical rating scale for overall average hip pain severity in the past week. Score range is 0 (no pain) to 10 (worst pain possible); higher score indicates worse pain.
‖ Relative risks and risk differences were adjusted for stratifying variables (site and sex) and fit using generalized estimating equations to account for clustering.
¶ Perceived overall change since baseline. Rated using a 7-point scale with terminal descriptors "much worse" to "much better," with those indicating "moderately better" or "much better" classified as improved.
** Perceived overall change since baseline. Rated using a 7-point scale with terminal descriptors "much less active" to "much more active," with those indicating "moderately more active" or "much more active" as improved.

The only hip RCT involved persons awaiting joint replacement surgery undertaking a fiber-enriched carbohydrate diet (13). The effects on symptoms were uncertain, which may be due to no between-group difference in weight loss and methodological issues, such as unbalanced groups at baseline. Results of uncontrolled studies are inconsistent. A systematic review of 9 cohort studies reported inconclusive effects of bariatric surgery on hip pain (39), whereas other cohort studies conflict as to whether weight loss reduces symptoms (40, 41) or rates of hip joint replacement (11, 12). Although providing a higher level of evidence, our RCT does not resolve the current uncertainty around the effects of weight loss on hip pain. This uncertainty contrasts studies in knee osteoarthritis (42). Based on a meta-regression of 14 knee RCTs, at least 7% weight loss is associated with clinically meaningful pain and function improvements (42). These potential differential effects of weight loss between hip and knee osteoarthritis may reflect differences in factors driving the pathogenesis of osteoarthritis and pain experience, such as epigenetics, anatomical and biomechanical factors, and clinical features (14).

Strengths of this study include radiographic confirmation of hip osteoarthritis, robust RCT design and analysis, 12-month follow-up, use of a diet intervention known to result in substantial weight loss, excellent adherence and retention rates, and blinding of body composition assessors and the biostatistician. This study has limitations. Clinicians and participants were unblinded to treatment, which can lead to overestimation of treatment benefits, particularly participant-reported outcomes (43). Our findings do not necessarily generalize to persons with a BMI less than 27 kg/m^2 or who do not speak English. Hip osteoarthritis has similar prevalence in men and women (9), yet most of our participants were women (70%). Hence, caution should be used extrapolating findings to men. Approximately 10% of screened participants were enrolled in the trial. Although this may affect external validity, most exclusions were due to low BMI, for which weight loss would be inappropriate. Our study was restricted to 12 months of follow-up, thus the effect of weight loss remains inconclusive in the longer term. We chose to use a VLCD as a proxy to evaluate whether weight loss influenced outcomes. However, 18% of the VLCD plus exercise group did not achieve the minimum target of at least 5% weight loss at 6 months, whereas 16% of the exercise only group lost at least 5% body weight, possibly due to undertaking a dietary intervention (**Table 8 of Supplement 1**). This may have attenuated between-group differences in outcomes. We also did not capture the use of some other medications that can influence osteoarthritis pain, such as glucagon-like peptide-1 receptor agonists (44) or metformin (45). However, random allocation is expected to balance out any potential influence of such medications.

Although the effects of weight loss on hip pain are uncertain from our results, weight loss has broader benefits for persons with hip osteoarthritis and obesity, including lowered risk for postoperative complications after joint replacement (46) and preventing and managing other chronic conditions (47). Use of pain medication is widespread in hip osteoarthritis (48, 49), indeed more than 80% of our sample were taking more than 1 pain medication at baseline. We

found less pain medication use in VLCD plus exercise than exercise only at follow-up. This is advantageous given the serious adverse event profile of such medications (50). If recommending weight loss to manage hip osteoarthritis, clinicians should consider preserving lean mass. Despite incorporating strengthening exercise with the VLCD, this group lost approximately 1.5 kg of lean body mass. The effect of this is unclear, but it could potentially offset benefits of weight loss on physical function, particularly in older persons.

Our results stimulate further research. This includes whether weight loss effects on clinical outcomes become more pronounced with a follow-up longer than 12 months given evidence at the knee (51), and whether weight loss can reduce or delay hip joint replacement surgery. It is possible that more weight loss is needed for hip pain benefits given reports of a dose–response association between the amount of weight loss and symptom improvement in knee (52, 53) and hip (41) osteoarthritis. Further research could also consider other dietary interventions, such as the Mediterranean diet with its focus on targeting local and systemic inflammation. Finally, other effective treatments need to be identified for hip osteoarthritis, as having overweight or obesity seems less common than in knee osteoarthritis (10).

In persons with hip osteoarthritis and overweight or obesity, adding a VLCD to exercise that resulted in substantial weight loss did not affect the primary outcome of hip pain severity relative to exercise alone at either 6 or 12 months. However, it did benefit most secondary outcomes, including other pain outcomes, at 1 or both timepoints, suggesting that weight loss may be a potential treatment option for the overall management of hip osteoarthritis.

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Data Sharing Statement: The following data will be made available beginning 1 June 2025: deidentified participant data and data dictionary (contact Dr. Hall; e-mail, michelle.hall@sydney.edu.au). The following supporting documents will be made available beginning on 1 January 2023: statistical/analytic code and informed consent form (contact the principal investigator, Dr. Bennell; e-mail, k.bennell@unimelb.edu.au). The investigators endorse the concept of data sharing to advance medical science. All requests for data sharing will be reviewed by the principal investigator to ensure no conflict with any planned subanalyses and to ensure that the data are shared in an ethical and protected manner. Analyses aimed at improving treatment of knee osteoarthritis for noncommercial purposes are eligible. Data will be made available after review and approval by the principal investigator. Before any analysis, a signed confidentiality agreement and/or data sharing agreement is required (restrictions: none).

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