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Alternative models to support weight loss in chronic musculoskeletal conditions: effectiveness of a physiotherapist-delivered intensive diet programme for knee osteoarthritis, the POWER randomised controlled trial

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17 **Alternative models to support weight loss in chronic musculoskeletal**  
18 **conditions: Effectiveness of a physiotherapist-delivered intensive diet program**  
19 **for knee osteoarthritis, the POWER randomized controlled trial.**  
20

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42 **Abstract**

43  
44 **Objective:** To determine if physiotherapists can deliver a clinically effective very low energy diet  
45 (VLED) supplementary to exercise in people with knee osteoarthritis (OA) and overweight or  
46 obesity.

47 **Methods:** 88 participants with knee OA and body mass index (BMI)  $>27 \text{ kg/m}^2$  were randomized  
48 to either Intervention (n=42: VLED including two daily meal replacement products supplementary  
49 to Control) or Control (n=46: exercise), Both interventions were delivered by unblinded  
50 physiotherapists via six videoconference sessions over six months. Primary outcome was  
51 percentage change in body weight at six months measured by a blinded assessor. Secondary  
52 outcomes included BMI, waist circumference, waist-to-hip-ratio, self-reported measures of pain,  
53 function, satisfaction and perceived global change, and physical performance tests.

54 **Results:** The Intervention group lost a mean (standard deviation) 8.1 (5.2)% body weight  
55 compared with 1.0 (3.2)% Control (mean (95% confidence interval) between-group difference 7.2  
56 (5.1, 9.3)%,  $p<0.001$ ), with significantly lower BMI and waist circumference compared to Control  
57 at follow up. 75% of participants in the Intervention group achieved  $\geq 5\%$  body weight loss, 37%  
58  $\geq 10\%$  compared with 12% and 0% respectively in Control. More participants in Intervention  
59 [27/38 (71.1%)] reported global knee improvement than in Control [20/42 (47.6%)] ( $p=0.02$ ).  
60 There were no between-group differences in any other secondary outcomes. No serious adverse  
61 events were reported.

62 **Conclusion:** A VLED delivered by physiotherapists achieved clinically relevant weight loss, and  
63 was safe, in people with knee OA and overweight or obesity. Results have potential implications  
64 for future service models of care for OA and obesity.

65 **Trial registration:** NIH US National Library of Medicine, Clinicaltrials.gov NCT04733053 (Feb  
66 1, 2021)

67

68 **Key words**

69 Osteoarthritis, OA, Knee, Telehealth, Overweight, Obesity, Weight management, Physiotherapy,

70 Very low energy diet, Exercise, Physical activity, Clinical trial, RCT

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## Summary box

### **What is already known on this topic**

- A dietitian-delivered very low energy diet, alongside physiotherapist-delivered exercise, is effective for weight loss and symptoms in people with knee OA, however, access to dietitians for management of musculoskeletal conditions is limited for many people.
- While physiotherapists are also well placed to deliver weight loss support for synergistic benefit to exercise in people with knee OA, no studies have evaluated the effectiveness and safety of a physiotherapist-delivered weight loss intervention.

### **What this study adds**

- This is the first study to show that physiotherapists can deliver a very low energy diet program, in addition to exercise, that was effective for weight loss and safe in people with knee OA.
- The diet and exercise group lost 8.1% body weight over six months, comparable to that achieved with dietitians in previous studies, with over a third of participants losing over 10% body weight.

### **How this study might affect research, practice, or policy**

- This study provides the first proof-of-concept evidence of an alternate allied health clinician delivery model for weight loss in people with knee OA, which may guide future research and policy in the face of rising obesity rates and challenges facing healthcare systems

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77

78 **Background**

79

80

81 Knee osteoarthritis (OA) is a major cause of pain and disability globally, affecting over 350 million  
82 adults <sup>1</sup>. Overweight and obesity are significant risk factors for knee OA progression <sup>2</sup>, and rising  
83 rates of both obesity <sup>3</sup> and OA <sup>1</sup> are placing unprecedented demands on healthcare systems  
84 worldwide. International clinical guidelines for the management of knee OA include weight  
85 management as a core treatment where appropriate,<sup>4</sup> alongside exercise. However, for many  
86 people with OA and overweight or obesity, weight management support or referral for support is  
87 not routinely provided <sup>5 6</sup> or accessible due to workforce challenges. Innovative care models that  
88 expand practice roles of healthcare practitioners may increase patient access to weight  
89 management support.

90

91 As providers of lifestyle and exercise management for people with knee OA, there is an  
92 opportunity for physiotherapists to engage in extended scope weight loss support alongside  
93 exercise prescription to optimize management <sup>7-12</sup>. Nonetheless, upskilling is required as many  
94 physiotherapists currently lack confidence and the requisite competencies in weight management  
95 <sup>12 13</sup>. We have shown that a customized self-directed e-learning program for physiotherapists can  
96 increase physiotherapists' confidence in both knowledge and skills in lifestyle-interventions for  
97 weight management for patients with knee OA <sup>14</sup>. However, no studies have investigated the  
98 efficacy and safety of a physiotherapist-delivered weight loss program in any patient population.

99

100 Clinical guidelines for OA do not specify a dietary approach for weight loss <sup>4</sup> but meta-analysis  
101 data indicate that people adhering to a very low energy diet (VLED) over a 12-week period  
102 frequently achieve the desired target of five percent body weight loss <sup>15</sup> thought to be required for

103 symptomatic benefits <sup>16 17</sup>. Importantly, we have shown a VLED delivered by dietitians was  
104 effective <sup>18</sup> and acceptable to people with knee OA <sup>19</sup>. The nutritionally complete composition of  
105 a VLED diet using meal replacements means that healthcare practitioners without formal nutrition  
106 qualifications, such as physiotherapists, may be capable of effectively and safely supporting a  
107 VLED for selected people with knee OA.

108

109 We aimed to evaluate whether physiotherapists could effectively deliver a 6-month telehealth  
110 intensive dietary weight loss program, in addition to exercise a core recommended treatment for  
111 knee OA. <sup>4</sup> Our primary hypothesis was that a diet program combined with exercise (Intervention)  
112 would lead to greater weight loss than exercise (Control) at 6 months.

113

114

## 115 **Methods**

116

117 This was a two-group, superiority, parallel-design randomized controlled trial (RCT) prospectively  
118 registered (Clinicaltrials.gov NCT04733053), protocol published <sup>20</sup>, approved by the University  
119 of Melbourne Human Research Ethics Committee (HREC 1955042). The only change to trial  
120 methods was allowing participants to self-report follow-up body weight over the telephone using  
121 their own scales if unable to attend follow-up.

122

## 123 **Patient and public involvement**

124

125 During project development, people with knee OA and physiotherapists were interviewed to  
126 understand the acceptability of a physiotherapist-delivered weight loss program <sup>11 12</sup> and study  
127 resources developed with input from people with knee OA <sup>21</sup>.

128

## 129 **Participants**

130

131 Participants were recruited via print/radio/social media advertisements and our volunteer database.  
132 Inclusion criteria were: diagnosis of knee OA using National Institute for Health and Care  
133 Excellence clinical OA criteria (age $\geq$ 45 years; activity-related knee pain; no knee morning  
134 stiffness  $\geq$ 30 minutes) <sup>22</sup>; history of knee pain  $\geq$  3 months; knee pain on most days of past month;  
135 knee pain during walking over past week of  $\geq$ 4 on an 11-point numeric rating scale (NRS); body  
136 mass index (BMI)  $>$ 27 kg/m<sup>2</sup>; willing to monitor blood pressure if using hypertensive medication  
137 and light-headed/dizzy during the trial; able to give informed consent and participate fully in trial  
138 procedures. Exclusion criteria are included in Supplement 1.

139

140

## 141 **Randomization and blinding**

142

143 Two randomization lists were computer-generated by an independent biostatistician. Participants  
144 were randomly allocated, first to physiotherapist in a 1:1 ratio, using permuted blocks of sizes 6  
145 and 12, and then to treatment group in a 1:1 ratio, using permuted blocks of sizes 2 and 4, stratified  
146 by physiotherapist and participant sex <sup>23 24</sup>. Allocation was concealed in password-protected  
147 software (REDCap<sup>TM</sup>) <sup>25</sup> and revealed following baseline assessment by a researcher not involved  
148 in recruitment or assessment. A blinded assessor collected primary outcome and physical

149 performance measures at 6 months and was a different person from the one collecting baseline  
150 data to negate unblinding due to physically obvious weight loss. It was not possible to blind  
151 physiotherapists or participants.

152

### 153 **Physiotherapists and training**

154

155 We recruited six (2 female, 4 male) physiotherapists in private practice in Melbourne, Australia  
156 who completed ~20 hours of mandatory training including: (i) self-directed e-learning modules  
157 (~10-12 hours over 6 weeks, previously described and evaluated <sup>14</sup> and since launched for  
158 clinicians ([www.futurelean.com/courses/eduweight](http://www.futurelean.com/courses/eduweight))) and additional trial protocol specific  
159 modules; (ii) six practice consultations delivering sessions 1, 2 and 4 of the VLED program to one  
160 ‘mock’ patient (research team member) and one ‘practice’ patient with knee OA. Sessions were  
161 audio-recorded, and a researcher provided itemized and patient feedback. Physiotherapists  
162 participated in a final hour-long teleconference to clarify study procedures.

163

### 164 **Treatment groups**

165

166 Participants in both groups consulted their physiotherapist via videoconference using Zoom (Zoom  
167 Video Communications, Inc., USA) for six sessions over six months. Participants were provided  
168 with hard copy OA educational resources, activity booklets, logbooks, and resistance bands  
169 (Appendix 1). Physiotherapists used semi-structured electronic consultation notes containing  
170 scripts, prompts and checklists for each consultation to enhance protocol fidelity.

171

#### 172 ***a) Control***

173

174 Consultations lasted 30 minutes initially, 20 minutes thereafter. Physiotherapists prescribed a  
175 home exercise program (5-6 lower limb strengthening exercises performed three times per week,  
176 (Appendix Table 2) from an established program<sup>18 26 27</sup>, exercising at a moderate intensity ( $\geq 5$  out  
177 of 10 ('hard') on a modified Borg Rating of Perceived Exertion scale<sup>28</sup>). A personalized,  
178 progressive physical activity plan was collaboratively developed with the participant.

179

### 180 ***b) Intervention***

181

182 Consultations lasted 75 minutes initially (45 minutes diet component), 50 minutes thereafter (30  
183 minutes diet component). Exercise components were the same as for the Control. Participants  
184 received Optifast (Nestlé Health Science, Rhodes, Australia) or Optislim (Optipharm, Australia)  
185 meal replacements, at no cost to themselves, for the first 14 weeks and additional hardcopy  
186 dietary/behavioural resources<sup>18</sup> (Appendix 1).

187

188 The diet intervention included three physiotherapist-supported phases (Table 1). Phase 1 'Weight  
189 loss' (0 to  $\leq 12$  weeks): aim  $\geq 10\%$  body weight loss via a VLED (two meal replacement products  
190 per day). Phase 2 'Transition': (once 10% weight loss was achieved/week 13 whichever came first,  
191 unless participants wanted to continue self-funding meal replacement products), participants were  
192 supported to transition over two weeks to a longer-term eating plan (reducing meal replacements,  
193 re-incorporating low glycaemic index carbohydrates). Phase 3 'Weight maintenance': healthy diet  
194 in concordance with the Commonwealth Scientific and Industrial Research Organisation (CSIRO)  
195 Total Wellbeing diet<sup>29</sup>. If participants regained 2 kg or more, they were advised to re-commence  
196 two meal replacements per day for 1–2 weeks.

197

198 **Outcome measures**

199

200 Change in body weight from baseline to six months, expressed as a percentage, was the primary  
201 outcome  $((\text{baseline-follow up})/\text{baseline} \times 100\%)$ . Body weight was measured at baseline and 6  
202 months on the same set of calibrated digital laboratory platform scales (TCS-2 series) (participants  
203 in bare feet and light clothing).

