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Health-related quality of life and psychological well-being in obese New Zealand children and adolescents at enrolment in an obesity intervention programme

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Manuscripts

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3 1 **Health-related quality of life and psychological well-being in obese New Zealand children**
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5 2 **and adolescents at enrolment in an obesity intervention programme**
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55 24 **Keywords:** Paediatric, obesity, adolescent, quality of life, lifestyle intervention, Whānau Pakari
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6 26**ABSTRACT**

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8 27 **Objective:** To describe health-related quality of life (HRQOL) and psychological characteristics
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10 28 of obese children/adolescents at enrolment in an obesity programme in Taranaki, New Zealand,
11
12 29 and whether these are related to ethnicity.

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14
15 30 **Methods:** Participants had a body mass index (BMI) $\geq 98^{\text{th}}$ percentile or $> 91^{\text{st}}$ centile with
16
17 31 weight-related comorbidities. HRQOL and psychological characteristics were assessed using the
18
19 32 PedsQL 4.0TM (parent and child reports), and the Achenbach's Child Behaviour Checklist
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21 33 (CBCL).

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23
24 34 **Results:** Assessments were undertaken for 239 participants (45% Māori, 45% New Zealand
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26 35 European, 10% other), aged 4.8-16.8 years. The mean BMI standard deviation score (SDS) was
27
28 36 3.09 (range 1.52-5.34). Total PedsQL generic scaled score on parent report was lower
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30 37 (mean=65.4, SD=16.2) than a group of non-obese Australian children from the Health of Young
31
32 38 Victorians study (mean=83.1, SD=12.5). Behavioural difficulties (CBCL total score) were
33
34 39 reported in forty four percent of participants, with emotional/behavioural difficulties 6 times
35
36 40 higher than reported norms ($p < 0.0001$), irrespective of ethnicity.

37
38 41 **Conclusions:** Obese children and adolescents in this cohort had a low HRQOL, and a
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40 42 concerning level of psychological difficulties.

Strengths:

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- This study is the first to report HRQOL in obese children and adolescents in New Zealand.
 - To our knowledge, there is very limited data regarding ethnicity and HRQOL. Due to the high participation rate from Māori, we were able to evaluate the impact of ethnicity on HRQOL.

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49 Limitations:

- 50 • Due to the lack of NZ HRQOL data, comparisons have been made with population groups of
51 varying age ranges, which may have affected results.
- 52 • The study participants were a referred cohort, which means our findings are not
53 representative of the general population. The data from the Victorian cohort were collected in
54 2000, and the differences noted may have been impacted by the difference in dates of data
55 collection.
- 56 • Mean BMI SDS for the Victorian cohort identified as obese was not available, which would
57 be important if it was considerably lower than the Whānau Pakari participants.

59 INTRODUCTION

60 Obesity in childhood and adolescence is well known to be associated with many weight-related
61 comorbidities.¹ Indigenous populations often have higher rates of obesity compared with non-
62 indigenous counterparts where this information has been collated.^{2,3} In New Zealand,
63 approximately 11% of New Zealand children aged two to fourteen years are obese, with Māori
64 (New Zealand's indigenous population) being 1.6 times more likely to be obese compared with
65 non-Māori counterparts.³ In addition, children living in households in the most
66 socioeconomically deprived quintile for New Zealand are five times more likely to be obese than
67 children living in the least deprived areas.³ In the United States, whilst rates of childhood obesity
68 are not readily available for American Indian populations, rates of Type 2 Diabetes Mellitus (a
69 known weight-related comorbidity) are higher.² Globally, indigenous populations have
70 experienced historical trauma secondary to colonisation, are over-represented in socioeconomic

