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Choosing and following a very low calorie diet program in Australia: a quasi-mixed methods study to understand experiences, barriers, and facilitators in a self-initiated environment

Running heading: Qualitative description of a VLCD in Australia

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2 **Abstract**

3 **Aim:** In Australian adults, this study seeks to describe the experiences and factors associated with
4 the perceived outcomes of using a VLCD program for ≥ 4 -weeks.

5 **Methods:** A mixed method study using the method perspective was conducted to analyse individual
6 semi-structured interviews conducted via videoconference and cross-sectional survey data.

7 Australians 18-65-years were eligible if they were currently consuming at least one VLCD product
8 daily for ≥ 4 -weeks or had ceased consumption within 4-weeks. Interviews were thematically

9 analysed.**Results:** Weight-loss (19kg [SD: 18kg]) and duration (5-months (SD: 5-months) of VLCD
10 product use of the 31 participants (female: 97%, 44 (SD: 11) years, BMI $>30\text{kg/m}^2$: 84%) were

11 strongly correlated ($r= 0.73$, $p<0.001$). Participants' experiences were influenced by a journey of
12 learning from their previous weight loss attempts, discerned the VLCD program has credible, and

13 chose to commence the VLCD due to a convergence of internal motivators. Early health-related
14 outcomes were a reinforcing stimulus and participants developed new health behaviours but felt

15 dependent on the VLCD long term. Throughout these experiences the participants identified various
16 individual, program structure, and environment related factors which either facilitated their VLCD

17 program use or created barriers to achieving their goals. Health care professionals were minimally
18 engaged.

19 **Conclusions:** A model of care to support facilitators and overcome barriers would mean more

20 meaningful engagement of HCPs to ultimately improve the experience and adherence of the VLCD
21 program users in Australia.

22 **Keywords:** Weight loss; VLCD; Qualitative Research; Ketogenic Diet; Weight Reduction Program;
23 Obesity Management

24 **Introduction**

25 The mean body mass index (BMI) of the Australian adult population has steadily increased over the
26 past several decades, with 66.4% of adults having a BMI $\geq 25\text{kg/m}^2$ ¹. Due to the positive association

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27 of increased population BMIs with non-communicable disease rates including cancer, cardiovascular
28 disease, and type 2 diabetes ²; surgical, medical, and lifestyle weight loss treatments have been a
29 research priority nationally and internationally ³⁻⁵. There is high level evidence supporting the
30 efficacy of VLCDs for weight loss and favourable changes in biochemistry for adults with and without
31 type 2 diabetes ^{6,7}. This has seen widespread translation to practice in the use of VLCDs
32 internationally. For example, VLCDs are part of the standard preoperative treatment for bariatric
33 surgery candidates ⁸ and may be prescribed and funded by health services or insurance schemes
34 internationally ⁹; however, regulation and prescription requirements frequently change. In Australia,
35 the recommendations for obesity (BMI $\geq 30\text{kg/m}^2$) management in general practice include VLCDs as
36 an intensive weight loss strategy ¹⁰.

37 VLCDs are usually achieved by meal replacement products, where meals with or without snacks are
38 replaced with pre-packaged nutritionally complete products such as shakes, soups, and bars, plus
39 additional intake of low-starch vegetables ¹¹. VLCD programs and products are widely available in
40 Australian pharmacies ^{12,13}. This availability reflects a key difference in the use of VLCDs in Australia
41 and New Zealand compared to many other countries. In Australia, VLCD programs may be self-
42 initiated rather than prescribed by a health care professional (HCP) such as doctors and dietitians.
43 Although it is recommended by many VLCD programs, HCP guidance is not mandated ¹⁴. As VLCD
44 programs are available in Australia for self-initiation, an individual may choose how to follow the
45 program and if they will engage support. Therefore, Australian adults' experiences with VLCD
46 programs, their outcomes, and the level of support that they receive with VLCD programs is likely to
47 be different compared to adults living in countries where VLCDs are only available by HCP
48 prescription or mandate medical supervision.

49 A model of care is a multidimensional concept that defines the way in which health care services are
50 delivered; and qualitative explorations are essential to ensure models of care are patient-centred ^{15,16}.

51 Although there have been several randomised trials published on clinical efficacy ^{17,18}, there is

52 currently a lack of qualitative research to understand the perspective and experience of adults who
53 have undertaken VLCD programs. Three qualitative studies in Europe concluded that with targeted
54 and effective support, participants felt VLCDs were easily adhered to and reinforced positive lifestyle
55 habits to maintain clinical outcomes ¹⁹. However, due to the differences in how VLCDs are accessed,
56 such findings may not be generalisable to Australian adults. Understanding the Australian experience
57 will help identify the factors associated with the perceived outcomes of VLCD programs and inform
58 models of care to facilitate engagement with HCP support. In Australian adults, this study seeks to
59 describe the experiences and factors associated with the perceived outcomes of using a VLCD
60 program for ≥4-weeks.

61 **Methods**

62 This was a mixed methods study using the methods perspective, also known a quasi-mixed methods
63 ²⁰, which collected, analysed, and then connected both quantitative and qualitative data to answer
64 the single research question. Quantitative data were collected by a cross-sectional survey.
65 Qualitative data were collected and analysed using qualitative description which has been reported
66 according to the Standards for Reporting Qualitative Research (SRQR) ²¹.

67 The research team were all female researchers with a health professional degree, BMI in the
68 recommended range (18.5 to 24.9 kg/m²) and had never used nor researched a VLCD program. The
69 data analysts were aware of, but had minimal initial knowledge of VLCD programs. This limited
70 experience with VLCDs facilitated open and balanced questioning of positive and negative
71 experiences. The interviewer had prior experience conducting and analysing semi-structured 1:1
72 interviews. Therefore, she established a good rapport with participants and was conscious to avoid
73 judgmental or assumptive statements or questions. All data analysts had prior experience in
74 conducting and analysing qualitative data.

75 English-speaking adults aged up to 65 years living in Australia were eligible to participate in the study
76 if they were currently consuming at least one VLCD product, from a single brand, daily for ≥4-weeks
77 or had ceased such consumption within the last 4-weeks. The VLCD brand is well-known and widely
78 available to both the public and within health services in Australia. Exclusion criteria were
79 contraindications of the VLCD program: if adults were pregnant or breastfeeding; BMI was <25.0
80 kg/m² when they began the program; had been diagnosed with porphyria, renal or liver disease; and
81 experienced a heart attack or chest pain within the past 12 months. The target sample size was 30
82 participants as theoretical sufficiency has been reported to occur at this number from various
83 sources ^{22,23}.

84 Participants were recruited between August 2019 and February 2020. A combination of
85 convenience and snowball sampling, followed by purposive sampling, was used in an attempt to
86 obtain a diverse sample²⁴. Participants were recruited from the community via online advertising in
87 social media peer support groups, advertising on the VLCD program home page and through an
88 VLCD online support forum. Interested individuals were asked to click a link that directed them to
89 the study landing page that contained a brief description of the study, the Participant Information
90 Form, and an online eligibility screening questionnaire. Potential participants were asked to provide
91 contact details to enable investigators to confirm their interest, eligibility, and enrolment. Eligible
92 participants who consented to participate were enrolled sequentially until the recruitment targets
93 were met. A unique study ID was allocated to each participant and identifying information was
94 removed from the qualitative transcript data.