204

205 Secondary outcomes, (baseline and six-months), included: BMI; Waist circumference at mid-  
206 abdomen level at its smallest circumference; Waist-to-hip ratio (waist circumference divided by  
207 hip circumference); Average knee pain on walking in the last week using an 11-point NRS ('no  
208 pain'='0' and 'worst pain possible'='10'<sup>30</sup>; Intermittent (scored 0-24) and constant (scored 0-20)  
209 osteoarthritis pain measure (iCOAP)<sup>31</sup> (higher scores indicating higher pain); Physical function  
210 subscale of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)<sup>32</sup> (0-  
211 68, higher scores indicating greater dysfunction); Perceived global change in knee problems (7-  
212 point Likert scale from 'much worse' to 'much better'<sup>33</sup>) at 6-months ('moderately better' or  
213 'much better' categorized as 'improved'); Assessment of Quality of Life (AQoL) (version AQoL-  
214 6D)<sup>34</sup>, (-0.04 to 1.0, higher scores indicating higher quality of life); Physical activity scale for the  
215 elderly (PASE)<sup>35</sup> (0 to 400, higher scores indicating greater physical activity levels); Weight Self-  
216 Stigma Questionnaire (WSSQ)<sup>36</sup> (0-60, higher scores indicating greater internalized weight  
217 stigma); Physical performance measures<sup>37</sup> including 30 sec chair sit-to-stand test (n), 40m fast-  
218 paced walk test (m/s) and 6-step stair climb test (sec), where greater number, faster speed and  
219 shorter time taken respectively indicate better physical function; Maximum voluntary isometric

220 knee extensor strength (Nm/kg) from three repetitions, measured on an isokinetic dynamometer  
221 (HUMAC, CSI, Boston), knee at 60 degrees flexion.

222

### 223 **Adherence and fidelity measures**

224

225 Adherence measures included: Number of consultations attended (0-6); Self-reported number of  
226 prescribed home exercise sessions in the last two weeks at 6 months; Self-rated adherence to the  
227 home strengthening program, physical activity plan, and diet program (Intervention only),  
228 (separate 11-point NRS, higher scores indicating greater adherence); Total number of weeks meal  
229 replacements used (Intervention only).

230

231 Physiotherapist fidelity to the protocol was assessed from electronic consultation notes and  
232 reported as: Consultation duration (minutes); and Proportion of participants where required  
233 elements of diet and exercise components were delivered.

234

### 235 **Other measures**

236

237 Participant satisfaction with their intervention was assessed using a 7-point global rating scale  
238 ('extremely dissatisfied', to 'extremely satisfied', 'moderately' or 'extremely' satisfied  
239 categorized as 'satisfied'). Other process measures collected and a nested qualitative study of  
240 participants and physiotherapists<sup>20</sup> will be reported separately.

241

242 Descriptive measures and expectation of treatment outcome (self-reported via 5-point Likert scale,  
243 'no effect at all' to 'complete recovery') were collected at baseline. At 6 months, participants

244 reported co-interventions used to manage their knee pain and weight during the trial. Adverse  
245 events were reported in the 6-month questionnaire.

246

### 247 **Trial sample size**

248

249 The trial was powered to detect a between-group difference in weight loss of 5% of body weight  
250 assuming no weight loss in the Control group <sup>38 39</sup>. While the between-participant standard  
251 deviation of percentage change in body weight was 5% in another study <sup>39</sup>, we assumed a  
252 conservative standard deviation of 7.5% given that our program had less clinician contact <sup>39</sup>. For  
253 a power of 0.8 and a two-tailed significance level of 0.05, we required 37 participants per group,  
254 increased to 44 allowing for 15% loss to follow up <sup>18</sup>.

255

### 256 **Data analysis**

257

258 A priori statistical analysis plan was developed. Biostatisticians (PL,ADS) analysed data blinded  
259 to group name. Comparative analyses between groups used all randomized participants based on  
260 the intention-to-treat principle. Missing outcomes were multiply imputed, separately by group,  
261 using chained equations and predictive mean matching with five nearest neighbours. See  
262 Supplementary Material 2 for further details on handling missing data.

263

264 The primary outcome, percentage change in body weight was compared between groups using a  
265 linear regression modelling adjusted for baseline weight to obtain an estimated mean difference,  
266 corresponding two-sided 95% confidence interval and p-value. Similar analyses were conducted  
267 for continuous secondary outcomes. Binary secondary outcomes were compared between groups

268 using log-binomial regression, with adjustment for baseline weight for achieving different weight  
269 loss %. In the case of rare events, binary outcomes were analyzed using Firth logistic regression  
270 <sup>40</sup>. Estimated risk differences and risk ratios, corresponding two-sided 95% confidence intervals  
271 and p-values were obtained. A sensitivity analysis was performed for the primary outcome,  
272 excluding those participants who self-reported follow-up body weight. An exploratory subgroup  
273 analysis for the primary outcome was conducted for the subgroups of BMI ( $\geq 30$  kg/m<sup>2</sup> vs  
274  $<30$ kg/m<sup>2</sup>), by fitting a linear regression model, adjusted for baseline weight with an interaction  
275 term between treatment group and subgroup in the model. All models were adjusted for  
276 stratification variables of sex and physiotherapist. Standard diagnostic plots were used to check  
277 model assumptions. No adjustment for multiple testing were conducted. All statistical analyses  
278 were conducted using Stata 17.0 <sup>41</sup>.

279

## 280 **Equity, Diversity and Inclusion**

281 Our authors comprise early, mid-career and senior researchers from different disciplines across  
282 multiple countries. A full description of participant characteristics is included in Table 1,  
283 Supplementary Table 1. Accessibility was prioritized, with care delivered via freely available  
284 software, meal replacements provided at no cost and protocol modification to allow self-reported  
285 weight at follow-up.

286

## 287 **Results**

288

### 289 **Participant characteristics**

290 88 participants (42 Intervention) were enrolled from 507 people screened between October 2021  
291 and October 2022, follow up completed May 2023 (Figure 1). Baseline participant characteristics

292 and treatment expectations were comparable between groups (Table 2). The primary outcome was  
293 completed by 38/42 (91%) participants in the Intervention and 42/46 (91%) in Control groups  
294 (Supplementary Table 1), with one participant in the Intervention and three in Control self-  
295 reporting weight.

296

### 297 **Primary outcome**

298 Physiotherapists were able to effectively deliver a weight loss program as shown by a mean  
299 (standard deviation) percentage body weight loss in the Intervention group of 8.1 (5.2)% compared  
300 to 1.0 (3.2)% in the Control (between-group mean (95% confidence interval (CI)) difference, 7.2  
301 (5.1, 9.3)%), (Table 3). A greater proportion of Intervention participants achieved at least 5%  
302 [29/38 (76.3%)] and 10% [14/38 (36.8%)] weight loss than in Control [5/42 (11.9%); 0/42 (0%),  
303 respectively] (Table 4). Analysis using complete case data (Supplementary Tables 2 & 3) and  
304 sensitivity analysis excluding 4 (4.5%) participants who provided self-reported body weight at  
305 follow up showed similar results (Supplementary Table 4). The percentage weight loss achieved  
306 by Intervention participants allocated to each physiotherapist was variable ranging from 5.3% to  
307 10.2% (Supplementary Table 6). We observed negligible differences in the effect of the  
308 intervention on the primary outcome between BMI subgroups ( $\geq 30\text{kg/m}^2$ ,  $<30\text{kg/m}^2$ )  
309 (Supplementary Table 5).

310

### 311 **Secondary outcomes**

312 There was a greater reduction in BMI and waist circumference with Intervention than Control, but  
313 no between-group difference for changes in waist-to-hip ratio, pain, function, quality-of-life,  
314 physical activity, weight self-stigma or physical performance measures (Table 3). More

315 participants in Intervention [27/38 (71.1%)] reported global knee improvement than in Control  
316 [20/42 (47.6%)] (Table 4).

317

### 318 **Treatment and protocol adherence and satisfaction**

319 There was generally good adherence to diet and exercise components in both groups, with number  
320 of consultations attended and exercise sessions comparable between groups (Table 5). All  
321 participants in Intervention attempted the VLED, with meal replacements used for a mean (SD) of  
322 16 (6.4) weeks. More participants in Intervention were satisfied with their program [36/38 (95%)]  
323 than in Control [26/42 (62%)] (Table 5).

324

325 Physiotherapist fidelity to the protocol in both groups was excellent (Supplementary Table 8). A  
326 strengthening program was prescribed for all, and a physical activity plan for 83/88 (94%)  
327 participants in both groups. The mean (SD) fidelity to all elements of the diet protocol was 82  
328 (18)%.

329

### 330 **Adverse events**

331 Physiotherapists were able to safely deliver the weight loss intervention as shown by no serious  
332 intervention-related adverse events, and no participant discontinuing the trial due to an adverse  
333 event (Table 5). A small number of participants reported non-serious adverse events in both  
334 groups. At 6 months, more Control participants reported taking pain medication and using co-  
335 interventions than in the Intervention group (Table 2).

336

## 337 **Discussion**

338 We found that the physiotherapists in this study were able to deliver a VLED alongside an exercise  
339 program that resulted in substantial weight loss, was safe and yielded high satisfaction in people  
340 with knee OA who had overweight or obesity. The mean weight loss in the Intervention group  
341 exceeded the desired 5% loss recommended by OA management guidelines<sup>18 17</sup>, with over a third  
342 achieving more than 10% loss at 6 months.

343

## 344 **Comparison with other studies**

345 To our knowledge, this is the first RCT to evaluate whether physiotherapists can safely and  
346 effectively deliver a dietary intervention with the aim of weight loss in any patient population. The  
347 magnitude of weight loss of participants in the Intervention group at six months (8.1% body  
348 weight) was comparable to other dietitian-delivered VLEDs in people with knee OA (8.7 %<sup>39</sup>  
349 9.4%<sup>38</sup>), despite these studies having significantly greater therapist contact (26<sup>39</sup> and 56<sup>38</sup>  
350 dietitian sessions). While the aim of our intensive diet phase was 10% body-weight loss, only 37%  
351 of participants achieved this, which is less than other studies with more intensive VLED  
352 interventions with greater clinician support<sup>38,39</sup>. Of note, the mean between-group difference in  
353 weight loss (7.5% body weight) in the present study is comparable to our previous RCT which  
354 included the same two treatment protocols but with the VLED delivered by dietitians (8.2% body  
355 weight loss)<sup>18</sup> and meal replacements being provided for substantially longer (26 weeks)<sup>18</sup>.

356

357 Despite considerably greater weight loss in the Intervention group than Control, this was not  
358 reflected in better pain and function outcomes, with both groups showing clinically relevant  
359 improvements<sup>42</sup>. Diet plus exercise has previously been shown to provide slightly greater

360 improvements in self-reported pain and function compared to exercise alone in people with knee  
361 OA<sup>18 39 43 38</sup>, with weight loss partially mediating this improvement<sup>44</sup>. However, the clinical  
362 significance of this supplementary benefit remains ambiguous<sup>18 39 43</sup>.

363

### 364 **Strengths and limitations**

365 Strengths of this study include blinding of the assessor for the primary outcome, high level of  
366 participant retention and physiotherapist fidelity to the treatment protocols. Participant adherence  
367 to the dietary intervention protocol was generally good and comparable with our trial of the same  
368 VLED intervention but delivered by dietitians<sup>18</sup>. Only six physiotherapists delivered the  
369 intervention, so it may not be appropriate to generalise results to all physiotherapists. Given  
370 physiotherapists delivered both intervention arms, there is potential for contamination by greater  
371 focus on weight in control interactions. However, this would attenuate between-group differences.  
372 We did not include a follow-up period to assess weight loss maintenance, as this was not a study  
373 aim, and it is well known that weight is regained without ongoing support<sup>45</sup>. As no participants in  
374 the Control achieved  $\geq 10\%$  weight loss, sparse data may lead to biased estimates of the treatment  
375 effect<sup>46</sup>. Firth logistic regression was used to analyse this binary secondary outcome to minimise  
376 bias, however, we still observed wide 95% confidence intervals corresponding to risk ratio  
377 estimates<sup>40</sup>. Four participants self-reported body weight, a risk for measurement error bias,  
378 however sensitivity analysis excluding these participants yielded similar results.