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3 71 household deprivation, and both experience the resultant health disparities.² The social
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5 72 determinants of health, such as poverty, limited educational attainment, and critically the loss of
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8 73 a traditional diet all contribute to the impact on these population groups in terms of health and
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10 74 well being.² Overweight and obesity in adolescence have been shown to be strongly associated
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12 75 with medical complications, including an increase in cardiovascular mortality in adulthood.⁴
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15 76 Emerging evidence suggests that obesity also affects the emotional health and wellbeing of
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17 77 children and adolescents, commonly referred to as health-related quality of life (HRQOL).⁵
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19 78 However, little is known about the HRQOL of indigenous children and adolescents.
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24 80 Quality of life is a broad construct that encompasses various aspects pertaining to health and
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26 81 well-being.⁶ The assessment of HRQOL is increasingly recognised as a necessary component of
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28 82 health and wellbeing evaluation, assessing physical, emotional, and social health dimensions.^{7, 8}
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30 83 Measurement of HRQOL has been shown to have utility in paediatric healthcare settings
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32 84 encompassing numerous chronic health conditions⁹⁻¹¹ and in the assessment of health in young
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34 85 adults.⁶
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41 87 Obesity during childhood is associated with impaired HRQOL. In one United States (US) study,
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43 88 106 severely obese children and adolescents attending an obesity clinic reported significantly
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45 89 lower HRQOL than 401 healthy weight comparison children recruited through private practice
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47 90 paediatrician offices and health clinics, and similar HRQOL to 106 children and adolescents
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49 91 undergoing chemotherapy for cancer.¹² The HRQOL of 9 to 12-year-old children enrolled in an
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51 92 Australian community-based longitudinal study was significantly lower among those with
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53 93 obesity versus those without obesity, with the differences not as marked as in the US study, but
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3 94 more likely to represent those of obese children not being seen in a specialised clinic setting.¹³
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5 95 Pooled results from 22 cross-sectional and population-based studies report that children and
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8 96 adolescents with obesity have reduced overall HRQOL compared with normal weight
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10 97 counterparts, with 12 of these studies demonstrating an inverse relationship between overall
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12 98 HRQOL and weight status.⁵ Potential factors contributing to HRQOL in obese child and
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14 99 adolescent populations include treatment seeking versus community counterparts, gender, age,
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16 100 and weight-related comorbidities.⁵
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22 102 Alongside, and likely to be contributing to lower HRQOL, children and adolescents with obesity
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24 103 are at increased risk of behavioural and emotional difficulties. In addition to differences in
25
26 104 HRQOL, studies have found concerning levels of internalising (anxiety/depression, social
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28 105 withdrawal, and somatic complaints) and externalising behaviours (delinquency and rule-
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30 106 breaking behaviours) in obese children and adolescents.^{14, 15} Others have identified higher rates
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32 107 of depression, behavioural problems, and low self-esteem in obese adolescents attending obesity
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34 108 clinics compared to obese counterparts in the community.¹⁶ Children who are overweight and
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36 109 obese have also been shown to be at risk for psychosocial difficulties such as body image
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38 110 concerns, and emotional, social, and school difficulties.¹⁷
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45 112 Currently there are no published data on the HRQOL of obese children and adolescents in New
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47 113 Zealand. To our knowledge, there has only been quality of life data published on oral quality of
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49 114 life as it relates to dental caries,¹⁸ and Type 1 Diabetes in New Zealand.¹¹ In addition, there is an
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51 115 absence of cross-cultural evaluation of obesity and HRQOL. In this study, we aimed to describe
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53 116 the HRQOL (parent and child reports) and behavioural and emotional problems of obese
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3 117 children and adolescents at enrolment in a multi-disciplinary obesity intervention programme. In
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5 118 addition, we compared this cohort to other populations or to normative data, and also examined
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8 119 potential ethnic differences between indigenous and non-indigenous children and adolescents.
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11 121 **METHODS**

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15 122 Children and adolescents were recruited into “Whānau Pakari”, a community-based, unblinded
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17 123 randomised controlled trial of a multi-disciplinary obesity intervention programme,¹⁹ based in
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19 124 Taranaki (New Zealand). This region has a population of 23,139 children aged 0-15 years, of
20
21 125 whom 81% identify as New Zealand European, 28% as Māori, and 1% as other ethnicity.²⁰

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24 126 Eligibility was defined by residence in Taranaki, being aged 4.8 to 16.8 years, and being either
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27 127 obese [body mass index (BMI) $\geq 98^{\text{th}}$ centile], or overweight (BMI $> 91^{\text{st}}$ centile) with weight-
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29 128 related comorbidities.²¹ Referrals were received from a wide range of health professionals
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31 129 (including paediatricians, primary care providers, and public health nurses), Māori health
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33 130 workers, school counsellors and self-referrals.
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39 132 Ethics approval for the programme was granted by the New Zealand Health and Disability Ethics
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41 133 Committee (CEN/11/09/054). Written and verbal informed consents were obtained from all
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43 134 participants or their guardians. The trial was registered with the Australian New Zealand Clinical
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45 135 Trials Registry (ANZCTR: 12611000862943).
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49 137 **Assessments**

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52 138 Participants underwent a baseline assessment at home, which included taking anthropometric
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54 139 measurements, a medical history and weight-related physical examination, dietary history,
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56 140 physical activity questionnaire, and completion of psychometric questionnaires. Randomisation
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3 141 into 6 monthly assessments and advice or the intervention arm occurred if the participants
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5 142 indicated willingness to make healthy lifestyle change.¹⁹ The intervention consisted of weekly
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7 143 sessions delivered by a multi-disciplinary team for 12 months including physical activity, dietary
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9 144 advice, and psychology sessions (for example, the language of obesity, self-esteem, how to
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11 145 persist with healthy lifestyle change).
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17 147 **Measures**

