








# Real world evidence on the characteristics of regular and intermittent users of a very-low calorie diet program and associations with measures of program success, health, and quality of life

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## Abstract

**Background:** Very low-calorie diet (VLCD) programs are readily available in Australia. However, there is a lack of real-world evidence describing the characteristics related to positive outcomes.

**Aims:** To examine the demographic, eating, self-efficacy and program engagement characteristics of VLCD users in Australia, and the associations between user characteristics and program success, weight loss, quality of life (QOL) and health.

**Method:** Cross-sectional data from Australian adults: regular users ( $n = 189$ : VLCD user  $\geq 4$  days/week for  $>4$  weeks) and intermittent users ( $n = 111$ , VLCD user  $<4$  weeks and/or  $<4$  days/week). Self-reported data on demographics, VLCD program use, support, eating behavior, weight-related QOL, mental health, physical health, self-efficacy, and physical activity. Descriptive and inferential statistics were performed in R.

**Results:** Compared to regular users, intermittent users reported lower percentage weight loss ( $15.1\% \pm SD 9.8$  vs.  $9.9\% \pm SD 6.8$ , relative to starting weight), fewer reported their VLCD program as very successful (44% vs. 35%), higher depressive symptom scores ( $8.7 \pm SD 2.8$  vs.  $6.7 \pm SD 5.1$ ), and lower general self-efficacy ( $23.9 \pm SD 4.7$  vs.  $29.4 \pm SD 5.7$ ), nutrition self-efficacy ( $11.9 \pm SD 2.0$  vs.  $14.5 \pm SD 3.1$ ) and weight-related QOL scores ( $60.9 \pm SD 22.2$  vs.  $65.0 \pm SD 11.8$ ;  $p < 0.001$  for all). In regular users, older age and longer program duration were associated with greater total weight loss, support, and program success ( $p < 0.001$  for all). In intermittent users, program success was greater when dietitian support was used (odds ratio [OR] 6.50) and for those with higher BMIs (OR 1.08,  $p < 0.001$  for all). In both groups, more frequent support was associated with better weight-related QOL ( $p < 0.001$ ).

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**Conclusion:** This study provides real-world evidence that regular VLCD users had greater success and weight loss than intermittent program users. These findings may be used to tailor and improve the delivery of VLCD programs in Australia and other countries with retail access to VLCDs.

**KEYWORDS**

health surveys, low calorie diet, obesity management, weight loss diet

## 1 | INTRODUCTION

Obesity is a well-recognized public-health issue.<sup>1-4</sup> As such, patient-centered interventions to improve health outcomes are needed. Very low-calorie diet (VLCD) programs are one potential tool to support improved outcomes in those with weight-related impacts to their health and quality of life (QOL). VLCDs frequently use meal replacements, such as shakes or soups, rich in protein and micro-nutrients, with reduced carbohydrate, fat, and energy.<sup>5-7</sup> VLCDs assist with weight loss by providing a restricted energy intake of up to 800 kcal/day, compared to an average 2000 kcal/day diet.<sup>5,6</sup> VLCD programs include levels, differing in energy and dietary restrictions, supporting a range of goals (e.g., weight loss or maintenance).<sup>8,9</sup> The reduced carbohydrate component (approximately 50-70 g/day) further supports weight loss and diet adherence by promoting mild ketosis, assisting in appetite suppression.<sup>10,11</sup>

VLCDs are used globally; however, accessibility varies. In many countries, VLCDs are only available by prescription under healthcare professional (HCP) guidance.<sup>12</sup> In Australia, VLCDs can be self-initiated without HCP guidance, with products available from pharmacies or online.<sup>12</sup> Australian VLCD users are therefore largely autonomously following these programs, with there being a lack of insight as to whether these programs are successful when provided under a largely retail (direct to consumer) model, and a paucity of data and knowledge around factors that may influence success, engagement, and access to support in these types of VLCD programs. A previous mixed methods study identified several individuals (e.g., mental health), program (e.g., program structure/levels), and environmental (e.g., online or HCP support) barriers and facilitators which may influence success and adherence to a VLCD program in Australian adults ( $n = 31$ ).<sup>13</sup>

Therefore, this study aimed to determine the demographic, eating, self-efficacy and program engagement characteristics of different types of VLCD users in Australia (regular vs. intermittent users) and the associations between these user characteristics and self-perceived program success on weight loss, QOL, mental health and physical health. It was hypothesized that user type (regular vs. intermittent use) would be related to different demographic, eating, self-efficacy, and engagement factors, which may relate to program success. Gained insight in this area may inform improvements in

VLCD programs offered under retail models in countries such as Australia.