95 Once enrolled, participants completed a cross-sectional survey to collect quantitative data, followed
96 by a semi-structured 1:1 interview to collect qualitative data. Survey data were collected on
97 participant demographics (country of birth, sex, education level, ethnicity, income, work situation,
98 and marital status) and health characteristics (BMI, weight loss on the VLCD, comorbidities,
99 medications, smoking), perceptions of the VLCD program and products, and awareness and use of
100 the official VLCD program online support.

101 All quantitative survey data manipulation and analyses were conducted using SPSS (Version 26, IBM
102 Corp, Armonk, NY, 2019). Variables used in analyses were tested for normality using a histogram and
103 the Shapiro-Wilk test. To compare the difference between participants who completed the study
104 and those who withdrew prior to the interview, comparisons were performed by using 2-sample *t*-
105 tests or the Mann-Whitney U test for continuous data and the chi-square statistic or Fisher's exact
106 test for categorical data. Correlations between variables were assessed using Pearson coefficient. P-
107 values <0.05 were considered statistically significant.

108 Fundamental qualitative description methodology was used to collect and analyse qualitative data
109 ²⁵. Qualitative description is a method in which analysts use and describe low-interference
110 interpretation of the subjective experiences of participants ²⁵. Interpretation is inductive rather than
111 seen through the lens of an a-priori framework or system; and the description offers a
112 comprehensive summary of a phenomena, thus being useful for HCPs who need to translate findings
113 to practice ^{25,26}. Qualitative data were collected via a semi-structured 1:1 interview via
114 videoconference by a single investigator not involved in the recruitment process. After pilot testing,
115 the interview used 10 open-ended questions with prompts to elucidate further detail (Table S1).
116 Participants who completed the interview received an AUD\$30 gift card as compensation for their
117 time. Interviews were recorded via the videoconferencing software by Zoom Video Communications
118 Inc (San Jose, USA) and were transcribed verbatim by GoTranscript Ltd (United Kingdom). Most
119 participants opted to have their video disabled for the interview.

120 Interview data were analysed thematically, using an inductive approach ²⁷, reflecting the steps
121 proposed by Braun and Clarke ²⁸. NVivo software (Version 12 Pro, QSR International Pty Ltd) was
122 used for coding the data. Constant comparative analysis was used from step 2 with the aim of
123 refining the developing concepts ²⁹. The specific steps employed in the qualitative data analysis
124 were:

- 125 1. Two Analysts familiarised themselves with data then performed open line-by-line coding ²⁹
126 for the first five transcripts.
- 127 2. The incidents and generated codes were compared and collapsed into categories to develop
128 higher-level 'focus codes'.
- 129 3. Two analysts met to gain consensus on focus codes and a codebook ³⁰ was generated. The
130 first five transcripts were re-coded based on the focus codes. As analysis proceeded, the
131 codebook was revised and updated for new codes.

- 132 4. The remaining 26 transcripts were divided and between two analysts for further coding. The
133 analysts met during their analyses to discuss changes and emerging findings. During this
134 process, some codes were collapsed into a larger category or separated into smaller
135 categories.
- 136 5. After generating focus codes, memoing²⁹ was used. Memos were about: (a) codes or
137 categories, (b) links between codes or categories, (c) gaps in codes or categories, (d)
138 usefulness of a category, or (e) practical implications. Memos were treated analytically and
139 were also used for an audit trail³¹. A second series of memoing was performed so that both
140 analysts could be involved in reflecting on their thoughts and ideas for each transcript.
- 141 6. Emerging codes were compared based on participant characteristics. Patterns were
142 compared between participants who reported negative or positive experiences.
- 143 7. After all data were coded and memoing was completed, analysts met to develop a list of
144 potential themes and outline a framework. Every developed theme was defined by what
145 was involved in it, its properties, under which condition the properties emerged, and what
146 constituted the data informing the theme.
- 147 8. The themes were reviewed and refined further by re-reading transcripts to compare
148 incidents and codes against the themes to ensure the data formed a coherent pattern.
149 Analysts refined their earlier codes in light of later codes²⁹, and had regular meetings to
150 discuss how the themes were changing. As themes changed, the analysts looked for the new
151 or modified themes in the data they read thereafter.
- 152 9. The two analysts met with a third analyst to confirm the themes, connect quantitative
153 findings to the qualitative themes, and refined the framework via triangulation and a fourth
154 reviewed the audit trail and contributed to the description and interpretation of themes
155 after data familiarisation.

156 Several techniques were used to enhance trustworthiness and credibility of the findings. Firstly, an
157 audit trail of all the steps and decisions made during the research process was recorded ¹⁵. The
158 researcher triangulation method ¹⁵ was used by involving four analysts to bring different
159 perspectives into the findings. An analyst also contacted a random sample of five participants by
160 email to conduct a respondent validation ³²; no corrections or changes were requested.

161 The study was approved by the Bellberry Human Research Ethics Committee (Protocol ID: 2019-03-
162 170). Electronic informed consent was obtained for all participants with further verbal consent
163 before each interview.

164 Results

165 Seventy of the 178 adults that completed the screening questionnaire were eligible and 31 were
166 interviewed. The most common reason for ineligibility was related to how the VLCD program was
167 used, such as not using products daily or using the program for less than 4-weeks (**Figure 1**).

168 There were no significant differences in demographic or medical characteristics between those that
169 completed the interview and those that withdrew (**Table 1**). Most participants (84%) had a BMI ≥ 30
170 kg/m², where 19% reported a perceived need for weight loss surgery and 94% reported having one
171 or more comorbidities (**Table 1**). Participants were mostly married (81%), females (97%), aged 44
172 (SD: 11) years, and born in Australia (84%). Participants were highly educated and the majority were
173 employed, where more than half reported a household income of $\geq \$100,000$ /year (**Table 1**). The
174 most reported comorbidities were back pain/joint pain/poor mobility (52%) and depression/anxiety
175 (48%); accordingly, the most common type of prescription medication used was anti-depressant or
176 anti-anxiety (43%).

177 Most participants were current (90%) and first time (52%) users, and almost all participants (97%)
178 reported they would recommend the VLCD program to a friend or family member. Only 40% of
179 participants reported using the official VLCD program online support platform which provided access
180 to HCP support, despite 97% being aware of the support. The VLCD products most consumed were
181 shakes (97%), non-cereal bars (74%), and desserts (61%).

182 All participants reported losing weight since commencing the VLCD program ≥ 4 -weeks prior to the
183 interview, which ranged from 3-90kg (mean 19.1kg [SD: 17.8kg]) over a mean of 5.2-months (SD:
184 4.9-months) (**Table S2**). All but one participant reported that their main goal was weight loss, where
185 weight maintenance was their primary objective. There was a strong correlation between weight
186 loss and duration of VLCD program use ($r = 0.73, p < 0.001$). No association was found between weight
187 loss and age ($r = 0.27, p = 0.17$) or number of times using the VLCD program ($r = -0.26, p = 0.18$).