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20 148 BMI percentile and standard deviation score (SDS) were calculated using UK Cole normative
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22 149 data²² with the KIGS auxology software (Pfizer Endocrine Care TM). Socioeconomic
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24 150 deprivation was measured at the household level using the New Zealand Deprivation Index
25
26 151 2006.²³ This area level deprivation index is a well-validated measure of socioeconomic
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28 152 deprivation in New Zealand, which is derived from national census data on nine socioeconomic
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30 153 characteristics.
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36 155 Quality of life was measured using the Pediatric Quality of Life Inventory (PedsQL)TM, which
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38 156 has been specifically designed to evaluate HRQOL in children and adolescents. The PedsQL
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40 157 questionnaire has both parent-proxy and child self-report versions, which take approximately 5
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42 158 minutes to administer. It consists of a 23-item Generic Core Scale questionnaire that assesses
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44 159 problems over the preceding month related to Physical, Emotional, Social and School
45
46 160 functioning.^{8, 10} The reliability and content validity of this instrument has been demonstrated (in
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48 161 ages 2-16 years).^{7, 24} A meaningful cut-off to identify those at risk of impaired HRQOL has been
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50 162 proposed as one SD below the population mean.²⁴ Individual questions for each area are reverse
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53 163 scored and linearly transformed into a 0-100 scale, where higher scores indicate better HRQOL.
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6 165 The existence of behavioural difficulties was assessed using the Achenbach Child Behaviour
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8 166 Checklist (CBCL).²⁵ The CBCL generates ratings of behavioural, emotional, and social
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10 167 problems with these measured on Likert scales. The CBCL, which requires 15 to 20 minutes to
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12 168 complete, can be completed by parents, caregivers, and others who see children in family
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14 169 contexts, or by the young person themselves in the case of the youth self-report (YSR), designed
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16 170 for those aged 11 to 18 years. Similar questions are grouped into a number of subscales, for
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18 171 example, aggressive behaviour, and scores for these questions are added to produce an overall
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20 172 score for that subscale. Subscales are further added to obtain scores for *internalising* and
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22 173 *externalising* problem scales and a total score (T-score) is also derived. Scores are determined to
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24 174 represent *normal*, *borderline*, or *clinical* behaviour, based on quartiles from a normative
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26 175 sample.²⁵ The normative data for the CBCL has been derived from the 1999 National Survey of
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28 176 Children, Youth and Adults, a US population survey of 2,029 children and adolescents of four
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30 177 ethnic groups (60% Latino white, 20% African American, 12% Mixed other, and 9% Latino), of
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32 178 mixed socioeconomic status (33% “upper”, 16% “lower”), equal gender split, and ranging in age
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34 179 from 6-18 years.²⁶

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42 43 181 **Data analyses**

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45 182 PedsQL scores from the children and adolescents enrolled in this study were compared to three
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47 183 populations using 2-sample t-tests. These comparison populations were:

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49 184 1) A predominantly non-obese cohort of children from the Taranaki region (n=42) with a long-
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51 185 term chronic condition (type 1 diabetes), with a mean age of 11.5 years (range 2-17 years), who
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53 186 were predominantly of New Zealand European [71%] or Māori [19%] ethnicity, and with
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3 187 representation from all levels of household deprivation.¹¹ This cohort were utilised as they are
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5 188 resident in the same region as Whānau Pakari participants, and the only group of New Zealand
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8 189 children for which published HRQOL data using PedsQL exists.

9
10 190 2) A cohort of Australian children (n=63) from the Health of Young Victorians Study, who were
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12 191 identified as obese.¹³ We utilised Australian data due to the lack of New Zealand data available.

13
14 192 3) A cohort of Australian children from the above study, identified as having normal weight
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17 193 (n=1099). The children in the entire Health of Young Victorians cohort were aged 10.4 years
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19 194 (range 9-12 years), with representation from all quintiles of socioeconomic disadvantage, but
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21 195 ethnicity of participants was not reported.¹³ Given that developmental stage may be a
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23 196 contributing factor to HRQOL scores,^{5,27} the Whānau Pakari cohort comparison was limited to
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25 197 9-12 years.
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31 199 Exploratory analyses of the PedsQL data examined potential associations between a number of
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33 200 sociodemographic and clinical parameters with parental and child's generic scaled scores, using
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35 201 simple linear regressions and one-way ANOVA. Multivariable models were used to examine
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37 202 possible associations between the generic scaled scores and important confounding factors,
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39 203 namely age, sex, ethnicity, and socioeconomic deprivation. The above analyses were also run to
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41 204 examine associations with CBCL total scores. One-tailed one-sample proportion tests were used
42
43 205 to compare the rates of participants classified as borderline clinical or clinical in each CBCL
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45 206 subscale to the normative data (i.e. expected to be $\leq 7\%$ of the population). Data were analysed in
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47 207 Minitab v.16 (Pennsylvania State University, State College, PA, USA) and SAS v.9.4 (SAS
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49 208 Institute, Cary, NC, USA). All statistical tests (except one-sample proportion tests) were two-
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51 209 tailed, and significance level was maintained at $p < 0.05$.
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211 **Results**

212 Enrolled participants (n=239) had a mean age of 10.7 years (range 4.8-16.8 years), 52% were
 213 females, and the sample were predominantly either of Māori (45%) or New Zealand European
 214 (45%) ethnicity. Nearly a third (29%) resided in households among the most deprived quintile
 215 (compared with 15% amongst the population of Taranaki).^{23, 28, 29} Forty-five percent of Māori
 216 participants were from the most deprived quintile of household deprivation, compared with 19%
 217 of New Zealand European participants (p<0.001). BMI SDS at enrolment was 3.09 (SD=0.60,
 218 range 1.52-5.34 SDS).