## 2 | METHODS

### 2.1 | Participants

A cross-sectional survey of Australian adults who had recently used a specified VLCD program was conducted online via Qualtrics (Qualtrics, Provo, UT; May 2021-May 2022). Eligible participants were those who had used the specified VLCD program within the last 4 weeks at the time of completing the survey. The specified VLCD program was a brand widely available online, in pharmacies or in health services in Australia, representing the most commonly used VLCD program in Australia. Convenience sampling techniques were used to recruit a broad range of users, and included advertising to participants of a prior Australian VLCD study<sup>13</sup> and on online VLCD support groups and social media. Two user groups were recruited; (1) "regular users" represented participants who have consistently used the VLCD program, defined as those who had used the VLCD program for >4 weeks at the time of the survey, and at least daily for  $\geq 4$  days/week, and (2) intermittent users represented participants who have inconsistently used the VLCD program or are very new to using the program, defined as those who had used the VLCD program for <4 weeks, and/or <4 days/week for a longer period. Therefore, all participants were currently using the VLCD program but with varying degrees of consistency and duration. Regular users under this definition were using the program consistently for at least a month, whereas intermittent users were not.

Individuals were ineligible if they resided outside Australia, were pregnant, did not use the specific brand of VLCD program within the last 4 weeks, or were unable to read and write in English. A minimum target sample size of 200 participants was considered sufficient to answer the research aim and allow adequate inter-group comparisons.

The study was approved by the Bellberry Human Research Ethics Committee (Approval No. 2020-10-996-A-2). Participants provided electronic consent before commencing the survey. This study has been reported according to the Strengthening the Reporting

of Observational Studies in Epidemiology (STROBE) reporting checklist<sup>14</sup> and was prospectively registered with the Australia New Zealand Clinical Trials Registry (Registration number: ACTRN12620001288910p).

## 2.2 | Survey components

The survey composed of seven sections, derived from validated questionnaires where appropriate, covering (1) demographic characteristics (9 items), (2) use and support during the VLCD program (30 items), (3) eating behaviors (18 items: the Three-Factor Eating Questionnaire [TFEQ-R18])<sup>1</sup>, (4) weight-related QOL (31 items: the IWQOL-Lite questionnaire<sup>2</sup>), (5) mental health (21 items: DASS-21)<sup>3</sup>, (6) self-efficacy (39 items: General Self-Efficacy [GSE]<sup>4</sup> and Nutrition Self-Efficacy Questionnaires<sup>5</sup>), and (7) physical activity (4 items). For further description of survey components, see Table S1. Independent variables were (1) demographic variables: sex (biological, self-reported), age, body mass index (BMI), education, household income, employment and marital status, (2) VLCD program engagement and (3) eating behaviors. Outcome variables were (1) self-reported weight loss and success in the VLCD program, (2) weight-related QOL, (3) mental health, (4) self-efficacy and (5) physical activity.

## 2.3 | Data cleaning and analysis

Participants who completed less than 50% of the main survey were considered as withdrawn, with responses further excluded if they were flagged as bot responses on the Qualtrics platform or had completion times of less than a quarter (<8 min) of the median response time (32 min) or >2 weeks. Data analyses were conducted using R (packages: *readxl*, *tidyverse*, *fastDummies*, *psych*, *summarytools*, *car*, *vctrs*).<sup>15</sup> Descriptive statistics (means [SD: standard deviation] for continuous data and counts [%] for categorical data) were generated to describe user characteristics. Participants were grouped by VLCD product usage patterns (regular or intermittent users). Linear and logistic linear regression assessed relationships between user characteristics and outcome variables within each user group. *T*-tests, ANOVA, and chi-square ( $\chi^2$ ) tests for independence were used to assess relationships between groups. Post-hoc comparisons were

used to investigate pairwise significance between user categories. The level of significance was adjusted to <0.001 using the Bonferroni method to account for multiple testing.<sup>16</sup>

## 3 | RESULTS

Three hundred adults completed the survey, including 189 regular and 111 intermittent users ( $n = 49$  invalid responses excluded, Figure 1). The average BMI of all participants was 32.0 kg/m<sup>2</sup> (SD:9.8 kg/m<sup>2</sup>), with no differences between user groups (Table 1). Age and sex differed between the groups. Regular users were, on average, older (40.6 years [SD:12.0] vs. 29.1 years [SD:8.4],  $p < 0.001$ ) and fewer were males (25.9% vs. 72.1%,  $p < 0.001$ ), compared to intermittent users. Differences between user groups were found for education, employment, household income and smoking status (Table S2). Compared to regular users, intermittent users were less likely to be tertiary educated (49.8% vs. 25.2%,  $p < 0.001$ ), less likely to work full-time (51.3% vs. 37.8%,  $p < 0.001$ ), and more likely to have higher annual household incomes (Table S2). Regular users were less likely to report being divorced (6.3% vs. 32.4%,  $p < 0.001$ ) or were less likely to be current smokers (19.6% vs. 72.1%,  $p < 0.001$ , Table S2).