379

### 380 **Implications for clinical practice**

381

382 The primary outcome of this study, together with safety and fidelity measures, provides evidence  
383 that physiotherapists can be upskilled to deliver a VLED intervention for people with knee OA  
384 with overweight or obesity. Future research could directly compare a physiotherapist-delivered  
385 VLED to a dietitian-delivered or self-managed VLED on weight loss outcomes and consider  
386 conversely if dietitians could be upskilled to deliver exercise alongside a VLED. Of the  
387 physiotherapists recruited, two thirds were relatively inexperienced in clinical practice (<five  
388 years), and none had previous weight management training. Our findings have potential relevance  
389 to healthcare settings where physiotherapists have similar professional standards to Australia,<sup>47-</sup>  
390 <sup>49</sup>. Further research is required to understand feasibility and costing approaches of training a larger  
391 group of physiotherapists in VLED delivery and including dietary support in routine physiotherapy  
392 clinical practice and existing or new care models.

393

## 394 **Conclusion**

395 A six-month VLED plus exercise intervention delivered by physiotherapists led to clinically  
396 significant substantial weight loss, was safe, and resulted in high levels of patient satisfaction  
397 compared to exercise alone for people with knee OA and overweight or obesity. This study  
398 provides the first evidence that with additional training, physiotherapists can effectively and safely  
399 deliver an intensive dietary weight loss program.

400

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405

## 406 **Contributor Statement**

407 KLB and KA obtained funding for the trial; KA, KLB and RSH designed the trial with input from  
408 SEJ, PS, JQ, FM, MH, NEF and ESG. SEJ, KA and KLB developed the training modules, and SEJ  
409 conducted the mock patient training, audited the practice patient training and provided training  
410 feedback to physiotherapists. SEJ and JP co-ordinated the trial. PL, ADS and KLB prepared the  
411 statistical analysis plan blinded and PL performed statistical analyses with guidance from ADS.  
412 KA and KLB wrote the draft of this paper and all authors edited and approved the final version.

413

## 414 **Competing Interests**

415 The authors have no competing interests to declare.

416

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424

## 425 **Ethical Approval**

426 The University of Melbourne Human Research Ethics Committee approved the study (HREC  
427 1955042).

428

429 **Availability of data and material**

430

431 The datasets used and/or analysed during the current trial will be made available from the  
432 corresponding author on reasonable request.

433

434

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- 569

**Table 1. Diet intervention outline**

| Phase  | Aim   | Diet   | Timing   | Physiotherapy session principles & topics   |
|--|---|--|--|---|
| <b><u>Phase 1:</u><br/>Intensive weight loss via VLED</b>                    | Weight loss of 5-10% body weight loss, replacing 2 meals per day with meal replacement products and a third low carbohydrate meal.  | VLED (800 kcal (3280 kJ) per day with a carbohydrate intake of ≤ 50-60 g per day including 2 x meal replacements, 1 x meal of high protein, low carbohydrate consisting of protein, non-starchy vegetables or salad, and a tablespoon of oil/fat (if gall bladder in situ) per day)<br>OR<br>Modified VLED if participant unwilling to undergo VLED diet (number and frequency of meal replacements negotiated with participant)<br>OR<br>Healthy eating plan (if participant unwilling to undergo VLED or modified VLED). | Weeks 0-12 maximum (Physiotherapy sessions 1, 2, 3 +/-4)   | <u>Session 1:</u> Introduction and collaborative development of a tailored management plan including weight loss goals and weight loss target and information about the VLED diet.<br><br><u>Sessions 2-3:</u> Discuss progress and use motivational interviewing principles to help motivation, self-efficacy and to overcome barriers preventing participants completing their weight loss plan, progress and familiarize participants with their resource booklets.<br>Specific topics and activities: <ul style="list-style-type: none"> <li>• Portion sizes</li> <li>• Carbohydrates and glycaemic index</li> <li>• Supermarket shopping guide</li> <li>• Healthy snacks</li> <li>• Choosing a support person</li> <li>• If-Then Planning</li> <li>• Identifying eating triggers</li> <li>• Overcoming barriers to losing weight and keeping it off</li> <li>• Hunger level scale</li> </ul> |
| <b><u>Phase 2a:</u><br/>Transition of VLED diet onto healthy eating plan</b> | Transition to 1 meal replacement per day and re-introduce low GI carbohydrates for one meal and maintain one low carbohydrate meal. | Transition to healthy eating plan including 1 x meal replacement, 1 x meal of high protein, low carbohydrate, 1 x meal of low GI carbohydrates +/- protein for two weeks.  | Two-week period starting Week 13 OR when participant lost 10% body weight OR if participant was unwilling or wished to discontinue VLED diet * | <u>Session 4:</u> To discuss progress and use motivational interviewing principles to help motivation, self-efficacy and to overcome barriers preventing participants for the transition phase, progress and familiarize participants with their resource booklets.<br>Specific topics and activities: <ul style="list-style-type: none"> <li>• Transition and potential challenges and strategies</li> <li>• Healthy eating habits</li> <li>• Identifying eating habits</li> <li>• Changing thought patterns</li> <li>• Food diary</li> </ul>  |

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | (Physiotherapy session 4 or 5)  |  |
| <b><u>Phase 2b:</u></b><br><b>Healthy eating plan for weight maintenance</b> | <b>AIM:</b> To adopt a healthy eating plan for weight maintenance. | Healthy eating plan of 3 meals per day including high protein, low glycaemic index carbohydrate, low fat foods consistent with the principles of the CSIRO total well-being diet | From end of transition to end of study at week 24 and beyond (Physiotherapy session 5 and/or 6) | <p><b><u>Session 5 &amp; 6:</u></b> To discuss progress, discharge goals and considerations and use motivational interviewing principles to help motivation, self-efficacy and to overcome barriers to healthy eating phase, progress and familiarize participants with their resource booklets.</p> <p>Specific topics and activities:</p> <ul style="list-style-type: none"> <li>• Healthy eating progress</li> <li>• Managing food portions</li> <li>• Choosing low GI foods</li> <li>• Snacking</li> <li>• Food diary</li> <li>• Problem solving for adherence</li> <li>• Weight and food diaries</li> <li>• Relapse management and problem solving</li> <li>• Weight monitoring and considerations for returning to a VLED in future</li> <li>• Major barriers</li> <li>• Role of physical activity</li> <li>• Other options for multidisciplinary input</li> </ul> |

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VLED = very low energy diet; GI = glycaemic index, CSIRO = Commonwealth Scientific and Industrial Research Organisation Total Well-being diet (29).

\* Meal replacements were provided to participants free of charge for 14 weeks (12 weeks for the VLED diet and 2 for the transition). If a participant did not wish to transition off the VLED diet by 14 weeks or if they wanted to recommence the diet between weeks 14 and 24 they were required to purchase the meal replacement products at their own cost.

**Table 2. Baseline characteristics of participants by group.**

| Baseline characteristic                                       | Control<br>(n=46) | Intervention<br>(n=42) |
|---|-------------------|------------------------|
| Age, (years), mean (SD)                                       | 60.0 (8.3)        | 60.5 (7.0)             |
| Female, n (%)   | 29 (63)           | 27 (64)                |
| Height (m), mean (SD)   | 1.7 (0.1)         | 1.7 (0.1)              |
| Weight (kg), mean (SD)  | 99.8 (18.0)       | 98.9 (15.0)            |
| Body mass index (kg/m <sup>2</sup> ), mean (SD)               | 35.3 (5.3)        | 35.2 (5.3)             |
| Highest education level, n (%)                                |                   |                        |
| Completed primary school                                      | 5 (11)            | 3 (7)                  |
| Completed secondary school/high school                        | 14 (30)           | 11 (26)                |
| Completed university bachelor degree or higher                | 27 (59)           | 28 (67)                |
| Currently employed, n (%)                                     | 30 (65)           | 34 (81)                |
| Unilateral symptoms, n (%)                                    | 16 (35)           | 18 (43)                |
| Knee symptom duration (years), median (IQR)                   | 3.0 (1.0-10.0)    | 3.0 (1.0-8.0)          |
| Number of other pain sites, median (IQR)                      | 3.0 (2.0-5.0)     | 3.0 (2.0-5.0)          |
| Comorbid conditions (self-reported), n (%)                    |                   |                        |
| ≥1 comorbid condition   | 30 (65)           | 27 (64)                |
| Heart disease   | 1 (2)             | 4 (10)                 |
| High blood pressure   | 12 (26)           | 13 (31)                |
| Depression  | 5 (11)            | 3 (7)                  |
| Diabetes  | 3 (7)             | 1 (2)                  |
| Spine condition   | 13 (28)           | 15 (36)                |
| Lung disease  | 0 (0)             | 3 (7)                  |
| Cancer  | 4 (9)             | 1 (2)                  |
| Ulcer or stomach disease                                      | 0 (0)             | 1 (2)                  |
| Kidney disease  | 0 (0)             | 0 (0)                  |
| Liver disease   | 0 (0)             | 1 (2)                  |
| Anaemia or other blood disease                                | 1 (2)             | 0 (0)                  |
| Treatments for knee in last 6 months, n (%)                   |                   |                        |
| ≥1 treatment  | 31 (67)           | 27 (64)                |
| Massage   | 6 (13)            | 8 (19)                 |
| Gait aid  | 8 (17)            | 2 (5)                  |
| Education course  | 3 (7)             | 4 (10)                 |
| Land-based and water exercises                                | 20 (44)           | 19 (45)                |
| Joint injections  | 2 (4)             | 2 (5)                  |
| Acupuncture   | 4 (9)             | 3 (7)                  |
| Herbal therapies  | 8 (17)            | 6 (14)                 |
| Hot/cold treatment  | 15 (33)           | 13 (31)                |
| Number of serious attempts to lose weight last 5 years, n (%) |                   |                        |

|   |         |         |
|---|---------|---------|
| No attempts                             | 5 (11)  | 6 (14)  |
| 1-2 attempts                            | 20 (44) | 22 (52) |
| 3-10 attempts                           | 17 (37) | 13 (31) |
| 10+ attempts                            | 4 (9)   | 1 (2)   |
| Current pain medication use, n (%) *    |         |         |
| ≥1 medication used                      | 25 (54) | 27 (64) |
| Non-steroidal anti-inflammatory drugs   | 19 (41) | 12 (29) |
| Acetaminophen                           | 20 (44) | 18 (43) |
| Topical anti-inflammatory drugs         | 11 (24) | 9 (21)  |
| Oral corticosteroids                    | 0 (0)   | 0 (0)   |
| Oral opioids                            | 0 (0)   | 1 (2)   |
| Expectation of treatment outcome, n (%) |         |         |
| No effect at all                        | 0 (0)   | 0 (0)   |
| Minimal improvement                     | 5 (11)  | 4 (10)  |
| Moderate improvement                    | 24 (53) | 19 (45) |
| Large improvement                       | 14 (31) | 19 (45) |
| Complete recovery                       | 2 (4)   | 0 (0)   |

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SD=standard deviation; kg=kilograms; m=metres; IQR= interquartile range (25th to 75th percentile);

\* Defined as ≥ 1 time per week over the last month for knee condition.