219

220 *Quality of life*

221 The PedsQL scores of the study's participants and the three other comparison populations are
 222 shown in Table 1. There was a moderately positive correlation between overall quality of life
 223 scores derived from child compared with parental reports (r=0.55; p<0.0001). However, for all
 224 three PedsQL measures, parents scored their children's HRQOL as being lower than that reported
 225 by the participants themselves (Table 1).

226

227 **Table 1.** Unadjusted PedsQL total generic scaled scores, as well as psychosocial and physical
 228 scaled scores (out of 100) for Whānau Pakari participants compared to other Taranaki children
 229 with type 1 diabetes (predominantly normal weight).¹¹ Data are means (SD).

	Whānau Pakari Type 1 diabetes	
Location	Taranaki, New Zealand	Taranaki, New Zealand
Source	This study	Mills et al. 2015
n	239	42
Age range	4.8-16.8 years	2-17 years

Child	Total generic scaled score	72.4 (16.2)††††	74.6 (15.3)
	Psychosocial scaled score	69.6 (18.5)††††	71.2 (17.1)
	Physical scaled score	77.1 (16.7)††††	80.8 (15.3)
Parent	Total generic scaled score	65.4 (16.2)	75.9 (13.4)****
	Psychosocial scaled score	64.4 (17.4)	73.7 (13.1)****
	Physical scaled score	66.6 (20.3)	79.9 (17.9)****

230 ****p<0.0001 for comparison with Whānau Pakari; ††††p<0.0001 for a difference between child and parental
231 scores

232

233 The Whānau Pakari participants had similar HRQOL scores to Taranaki youth who were

234 predominantly non-obese but with a chronic condition¹¹ (Table 1). However, obese youth in

235 Whānau Pakari had consistently lower HRQOL scores than normal-weight Australian children

236 (p<0.0001; Table 2), and an obese community sample.¹³ Whānau Pakari parents reported that

237 their children had lower HRQOL than those reported by the parents of all three of the

238 comparison groups (p<0.0001; Tables 1 and 2).

239

240 **Table 2.** Unadjusted PedsQL total generic scaled scores, as well as psychosocial and physical
241 scaled scores (out of 100) for Whānau Pakari participants aged 9 to 12 years, compared to
242 children and adolescents of two reference populations with a matching age range.^{11, 13} Data are
243 means (SD).

		Whānau Pakari	Normal weight	Obese
Location		Taranaki, New Zealand	Victoria, Australia	Victoria, Australia
Source		This study	Williams et al. 2005	Williams et al. 2005
n		94	1099	63
Age range		9-12 years	9-12 years	9-12 years
Child	Total generic scaled score	69.1 (15.9)†††	80.5 (12.2)****	74.0 (14.2)*
	Psychosocial scaled score	65.9 (18.4)†	77.7 (14.1)****	72.1 (14.1)*
	Physical scaled score	75.0 (15.6)††††	85.7 (12.4)****	77.5 (17.9)
Parent	Total generic scaled score	63.8 (14.4)	83.1 (12.5)****	75.0 (14.5)***
	Psychosocial scaled score	62.0 (15.5)	77.6 (14.5)****	73.9 (15.3)***
	Physical scaled score	67.0 (17.9)	87.8 (14.3)****	76.3 (17.6)**

244 *p<0.05, **p<0.01, ***p<0.001, and ****p<0.0001 for comparison with Whānau Pakari; †p<0.05, ††p<0.001, and
245 †††p<0.0001 for a difference between child and parental scores.

246
247 Exploratory analyses showed consistent associations between child and parent total generic
248 scaled scores, and certain sociodemographic and clinical parameters, indicating worse overall
249 quality of life with participants who had breathing pauses (p=0.026 child and p<0.0001 parent
250 respectively), reported difficulty getting to sleep (p=0.011 and p=0.0003), history of headaches
251 (p=0.026 and p=0.023), developmental problems (p=0.0002 and p=0.002), and a father being
252 identified as the sole/primary caregiver as opposed to children living in two-parent families
253 (p=0.009 and p=0.032). In addition, based upon parent scores, the greater the participant's BMI
254 SDS at entry to the programme, the worse the quality of life score (p=0.033). In multivariable
255 models, no association was evident between either child or parental generic scaled scores and
256 variables which described child age, sex, ethnicity, or household deprivation.