There were no group differences in mean program engagement time (210 days [SD:234]). No differences were found for the mean number of times using the VLCD program (2.6 [SD:1.2]). The most common program level followed was rapid weight loss (33.0%), where individuals consumed a diet of <800 kcal/day and replaced  $\geq 3$  meals/day with VLCD products. More intermittent users followed the VLCD program to improve the appearance, compared to regular users (37.8% vs. 18.0%), with more regular users following the program to improve physical health (9.0% vs. 40.2%, Table 1).

No statistical differences were found in total weight loss between groups (regular users mean 17.1 kg [SD:14.4 kg] loss; intermittent users mean 11.7 kg [SD:13.4,  $p = 0.46$ ] loss). Regular users reported higher percent weight loss (relative to starting weight) compared with intermittent users (15.1% [SD 9.8] vs. 9.9%  $\pm$  [SD 6.8], Table 1). However, a greater proportion of intermittent users were unsure of how much weight had been lost during the program (62.0% vs. 16.0%,  $\chi^2 = 295.86$ ,  $p < 0.001$ ) compared with regular users. Weight loss data are therefore based on the subsets of users who

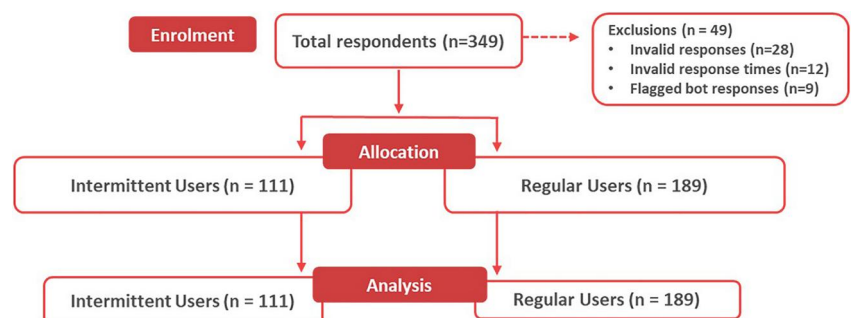


FIGURE 1 Overview of survey recruitment numbers.

TABLE 1 Demographics and program engagement characteristics of real world Australian VLCD program users.

	Regular users (n = 189)	Intermittent users (n = 111)	All (n = 300)
Continuous variables—mean (SD)			
Age (years)	40.6 (12.0) <sup>b</sup>	29.1 (8.4) <sup>a</sup>	36.3 (12.1)
BMI (kg/m <sup>2</sup> )	31.0 (9.4)	33.4 (10.3)	32.0 (9.8)
Weight loss (kg) <sup>1</sup>	17.1 (14.4)	11.7 (13.4)	16.1 (14.3)
Weight loss (%) <sup>2</sup>	15.1 (9.8) <sup>b</sup>	9.9 (6.8) <sup>a</sup>	14.1 (9.5)
Engagement in VLCD program (days) <sup>3</sup>	173 (257)	257 (170)	210 (234)
Number of times using VLCD program	2.6 (1.4)	2.7 (0.9)	2.6 (1.2)
Categorical variables—n (% of group)			
Sex: Male	49 (25.9) <sup>b</sup>	80 (72.1) <sup>a</sup>	126 (42.0)
VLCD program level			
Rapid weight loss: <800 kcals/day	60 (31.7)	39 (35.1)	99 (33.0)
Weight loss: 1000 kcals/day	34 (18.0)	18 (16.2)	52 (17.3)
Gradual weight loss: 1200 kcal/day	23 (12.2)	22 (19.8)	45 (15.0)
Maintenance: 1500 calories/day	13 (6.9) <sup>b</sup>	0 (0.0) <sup>a</sup>	13 (4.3)
Modified weight loss: 1000–1200 kcals/day, incl non-approved foods	19 (10.0)	16 (14.4)	35 (11.7)
Modified rapid weight loss: <800 kcals/day, incl non-approved foods	25 (13.2)	13 (11.7)	38 (12.7)
No specific level	10 (5.3)	3 (2.7)	13 (4.3)
Program motivations			
Improve appearance	35 (18.0) <sup>b</sup>	42 (37.8) <sup>a</sup>	76 (25.3)
Improve mental health	11 (5.8)	13 (11.7)	24 (8.0)
Improve physical health	76 (40.2) <sup>b</sup>	10 (9.0) <sup>a</sup>	86 (28.7)
Maintain weight	20 (10.6) <sup>b</sup>	26 (23.4) <sup>a</sup>	46 (15.3)
Prepare for bariatric surgery	6 (3.2) <sup>b</sup>	14 (12.6) <sup>a</sup>	20 (6.7)
No other reason but weight loss	26 (13.8) <sup>b</sup>	6 (5.4) <sup>a</sup>	32 (10.7)
Self-perceived success in program			
Very unsuccessful	1 (0.5) <sup>b</sup>	0 (0.0) <sup>a</sup>	1 (0.3)
Unsuccessful	1 (0.5) <sup>b</sup>	11 (9.9) <sup>a</sup>	12 (4.0)
Neither successful nor successful	22 (11.6) <sup>b</sup>	23 (20.7) <sup>a</sup>	45 (15.0)
Successful	80 (42.3) <sup>b</sup>	38 (34.2) <sup>a</sup>	118 (39.3)
Very successful	84 (44.4) <sup>b</sup>	39 (35.1) <sup>a</sup>	123 (41.0)