**Table 3. Summary measures and estimated between-group mean differences (95% CI) for each outcome as appropriate using multiply imputed data**

|  | Baseline <sup>a</sup> |                       | 6 months <sup>a</sup> |                      | Within-group change <sup>b</sup> |                      | Difference in change between groups <sup>c</sup> |         |
|--|-----------------------|-----------------------|-----------------------|----------------------|----------------------------------|----------------------|--|---------|
|  | mean (SD)             |                       | mean (SD)             |                      | mean (SD)                        |                      | Intervention vs Control                          |         |
|  | Control<br>N=46       | Intervention<br>N=42§ | Control<br>N=46‡      | Intervention<br>N=42 | Control<br>N=46                  | Intervention<br>N=42 | Mean<br>(95% CI)                                 | P-value |
| <b>Primary outcome</b>                 |                       |                       |                       |                      |                                  |                      |  |         |
| Percentage change in weight †#         | N/A                   | N/A                   | 1.0 (3.2)             | 8.1 (5.2)            | 1.0 (3.2)                        | 8.1 (5.2)            | 7.2 (5.1, 9.3)                                   | <0.001  |
| <b>Secondary outcomes</b>              |                       |                       |                       |                      |                                  |                      |  |         |
| Body mass index (kg/m <sup>2</sup> ) † | 35.3 (5.3)            | 35.2 (5.3)            | 34.6 (4.6)            | 31.9 (5.3)           | 0.4 (1.2)                        | 2.8 (1.7)            | 2.4 (1.7, 3.0)                                   | <0.001  |
| Waist circumference (cm) †             | 108.0 (11.1)          | 109.3 (11.2)          | 108.0 (10.2)          | 103.6 (12.4)         | -0.7 (7.2)                       | 5.4 (5.7)            | 5.8 (2.9, 8.7)                                   | <0.001  |
| Waist-to-hip ratio †                   | 0.9 (0.1)             | 0.9 (0.1)             | 0.9 (0.1)             | 0.9 (0.1)            | 0.0 (0.1)                        | 0.0 (0.1)            | 0.0 (0.0, 0.0)                                   | 0.10    |
| Knee pain walking (NRS) †              | 6.2 (1.3)             | 5.5 (1.2)             | 3.5 (2.2)             | 3.2 (1.8)            | 2.8 (2.2)                        | 2.4 (1.9)            | -0.1 (-1.0, 0.8)                                 | 0.82    |
| Intermittent pain (iCOAP) †            | 12.0 (4.4)            | 12.5 (3.3)            | 6.1 (5.1)             | 4.9 (4.6)            | 5.8 (5.3)                        | 7.5 (4.2)            | 1.4 (-0.6, 3.4)                                  | 0.17    |
| Constant pain (iCOAP) †                | 8.7 (4.6)             | 9.1 (3.5)             | 5.9 (4.1)             | 5.3 (3.9)            | 2.6 (4.6)                        | 3.6 (4.5)            | 0.6 (-1.1, 2.4)                                  | 0.48    |
| Physical function (WOMAC) †            | 26.5 (11.4)           | 23.1 (10.9)           | 16.7 (14.0)           | 13.3 (9.5)           | 10.0 (11.0)                      | 9.9 (13.3)           | 1.2 (-3.8, 6.2)                                  | 0.63    |
| Quality-of-life (AQoL-6D) *            | 0.7 (0.2)             | 0.7 (0.1)             | 0.7 (0.2)             | 0.8 (0.1)            | -0.1 (0.1)                       | -0.1 (0.1)           | 0.0 (-0.1, 0.0)                                  | 0.08    |
| Physical activity (PASE) *             | 129.2 (82.8)          | 165.0 (87.8)          | 157.5 (77.6)          | 207.2 (121.9)        | -33.9 (68.8)                     | -34.1 (80.6)         | -1.4 (-37.2, 34.5)                               | 0.94    |
| Weight self-stigma (WSSQ) †            | 32.2 (8.8)            | 33.9 (8.8)            | 31.3 (7.7)            | 30.5 (9.7)           | 1.4 (5.8)                        | 3.4 (7.5)            | 1.7 (-1.3, 4.8)                                  | 0.26    |

|                                 |           |           |            |            |            |            |                  |      |
|---------------------------------|-----------|-----------|------------|------------|------------|------------|------------------|------|
| 30 sec chair sit-to-stand (n) * | 8.9 (2.7) | 9.3 (2.9) | 11.6 (3.6) | 12.5 (3.2) | -3.0 (2.1) | -3.0 (2.6) | 0.0 (-1.1, 1.1)  | 0.99 |
| 40m fast paced walk (sec) †     | 1.6 (0.3) | 1.7 (0.4) | 1.7 (0.3)  | 1.9 (0.4)  | -0.2 (0.2) | -0.2 (0.3) | 0.0 (-0.1, 0.1)  | 0.97 |
| 6-step stair climb (sec) †      | 9.9 (4.0) | 9.5 (4.3) | 7.9 (3.6)  | 7.0 (2.1)  | 2.3 (2.5)  | 2.2 (2.6)  | 0.0 (-1.1, 1.1)  | 0.98 |
| Quadriceps strength (Nm/kg) *   | 1.2 (0.6) | 1.3 (0.6) | 1.4 (0.5)  | 1.6 (0.6)  | -0.2 (0.2) | -0.3 (0.3) | -0.1 (-0.2, 0.0) | 0.20 |

SD=standard deviation; CI=confidence interval; kg=kilogram; m=metre; cm=centimetre; n=number; sec=second; Nm=newton metre; NRS=numerical rating scale, 0-10 with higher scores indicating more pain; iCOAP=Intermittent and Constant Osteoarthritis Pain measure, 0-20 for constant pain subscale and 0-24 for intermittent pain subscale with higher scores indicating more pain; WOMAC= Western Ontario and McMaster Universities Osteoarthritis Index, 0-68 for physical function with higher scores indicating worse function AQoL-6D=Assessment of Quality-of-Life instrument-6 dimension, -0.04–1.00 with higher scores indicating better quality of life; PASE=Physical Activity Scale for the Elderly, 0-400+ with higher scores indicating greater levels of physical activity; WSSQ=Weight Self-Stigma Questionnaire, 12-60 with higher scores indicating greater internalized weight stigma

<sup>a</sup> Mean and standard deviation for baseline and 6-months are based on the available complete case data (observed data).

<sup>b</sup> Within-group change was calculated as baseline minus follow up for all outcomes based on the available complete case data (observed data), except primary outcome where the 6-month measure is the same as the within-group measure

<sup>c</sup> Difference in change between groups was adjusted for the outcome at baseline (except primary outcome where baseline weight was used) and the randomisation stratification variables of sex and physiotherapist

§ N=41 for 40m fast paced walk.

‡ N=42 for weight, body mass index, NRS, iCOAP intermittent pain, iCOAP constant pain, WOMAC, AQoL-6D, PASE, and WSSQ. N=36 for waist circumference, waist-to-hip ratio, 30 sec chair sit-to-stand, 40m fast paced walk, 6-step stair climb, and quadriceps strength.

|| N=38 for weight, body mass index, NRS, iCOAP intermittent pain, iCOAP constant pain, WOMAC, AQoL-6D, and WSSQ. N=37 for waist circumference, waist-to-hip ratio, PASE, 30 sec chair sit-to-stand, 40m fast paced walk, 6-step stair climb, and quadriceps strength.

\* For change within groups, negative changes indicate improvement. For difference in change between groups, negative differences favour Diet+Exercise.

† For change within groups, positive changes indicate improvement. For difference in change between groups, positive differences favour Diet+Exercise.

# Calculated as (baseline weight minus follow up weight/baseline weight) x 100

**Table 4: Binary secondary outcomes and adjusted relative risks and risk differences.**

|   | <b>Control</b><br><b>N=46</b><br><b>n/Total (%)</b> | <b>Intervention</b><br><b>N=42</b><br><b>n/Total (%)</b> | <b>Relative Risk *</b><br><b>(95% CI)</b> | <b>P-value</b> | <b>Risk Difference *</b><br><b>(95% CI)</b> | <b>P-value</b> |
|---|---|--|---|----------------|---|----------------|
| Global knee improvement <sup>a,b</sup>                    | 20/42 (48)  | 27/38 (71)   | 1.5 (1.0, 2.0)                            | 0.03           | 0.2 (0.0, 0.4)                              | 0.02           |
| Achieving $\geq 5\%$ loss of body weight <sup>c</sup>     | 5/42 (12)   | 29/38 (76)   | 5.8 (2.7, 12.7)                           | <0.001         | 0.6 (0.5, 0.8)                              | <0.001         |
| Achieving $\geq 10\%$ loss of body weight <sup>c, d</sup> | 0/42 (0)  | 14/38 (37)   | 24.79 (1.68, 366.04)                      | 0.02           | 0.38 (0.23, 0.53)                           | <0.001         |

CI=confidence intervals

The counts and proportions are based on the available complete case data (observed data). The relative risks and risk differences are from models fit using multiply imputed data.

<sup>a</sup> Rated using a 7-point scale with terminal descriptors ‘much worse’ to ‘much better’, those indicating ‘moderately better’ or ‘much better’ classified as improved.

<sup>b</sup> Adjusting for randomisation stratification variables of sex and physiotherapist

<sup>c</sup> Adjusting for baseline weight and randomisation stratification variables of sex and physiotherapist

<sup>d</sup> Analysed using a Firth logistic regression model due to rare events

\* Risk differences > 0 and relative risks > 1 favour Intervention

**Table 5. Adverse events, pain medications, other co-interventions and patient adherence, fidelity and program satisfaction**

| Characteristic   | Control<br>N=46 | Intervention<br>N=42 |
|--|-----------------|----------------------|
| <b>Adverse events *</b>  |                 |                      |
| Discontinued due to related adverse event, n (%)   | 0/42 (0%)       | 0/38 (0%)            |
| Any serious adverse events, n (%) †  | 0/42 (0%)       | 0/38 (0%)            |
| Number of non-serious related adverse events   | 6               | 3                    |
| Knee pain  | 1               | 0                    |
| Pain at other sites  | 5               | 2                    |
| Medical occurrence   | 0               | 1                    |
| Participants with non-serious related adverse events (self-reported), n(%)                         | 5/42 (12%)      | 2/38 (5%)            |
| Knee pain  | 1/42 (2%)       | 0/38 (0%)            |
| Pain at other sites  | 4/42 (10%)      | 2/38 (5%)            |
| Low blood pressure   | 0/42 (0%)       | 1/38 (3%)            |
| <b>Pain medication use ‡</b>   |                 |                      |
| ≥1 medication  | 21/42 (50%)     | 13/38 (34%)          |
| Acetaminophen alone or in combined formulations  | 15/42 (36%)     | 10/38 (26%)          |
| Topical anti-inflammatory drugs  | 8/42 (19%)      | 5/38 (13%)           |
| Non-steroidal anti-inflammatory drugs  | 9/42 (21%)      | 3/38 (8%)            |
| Oral glucocorticoids   | 1/42 (2%)       | 0/38 (0%)            |
| Oral opioids   | 3/42 (7%)       | 1/38 (3%)            |
| <b>Other co-interventions §</b>  |                 |                      |
| ≥1 treatment   | 38/42 (90%)     | 27/38 (71%)          |
| Stretching exercises   | 33/42 (79%)     | 22/38 (58%)          |
| Hot/cold treatment   | 14/42 (33%)     | 10/38 (26%)          |
| Education course   | 10/42 (24%)     | 9/38 (24%)           |
| Hydrotherapy   | 9/42 (21%)      | 7/38 (18%)           |
| Herbal therapies   | 7/42 (17%)      | 6/38 (16%)           |
| Massage  | 5/42 (12%)      | 6/38 (16%)           |
| Phone counselling  | 3/42 (7%)       | 7/38 (18%)           |
| Aerobic exercise class   | 1/42 (2%)       | 5/38 (13%)           |
| <b>Participant adherence, fidelity, and program satisfaction</b>                                   |                 |                      |
| Number of consultations attended (0-6) **  | 4.5 (1.9)       | 5.0 (1.2)            |
| Duration of consultations (mins) **  | 24.8 (4.2)      | 51.3 (7.9)           |
| Self-reported number of completed prescribed exercise sessions in past 2 weeks at 6 months (0-6) + | 3.9 (2.0)       | 4.0 (1.8)            |
| Percentage adherence to exercise sessions in past 2 weeks at 6 months+                             | 64.7 (34.0)     | 66.7 (30.7)          |

|   |             |             |
|---|-------------|-------------|
| Rating of adherence to exercise program (0-10) ^  | 6.5 (2.9)   | 7.3 (1.8)   |
| Rating of adherence to physical activity plan (0-10) ^  | 6.3 (3.1)   | 7.5 (1.8)   |
| Rating of adherence to diet program (0-10) ^  | N/A         | 7.8 (1.8)   |
| Number of weeks used meal replacements (0-24)   | N/A         | 16 (6.4)    |
| Number of participants who reported purchasing their own meal replacements beyond 14 weeks of funded replacements | N/A         | 22/37 (60%) |
| Satisfied with treatment program, n (%) †   | 26/42 (62%) | 36/38 (95%) |

Data are presented as mean (SD) for continuous measures and n/Total (%) for categorical measures based on complete data.