257

258 **Child Behaviour Checklist**

259 The median CBCL total score was 58 (IQR=15.3). The distribution of participants' scores is
260 shown in Figure 1. Just over half of the participants had CBCL total scores in the normal range
261 (56.3%), while a total of 43.7% had scores in the borderline clinical (16%) and clinical (27.7%)
262 ranges (Figure 1). From US normative data previously described, the overall proportion of
263 population falling into the borderline clinical or clinical range is $\leq 7\%$.²⁶ This means that
264 children in our study had a prevalence of emotional and behavioural problems that was more
265 than 6 times higher (p<0.0001) than normative populations.

266

267 The classification of participants according to individual CBCL subscales is shown in Table 3.

268 Based on CBCL findings, children and adolescents in our cohort were significantly more likely

269 to display emotional and behavioural difficulties than those in the general population. Compared
 270 to normative data, the proportion of participants in borderline clinical or clinical ranges was
 271 considerably greater for all subscales (Table 3).

272
 273 **Table 3.** Number of participants with T-scores from Child Behavior Checklist (CBCL)
 274 falling into normal, borderline clinical, and clinical ranges at baseline (n=209). Data are n (%).

CBCL subscale	Normal ^a	Borderline Clinical ^b	Clinical ^c
Anxious	203 (85.3%)****	20 (8.4%)	15 (6.3%)
Withdrawn	176 (74.0%)****	42 (17.7%)	20 (8.4%)
Somatic complaints	181 (76.1%)****	37 (15.6%)	20 (8.4%)
Social difficulties	159 (76.1%)****	31 (14.8%)	19 (9.1%)
Thought problems	178 (85.2%)****	15 (7.2%)	16 (7.7%)
Attention difficulties	197 (82.8%)****	24 (10.1%)	17 (7.1%)
Rule breaking	167 (80.0%)****	32 (15.3%)	10 (4.8%)
Aggressive	198 (83.2%)****	26 (10.9%)	14 (5.9%)
<i>Internalising</i>	134 (56.3%)****	37 (15.6%)	67 (28.2%)
<i>Externalising</i>	153 (64.3%)****	34 (14.3%)	51 (21.4%)
<i>Total</i>	134 (56.3%)****	38 (16.0%)	66 (27.7%)

276 *Note.* ^a< 65 which is below 93rd centile

277 ^b65-70 which is 93-98th centile (apart from internalising/externalising/total 60-63)

278 ^c>70 which is 98th centile (apart from internalising/externalising/total >63)

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3 279 **** $p < 0.0001$ for comparison with normative data (i.e. expected $\leq 7\%$ of participants in borderline clinical or
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5 280 clinical ranges combined)
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10 282 Exploratory analyses showed a higher probability of behavioural and emotional problems (as per
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12 283 CBCL total scores) in those who experienced breathing pauses ($p = 0.011$) or displayed
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14 284 developmental problems ($p = 0.0002$). Multivariable analyses showed no associations between
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17 285 CBCL total scores and age, sex, ethnicity, or socioeconomic deprivation.
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21 287 **Ethnic comparisons**

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24 288 There were no differences between obese Māori and New Zealand European participants with
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26 289 respect to the child's reported overall PedsQL scores ($p = 0.09$) or PedsQL psychosocial ($p = 0.15$)
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28 290 scores, but Māori children reported higher PedsQL physical scores (80.3 versus 75.0,
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31 291 respectively, $p = 0.02$). With respect to parental report, there were no ethnic differences in total
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33 292 quality of life ($p = 0.85$), psychosocial ($p = 0.77$), or physical ($p = 0.58$) scores. There were no
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36 293 differences between Māori and New Zealand European participants on CBCL total ($p = 0.41$),
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38 294 internalizing ($p = 0.07$), or externalizing ($p = 0.90$) scores.
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42 296 **DISCUSSION**