Note: Values with different letters within the same row represent significant differences between groups (*T*-tests/ $\chi^2$  tests,  $p < 0.001$ ).

Abbreviations: BMI, body mass index; SD, standard deviation; VLCD, very low-calorie diet.

<sup>1</sup>62% of intermittent ( $n = 69$ ) were unsure of their weight loss, compared to 14% ( $n = 26$ ) of regular users.

<sup>2</sup>Weight loss (%) was based on  $n = 42$  (37%) of short/term intermittent data and  $n = 77$  (41%) of regular users due to participants reporting they are unsure on weight loss and starting weight.

<sup>3</sup>Program engagement was left skewed and log transformed before *t*-tests for group differences were performed.

reported a known weight loss (intermittent users:  $n = 42$ , regular users:  $n = 158$ ). More regular users reported their program as very successful (44.4% vs. 35.1%) or successful (42.3% vs. 34.2%), compared to intermittent users (Table 1).

Mean emotional eating and cognitive restraint eating behavior scores did not differ by group (Table 2) and indicated moderate levels

of emotional eating behavior. Comparatively, intermittent users had higher mean scores for uncontrolled eating behaviors than regular users (56.3 [SD:11.5] vs. 50.5 [SD:21.6],  $p < 0.001$ , Table 2). Weight-related QOL scores were higher in regular users (65.0 [SD:11.8] vs. 60.9 [SD:22.2],  $p < 0.001$ ), and were moderate across all domains, reflecting average weight-related QOL.

TABLE 2 Eating behavior and health characteristics of real world Australian VLCD program users.

	Regular users (n = 189)	Intermittent users (n = 111)	All (n = 300)
Continuous variables—mean (SD)			
Eating behaviors scores			
Cognitive restraint <sup>1</sup>	50.3 (10.3)	52.9 (16.7)	51.9 (14.7)
Uncontrolled eating <sup>1</sup>	56.3 (11.5) <sup>a</sup>	50.5 (21.6) <sup>b</sup>	52.7 (18.7)
Emotional eating <sup>1</sup>	57.3 (17.1)	61.1 (28.2)	59.7 (24.7)
Weight-related quality of life scores <sup>1</sup>			
Physical functioning	66.0 (14.4)	65.6 (25.1)	65.7 (21.6)
Self-esteem	63.2 (14.8) <sup>a</sup>	46.2 (26.2) <sup>b</sup>	52.9 (23.9)
Sexual life	65.4 (16.9) <sup>a</sup>	59.4 (29.9) <sup>b</sup>	61.7 (25.7)
Public distress	64.5 (15.4)	65.8 (28.2)	65.3 (24.0)
Work	65.4 (15.3)	69.5 (27.2)	67.9 (23.3)
Total	65.0 (11.8) <sup>a</sup>	60.9 (22.2) <sup>b</sup>	62.5 (13.7)
Mental health scores <sup>2</sup>			
Depression	8.7 (2.8) <sup>a</sup>	6.7 (5.1) <sup>b</sup>	7.5 (4.4)
Stress	9.0 (2.7) <sup>a</sup>	7.4 (4.9) <sup>b</sup>	8.0 (4.2)
Anxiety	8.7 (2.4) <sup>a</sup>	5.9 (4.8) <sup>b</sup>	7.0 (4.3)
General self-efficacy scores <sup>3</sup>	23.9 (4.7) <sup>a</sup>	29.4 (5.7) <sup>b</sup>	27.2 (6.0)
Nutrition self-efficacy scores <sup>4</sup>	11.9 (2.0) <sup>a</sup>	14.5 (3.1) <sup>b</sup>	13.5 (3.0)
Physical activity—METs [SD]	2256 (2148)	1609 (2529)	1741 (2464)

Note: Values with different letters within the same row represent significant differences between groups (*T*-tests/ $\chi^2$  tests,  $p < 0.001$ ).