188 The median duration of the 31 interviews was 49-minutes (IQR: 16-minutes). Data analysis of
189 participants' experiences identified a theoretical framework which described how Australian adults
190 chose and followed the VLCD program, and the factors which facilitated or acted as a barrier to their
191 perceived outcome (**Figure 2**). Thematic analysis identified two domains: "choosing the VLCD
192 program" and "following the VLCD program". Overlapping themes within the "choosing the VLCD
193 program" domain were "*a journey of learning*", "*convergence of internal motivations*", and
194 "*differentiating credibility*". Overlapping themes within the "following the VLCD program" domain
195 were "*outcome as a reinforcing stimulus*", "*learning healthy behaviours*", and "*fear-based*
196 *dependency*".

197 The interrelationship of the domains, themes, and factors are represented in **Figure 3**. Specifically,
198 this study found that participants who self-initiated the VLCD program were influenced by a journey
199 of learning from their previous weight loss attempts, discerned the VLCD program has credible, and
200 despite having low expectations of success still chose to commence the VLCD due to a convergence
201 of internal motivators. In this sample, early health-related outcomes acted as a reinforcing stimulus
202 to adhere to the program, and for many this led to learning new health behaviours. Although new
203 behaviours were learned, participants reported feeling dependent on the VLCD program due to fear
204 of losing the gained benefits if the program was completely ceased. Throughout these experiences
205 the participants identified various individual, program structure, and environment related facilitators
206 and barriers to VLCD program use and to achieving their goals (**Table 2**). Engagement with HCPs was
207 minimal and was not perceived by participants as important facilitators for perceived success nor for
208 supporting program structure, environment, or individual factors. Each of the themes is described
209 below.

210 A "*journey of learning*" was a theme identified when exploring why participants chose the VLCD
211 program and their perceived outcome. Participants described various weight loss journeys they had

212 taken and how their previous experiences, learnings, and outcomes provided a foundation of
213 knowledge on which to build their current weight loss efforts.

214 *"[description of previous weight loss programs]... but learning stuff all along that journey."*
215 (39)

216 The "journey of learning" was heavily influenced by previous negative, demotivating, and
217 unsustainable weight loss experiences which ultimately lead to the cost or burden of the weight loss
218 strategy outweighing the benefits.

219 *"I just stopped doing it. So then... the weight crept on and then... obviously then...you feel*
220 *crap about yourself." (02)*

221 Despite historical negative experiences with weight loss strategies, a theme of "convergence of
222 internal motivations" led participants to attempt weight loss again. Many overlapping internal
223 motivations were described by participants and were predominately those which affect weight-
224 related quality of life including the impact of weight on health, social participation, physical
225 functioning, discrimination, and self-esteem.

226 *"... then I got to this stage of ... having the health problems and ... basically deciding I needed*
227 *to do something about it ... I need to be around for my kids basically." (32)*

228 Although, internal motivations were influenced by external pressures on body size, such as seat sizes
229 and clothing comfort, and external experiences of obesity stigmatisation.

230 *"...and [he] said, 'you have to be honest about [your weight to the helicopter pilot]' and I said*
231 *'Yes, I know'...and I said to him 'I'm 115 kilos'...it blew him away. I was embarrassed... and*
232 *ashamed." (41)*

233 Diverging within the theme of internal motivations, a few participants reported external pressure to
234 lose weight imposed by family and HCPs.

235 *“Differentiating credibility”* was a theme identified across interviews when exploring how
236 participants were introduced to and decided to use the VLCD program. Most participants perceived
237 that they were introduced to the program by a credible source, which included a HCP or a friend
238 who they had observed as having a good outcome. However, a key benefit of the program was
239 described by the participants as fast weight loss. “Fast” or “rapid weight loss” is a phrase usually
240 associated with and considered a red flag for non-evidence based “fad” diets³³. Despite this red flag
241 terminology, the VLCD programs’ association with HCPs and recommendation by HCPs led
242 participants to identify the program as evidence-based and credible.

243 *“When I read that [VLCD] were offered to people by doctors, that’s when I thought, ‘Okay,*
244 *that’s a good one then if doctors are recommending them’ ... it sort of gave a bit more*
245 *credibility. More legitimate, and I didn’t feel like I was just doing a fad diet.” (47)*

246 Nutrition also contributed to the participants differentiating the VLCD brand as credible, with
247 participants describing the program as nutritionally complete and appropriate for diabetes and
248 lactose-intolerance. However, despite the program being perceived as credible, participants’
249 *“journey of learning”* led to low expectations of success, sustainability, and adaptability to special
250 events.

251 *“[the shakes] won’t work and, you know, I’ll just go and have my stomach stapled or I’ll just*
252 *go on to the medication...it’s not gonna work.” (21)*

253 *“Outcome as a reinforcing stimulus”* represents how early health- and weight-related improvements
254 led to maintained and renewed motivation to continue the program. Linking back to internal
255 motivators, rather than focusing solely on weight loss, the perceived program outcome was often

256 described in terms of quality of life. This included domains of vitality, physical health, social
 257 engagement, mental health, discrimination, and physical functioning.

258 *"... my whole life has changed...I'm a better... person, better wife, better mum, better*
 259 *daughter."* (02)

260 *"feeling less anxious about engaging with people in general and feeling judged."* (11)

261 Although such outcomes were subjective, participants also valued objective clinical markers of
 262 health improvement such as blood sugar levels, blood pressure, serum cholesterol, and decreased
 263 medication dose. Some participants described negative health outcomes such as vitamin A
 264 deficiency and gall stones; however, in neither case were such adverse events strongly linked to
 265 VLCD in the minds of the participants. Participants reported that the speed of weight loss varied
 266 depending on their adherence to the program, but that ultimately seeing initial weight loss and
 267 improvements to their health positively impacted their motivation to continue the program.

268 *"And once the weight started coming off... then it...just made my resolve stronger, and after*
 269 *a period of time, I noticed that I wasn't coughing anymore... I can now sleep."* (05)

270 Participants recognised that these perceived positive outcomes contrasted with their low
 271 expectations. The reinforcing stimulus extended beyond self-motivation, leading to role modelling
 272 behaviour, where participants reported widely recommending the program within their social
 273 networks.

274 Over time, participants moved beyond the reinforcing stimulus of outcomes to describe a
 275 phenomenon of *"learning healthy behaviours"*. Once motivation had sustained them on the
 276 program, participants described that they noticed changes to their food preferences and eating
 277 patterns.

278 *“So it's... teaching me to enjoy... veggies and salad again. And it's also just making me realise*
279 *I don't actually need the other stuff to feel happy or content or fulfilled.” (28)*

280 *“Cause I was in a terrible habit of not eating three meals a day, so if anything, it's improved.*
281 *I've improved in that way that I would actually eat.” (44)*

282 Although participants identified improved food and eating behaviours, their perceived outcomes
283 were strongly linked to the VLCD program rather than the behaviour change.

284 *“It's like magic in a container.” (21)*

285 Associating the VLCD but not behaviour change with their perceived outcomes led to participants
286 describing hesitation through to outright fear of returning to a diet without VLCD products, in the
287 theme *“fear-based dependency”*. Although participants mostly reported not yet reaching their goal
288 weight, many reported that they planned to use the VLCD program in the long term, for either years
289 or their entire life. Dependency upon the program was both theoretically anticipated in first time
290 users and a known experience in those who had experienced weight regain after ending use of the
291 program.