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45 297 The main findings of this study were that obese children and adolescents in this region of New
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47 298 Zealand had lower HRQOL on parent report measures when compared with those with a chronic
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49 299 condition (i.e. diabetes that requires daily testing and treatment), and other obese and non-obese
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51 300 samples. In addition, as defined by the CBCL total score, a large proportion (44%) had
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54 301 psychological difficulties, with the majority of these being in the clinical rather than the sub-
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57 302 clinical range. The parent report quality of life scores were not dissimilar to those described in
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3 303 children with obesity attending a specialist clinic, and were similar to children and adolescents
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5 304 diagnosed with cancer.¹² The degree to which HRQOL appeared to be affected in our cohort was
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7
8 305 not surprising, given that treatment-seeking parents of obese children are more likely to perceive
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10 306 their child as having a poorer HRQOL and more psychological difficulties when compared with
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12 307 parents of obese children in the community not seeking treatment.^{5,30} Our cohort consisted of
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14 308 participants referred to an obesity-intervention programme, so were not a true community-based
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16 309 sample. Nor were they directly comparable to a hospital outpatient clinic population given that
17
18 310 Whānau Pakari was specifically designed to address barriers to access which exist for hospital-
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20 311 based outpatient clinical care, particularly for indigenous children.¹⁹ Even allowing for this not
21
22 312 being a complete non-referred sample, the difference in HRQOL scores in our cohort compared
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24 313 with a published large (n=10,241) population study of predominantly normal weight children
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26 314 aged 2-16 years (mean score 65.4 vs. 81.3) is considerable.³¹
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32 316 Differences between parent-proxy and child self-report on PedsQL questionnaires have been
33
34 317 previously reported. A systematic review of the relationship between parents and children's
35
36 318 HRQOL scores found better agreement among parents and chronically sick children than
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38 319 between parents and their healthy children.³² It was argued that both parent and child reports
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40 320 should be obtained as they provide different perspectives. A further review noted differences in
41
42 321 parent-child agreement in HRQOL across four different instruments.³³ The authors suggested
43
44 322 that the disagreement was a consequence of varying individual beliefs about the child's health
45
46 323 and wellbeing, rather than parent or child reports being wrong or right.³³ A Norwegian study
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48 324 reviewed this in relation to children and adolescents seeking treatment for obesity versus a
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50 325 community sample of children of any BMI.³⁰ Parents reported the quality of life of the obese
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3 326 children seeking treatment as lower than those in the community, which was not seen with the
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5 327 child self-report.³⁰ Pooled analyses however show that paediatric HRQOL can be accurately
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8 328 predicted from parent proxy reports with moderate to strong linear relationships between the two
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10 329 methods of report.⁵

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15 331 We observed that psychological difficulties were prevalent in our cohort. Our participants
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17 332 reported a mean total CBCL score of 64.3 (SD=8.2), which lies in the clinical range, and it was
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19 333 higher than a small non-clinical group of obese adolescents from Turkey (n=30) with a total
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21 334 problem score of 58.2 (SD=7.7).¹⁶ We have no national data for comparison with CBCL, but
22
23 335 there is nothing to suggest that scores in the Taranaki region would be higher than those
24
25 336 nationally, and there is no known biological reason for this cohort to have higher rates of mental
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27 337 health problems outside of their obesity. The absence of Paediatric psychology services are a
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29 338 notable issue in the region (child and adolescent mental health services are available), and it is
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31 339 unclear if this may contribute to these findings. The randomised clinical trial we are undertaking
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33 340 will be able to assess if the intervention can address the relationships between these variables
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35 341 over time.

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41 343 Child obesity is a major health concern in New Zealand, with the third highest prevalence of
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43 344 overweight and obesity in the OECD (Organisation for Economic Co-operation and
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45 345 Development).³⁴ Recent studies in this cohort of obese children and adolescents have found
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47 346 suboptimal eating behaviour,³⁵ suboptimal physical activity,³⁶ and a high prevalence of weight-
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49 347 related comorbidities, including hypertension and obstructive sleep apnoea.³⁷ We were not
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51 348 surprised that breathing pauses were associated with poorer HRQOL and higher total scores on
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3 349 the CBCL. Breathing pauses in obese children and adolescents are associated with obstructive
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5 350 sleep apnoea,³⁸ and obese children and adolescents with this condition have reported lower
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8 351 HRQOL total scores than obese peers without the condition.¹² Moderate to severe obstructive
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10 352 sleep apnoea is associated with increased rates of aggressive behaviour, attention problems, and
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12 353 internalizing problems on the CBCL.³⁹ These observations are important, given the considerable
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14 354 prevalence of breathing pauses reported in this obese cohort,³⁷ and the wider impact of
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16 355 obstructive sleep apnoea on a child's health, cognitive and behavioural functioning.⁴⁰
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21
22 357 Strengths of this study are that it is the first to report HRQOL in obese children and adolescents
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24 358 in the New Zealand population. Due to the high participation rate from Māori, we were also able
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26 359 to undertake evaluation of the impact of ethnicity. What was interesting and important about our
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28 360 findings in terms of ethnicity was the lack of disparity in HRQOL scores. This was despite a
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30 361 larger proportion of Māori participants being from the most deprived quintile of households. It
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32 362 therefore appears that obesity itself rather than factors such as deprivation is the main identified
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34 363 factor in our participants contributing to lower HRQOL scores.
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39 365 A limitation of this study, as with all HRQOL assessments, is the use of an assessment tool to
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41 366 extrapolate one's psychological health and wellbeing. Comparisons of our study have been made
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43 367 with population groups of varying age ranges, which may have affected results. However, age
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45 368 did not appear to have any influence on HRQOL scores in our cohort. Another limitation of this
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47 369 study is that this was a referred cohort, which means our findings are not necessarily
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49 370 representative of the general population. We compared our data with the Health of Young
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51 371 Victorians cohort from Australia, as this was the most comparable group we had access to.
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3 372 However, the data were collected in 2000, and the differences noted may have been impacted by
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5 373 the difference in dates of data collection. Mean BMI SDS for the obese Victorian cohort was not
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8 374 available, which would be important if it was considerably lower than the Whānau Pakari
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10 375 participants.
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15 377 In conclusion, this study highlights a lower HRQOL and a higher prevalence of psychological
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17 378 difficulties for this referred community-based group of obese children and adolescents compared
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20 379 with normative population data. No differences were found between Māori and New Zealand
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22 380 Europeans. This is despite Māori being represented in greater numbers in the more deprived
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24 381 households of the region compared with their non- Māori counterparts, suggesting that obesity
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26 382 itself rather than deprivation is the main contributor to lower HRQOL scores. This study
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29 383 highlights the importance of psychologist involvement and screening in the obese child and
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31 384 adolescent population as part of any multi-disciplinary team. Improvement in HRQOL should be
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34 385 considered a goal of all child and adolescent obesity intervention and management. Further
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36 386 research is required to ascertain how to maximise improvements in what is now recognised as an
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39 387 important health outcome.
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13 399 **Competing interests**