Abbreviations: METs, metabolic equivalents; SD, standard deviation.

<sup>1</sup>Scale scores ranged from 0 to 100, with larger scores unfavorable.

<sup>2</sup>Scale scores ranged from 0 to 21, with larger scores indicating adverse mental health scores; depression: normal (0–4), mild (5–6), moderate (7–10), severe (11–13), extremely severe (14+); anxiety: normal (0–3), mild (4–5), moderate (6–7), severe (8–9), extremely severe (10+); stress: normal (0–7), mild (8–9), moderate (10–12), severe (13–16), extremely severe (17+).

<sup>3</sup>Scale scores ranged from 10 to 40, with larger scores indicating better general self-efficacy.

<sup>4</sup>Scale scores ranged from 5 to 20, with larger scores indicating better nutrition self-efficacy.

Overall, across all domains, mental health scores were higher (indicative of poorer mental health) in intermittent users than in regular users. Both groups had mean scores indicative of moderate depression and intermittent users had higher scores than regular users (8.7 [SD:2.8] vs. 6.7 [SD:5.1],  $p < 0.001$ ). Similarly, mean stress scores in both groups were indicative of mild stress, with a higher mean score (indicative of higher stress) in intermittent users (9.0 [SD:2.7] vs. 7.4 [SD:4.9],  $p < 0.001$ ). Mean anxiety scores were higher in intermittent users (8.7 [SD:2.4], indicative of severe anxiety) compared with regular users (5.9 [SD:4.8],  $p < 0.001$ , indicative of mild anxiety). Intermittent users also had lower GSE scores (23.9 [SD:4.7] vs. 29.4 [SD:5.7],  $p < 0.001$ ) and nutrition-related self-efficacy scores (11.9 [SD:2.0] vs. 14.5 [SD:3.1],  $p < 0.001$ ), compared to regular users. Physical activity level was similar between the groups (Table 2).

Use of HCPs or peer support differed between groups. Over half of the intermittent users (56.8%) reported consulting with dietitians during the program, compared with 36.0% of regular users. Comparatively, a higher proportion of regular users reported not consulting an

HCP at all during their program (21.2% vs. 0.9%,  $p < 0.001$ , Table S3). Intermittent users consulted more regularly with HCP, with 56.9% consulting daily or weekly, compared to just 18% of regular users ( $p < 0.001$ , Table S3). Intermittent users frequently engaged with Facebook groups (45.0% weekly), friends or someone experienced with the program (46.8% weekly), the VLCD product website (45.0% weekly) and product pamphlet (45.5% weekly), with these supports used less frequently by regular users (Table S3). Regular users most commonly engaged with Facebook groups (32.0% daily), with most consulting a friend or other person experienced with the program at least once (62.4%), or the VLCD program website (24.9%) and program pamphlet (24.3%) for support (Table S3).

Among intermittent users, greater success in the VLCD program was associated with a higher current BMI, lower household incomes and dietitian support. For these users, a one-unit increase in BMI was associated with 1.08 higher odds of program success (OR: 1.08 [95% CI:1.02–1.14],  $p < 0.001$ ). Intermittent users who reported annual household incomes of  $> \$60,000$  AUD had lower odds of reporting VLCD program success compared with users with annual household

incomes <\$60,000 (OR<sub>range</sub> = 0.02–0.52 across income groups, Table 3). Intermittent users who engaged with dietitians during their program had 6.5 times higher odds of reporting program success compared with intermittent users who did not engage with dietitians (95% CI:2.70, 18.80,  $p < 0.001$ , Table 3). For regular users, these demographic and support factors were not associated with program success; however, greater support from friends and family was related to higher odds of perceived program success in this user group (OR: 1.15 [95% CI:1.42–3.15],  $p < 0.001$ ).

In regular users, older age ( $\beta = 1.02$  [95% CI:1.01–1.03],  $p < 0.001$ ) and longer program engagement ( $\beta = 1.00$ , [95% CI:1.01–1.02],  $p < 0.001$ ) were associated with higher self-reported total weight loss. Regular users also reported a greater percentage (relative to starting weight) weight loss with greater program engagement ( $\beta = 0.02$  [95% CI:0.01–0.03],  $p < 0.001$ , Table 3).