\* Adverse events defined as any untoward medical occurrence in a participant that does not necessarily have a causal relationship with the treatment. Denominator varies depending on the number of participants who completed the adverse events section of the questionnaire in each group.

† Serious adverse events defined as any untoward medical occurrence that resulted in death, was life threatening, required hospitalisation, resulted in persistent or significant disability or incapacity, or any other important medical condition which, although not included in the above, may require medical or surgical intervention to prevent one of the outcomes listed.

‡ Defined as taken at least once per week for their knee problem over the prior month.

§ Defined as having tried the co-intervention specifically for their knee pain or to reduce their body weight in the previous 24 weeks (but not including study interventions).

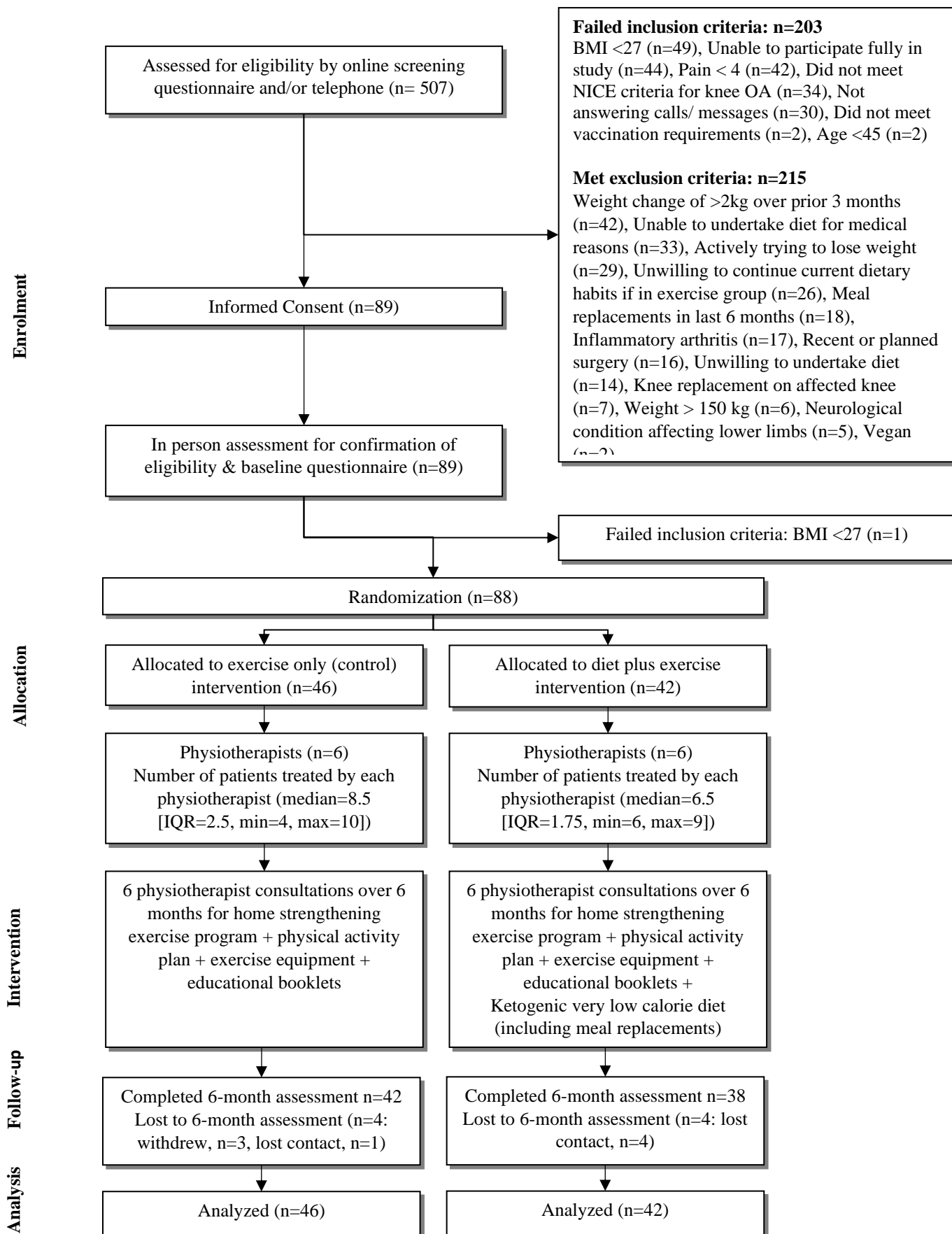
Self-reported adherence data Control N=42, Intervention= 38

\*\* Control N=46, Intervention N= 42

+ Control N=42, Intervention=37

^ Scored on an 11-point numeric rating score with higher scores indicating greater self-reported adherence

† Scored on a 7-point global rating of change scale with response options from “extremely dissatisfied” to “extremely satisfied” with participants indicating they are moderately or extremely satisfied deemed to be “satisfied” with the program



**Figure 1.** Flow chart describing progression of participants through the randomized controlled trial.

1 **Supplement 1: Exclusion Criteria**

2  
3 Exclusion criteria included: age >80 years; weight >150 kgs; planning knee/hip/bariatric surgery  
4 in next 6 months; previous arthroplasty or recent surgery (<6 months) on affected knee;  
5 inflammatory arthritis; weight loss >2 kg over past 3 months; actively trying to lose weight;  
6 unwilling to continue current dietary patterns if randomized to exercise group; conditions where  
7 the dietary intervention necessitated medical monitoring <sup>1</sup>; fluid intake restriction; unstable  
8 cardiovascular condition; neurological condition affecting lower limbs; vegan dietary  
9 requirements; unable to speak English.

10 **Supplement 2: Statistical methods for missing data.**

11 Missing baseline characteristics (1.1%) were imputed using single mean imputation. Missing  
12 outcomes were multiply imputed, separately by treatment group, using chained equations and  
13 predictive mean matching with five nearest neighbours. Missing data in the two binary outcomes  
14 (achieving  $\geq 5\%$  or  $\geq 10\%$  weight loss) were imputed passively within the imputation algorithm,  
15 using the imputed continuous primary outcome <sup>2</sup>. Imputation models included participant  
16 characteristics at baseline (age, physiotherapist, sex, height, education level, employment status,  
17 knee symptom duration, comorbid conditions, treatments for knee in last 6 months, and  
18 expectation of treatment outcome), and baseline values of outcomes (if available). Ten imputations  
19 were used as we had approximately 10% missing data. <sup>3</sup>

20 **References:**

- 21
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28 3. White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues  
29 and guidance for practice. *Statistics in Medicine* 2011, 30(4):377-99.

30

31 **Supplementary Table 1. Baseline characteristics of participants who provided the primary**  
 32 **outcome at 6 months (completers) and those who did not (non-completers).**  
 33

| <b>Baseline characteristic</b>                  | <b>Non-completers<br/>(n=8)</b> | <b>Completers<br/>(n=80)</b> |
|---|---------------------------------|------------------------------|
| Control group, n                                | 4                               | 42                           |
| Age, (years), mean (SD)                         | 55.6 (8.4)                      | 60.7 (7.5)                   |
| Female, n (%)                                   | 5 (63)                          | 51 (64)                      |
| Height (m), mean (SD)                           | 1.7 (0.1)                       | 1.7 (0.1)                    |
| Weight (kg), mean (SD)                          | 110.1 (22.4)                    | 98.2 (15.6)                  |
| Body mass index (kg/m <sup>2</sup> ), mean (SD) | 38.6 (7.2)                      | 34.9 (5.0)                   |
| Highest education level, n (%)                  |                                 |                              |
| Completed primary school                        | 0 (0)                           | 8 (10)                       |
| Completed secondary school/high school          | 5 (63)                          | 20 (25)                      |
| Completed university bachelor degree or higher  | 3 (38)                          | 52 (65)                      |
| Currently employed, n (%)                       | 4 (50)                          | 60 (75)                      |
| Unilateral symptoms, n (%)                      | 3 (38)                          | 31 (39)                      |
| Knee symptom duration (years), median (IQR)     | 2.0 (0.6-6.0)                   | 3.0 (1.5-10.0)               |
| Number of other pain sites, median (IQR)        | 2.0 (2.0-4.0)                   | 3.0 (2.0-5.0)                |
| Comorbid conditions, n (%)                      |                                 |                              |
| ≥1 comorbid condition                           | 5 (63)                          | 52 (65)                      |
| Heart disease                                   | 0 (0)                           | 5 (6)                        |
| High blood pressure                             | 2 (25)                          | 23 (29)                      |
| Depression                                      | 2 (25)                          | 6 (8)                        |
| Diabetes  | 0 (0)                           | 4 (5)                        |
| Spine condition                                 | 3 (38)                          | 25 (31)                      |
| Lung disease                                    | 1 (13)                          | 2 (3)                        |
| Cancer  | 0 (0)                           | 5 (6)                        |
| Ulcer or stomach disease                        | 0 (0)                           | 1 (1)                        |
| Kidney disease                                  | 0 (0)                           | 0 (0)                        |
| Liver disease                                   | 0 (0)                           | 1 (1)                        |
| Anemia or other blood disease                   | 0 (0)                           | 1 (1)                        |
| Treatments for knee in last 6 months, n (%)     |                                 |                              |
| ≥1 treatment                                    | 5 (63)                          | 53 (66)                      |
| Massage   | 0 (0)                           | 14 (18)                      |
| Gait aid  | 2 (25)                          | 8 (10)                       |
| Education course                                | 0 (0)                           | 7 (9)                        |
| Land-based and water exercises                  | 3 (38)                          | 36 (45)                      |

|   |        |         |
|---|--------|---------|
| Joint injections  | 0 (0)  | 4 (5)   |
| Acupuncture   | 1 (13) | 6 (8)   |
| Herbal therapies  | 0 (0)  | 14 (18) |
| Hot/cold treatment  | 2 (25) | 26 (33) |
| Number of serious attempts to lose weight last 5 years, n (%) |        |         |
| No attempts   | 0 (0)  | 11 (14) |
| 1-2 attempts  | 5 (63) | 37 (46) |
| 3-10 attempts   | 3 (38) | 27 (34) |
| 10+ attempts  | 0 (0)  | 5 (6)   |
| Current pain medication use, n (%) *                          |        |         |
| ≥1 medication used  | 4 (50) | 48 (60) |
| Non-steroidal anti-inflammatory drugs                         | 2 (25) | 29 (36) |
| Acetaminophen   | 4 (50) | 34 (43) |
| Topical anti-inflammatory drugs                               | 2 (25) | 18 (23) |
| Oral corticosteroids  | 0 (0)  | 0 (0)   |
| Oral opioids  | 0 (0)  | 1 (1)   |
| Expectation of treatment outcome, n (%)                       |        |         |
| No effect at all  | 0 (0)  | 0 (0)   |
| Minimal improvement   | 0 (0)  | 9 (11)  |
| Moderate improvement  | 2 (25) | 41 (52) |
| Large improvement   | 6 (75) | 27 (34) |
| Complete recovery   | 0 (0)  | 2 (3)   |