292 *“All I can tell you is, if you're a kid and you touch a hotplate on the stove when your mum*
293 *says, ‘Don't touch the hotplate’ Only an idiot goes back to the hotplate.” (40)*

294 One aspect identified by participants as a contributing factor to this fear is the variety of food
295 available when consuming a regular diet, which they associated with a loss of control and
296 subsequent weight regain.

297

298 Discussion

299 This is the first study to explore and describe the real world experience of VLCD program usage in
300 Australia, with a focus on understanding the factors that are associated with perceived outcomes.
301 Themes identified within the “choosing” and “following” VLCD domains were not only interrelated
302 with each other but were also linked to many of the factors associated with perceived outcomes.
303 The theoretical framework captures the process by which Australians choose, follow, and engage
304 with a VLCD program and this differs significantly to how the program is used internationally. In
305 particular, this study found that HCPs were minimally engaged by participants, and that engaging
306 support from HCPs was not considered a factor associated with improved adherence to the
307 program. This theme is further supported by the survey data which reveal that less than one in two
308 users chose to access the online HCP support. This is in direct contrast to the three qualitative
309 studies from Europe which found targeted and effective HCP support were critical factors in the
310 achievement of a positive outcome ¹⁹.

311 The experiences interpreted from the interviews are largely defined by how long the participants
312 had been using the VLCD program. All participants had been using the program daily for at least 4-
313 weeks as reflected in the eligibility criteria; however, many participants had been using the products
314 for months, or in some cases years. This means the findings represent those who have been able to
315 continue the VLCD program for this period with a self-perceived successful outcome. Although the
316 findings do not represent those who tried the program but ended it within the month, this study
317 provides valuable understanding of facilitators to maintain motivation and program adherence for a
318 product which is widely utilised in health care environments. This is immediately evident in the first
319 theme described, “*journey of learning*”. Across interviews, previous experiences of weight loss
320 attempts built wisdom in the participants, which enabled them to adhere to the program. Such
321 learnings are captured in the factors associated with perceived outcomes and included self-
322 compassion, and avoiding an “all or nothing” mindset which is a characteristic of rigid restraint

323 eating behaviour³⁴. It also included more practical learnings such as the importance of engaging
324 peer and family support and planning and preparing meals.

325 A “*journey of learning*” was further linked to the “*differentiating credibility*” theme. Previous weight
326 loss experiences were used by participants to make judgements on integrity and trustworthiness.
327 Whilst this theme did not seem to share any commonality with other themes, it was closely linked to
328 environmental factors associated with perceived outcomes. Participants showed health literacy by
329 drawing upon multiple sources to make such judgements including packaging, educational
330 information, and engaging HCPs. Recommendations by trusted HCPs has previously been described
331 as assisting individuals to initiate weight loss interventions³⁵. This finding may not be translatable to
332 other VLCD programs in Australia which are not endorsed by HCPs or advertised in health care
333 environments. However, common to other health care settings³⁶, participants still placed high value
334 in the experiences of others and recommendations from social networks. This may be explained by
335 social cognitive theory, which considers behaviours as learnt through observational learning and
336 modelling³⁷. Participants described acting or wanting to act as health literacy mediators, or
337 otherwise sought support from health literacy mediators via their participation in social media
338 groups. This mediation was seen as valuable, reflecting the findings by Edwards et al³⁸, who
339 reported that health literacy was distributed through social networks. This finding may also reflect
340 the unique participant group which was predominately recruited via non-official social media
341 support groups.

342 The “*journey of learning*” theme looks to have influenced the motivations of participants to follow
343 the VLCD program. Although a goal may have been weight-related, aligning with other VLCD
344 research¹⁹, motivators were not. Through their previous journeys, participants placed motivating
345 value on quality of life, a finding which reflects patient values of health care treatments³⁹. Whilst the
346 “*convergence of internal motivators*” was a theme across interviews, the internal motivators
347 represented both intrinsic and extrinsic aspirations when looking through the lens of self-

348 determination theory⁴⁰. For example, motivators related to mental health, physical health, and
349 social engagement were intrinsic; whereas aiming to improve appearance and avoid discrimination
350 were extrinsic. The dominance of intrinsic motivations may be a characteristic of recruiting a sample
351 which had been able to adhere to the program for ≥ 4 -weeks. According to the self-determination
352 theory, intrinsic motivation is an important facet of self-determination and consequent behaviour
353 change⁴⁰. Intrinsic motivations are more likely to support satisfaction of the psychological needs,
354 which helps to understand why “*outcome as reinforcing stimulus*” was a theme related to
355 maintaining motivation. It also explains why early outcomes described by participants were
356 predominately related to improvements in quality of life rather than solely or heavily dependent
357 upon weight loss. Social cognitive theory suggests that this early achievement of weight loss and
358 quality of life improvements built self-efficacy and maintained motivation⁴¹.

359 Outcomes achieved by the participant themselves were not the only motivators, but many
360 participants drew upon the experiences of others as shared on social media support groups.
361 “*Outcome as a reinforcing stimulus*” from the perspective of observing other peoples’ outcome can
362 be understood within social cognitive theory. By seeing someone else role model a behaviour
363 successfully, belief was created in the participants that they could also complete the behaviour³⁷. A
364 snowballing effect was observed, where participants then wanted to act as role models themselves.

365 Participants were able to recognise that positively-perceived outcomes were associated with their
366 ability to “*learn healthy behaviours*”. It is interesting that despite recognising new healthy food and
367 eating behaviours, participants still felt dependent upon the VLCD program, as described within the
368 theme “*fear of the hotplate*”. The program structure flexibly used by participants, whilst a facilitator
369 to adherence, may also be contributing to the fear of ending the program entirely. This may be a
370 phenomenon unique to the Australian setting, as using the program as prescribed with close
371 supervision of health professionals may prevent this dependence from forming. Whilst dependence
372 can be considered a negative outcome, it is also rational. Sixty percent of weight lost on VLCDs is

373 commonly regained over an average of 1.9 years^{42,43}; a phenomenon common to most weight loss
374 interventions⁴⁴.

375 Models of care which facilitate access to HCPs for Australians using VLCD programs should focus on
376 improving self-efficacy in the adults' health behaviour change; with a particular focus on eating
377 behaviours. One Australian study suggested that HCPs lack knowledge about obesity treatment⁴⁵
378 and patient needs for weight loss support are not met by HCPs⁴⁶. McVay et al found that
379 participants who completed a weight loss diet without engaging support wanted to maintain
380 autonomy, as having external monitoring provided a risk of disappointment and judgement³⁵. This
381 suggests a lack of trust in HCPs, and models of care which overcome these barriers to support adults
382 on VLCD diets should be designed using a translation to practice model to ensure relevance and
383 patient-centredness. Further profiling of the eating behaviours of Australian adult VLCD users would
384 improve the patient-centredness of HCP models of care.