Associations between demographics, eating behavior, program engagement and weight-related QOL, mental health and physical activity are presented in Table S4. In regular users, poorer weight-related QOL scores correlated with higher BMIs ( $\beta = -0.93$  [95% CI:-1.26, 0.60],  $p < 0.001$ ), uncontrolled eating ( $\beta = -0.42$  [95% CI:-0.56, -0.28],  $p < 0.001$ ), and emotional eating ( $\beta = -0.31$  [95% CI:-0.43,-0.20],  $p < 0.001$ , Table S4). In regular users, higher emotional eating was associated with lower GSE scores ( $\beta = -0.05$  [95% CI:0.08, -0.02],  $p < 0.001$ ), higher stress ( $\beta = 0.05$  [95%CI:0.02, 0.08],  $p < 0.001$ ), and higher depressive symptom scores ( $\beta = 0.05$  [95% CI:0.02, 0.08],  $p < 0.001$ ). Higher uncontrolled eating scores positively correlated with anxiety ( $\beta = 0.07$  [95% CI:0.04, 0.11],  $p < 0.001$ ) and stress ( $\beta = 0.08$  [95% CI:0.04, 0.11],  $p < 0.001$ ) scores,

with longer program engagement also associated with depressive symptom scores ( $\beta = 0.01$  [95% CI:0.00, 0.02],  $p < 0.001$ , Table S4). In intermittent users, an increase in the number of times the program had been initiated was related to depressive symptom scores ( $\beta = 1.04$  [95% CI:0.47, 1.62],  $p < 0.001$ ), and higher adverse emotional eating scores were linked to higher nutrition self-efficacy scores ( $\beta = 0.04$  [95% CI:0.01–0.06],  $p < 0.001$ , Table S4).

Relationships between program support and mental health, weight-related QOL, and self-efficacy are presented in Table S5. In intermittent users, increases in weight related QOL correlated with more frequent engagement with multiple supports (Table S5), with the largest effect sizes seen between users who used (i) HCP support daily versus every few months ( $\beta = 26.6$  [95% CI:13.2–40.0]  $p < 0.001$ ), (ii) a friend or other experienced support daily versus every few months ( $\beta = 27.1$  [95%CI:9.9–44.3],  $p < 0.001$ ), (iii) the VLCD product website daily versus never ( $\beta = 32.3$  [95%CI:16.9–47.7],  $p < 0.001$ , and (iv) the VLCD product pamphlet daily versus 1–2 times yearly ( $\beta = 39.4$  [95% CI:21.2–57.6],  $p < 0.001$ , Table S5). In these users, more frequent support from HCPs, Facebook groups, and VLCD product websites and pamphlets was also associated with higher self-efficacy (general and nutrition). For GSE, the greatest differences were between users engaging with Facebook groups daily versus monthly ( $\beta = 10.8$  [95% CI:4.3–16.3]  $p < 0.001$ ). For nutrition self-efficacy, the largest difference in scores was between those using Facebook groups for daily support versus every few months ( $\beta = 4.30$  [95% CI:1.33–7.27],  $p < 0.001$ , Table S5).

In regular users, those who engaged with a friend or someone experienced in the program on a daily basis had better scores for

TABLE 3 Demographic and program characteristics associated with self-reported program success.

Program success <sup>a</sup>	Regular users (n = 189)		Intermittent users (n = 111)	
	OR	p value	OR	p value
BMI	0.90 (0.86–1.24)	0.18	<b>1.08 (1.02–1.14)</b>	<b>&lt;0.0001</b>
Annual household income: <\$60K versus \$60–99K	1.00 (0.00–∞)	1.00	<b>0.52 (0.12–2.28)</b>	<b>&lt;0.0001</b>
Annual household income: <\$60K versus \$100–199K	1.00 (0.00–∞)	1.00	<b>0.10 (0.02–0.35)</b>	<b>&lt;0.0001</b>
Annual household income: <\$60K versus >\$200K	1.00 (0.00–∞)	1.00	<b>0.02 (0.01–0.09)</b>	<b>&lt;0.0001</b>
Rated support from friends/family	<b>2.15 (1.42–3.15)</b>	<b>&lt;0.001</b>	1.38 (0.91–2.19)	0.15
Dietitian support	1.00 (0.00–∞)	1.00	<b>6.50 (2.70–16.80)</b>	<b>&lt;0.0001</b>
<b>Weight loss (kg)<sup>b</sup></b>	<b>Effect size <math>\beta</math> (95% CI)</b>	<b>p value</b>	<b>Effect size <math>\beta</math> (95% CI)</b>	<b>p value</b>
Age (years)	<b>1.02 (1.01–1.03)</b>	<b>&lt;0.001</b>	0.98 (0.96–0.99)	0.01
Program engagement (days)	<b>1.00 (1.01–1.02)</b>	<b>&lt;0.001</b>	1.00 (0.99–1.01)	0.30
Weight loss (%)				
Program engagement (days)	<b>0.02 (0.01–0.03)</b>	<b>&lt;0.0001</b>	0.00 (–0.01–0.01)	0.86

Note: Bolded values are significant ( $p \leq 0.001$ ). ∞ denotes an infinite odds ratio, with no upper 95% confidence limit.