34 SD=standard deviation; kg=kilograms; m=metres; IQR= interquartile range (25th to 75th percentile);

35 \* Defined as ≥ 1 time per week over the last month for knee condition

**Supplementary Table 2. Summary measures and estimated between-group mean differences (95% CI) for each outcome as appropriate using complete case data.**

|  | Baseline     |               | 6 months     |               | Within-group change <sup>a</sup> |               | Difference in change between groups <sup>b</sup> |         |
|--|--------------|---------------|--------------|---------------|----------------------------------|---------------|--|---------|
|  | Exercise     | Diet+Exercise | Exercise     | Diet+Exercise | mean (SD)                        |               | Diet+Exercise vs Exercise                        | P-value |
|  | N=46         | N=42§         | N=46‡        | N=42          | Exercise                         | Diet+Exercise | Mean<br>(95% CI)                                 |         |
| <b>Primary outcome</b>                 |              |               |              |               |                                  |               |  |         |
| Percentage change in weight †#         | N/A          | N/A           | 1.0 (3.2)    | 8.1 (5.2)     | 1.0 (3.2)                        | 8.1 (5.2)     | 7.1 (5.2, 9.1)                                   | <0.001  |
| <b>Secondary outcomes</b>              |              |               |              |               |                                  |               |  |         |
| Body mass index (kg/m <sup>2</sup> ) † | 35.3 (5.3)   | 35.2 (5.3)    | 34.6 (4.6)   | 31.9 (5.3)    | 0.4 (1.2)                        | 2.8 (1.7)     | 2.4 (1.8, 3.1)                                   | <0.001  |
| Waist circumference (cm) †             | 108.0 (11.1) | 109.3 (11.2)  | 108.0 (10.2) | 103.6 (12.4)  | -0.7 (7.2)                       | 5.4 (5.7)     | 5.7 (2.6, 8.7)                                   | <0.001  |
| Waist-to-hip ratio †                   | 0.9 (0.1)    | 0.9 (0.1)     | 0.9 (0.1)    | 0.9 (0.1)     | 0.0 (0.1)                        | 0.0 (0.1)     | 0.0 (0.0, 0.0)                                   | 0.15    |
| Knee pain walking (NRS) †              | 6.2 (1.3)    | 5.5 (1.2)     | 3.5 (2.2)    | 3.2 (1.8)     | 2.8 (2.2)                        | 2.4 (1.9)     | -0.1 (-1.0, 0.8)                                 | 0.83    |
| Intermittent pain (iCOAP) †            | 12.0 (4.4)   | 12.5 (3.3)    | 6.1 (5.1)    | 4.9 (4.6)     | 5.8 (5.3)                        | 7.5 (4.2)     | 1.5 (-0.5, 3.5)                                  | 0.14    |
| Constant pain (iCOAP) †                | 8.7 (4.6)    | 9.1 (3.5)     | 5.9 (4.1)    | 5.3 (3.9)     | 2.6 (4.6)                        | 3.6 (4.5)     | 0.7 (-1.0, 2.5)                                  | 0.41    |
| Physical function (WOMAC) †            | 26.5 (11.4)  | 23.1 (10.9)   | 16.7 (14.0)  | 13.3 (9.5)    | 10.0 (11.0)                      | 9.9 (13.3)    | 1.6 (-3.3, 6.6)                                  | 0.51    |
| Quality-of-life (AQoL-6D) *            | 0.7 (0.2)    | 0.7 (0.1)     | 0.7 (0.2)    | 0.8 (0.1)     | -0.1 (0.1)                       | -0.1 (0.1)    | -0.1 (-0.1, 0.0)                                 | 0.06    |
| Physical activity (PASE) *             | 129.2 (82.8) | 165.0 (87.8)  | 157.5 (77.6) | 207.2 (121.9) | -33.9 (68.8)                     | -34.1 (80.6)  | -7.1 (-43.0, 28.7)                               | 0.69    |
| Weight self-stigma (WSSQ) †            | 32.2 (8.8)   | 33.9 (8.8)    | 31.3 (7.7)   | 30.5 (9.7)    | 1.4 (5.8)                        | 3.4 (7.5)     | 1.6 (-1.3, 4.4)                                  | 0.28    |
| 30 sec chair sit-to-stand (n) *        | 8.9 (2.7)    | 9.3 (2.9)     | 11.6 (3.6)   | 12.5 (3.2)    | -3.0 (2.1)                       | -3.0 (2.6)    | -0.1 (-1.2, 1.0)                                 | 0.89    |

|                               |           |           |           |           |            |            |                  |      |
|-------------------------------|-----------|-----------|-----------|-----------|------------|------------|------------------|------|
| 40m fast paced walk (sec) †   | 1.6 (0.3) | 1.7 (0.4) | 1.7 (0.3) | 1.9 (0.4) | -0.2 (0.2) | -0.2 (0.3) | 0.0 (-0.1, 0.1)  | 0.94 |
| 6-step stair climb (sec) †    | 9.9 (4.0) | 9.5 (4.3) | 7.9 (3.6) | 7.0 (2.1) | 2.3 (2.5)  | 2.2 (2.6)  | 0.3 (-0.7, 1.2)  | 0.59 |
| Quadriceps strength (Nm/kg) * | 1.2 (0.6) | 1.3 (0.6) | 1.4 (0.5) | 1.6 (0.6) | -0.2 (0.2) | -0.3 (0.3) | -0.1 (-0.2, 0.0) | 0.24 |

SD=standard deviation; CI=confidence interval; kg=kilogram; m=metre; cm=centimetre; n=number; sec=second; Nm=newton metre; NRS=numerical rating scale, 0-10 with higher scores indicating more pain; iCOAP=Intermittent and Constant Osteoarthritis Pain measure, 0-20 for constant pain subscale and 0-24 for intermittent pain subscale with higher scores indicating more pain; WOMAC= Western Ontario and McMaster Universities Osteoarthritis Index, 0-68 for physical function with higher scores indicating worse function AQoL-6D=Assessment of Quality-of-Life instrument-6 dimension, -0.04–1.00 with higher scores indicating better quality of life; PASE=Physical Activity Scale for the Elderly, 0-400+ with higher scores indicating greater levels of physical activity; WSSQ=Weight Self-Stigma Questionnaire, 12-60 with higher scores indicating greater internalized weight stigma

<sup>a</sup> Within-group change was calculated as baseline minus follow up for all outcomes, except primary outcome where the 6-month measure is the same as the within-group measure

<sup>b</sup> Difference in change between groups was adjusted for the outcome at baseline (except primary outcome where baseline weight was used) and the randomisation stratification variables of sex and physiotherapist

§ N=41 for 40m fast paced walk.

‡ N=42 for weight, body mass index, NRS, iCOAP intermittent pain, iCOAP constant pain, WOMAC, AQoL-6D, PASE, and WSSQ. N=36 for waist circumference, waist-to-hip ratio, 30 sec chair sit-to-stand, 40m fast paced walk, 6-step stair climb, and quadriceps strength.

|| N=38 for weight, body mass index, NRS, iCOAP intermittent pain, iCOAP constant pain, WOMAC, AQoL-6D, and WSSQ. N=37 for waist circumference, waist-to-hip ratio, PASE, 30 sec chair sit-to-stand, 40m fast paced walk, 6-step stair climb, and quadriceps strength.

\* For change within groups, negative changes indicate improvement. For difference in change between groups, negative differences favour Diet+Exercise.

† For change within groups, positive changes indicate improvement. For difference in change between groups, positive differences favour Diet+Exercise.

# Calculated as (baseline weight minus follow up weight/baseline weight) x 100

**Supplementary Table 3. Binary secondary outcomes and adjusted relative risks and risk differences using complete case data.**

|   | <b>Exercise</b><br><b>n/Total (%)</b> | <b>Diet+Exercise</b><br><b>n/Total (%)</b> | <b>Relative Risk *</b><br><b>(95% CI)</b> | <b>P-value</b> | <b>Risk Difference *</b><br><b>(95% CI)</b> | <b>P-value</b> |
|---|---------------------------------------|--|---|----------------|---|----------------|
| Global knee improvement <sup>a,b</sup>            | 20/42 (48)                            | 27/38 (71)                                 | 1.5 (1.1, 2.2)                            | 0.02           | 0.3 (0.1, 0.5)                              | 0.01           |
| Achieving ≥5% loss of body weight <sup>c</sup>    | 5/42 (12)                             | 29/38 (76)                                 | 6.2 (2.8, 13.5)                           | <0.001         | 0.6 (0.5, 0.8)                              | <0.001         |
| Achieving ≥10% loss of body weight <sup>c,d</sup> | 0/42 (0)                              | 14/38 (37)                                 | 21.45 (1.48,<br>310.77)                   | 0.03           | 0.37 (0.22, 0.52)                           | <0.001         |

CI=confidence intervals

<sup>a</sup> Rated using a 7-point scale with terminal descriptors ‘much worse’ to ‘much better’, those indicating ‘moderately better’ or ‘much better’ classified as improved.

<sup>b</sup> Adjusting for randomisation stratification variables of sex and physiotherapist

<sup>c</sup> Adjusting for baseline weight and randomisation stratification variables of sex and physiotherapist

<sup>d</sup> Analysed using a Firth logistic regression model due to rare events

\* Risk differences > 0 and relative risks > 1 favour Diet+Exercise

**Supplementary Table 4. Summary measures and estimated between-group mean differences (95% CI) for the primary outcome excluding participants who self-reported follow-up body weight**

|                                | <b>6 months</b>                |                                     | <b>Between-group difference <sup>a</sup></b> |                |                                |                |
|--------------------------------|--------------------------------|-------------------------------------|--|----------------|--------------------------------|----------------|
|                                | <b>Exercise</b><br><b>N=39</b> | <b>Diet+Exercise</b><br><b>N=37</b> | <b>Complete case data</b>                    |                | <b>Multiply imputed data *</b> |                |
|                                |                                |                                     | <b>Mean</b><br><b>(95% CI)</b>               | <b>P-value</b> | <b>Mean</b><br><b>(95% CI)</b> | <b>P-value</b> |
| Percentage change in weight †# | 0.7 (2.9)                      | 8.3 (5.1)                           | 7.5 (5.6, 9.5)                               | <0.001         | 7.7 (5.9,<br>9.4)              | <0.001         |

The mean and standard deviation at 6-months are based on the complete case data (observed data).

<sup>a</sup> Difference between groups was adjusted for baseline weight and the randomisation stratification variables of sex and physiotherapist with positive difference favouring Diet+Ex

† Positive change indicates improvement.

# Calculated as (baseline weight minus follow up weight/baseline weight) x 100

\* N=46 in Control; N=42 in Diet+Exercise

**Supplementary Table 5: Moderation of the treatment effect (Diet+Exercise) on the primary outcome by body mass index using multiply imputed data**

| Outcome                            | Moderator              | Exercise<br>(n=42) |            | Diet+Exercise<br>(n=38) |           | Between group difference <sup>a</sup><br>(95%CI)<br>(n=88) | Interaction Term<br>(95% CI; P-value) |
|------------------------------------|------------------------|--------------------|------------|-------------------------|-----------|--|---------------------------------------|
|                                    |                        | N (%)              | Mean (SD)  | N (%)                   | Mean (SD) |  |                                       |
| Percentage change in body weight # | Body mass index        |                    |            |                         |           |  |                                       |
|                                    | < 30 kg/m <sup>2</sup> | 7 (16.7%)          | -0.3 (3.1) | 10 (26.3%)              | 9.8 (7.0) | 9.9 (5.7, 14.1)  |                                       |
|                                    | ≥ 30 kg/m <sup>2</sup> | 35 (83.3%)         | 1.2 (3.2)  | 28 (73.7%)              | 7.5 (4.3) | 6.4 (4.1, 8.8)   | -3.5 (-8.4, 1.5; 0.17)                |

SD=standard deviation; CI=confidence intervals

N (%) of participants in each BMI group by treatment arm with complete outcome data.

The mean and standard deviation of percentage change in body weight in Control and Diet+Ex are based on the complete case data (observed data).