385 Barriers to VLCD program use included adverse events. Although the adverse events described by
386 participants were minor and commonly reported in VLCDs⁴⁷, they could be traumatising, particularly
387 those related to gastrointestinal function and hair loss. All participants who had adverse events in
388 this study continued the program. Considering the minimal engagement of HCPs and the self-
389 customised VLCD programs used by participants, adverse events experienced by Australians who did
390 not continue the program for ≥ 4 -weeks should be explored. Further, quantitative surveys and
391 observational cohort studies are needed to fully describe how VLCD programs and products are
392 utilised and modified over time by Australian adults.

393 The qualitative component of this study was limited by not utilising field notes to ensure
394 confirmability; however, credibility was established by asking a random subsample of participants to
395 confirm the interpretation and description of their subjective experiences. Dependability was
396 established by using the method of constant comparison and having a fourth analyst review the
397 audit trail to confirm the accuracy of the findings and that they are integrated with the quantitative

398 data. Further observational research is required to evaluate transferability and to fully characterise
399 the experiences of Australian adults who use VLCD products, including those who end use in less
400 than 4-weeks, and people from different socio-economic backgrounds.

401 In conclusion, this study found that Australian adults who self-initiated the VLCD program were
402 influenced by a journey of learning from their previous weight loss attempts, discerned the VLCD
403 program as credible, and despite having low expectations of success still chose to commence the
404 VLCD due to a convergence of internal motivators. In this sample, who had continued the program
405 for ≥ 4 -weeks, early health-related outcomes acted as a reinforcing stimulus to adhere to the
406 program, and for many this led to learning new health behaviours. Although new behaviours were
407 learned, participants reported feeling dependent on the VLCD program due to fear of losing the
408 gained benefits if the program was completely ceased. Throughout these experiences the
409 participants identified various individual, program structure, and environment related factors which
410 either facilitated their VLCD program use or created barriers to achieving their goals. These themes
411 provide guidance and direction to HCPs to support Australian adults who have chosen to commence
412 VLCDs; and should be viewed within the context that HCPs were not seen as essential and were
413 minimally engaged. A model of care to support facilitators and overcome barriers would mean more
414 meaningful engagement of HCPs to ultimately improve the experience, safety, adherence of VLCD
415 program and product users in Australia.

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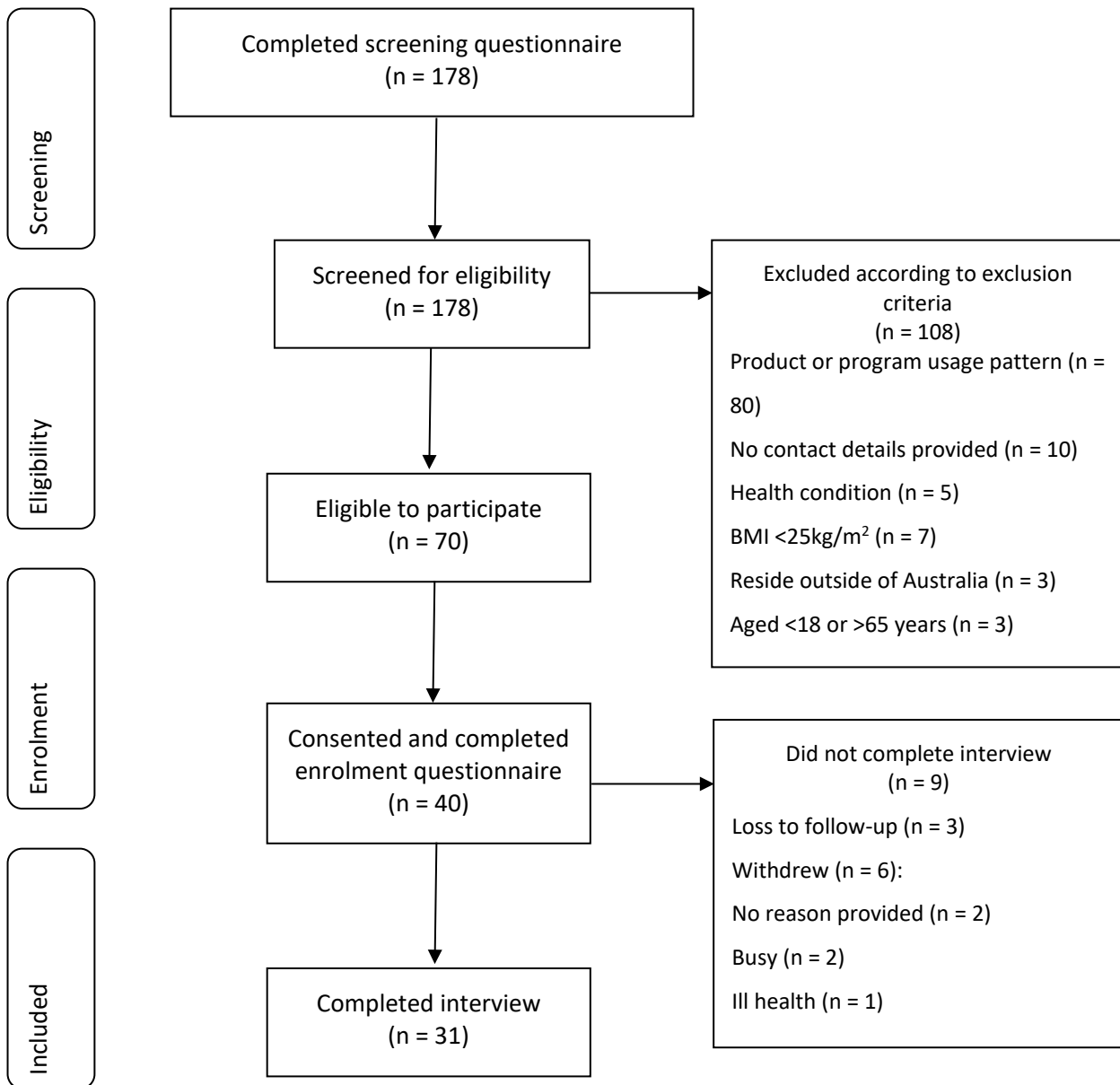


Figure 1. Flowchart of the recruitment process.

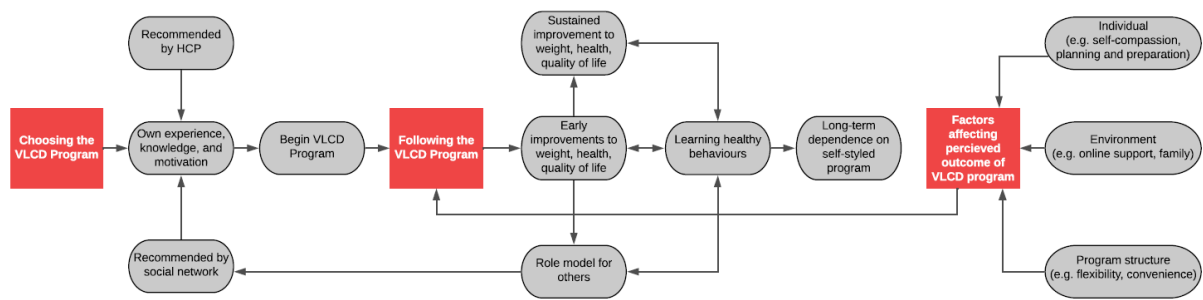


Figure 2. Theoretical framework of how Australian adults choose and follow the VLCD program, and the factors which impact upon those experiences, from the perspective of adults who have continued the program for ≥ 4 -weeks.