Abbreviations: BMI, body mass index; CI, confidence interval; OR, odds ratio.

<sup>a</sup>Several categorical variables were condensed for analysis to enable sufficient across category analyses: Program success (very unsuccessful/successful vs. very successful/successful). Annual household income (<60K, 60–99K, 100–199K, >200K), marital status (married or de factor, non-married), employment status (full time, part-time, other employment type), education (high school qualification, diploma/certificate, trade, university degree).

<sup>b</sup>Weight loss was log-transformed for analyses and then back-transformed.

weight-related physical functioning compared to users who never engaged with this support type ( $\beta = -0.93$  [95% CI: -1.26-0.60],  $p < 0.001$ ). However, regular users supported by a friend or someone experienced more often (monthly vs. never) reported higher anxiety scores ( $\beta = -5.4$  [95% CI: 2.1-5.4],  $p < 0.001$ ). In regular users, daily use of the product pamphlet was associated with higher weight-related physical functioning scores ( $\beta = 21.9$  [95% CI: 8.35-35.37],  $p < 0.001$ ), when compared to users never using the pamphlet. Higher support from friends and family was also linked to higher GSE in these users ( $\beta = 1.4$  [95% CI: 0.66-2.22],  $p < 0.001$ , Table S5).

## 4 | DISCUSSION

This study provides new insights into Australian adults using VLCD programs in a real-world setting, and the individual, eating behavior, and program engagement factors associated with self-reported program success, weight loss, and physical and mental health. While regular and intermittent users of the VLCD program were similar in several characteristics, distinct profiles emerged across user groups for percent weight loss (relative to starting weight) and several demographic, eating behavior and health factors. Regular users reported a higher per cent weight loss (relative to starting weight), program success, and score indicative of higher mental health and weight-related QOL; however, weight-related QOL and mental health across user groups were comparable to other populations with obesity, seeking or not seeking treatment.<sup>17-21</sup> Furthermore, intermittent users reported lower self-efficacy and greater emotional and uncontrolled eating behaviors. This may suggest that longer and more regular use improves these factors or that these factors drive longer and more regular term use. Regular VLCD users more commonly engaged with Facebook groups for support, while intermittent users more frequently engaged dietitians, friends or someone experienced in the program, and VLCD website and product resources. This may suggest inherent engagement differences between individuals using VLCD programs on a regular versus intermittent basis, or a potential shift in the support required that occurs as users become more familiar with the VLCD program. This study demonstrates the opportunity for tailored VLCD program support in a real-world setting that takes into account individual's demographics and health profile to enhance program success.

Predictors of mental health, QOL, self-efficacy, and program success in Australians following VLCD programs have not been examined previously; population studies have examined potential weight loss predictors in VLCD programs. A Swedish cohort study of VLCD program users ( $n = 267$ ) found that age, sex, education, physical health and living situation predicted weight loss, program success, and attrition.<sup>22</sup> One randomized controlled trial comparing VLCDs ( $n = 96$ ) and low-calorie diets ( $n = 167$ ) in the United States found no evidence that demographics, health, or behaviors predicted weight loss and program success.<sup>23</sup> Given that VLCD products are available over the counter in Australia, user experience and program success may differ from populations where HCP guidance is included,

such as the United States. Program experience and success may also vary depending on how programs are used, with this study comparing regular versus intermittent use. The presented data show that program success and weight loss differ depending on the type of program use, with those who followed the VLCD program more regularly or for longer at the time of the survey, reporting greater program success and percent weight loss (relative to starting weight).