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16
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18
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24
25 405 been paid in a fellowship capacity from the Health Research Council of New Zealand, TLC has
26
27 406 been paid as a research assistant, JGBD has been paid for data analysis.
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34 408 **Contributorship statement**

35
36 409 YCA designed the study, was involved with data interpretation, and drafted this manuscript.
37
38 410 LEW recruited participants, and undertook assessments and data entry. KFT provided
39
40 411 psychologist oversight and analysis of patient data. CCG is secondary supervisor for the research
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42 412 team, and assisted with the interpretation of the study. JMS was involved in study design. TLC
43
44 413 assisted with data entry and analysis. TAW was involved in interpretation of data. JGBD
45
46 414 analysed the data. WSC contributed to study design. PLH contributed to study design and
47
48 415 supervises the research team. All authors critically revised the manuscript, gave final approval
49
50 416 for the version to be published, and are accountable for all aspects of the work.
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3 418 **Data sharing statement**
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5 419 Data cannot be made available in a public repository due to the strict conditions of the ethics
6
7 approval of this study. Nonetheless, anonymised and de-identified data will be made available to
8
9 other investigators upon request. Interested readers should contact the senior author Prof Paul
10
11 Hofman (p.hofman@auckland.ac.nz) to obtain the data.
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19 424 **References**
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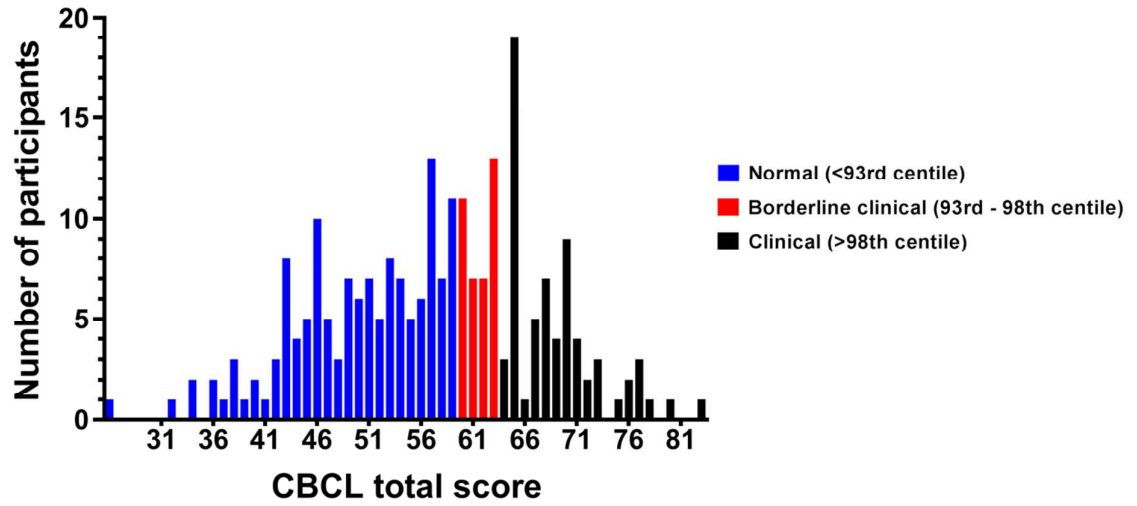


Figure 1. The frequency distribution of participants according to the Child Behaviour Checklist (CBCL) total scores.