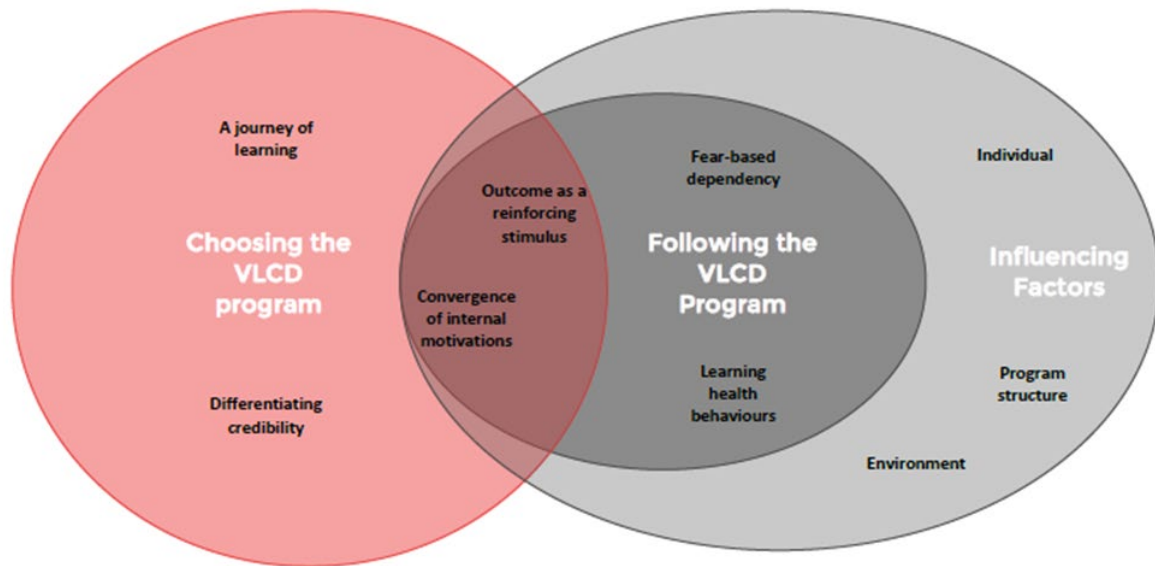


Figure 3: Representation of the domains, themes, and influencing factors which were interpreted from the experiences of Australian adults who participating in interviews regarding their experience with a VLCD program.

Table 1. Demographic characteristics of eligible Australian adults and medical status of those who participated in interviews regarding their experience with a VLCD program

Demographic characteristics ^a	All (n = 40)	Completed interview (n = 31)	Withdrew ^b (n = 9)	p-value ^c
Female	38 (95)	30 (97)	8 (89)	
Age (y)	44 ± 11	44 ± 11	44 ± 10	0.924
BMI ^d				0.642
25-29.9kg/m ²	6 (15)	5 (16)	1 (12)	
≥30kg/m ²	33 (85)	26 (84)	7 (88)	
Born in Australia ^e	35 (88)	26 (84)	9 (100)	
Caucasian ^f	38 (95)	31 (100)	7 (78)	
English as first language	37 (92)	28 (90)	9 (100)	
Highest level of education				0.190
Tertiary	29 (73)	24 (77)	5 (56)	
Secondary	11 (27)	7 (23)	4 (44)	
Marital status ^d				0.097
Married or de facto	29 (74)	25 (81)	4 (50)	
Separated, divorced, single or widowed	10 (26)	6 (19)	4 (50)	
Children living at home				0.998
None	18 (45)	14 (45)	4 (45)	
One	9 (22)	7 (23)	2 (22)	
≥ Two	13 (33)	10 (32)	3 (33)	
Employed	26 (65)	20 (65)	6 (67)	
Hours worked in past week	21 ± 20	20 ± 20	25 ± 20	0.711
Household income ^{g,h}				0.063
< \$30,000	5 (15)	3 (11)	2 (33)	
\$30,000-\$59,999	4 (12)	3 (11)	1 (17)	
\$60,000-\$99,999	8 (24)	5 (19)	3 (50)	
≥ \$100,000	16 (49)	16 (59)	0 (0)	
Smoker		2 (7)		
≥1 Comorbidity		29 (94)		
Type of comorbidity ⁱ				
Back/joint pain/poor mobility		16 (52)		
Depression/anxiety		15 (48)		
Asthma		9 (29)		
Hypertension		8 (26)		
Gall bladder disease		7 (23)		
Family history of heart disease		7 (23)		
Hypercholesterolaemia		6 (19)		
Sleep apnoea		4 (13)		
Type 2 diabetes		4 (13)		
Autoimmune condition ^j		4 (13)		
Epilepsy or seizures		3 (10)		

Other ^k	10 (32)
Believes requires weight loss surgery	6 (19)
Using prescribed medication	21 (68)
Prescription medication type ^l	
Antidepressant or anti-anxiety	9 (43)
Antihypertensive	7 (23)
Anti-reflux	5 (16)
Cholesterol	5 (16)
Pain	4 (13)
Asthma	4 (13)
Other ^m	2 (6)
Uses over-the-counter medication	10 (32)
Over-the-counter medication type	
NSAID	4 (13)
Allergy relief	3 (10)
Paracetamol	2 (7)
Anti-reflux	2 (7)
Uses a supplement	15 (48)
Supplement type ⁿ	
Vitamin D	5 (16)
Zinc or iron	4 (13)
Folate or B vitamins	4 (13)
Hair, skin, nails formula	3 (10)
Multivitamin	3 (10)
Magnesium	2 (7)
Fish oil	2 (7)
Other ^o	4 (13)

BMI, body mass index; NSAID, non-steroidal anti-inflammatory; SD, standard deviation; y, years.

a. All values are frequency and proportion as a percent in parentheses except as specified for 'Age' and 'Hours worked in past week' where values are mean and standard deviation in parentheses, with range below.

b. Defined as completed the screening questionnaire but did not attend the interview.

c. Comparison of completed and withdrawn participants.

d. Answered by n=39.

e. 'Other' included Germany (n=1), New Zealand (n=1), Papua New Guinea (n=1), United Kingdom (n=1), and United States (n=1) as countries of birth.

f. 'Other' ethnicities included White British (n=1) and Italian (n=1).

g. Income in AUD per annum.

h. Reasons for incomplete data included not all participants answered (n=33), not all interview completers answered (n=27).

i. Participants were able to select as many comorbidities and medications used as applicable. Reasons for incomplete data included: not all participants answered (n=29)

j. Autoimmune conditions reported included Lupus, Psoriasis, Hashimoto's and Sjogren's disease.

k. 'Other' comorbidities included anaemia, Subglottic stenosis, heart disease, endometriosis, gastric banding surgery, dizziness, polycystic ovarian syndrome and pneumonia.

l. Reasons for incomplete data included: not all participants answered (n=21).

m. 'Other' OTC medications includes weight loss and glucocorticosteroids.

n. Reasons for incomplete data included: not all participants answered (n=15).

o. 'Other' supplements includes vitamin A, calcium, dietary fibre, glucosamine.