In addition to the type of program use, findings suggest that differences in program success between user groups may be underpinned by program engagement, demographic, weight-related QOL, mental health, and self-efficacy differences across groups. Several factors were linked to self-reported program success and weight loss, with older age and longer program engagement associated with higher weight loss, and higher support from friends and family related to greater program success in regular users. For intermittent users, dietitian support, higher BMI, and lower household income were associated with greater self-reported program success. In addition, regular users had better weight-related QOL, mental health, and self-efficacy than intermittent users, with these users also reporting lower adverse eating behaviors and less utilization of program-specific or peer support. Taken together, these results suggest that regular users may have greater program success than intermittent users as they engage in the program more regularly, appear to need less program support and are less likely to face barriers that may impact program motivations and confidence, such as poor weight-related QOL or adverse eating behavior. Findings suggest a need for tailored guidance and support for different types of VLCD users in a real-world setting. Compared to regular users, intermittent users may require more support from HCPs, peers, and online resources, and may benefit from education around eating behaviors and mental health, to promote improvements in eating habits, self-efficacy, health and QOL, and potentially greater weight loss, during their VLCD program. For regular users, time in program and higher-rated support from friends and family appear to be key predictors of program success, with results potentially suggesting that minimal support from HCP and VLCD product resources may be needed. However, regular users may have previously engaged with HCPs or product resources that they may not have considered as part of their current program use.

More frequent support was associated with better QOL and self-efficacy, with these relationships more frequently reported in intermittent users. However, program support types were generally not predictors of weight loss or self-reported program success in this study, with exceptions to greater support from friends and family (for regular users), and dietitian support (for intermittent users) being associated with higher odds of program success. This finding in a real-world setting is contrary to prior research, with a 2016 meta-analysis finding that HCP and social support improves motivation, adherence, and results during weight loss interventions.<sup>24</sup> Differences in findings are likely reflective of differences in populations and study design (cross-sectional analysis of a real-world VLCD usage vs. controlled studies). This meta-analysis also examined a range of weight loss

programs. Mixed methods research in Australians using VLCD programs found that users express a need for diverse support to support motivation, particularly from online social platforms and family, with improvements in weight-related QOL, such as physical health, also key program motivators.<sup>13</sup> The mixed methods study also found that successful program outcome stories by other users, as shared on social platforms, were strong reinforcing motivators.<sup>13</sup> In the present study, reported associations between more frequent support (from HCPs and other types) and better QOL extends on this work and suggests that HCPs and other support avenues, such as Facebook groups, may play a role in supporting broader QOL improvements and program motivation during VLCD programs, above weight loss alone.

Limitations of this study include a paucity of weight loss data, with a large proportion of intermittent users unsure of their weight loss during the program. Self-reported and subjective data are susceptible to recall and response bias; however, they reflect lived experience and user perspective. This study was conducted during COVID-19, with reported impacts on the mental health likely influencing results.<sup>25</sup> The cross-sectional design does not enable causality to be inferred or temporal relationships between demographics, eating behaviors, and program engagement with outcomes to be determined. Further, for some outcomes, differences between user groups are statistically different, but may not be clinically meaningful; therefore, results should be interpreted with caution. For example, statistically significant differences in mean anxiety scores were reported across user groups; however, both mean scores were indicative of a low level of anxiety. This work represents the first quantitative study examining associations between these user characteristics and self-perceived program success and weight loss, QOL and mental and physical health in Australians using VLCD programs. Results provide direction for further studies in this area and may inform the improved delivery of VLCD programs in Australia and in populations with similar retail models.

## 5 | CONCLUSION

This study provides a new understanding of the usage of VLCD programs in the Australian population, and individual, eating behavior, and program engagement characteristics that are linked to self-reported program success, weight loss, QOL and mental health in these users. Intermittent users reported less per cent weight loss and program success compared with regular users, and also had greater scores for emotional/uncontrolled eating and poorer scores for mental health, weight-related QOL, and self-efficacy. In regular users, age, program duration and support from friends and family were associated with greater program success and/or weight loss, whereas in intermittent users, greater program success was linked to dietitian support, BMI, and household income. Across user groups, more frequent support was linked to better QOL. Findings suggest a need for guidance tailored to usage patterns for VLCD users to improve

the efficient management and delivery of VLCD programs in populations with retail access to VLCDs.

## AUTHOR CONTRIBUTIONS

Flavia Fayet-Moore, Skye Marshall, Michelle Blumfield, Kylie Abbott, and Emily Duve led the study conception and survey development. Patrice Jones, Michelle Blumfield and Flavia Fayet-Moore completed the data acquisition. Patrice Jones, Michelle Blumfield, Emma Beckett, and Flavia Fayet-Moore completed the data analysis and interpretation. Patrice Jones, Michelle Blumfield, and Emma Beckett led the drafting of the manuscript. All authors reviewed and approved the final version of the manuscript and declare this work has not been submitted for publication elsewhere.

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## CONFLICT OF INTEREST STATEMENT

All study authors declare no conflicts of interest and work independently for Nutrition Research Australia and/or other Australian-based universities and research institutions funded by government, not-for-profits, professional and industry organizations.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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