<sup>a</sup>Difference between groups was obtained by fitting a linear regression model with an interaction term between the treatment group and body mass index, adjusted for baseline weight and stratification variables sex and physiotherapist with positive difference favouring Diet+Exercise

# Calculated as (baseline weight minus follow up weight/baseline weight) x 100

**Supplementary Table 6. Percentage weight loss achieved by participants allocated to each of the study project physiotherapists.**

| Physiotherapist   | Exercise  |                                       |  |                               | Diet+Exercise |                                       |  |                               |
|-------------------|-----------|---------------------------------------|--|-------------------------------|---------------|---------------------------------------|--|-------------------------------|
|                   | N treated | N achieving $\geq 5\%$ loss of weight | N achieving $\geq 10\%$ loss of weight | Mean (SD) loss of weight (kg) | N treated     | N achieving $\geq 5\%$ loss of weight | N achieving $\geq 10\%$ loss of weight | Mean (SD) loss of weight (kg) |
| Physiotherapist 1 | 9         | 2                                     | 0                                      | 1.5 (4.0)                     | 7             | 5                                     | 2                                      | 10.2 (3.0)                    |
| Physiotherapist 2 | 4         | 1                                     | 0                                      | 2.1 (3.4)                     | 6             | 6                                     | 3                                      | 9.7 (2.0)                     |
| Physiotherapist 3 | 10        | 0                                     | 0                                      | 0.6 (2.4)                     | 8             | 7                                     | 4                                      | 9.5 (5.3)                     |
| Physiotherapist 4 | 8         | 0                                     | 0                                      | 0.0 (2.9)                     | 6             | 2                                     | 2                                      | 6.6 (10.5)                    |
| Physiotherapist 5 | 6         | 1                                     | 0                                      | 1.2 (3.1)                     | 6             | 5                                     | 2                                      | 8.1 (4.2)                     |
| Physiotherapist 6 | 9         | 1                                     | 0                                      | 0.9 (3.9)                     | 9             | 4                                     | 1                                      | 5.3 (3.5)                     |

The mean and standard deviation of weight loss in Exercise and Diet+Exercise are based on the complete case data (observed data). N=42 in Exercise. N=38 in Diet+Exercise.

**Supplementary Table 7: Fidelity of physiotherapists providing Diet+Exercise (Intervention) and Exercise (control) interventions at each of the consultations**

| <b>Consultation 1</b>  | <b>n/Total (%)</b>  |
|--|---|
| Set expectations & outlined aims of program                        | 79 / 84 (94%)<br>Diet+Ex 38 / 40 (95%)<br>Ex 41 / 44 (93%)    |
| Discussed understanding of knee OA                                 | 82/ 84 (98%)<br>Diet+Ex 38 / 40 (95%)<br>Ex 44 / 44 (100%)    |
| Discussed relationship between weight & OA symptoms                | 38 / 40 (95%)   |
| Discussed benefits of weight loss                                  | 38 / 40 (95%)   |
| Discussed evidence for ketogenic VLCD                              | 38 / 40 (95%)   |
| Assessed participant's readiness to change on scale 0-10           | 39 / 40 (98%)   |
| Asked whether person was willing to try to lose weight?            | 39 / 40 (98%)   |
| Set agreed initial weight loss goal (kg)                           | 40 / 40 (100%)  |
| Asked whether person willing to try ketogenic diet to lose weight? | 39 / 40 (98%)   |
| Provided explanation of the ketogenic diet                         |   |
| - Optifast meal replacements                                       | 40 / 40 (100%)  |
| - Allowed foods for 3 <sup>rd</sup> low carb meal & resources      | 40 / 40 (100%)  |
| - Ketosis days 1-3   | 40 / 40 (100%)  |
| - Avoiding carbohydrates   | 40 / 40 (100%)  |
| - Including a small amount of fat                                  | 40 / 40 (100%)  |
| - Keeping a food diary (optional)                                  | 38 / 40 (95%)   |
| - Recording weight once a week                                     | 40 / 40 (100%)  |
| - What to expect/side effects/where to get help if concerns        | 40 / 40 (100%)  |
| - Use of a fibre supplement  | 39 / 40 (98%)   |
| - Daily water intake - 2 litres                                    | 38 / 40 (95%)   |
| - If on BP medications, check BP if dizzy/lightheaded              | 38 / 40 (95%)   |
| - Alcohol intake if appropriate                                    | 38 / 40 (95%)   |
| - Diet lasts ≤ 3 months, then transition to healthy eating         | 39 / 40 (98%)   |
| - Asked if participant has any questions                           | 33 / 40 (83%)   |
| - Other useful resources   | 35 / 40 (83%)   |
| Checked participant's confidence to undertake diet plan            | 40 / 40 (100%)  |
| Prescribed 3 strengthening exercises                               | 84 / 84 (100%)<br>Diet+Ex 40 / 40 (100%)<br>Ex 44 / 44 (100%) |
| Checked participant recorded exercise program in knee plan book    | 82 / 84 (98%)<br>Diet+Ex 38 / 40 (95%)<br>Ex 44 / 44 (100%)   |
| Instructed use of log-book for recording adherence                 | 80 / 84 (95.2%)<br>Diet+Ex 38 / 40 (95%)<br>Ex 42 / 44 (96%)  |
| Discussed exercising with pain                                     | 81 / 84 (96%)<br>Diet+Ex 37 / 40 (93%)<br>Ex 44 / 44 (100%)   |

Note: Denominator shows number of participants where physiotherapist completed consultation notes

| <b>Consultation 2</b>   | <b>n/Total (%)</b>     |
|---|------------------------|
| Performed knee re-assessment                                    | 78 / 78 (100%)         |
|   | Diet+Ex 37 / 37 (100%) |
|   | Ex 41 / 41 (100%)      |
| Checked weight  | 37 / 37 (100%)         |
| Discussed progress of diet                                      |                        |
| - Questions from last consult                                   | 34 / 37 (92%)          |
| - Progress with diet / feeling hungry?                          | 36 / 37 (97%)          |
| - Preferred meal replacements & which meals? Ordering           | 36 / 37 (97%)          |
| - 3rd 'prepared' meals, ingredients, portion size. Difficulties | 37 / 37 (100%)         |
| - Snacks, types, when?  | 36 / 37 (97%)          |
| - Side effects and management                                   | 35 / 37 (95%)          |
| - Problems / Problem solving                                    | 36 / 37 (97%)          |
| - Facilitators  | 31 / 37 (84%)          |
| - Not losing weight, food/portion review                        | 29 / 37 (78%)          |
| Asked if participant happy to stay on ketogenic diet            | 37 / 37 (100%)         |
| Discussed weight loss resources/activities                      |                        |
| - Discussed 'Choosing a support person'                         | 35 / 37 (95%)          |
| - Discussed 'IF-THEN planning'                                  | 35 / 37 (95%)          |
| Checked exercises   | 78 / 78 (100%)         |
|   | Diet+Ex 37 / 37 (100%) |
|   | Ex 39 / 41 (95%)       |
| Discussed physical activity plan                                | 77 / 78 (99%)          |
|   | Diet+Ex 36 / 37 (97%)  |
|   | Ex 41 / 41 (100%)      |

Note: Denominator shows number of participants where physiotherapist completed consultation notes

| <b>Consultation 3</b>  | <b>n/Total (%)</b>     |
|--|------------------------|
| Performed knee re-assessment   | 71 / 71 (100%)         |
|  | Diet+Ex 40 / 40 (100%) |
|  | Ex 31 / 31 (100%)      |
| Checked weight   | 40 / 40 (100%)         |
| Discussed progress of diet   |                        |
| - Questions from last consult  | 35 / 40 (88%)          |
| - Progress with diet / feeling hungry?                                 | 36 / 40 (90%)          |
| - Preferred meal replacements & which meals? Ordering                  | 38 / 40 (95%)          |
| - 3rd 'prepared' meals, ingredients, portion size. Difficulties        | 35 / 40 (88%)          |
| - Snacks, types, when?   | 38 / 40 (95%)          |
| - Side effects and management  | 36 / 40 (90%)          |
| - Problems / Problem solving   | 38 / 40 (95%)          |
| - Facilitators   | 32 / 40 (80%)          |
| - Not losing weight, food/portion review                               | 32 / 40 (80%)          |
| Asked if participant happy to stay on ketogenic diet                   | 38 / 40 (95%)          |
| Discussed transition off ketogenic diet to healthy eating, if relevant |                        |
| - Challenge of weight maintenance                                      | 2 / 2 (100%)           |
| - How they are feeling about transitioning off diet                    | 2 / 2 (100%)           |
| - How to transition off ketogenic diet over 2 weeks                    | 2 / 2 (100%)           |
| - Reducing meal replacements to one meal per day                       | 2 / 2 (100%)           |
| - Re-introducing low GI carbohydrates one meal/day                     | 1 / 2 (50%)            |
| - Maintaining one low carbohydrate meal per day                        | 0 / 2 (0%)             |
| - After 2 wks, stopping replacements & eating 3 healthy meals          | 1 / 2 (50%)            |
| - Healthy eating principles  | 1 / 2 (50%)            |
| - Closely manage food portions   | 1 / 2 (50%)            |
| - Choosing foods with a low GI   | 1 / 2 (50%)            |
| - Choosing low-fat dairy options to reduce calorie intake              | 0 / 2 (0%)             |
| - Only snacking if hungry & choosing appropriate snacks                | 0 / 2 (0%)             |
| - Avoiding high sugar, low nutrient foods/drinks                       | 1 / 2 (50%)            |
| - Drinking lots of water   | 1 / 2 (50%)            |
| - Only having occasional treats  | 1 / 2 (50%)            |
| Discussed weight loss resources/activities                             |                        |
| - Discussed 'Identifying my eating triggers'                           | 32 / 40 (80%)          |
| - Discussed 'Overcoming barriers'                                      | 32 / 40 (80%)          |
| - Discussed 'Hunger level scale'                                       | 30 / 40 (75%)          |
| Checked confidence to undertake weight management plan                 | 35 / 40 (88%)          |
| Checked exercises  | 69 / 71 (97%)          |
|  | Diet+Ex 38 / 40 (95%)  |
|  | Ex 31 / 31 (100%)      |
| Discussed physical activity plan                                       | 67 / 71 (94%)          |
|  | Diet+Ex 37 / 40 (93%)  |
|  | Ex 30 / 31 (97%)       |

Note: Denominator shows number of participants where physiotherapist completed consultation notes

| <b>Consultation 4</b>  | <b>n/Total (%)</b>     |
|--|------------------------|
| Performed knee re-assessment   | 66 / 66 (100%)         |
|  | Diet+Ex 35 / 35 (100%) |
|  | Ex 31 / 31 (100%)      |
| Checked weight   | 34 / 35 (97%)          |
| Discussed progress of diet   |                        |
| - Questions from last consult  | 27 / 35 (77%)          |
| - Progress with diet / feeling hungry?   | 30 / 35 (86%)          |
| - Preferred meal replacements & which meals? Ordering                                      | 31 / 35 (89%)          |
| - 3rd 'prepared' meals, ingredients, portion size. Difficulties                            | 31 / 35 (89%)          |
| - Snacks, types, when?   | 31 / 35 (89%)          |
| - Side effects and management  | 24 / 35 (69%)          |
| - Problems / Problem solving   | 26 / 35 (74%)          |
| - Facilitators   | 25 / 35 (71%)          |
| - Not losing weight, food/portion review   | 25 / 35 (71%)          |
| Discussed transition off ketogenic diet to healthy eating, if relevant                     |                        |
| - Challenge of weight maintenance  | 25 / 30 (83%)          |
| - How they are feeling about transitioning off diet  | 27 / 30 (90%)          |
| - How to transition off ketogenic diet over 2 weeks  | 28 / 30 (93%)          |
| - Reducing meal replacements to one meal per day   | 27 / 30 (90%)          |
| - Re-introducing low GI carbohydrates one meal/day   | 27 / 30 (90%)          |
| - Maintaining one low carbohydrate meal per day  | 27 / 30 (90%)          |
| - After 2 wks, stopping replacements & eating 3 healthy meals                              | 26 / 30 (87%)          |
| - Healthy eating principles  | 26 / 30 (87%)          |
| - Closely manage food portions   | 26 / 30 (87%)          |
| - Choosing foods with a low GI   | 26 / 30 (87%)          |
| - Choosing low-fat dairy options to reduce calorie intake                                  | 24 / 30 (80%)          |
| - Only snacking if hungry & choosing appropriate snacks                                    | 24 / 30 (80%)          |
| - Avoiding high sugar, low nutrient foods/drinks   | 25 / 30 (83%)          |
| - Drinking lots of water   | 25 / 30 (83%)          |
| - Only having occasional treats  | 22 / 30 (73%)          |
| Discussed healthy eating behaviours, if relevant   |                        |
| - Reviewed questions from last consult   | 4 / 5 (80%)            |
| - Healthy eating principles  | 4 / 5 (80%)            |
| - Managing food portions   | 4 / 5 (80%)            |
| - Choosing food with a low GI  | 4 / 5 (80%)            |
| - Choosing low-fat dairy options to reduce calorie intake                                  | 2 / 5 (40%)            |
| - Only snacking if hungry & choosing appropriate snacks                                    | 2 / 5 (40%)            |
| - Drinking lots of water   | 3 / 5 (60%)            |
| - Having only occasional treats  | 3 / 5 (60%)            |
| - Problems / Problem solving   | 2 / 5 (40%)            |
| - Food diary use   | 4 / 5 (80%)            |
| - Relevant weight management activities  | 3 / 5 (60%)            |
| - $\geq 2$ kg gain, may recommence ketogenic diet for 1-2 weeks to return to target weight | 4 / 5 (80%)            |
| Discussed weight loss activities   |                        |