Table 2: Factors which were associated with the perceived outcomes of Australian adults who used the VLCD program for ≥4-weeks

Factors	Description	Evidence
Program structure		
Flexibility	Participants described modifying the three levels of the program structure as well as designing their own program to suit their lifestyle (e.g. for special events, to make less restrictive, or to eat meals with family) and their weight loss (e.g. extension of intensive phase or return to intensive phase). However, modification of the program for these reasons may be perceived as a 'failure' by some participants.	<p><i>"If... I'd gone on intensive and...stuck to it...I would have been at my goal weight months ago probably. But I didn't want to. I wanted to do it where I felt comfortable and where it was sustainable for me and where I could pick and choose how I use the program."</i> (13)</p> <p><i>"... I'm just choosing my own path"</i> (26)</p> <p><i>"I've had my [brand] shake, then I'm gonna have a scone and then I'm gonna have dinner tonight. You know, that's not really, really well organized, but...I have to do it like that because if the diet is too restrictive, I'll lose."</i> (19)</p> <p><i>"I have fallen off a couple of times, um, my daughter's birthday, I made the cake."</i> (14)</p>
Choice limitation	Choice and temptation of food in a regular diet was seen as a barrier to weight loss by some, where the removal of choice was a factor associated with adherence. Conversely, some participants found the choice limitation as a barrier to adhering to the program leading to participants modifying the program to cope with the choice limitation.	<p><i>"... using [a] diet where it's quite prescriptive and restrictive... is useful to me because there's not really options for... confusion."</i> (11)</p> <p><i>"I find it difficult because the options for eating on the [brand] are quite restrictive."</i> (27)</p> <p><i>"on the weekend, it was an Active 2 day. ... when I had visitors here or...f we go out...it's generally an Active 2 day and then if we-- if I eat things like-- sometimes we do have a dessert, which is, you know, not really allowed, but if I do, then I know the next few days, then I go back to full Intensive."</i> (23)</p>
Convenience	The products were consistently seen as convenient due to the lack of food preparation required and the transportability of the meals.	<p><i>"It's easy ... if it's going to be dinner time on the plane, if I'm traveling at that time or lunch, I just take a bottle of water with me, my [brand] [VLCD Program], mix it up there, have it on the plane."</i> (41)</p> <p><i>"it's the ease of the use of the products as well ... the bars are handy if you're on the go."</i> (28)</p>
Cost	Although acknowledged to be affordable in comparison to a regular diet, the VLCD was consistently perceived to be costly. However, no participants stated that the cost was currently influencing their adherence to the program.	<p><i>some people on these [social media] things are like, "Oh my gosh, it's so expensive." My argument is, from my point of view, it works out depending on where you're shopping."</i> (19)</p>

Flavour	Flavour pleasure and flavour variety were related to adherence by participants, drawing on both the current experience with and other VLCD products.	<p><i>"[VLCD desserts] don't taste like they should be allowed on a diet at all." (09)</i></p> <p><i>"you get used to [the flavour] and you get into a habit, but eventually... it gets a bit monotonous. And from my own kind of mental wellbeing, you have to [have a] bit of a break...just to feel like you can participate in life." (26)</i></p> <p><i>"I don't know what to expect...I'd had...some [other branded VLCD] before that...taste was horrendous." (01)</i></p>
Adverse symptoms	Participants widely reported experiencing minor adverse events such as those related to gastrointestinal function, lethargy, mood, and hair loss. Participants preferred to find a solution for the symptom or continue experiencing the symptom despite concern, rather than ceasing the program.	<p><i>"I eat a slice of toast and my body just decides it's the worst thing in the world. That's been a really big thing that I'm concerned about long term." (16)</i></p> <p><i>"[describing explosive diarrhoea whilst on public transport] I had to go to the bathroom right then, which was terribly embarrassing." (20)</i></p>
Environment		
Online support groups	Participants consistently expressed the need for support but reported diverse experiences with online support. Some participants found social media based online support groups enabled conversations amongst peers which improved their motivation. However, others expressed experiences with online peer engagement that could be harmful to motivation.	<p><i>"I'd take it [the information on social media] with a grain and salt 'cause I know that some people are like stupid on there and they don't know what they're saying." (47)</i></p> <p><i>"And I think seeing testimonials and real-life people doing it and the struggles that people have keeps me kind of going." (06).</i></p> <p><i>"... the [social media] groups actually been great. You just have to keep in mind that everyone's sort of starting at a different point, so you can't feel bad when you're not losing at the same rate as someone that's, you know, double the size that you are." (33)</i></p>
Educational information	Online support groups were consistently utilised as a source of educational information or a method in which to understand the educational information provided by the official programs or HCPs.	<p><i>"I'm in a [social media support] group, which I find more beneficial than the [official HCP] support page....the website I found is very basic and limited as to the meal suggestions they have....That's why I love that [social media support] group because they do share things like [recipes]." (14)</i></p> <p><i>"So it's great to have that [social media support group] group to bounce the ideas off rather than just having to read the standardized information that they have there." (14).</i></p>
Health care professionals	There were variations regarding the involvement of doctors, dietitians, and psychologists, but the unifying factor was that HCPs were infrequently involved. Participants who were on prescribed medication were more likely to involve their doctor in their experience; however, few followed the recommended check-ins with their usual doctor unless the program was being used as a preoperative phase for bariatric surgery. Some	<p><i>"And the doctor has gone with the... meal replacements ... But, I guess no... further support in that sense... I can do it myself." (02)</i></p> <p><i>"I checked in [with her doctor] when I first started and I haven't been back. I need to go see him. He wasn't overly fussed, really. He wasn't as-as supportive as I thought he would be." (06)</i></p> <p><i>"But I have decided to remain on intensive to lose as much weight as I can. So every 12 weeks I see [my doctor] and...she takes-- I have blood tests, et cetera to make sure that uh, liver and the kidneys and everything's working okay... The dietitian, she knows</i></p>

	participants purposefully did not tell their doctor about their experience because they believed the doctor didn't know enough about the topic, whereas others were recommended to start the program by their doctor. Few participants reported seeing a dietitian.	<i>a little bit more about the program... and I can always email her too if I'm unsure about the particular food product that...I might wanna try, but I'm not sure if it fits in."</i> (05)
Family	The type of family support was consistently noted as a factor important to the perceived outcome. Participants whose family were supportive felt they were more able to adhere to the program, whereas family who were not supportive led to more frequent intake of foods which were excluded from the program recommendations.	<i>"[in my last use of the VLCD program] I was living with family and so I had people around me that weren't doing the diet, were eating different meals, and, it wasn't fitting in with my lifestyle, you know. Whereas this time, it's been very easy because we've, both my partner and I and the whole home environment has shifted and we've just done the [brand] [VLCD Program] together. And, you know, there hasn't been much temptation to do anything different in our lifestyles."</i> (39)
Social gatherings	Social gatherings were consistently reported a barrier by participants, leading to multiple changes in their social behaviour. This included either avoiding social engagements or modifying their behaviour during a social engagement. Participants reported social gatherings often led to deviating from program recommendations.	<i>"Well yeah, I tend to go, if I'm doing something like that, I'll get an undressed salad. And depending on if it's like a dinner I'll get a grilled piece of fish or chicken."</i> (14)
Workplace	Working environments were also consistently identified as presenting barriers to program adherence due to practical aspects such as travel, dealing with stressful situations, and feelings of judgement from colleagues.	<i>"I think there was a lot of negativity when I used to flip my shake container at work, even though I had great results."</i> (35). <i>"The only struggle I have is when I'm working just cause I'm always on like-- I'm running on 12-hour shifts."</i> (06)
Individual		
All or nothing mindset	Participants described an "all or nothing" mindset as something they were currently experiencing or something they needed to avoid.	<i>"...I think if you just restrict yourself too much then you completely lose the plot and binge."</i> (23) <i>"I think that's the thing with diets. The minute you break the diet, you can feel that that's the end of it, you know, I'm a failure, that's it, forget it."</i> (13)
Self-compassion	Participants consistently described the need for having realistic expectations about both weight loss and level of adherence to the program. Having self-compassion formed a core part of this, where allowing for flexibility and periods of high and low adherence were important behaviours they had learned from previous experiences.	<i>"So, I try to sort of use it as a guideline, but I don't knock myself out if I don't. I try to be a bit realistic and make it work well with them."</i> (19) <i>"Where I'm trying to be a bit more kind to myself this time."</i> (26)
Planning and preparation	Participants frequently described that planning and preparation were important factors that they associated	<i>"So, I planned out my days probably a bit better [than the last time they attempted VLCD]. Better planning, but also I didn't have that gnawing hunger."</i> (26)

	with adherence to the program. This included examples of planning the meals for the week, leaving the house with recommended snacks, and reviewing restaurant menus in advance.	
Mental health	Some participants identified emotional distress, emotional eating, and symptoms of depression as being associated with not being able to adhere to the program. Some participants reported finding methods to help manage the impact of mental health on program adherence.	<p><i>"I've always been a comfort food eater... when things get tough, I start eating. So I kind of steered off the [branded VLCD] program for a while, before the 12 weeks was actually up." (32)</i></p> <p><i>"I think it's the fact that I have got a result and even though... the depression and the instinct to binge eat ... is there, I'll go grab a big handful of nuts and I'll eat them instead." (44)</i></p>

2 HCP, health care professional; VLCD, very low calorie diet.

Table S1. Semi-structured interview guide

Opening	<p>Thank you for participating in our research study, we really appreciate your time. Now I'd like to remind you that this interview is being recorded. Are you happy for me to begin the recording now?</p> <p>Before we begin, can you please tell me your name and date of birth and confirm that you have signed the electronic consent form to participate in this interview today?</p> <p>Do you have any questions about the study you wanted to ask me?</p> <p>In your own words, can you please tell me a little about your understanding of the study?</p>
Interview	<ol style="list-style-type: none"> 1. Could you tell me a bit about yourself? (Ice-breaker question) <ol style="list-style-type: none"> a. What are your interests? 2. I would like to hear about your weight loss journey so far. What have you tried in the past to lose or maintain your weight and what sort of response did you have? <ol style="list-style-type: none"> a. How has your weight changed during the program? (capture lost vs. maintained) 3. Can you recall and describe about when and how you first heard about [brand] VLCD? <ol style="list-style-type: none"> a. Prompt idea: Have you previously used [brand] VLCD or any other VLCD program? 4. What was happening in your life, your circumstances and your feelings, that lead you to decide to commence [brand] VLCD? <ol style="list-style-type: none"> a. Did someone recommend it to you? If so, who? b. What motivated you to try [brand] VLCD? c. What was your goal when you first started [brand] VLCD? (i.e. weight loss, weight maintenance, another reason?) d. What results or changes were you hoping for or expecting from using [brand] VLCD? 5. What has been your experience using [brand] VLCD so far? <ol style="list-style-type: none"> a. Prompt ideas: <ol style="list-style-type: none"> i. Have you had any positive or negative experiences? ii. What do you like/dislike about the program? 6. What has been your experience with health professionals regarding [brand] VLCD? (e.g. GP/doctor, dietician, other health professional?) <ol style="list-style-type: none"> a. How often do you check in with your healthcare provider? b. What support has your healthcare provider given you with the program? 7. Can you describe the positive and negative experiences you have had with [brand] VLCD? <ol style="list-style-type: none"> a. Prompt idea: <ol style="list-style-type: none"> i. What have you found to be the best part of using [brand] VLCD/the [brand] VLCD program? (e.g. convenience, efficacy, taste) ii. What have you found to be the most challenging part of using [brand] VLCD/the [brand] VLCD program? (e.g. lack of support, social isolation, hunger, eating out, family conflict, affordability, taste) iii. Have you noticed any effect that [brand] VLCD has had on your health? (e.g. blood markers such as HbA1c/Tg, more active, improved breathing, reduced pain, mental health such as depression or anxiety?) b. If applicable, have you changed your medication usage since starting on [brand] VLCD (e.g. reduced/ceased any medications)? 8. <i>Current users only:</i> How long do you intend to use [brand] VLCD? <ol style="list-style-type: none"> a. Why? 9. <i>Previous users only:</i> How long did you use [brand] VLCD? <ol style="list-style-type: none"> a. What was your reason for ceasing the [brand] VLCD program?

	10. Is there anything about the program that you'd like me to know that hasn't been included in any other questions so far?
Closing	When all the interviews are complete we would like to call a small number of people back to have a quick follow-up chat to see if we accurately captured our discussion. Are you happy to be contacted for follow-up by a member of the research team? You may or may not receive a call as we will randomly choose people. Or if you'd prefer, you can opt-out of the follow-up chat.

Table S2. Characteristics and weight loss of 31 Australian adults who participated in interviews regarding their experience with the VLCD program presented according to duration of program use

ID	Sex	Age (y)	Times using VLCD program ^a	Duration	Weight loss (kg)
43	F	65.7	3	4w	3.0
41	F	57.7	3	6w	12.0
20	F	42.1	1	6w	15.2
33	F	30.2	2	7w	11.5
28	F	34.4	2	7w	11.0
38	F	42.0	3	8w	8.5
01	F	28.9	2	8w	10.0
42	F	47.9	1	8w	15.0
26	F	39.7	4	9w	10.5
11	F	42.4	4	9w	12.0
12	F	30.0	3	10w	25.0
06	F	42.4	2	11w	17.0
32	F	41.1	1	12w	10.0
09	F	37.3	3	12w	10.5
14	F	30.4	1	12w	11.0
34	F	41.9	3	12w	24.9
39	F	47.4	4	14w	12.0
45	F	40.5	1	3m	5.0
16	F	24.7	1	3m	13.0
21	F	50.5	1	4m	12.5
47	F	35.2	1	4m	8.0
27	F	38.5	1	6m	20.0
05	F	61.5	1	9m	66.3
30	F	52.0	1	9m	15.0
23	F	53.2	1	9m	32.0
13	F	64.9	1	10m	16.7
02	F	44.8	2	11m	35.0
19	F	54.7	1	12m	21.0
44	F	48.3	1	15m	90.0
35	F	34.0	1	NR	30.0
40	M	62.1	≥5	4m (and 18m of maintenance)	8.0

F, female; M, male; w, weeks; m, months; y, years; NR, not reported.

a. Reflects number of times using the VLCD program; does not reflect use of other VLCD programs or products.