|  |                       |
|--|-----------------------|
| - Discussed 'Plating it up: the portion guide'               | 31 / 35 (89%)         |
| - Discussed 'Supermarket shopping guide'                     | 31 / 35 (89%)         |
| - Discussed 'Healthy snacks'                                 | 31 / 35 (89%)         |
| - Discussed Carbohydrates & Glycaemic index                  | 29 / 35 (83%)         |
| Checked confidence to undertake their weight management plan | 35 / 35 (100%)        |
| Checked exercises  | 62 / 66 (94%)         |
|  | Diet+Ex 33 / 35 (94%) |
|  | Ex 29 / 31 (94%)      |
| Discussed physical activity plan                             | 60 / 66 (91%)         |
|  | Diet+Ex 33 / 35 (94%) |
|  | Ex 27 / 31 (87%)      |

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Note: Denominator shows number of participants where physiotherapist completed consultation notes

| <b>Consultation 5</b>  | <b>n/Total (%)</b>     |
|--|------------------------|
| Performed knee re-assessment   | 52 / 52 (100%)         |
|  | Diet+Ex 26 / 26 (100%) |
|  | Ex only 26 / 26 (100%) |
| Checked weight   | 26 / 26 (100%)         |
| Discussed transition off ketogenic diet to healthy eating, if relevant                     |                        |
| - Challenge of weight maintenance  | 8 / 10 (80%)           |
| - How they are feeling about transitioning off diet  | 8 / 10 (80%)           |
| - How to transition off ketogenic diet over 2 weeks  | 8 / 10 (80%)           |
| - Reducing meal replacements to one meal per day   | 9 / 10 (90%)           |
| - Re-introducing low GI carbohydrates one meal/day   | 9 / 10 (90%)           |
| - Maintaining one low carbohydrate meal per day  | 8 / 10 (80%)           |
| - After 2 wks, stopping replacements & eating 3 healthy meals                              | 7 / 10 (70%)           |
| - Healthy eating principles  | 9 / 10 (90%)           |
| - Closely manage food portions   | 9 / 10 (90%)           |
| - Choosing foods with a low GI   | 9 / 10 (90%)           |
| - Choosing low-fat dairy options to reduce calorie intake                                  | 8 / 10 (80%)           |
| - Only snacking if hungry & choosing appropriate snacks                                    | 9 / 10 (90%)           |
| - Avoiding high sugar, low nutrient foods/drinks   | 9 / 10 (90%)           |
| - Drinking lots of water   | 8 / 10 (80%)           |
| - Only having occasional treats  | 8 / 10 (80%)           |
| Discussed healthy eating behaviours, if relevant   |                        |
| - Reviewed questions from last consult   | 14 / 16 (88%)          |
| - Healthy eating principles  | 15 / 16 (94%)          |
| - Managing food portions   | 12 / 16 (75%)          |
| - Choosing food with a low GI  | 14 / 16 (88%)          |
| - Choosing low-fat dairy options to reduce calorie intake                                  | 14 / 16 (88%)          |
| - Only snacking if hungry & choosing appropriate snacks                                    | 12 / 16 (75%)          |
| - Drinking lots of water   | 12 / 16 (75%)          |
| - Having only occasional treats  | 11 / 16 (69%)          |
| - Problems / Problem solving   | 12 / 16 (75%)          |
| - Food diary use   | 13 / 16 (81%)          |
| - Relevant weight management activities  | 12 / 16 (75%)          |
| - $\geq 2$ kg gain, may recommence ketogenic diet for 1-2 weeks to return to target weight | 14 / 16 (88%)          |
| - Reviewed questions from last consult   | 12 / 16 (75%)          |
| Discussed weight management activities   |                        |
| - Discussed 'Identifying my eating habits'   | 24 / 26 (92%)          |
| - Discussed 'Changing your thought patterns'   | 24 / 26 (92%)          |
| - Discussed Food Diary   | 23 / 26 (89%)          |
| Asked participant to review & use previous activities/resources                            |                        |
| - Choosing a support person  | 20 / 26 (77%)          |
| - IF-THEN planning   | 20 / 26 (77%)          |
| - Tracking your weight   | 21 / 26 (81%)          |
| - Identifying my eating triggers   | 21 / 26 (81%)          |
| - Overcoming barriers  | 19 / 26 (73%)          |

|  |                        |
|--|------------------------|
| - Hunger level scale   | 20 / 26 (77%)          |
| - Plating it up: the portion guide                           | 20 / 26 (77%)          |
| - Supermarket shopping guide                                 | 20 / 26 (77%)          |
| - Healthy snacks   | 19 / 26 (73%)          |
| - Carbohydrates & Glycaemic index                            | 19 / 26 (73%)          |
| - Identifying my eating habits                               | 20 / 26 (77%)          |
| - Changing your thought patterns                             | 19 / 26 (73%)          |
| - Food Diary   | 20 / 26 (77%)          |
| Checked confidence to undertake their weight management plan | 26 / 26 (100%)         |
| Checked exercises  | 51 / 52 (98%)          |
|  | Diet+Ex 26 / 26 (100%) |
|  | Ex only 25 / 26 (96%)  |
| Discussed physical activity plan                             | 51 / 52 (98%)          |
|  | Diet+Ex 26 / 26 (100%) |
|  | Ex only 25 / 26 (96%)  |

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Note: Denominator shows number of participants where physiotherapist completed consultation notes

| <b>Consultation 6</b>  | <b>n/Total (%)</b>     |
|--|------------------------|
| Performed knee re-assessment   | 48 / 48 (100%)         |
|  | Diet+Ex 23 / 23 (100%) |
|  | Ex only 25 / 25 (100%) |
| Checked weight   | 23 / 23 (100%)         |
| Discussed transition off ketogenic diet to healthy eating, if relevant   |                        |
| - Challenge of weight maintenance  | 2 / 2 (100%)           |
| - How they are feeling about transitioning off diet  | 2 / 2 (100%)           |
| - How to transition off ketogenic diet over 2 weeks  | 2 / 2 (100%)           |
| - Reducing meal replacements to one meal per day   | 2 / 2 (100%)           |
| - Re-introducing low GI carbohydrates one meal/day   | 2 / 2 (100%)           |
| - Maintaining one low carbohydrate meal per day  | 2 / 2 (100%)           |
| - After 2 wks, stopping replacements & eating 3 healthy meals  | 2 / 2 (100%)           |
| - Healthy eating principles  | 2 / 2 (100%)           |
| - Closely manage food portions   | 1 / 2 (50%)            |
| - Choosing foods with a low GI   | 2 / 2 (100%)           |
| - Choosing low-fat dairy options to reduce calorie intake  | 2 / 2 (100%)           |
| - Only snacking if hungry & choosing appropriate snacks  | 1 / 2 (50%)            |
| - Avoiding high sugar, low nutrient foods/drinks   | 1 / 2 (50%)            |
| - Drinking lots of water   | 1 / 2 (50%)            |
| - Only having occasional treats  | 1 / 2 (50%)            |
| Discussed progress in weight maintenance   |                        |
| - Reviewed questions from last consult   | 19 / 21 (91%)          |
| - Healthy eating principles  | 21 / 21 (100%)         |
| - Managing food portions   | 19 / 21 (91%)          |
| - Choosing food with a low GI  | 19 / 21 (91%)          |
| - Choosing low-fat dairy options to reduce calorie intake  | 18 / 21 (86%)          |
| - Only snacking if hungry & choosing appropriate snacks  | 18 / 21 (86%)          |
| - Drinking lots of water   | 18 / 21 (86%)          |
| - Having only occasional treats  | 18 / 21 (86%)          |
| - Problems / Problem solving   | 19 / 21 (91%)          |
| - Food diary use   | 19 / 21 (91%)          |
| - Relevant weight management activities  | 16 / 21 (76%)          |
| - Reviewed questions from last consult   | 19 / 21 (91%)          |
| Discussed weight relapse management  |                        |
| - Discussed importance of regularly monitoring weight  | 20 / 23 (87%)          |
| - Discussed recommencing ketogenic diet for 1-2 weeks to return to target weight (done at own cost) if weight gain $\geq 2$ kg   | 21 / 23 (91%)          |
| - Discussed any past efforts at weight maintenance & major obstacles to explore potential strategies                             | 20 / 23 (87%)          |
| - Talked about key role of physical activity   | 22 / 23 (96%)          |
| - Discussed option of seeing GP for medication to assist in weight maintenance   | 21 / 23 (91%)          |
| - Discussed option of seeing a psychologist to assist with cognition & behaviours that might sabotage weight maintenance efforts | 17 / 23 (74%)          |

|  |                        |
|--|------------------------|
| Asked participant to review & use previous activities/resources          |                        |
| - Choosing a support person  | 17 / 23 (74%)          |
| - IF-THEN planning   | 18 / 23 (78%)          |
| - Tracking your weight   | 18 / 23 (78%)          |
| - Identifying my eating triggers   | 18 / 23 (78%)          |
| - Overcoming barriers  | 19 / 23 (83%)          |
| - Hunger level scale   | 17 / 23 (74%)          |
| - Plating it up: the portion guide                                       | 17 / 23 (74%)          |
| - Supermarket shopping guide   | 17 / 23 (74%)          |
| - Healthy snacks   | 17 / 23 (74%)          |
| - Carbohydrates & Glycaemic index  | 18 / 23 (78%)          |
| - Identifying my eating habits   | 18 / 23 (78%)          |
| - Changing your thought patterns   | 18 / 23 (78%)          |
| - Food Diary   | 16 / 23 (70%)          |
| Checked confidence to undertake their weight management plan             | 23 / 23 (100%)         |
| Checked exercises  | 47 / 48 (92%)          |
|  | Diet+Ex 22 / 23 (96%)  |
|  | Ex only 24 / 25 (88%)  |
| Discussed how to change/progress strength program independently          | 48 / 48 (100%)         |
|  | Diet+Ex 23 / 23 (100%) |
|  | Ex only 25 / 25 (100%) |
| Discussed physical activity plan   | 46 / 48 (96%)          |
|  | Diet+Ex 21 / 23 (91%)  |
|  | Ex only 25 / 25 (100%) |
| Discussed how to change/progress physical activity program independently | 47 / 48 (98%)          |
|  | Diet+Ex 22 / 23 (96%)  |
|  | Ex only 25 / 25 (100%) |

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Note: Denominator shows number of participants where physiotherapist completed consultation notes