Peer review only

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Complete?
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	✓ 'enrolment' indicates baseline measures
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	✓
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	✓
Objectives	3	State specific objectives, including any prespecified hypotheses	✓
Methods			
Study design	4	Present key elements of study design early in the paper	✓
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	✓
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	✓
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	✓
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	✓
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	✓
Bias	9	Describe any efforts to address potential sources of bias	✓ Yes, by adjusting for potential confounders
Study size	10	Explain how the study size was arrived at	✓
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	✓
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	✓
		(b) Describe any methods used to examine subgroups and interactions	✓
		(c) Explain how missing data were addressed	
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	

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Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	✓
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	✓
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	✓
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	✓ ✓ ✓
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	✓
Discussion			
Key results	18	Summarise key results with reference to study objectives	✓
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	✓
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	✓
Generalisability	21	Discuss the generalisability (external validity) of the study results	✓
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	✓

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Health-related quality of life and psychological well-being of children and adolescents enrolled in a community-based New Zealand obesity intervention programme

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3 **1 Health-related quality of life and psychological well-being of children and adolescents**
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5 **2 enrolled in a community-based New Zealand obesity intervention programme**
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5 26 **Keywords:** Paediatric, obesity, adolescent, quality of life, lifestyle intervention, Whānau Pakari
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12
13 29 **ABSTRACT**
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15 30 **Objective:** To describe health-related quality of life (HRQOL) and psychological well-being of
16
17 31 children and adolescents at enrolment in a multi-disciplinary community-based obesity
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19 32 programme, and to determine association with ethnicity. This programme targeted indigenous
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21 33 people and those from most deprived households. Further, this cohort was compared to other
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23 34 populations/normative data.
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27 35 **Methods:** This study examines baseline demographic data of an unblinded randomised
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29 36 controlled clinical trial. Participants (recruited from January 2012-August 2014) resided in
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31 37 Taranaki, New Zealand (NZ), and for this study we only included those with a body mass index
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33 38 (BMI) $\geq 98^{\text{th}}$ percentile (obese). HRQOL and psychological well-being were assessed using the
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35 39 PedsQL 4.0TM (parent and child reports), and the Achenbach's Child Behaviour Checklist
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37 40 (CBCL)/Youth Self Report (YSR). The trial was registered with the Australian NZ Clinical
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39 41 Trials Registry (ANZCTR: 12611000862943).
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43 42 **Results:** Assessments were undertaken for 233 participants (45% Māori, 45% NZ European,
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45 43 10% other ethnicities, 52% female, 30% from the most deprived household quintile), mean age
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47 44 10.6 years. The mean BMI standard deviation score (SDS) was 3.12 (range 2.01-5.34). Total
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49 45 PedsQL generic scaled score (parent) was lower (mean=63.4, SD=14.0) than an age-matched
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51 46 group of Australian children without obesity from the Health of Young Victorians study
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53 47 (mean=83.1, SD=12.5). In multivariable models, child and parental generic scaled scores
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3 48 decreased in older children ($\beta=-0.70$ and $p=0.031$, $\beta=-0.64$ and $p=0.047$, respectively).
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5 49 Behavioural difficulties (CBCL/YSR total score) were reported in 43.5% of participants, with the
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7
8 50 rate of emotional/behavioural difficulties 6 times higher than reported norms ($p<0.001$).
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10 51 **Conclusions:** In this cohort, children and adolescents with obesity had a low HRQOL, and a
11
12 52 concerning level of psychological difficulties, irrespective of ethnicity. Obesity itself rather than
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14 53 ethnicity or deprivation appeared to contribute to lower HRQOL scores. This study highlights the
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16 54 importance of psychologist involvement in obesity intervention programmes.
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22 56 **Strengths:**

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24 57 • This study is the first to report HRQOL in children and adolescents with obesity in New
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26 58 Zealand.
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28 59 • To our knowledge, there are very limited data regarding ethnicity and HRQOL. Due to the
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30 60 high participation rate from Māori, we were able to evaluate the impact of ethnicity on HRQOL.
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36 62 **Limitations:**

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38 63 • Due to the lack of NZ HRQOL data, comparisons have been made with population groups of
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40 64 varying age ranges, which may have affected results.
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42 65 • The study participants were a referred cohort, which means our findings are not
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44 66 representative of the general population. The data from the Victorian cohort were collected in
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46 67 2000, and the differences noted may have been impacted by the difference in dates of data
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48 68 collection.
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50 69 • Mean BMI SDS for the Victorian cohort identified as obese was not available, which would
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52 70 be important if it was considerably lower than the Whānau Pakari participants.
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3 71 • There were no adjustments for multiple comparisons in our statistical analyses; due to the
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5 72 inflated likelihood of Type I errors, our findings (particularly from exploratory analyses) need to
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8 73 be interpreted accordingly.
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12 75 INTRODUCTION

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17 77 Obesity in childhood and adolescence is known to be associated with weight-related
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19 78 comorbidities.¹ Indigenous populations often have higher rates of obesity compared with non-
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21 79 indigenous counterparts where this information has been collated.^{2,3} In New Zealand,
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23 80 approximately 11% of New Zealand children aged two to fourteen years are classed as obese,
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25 81 with Māori (New Zealand's indigenous population) being 1.6 times more likely to be in the
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27 82 obese range compared with non-Māori counterparts.³ In addition, children living in households
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29 83 in the most socioeconomically deprived quintile for New Zealand are five times more likely to
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31 84 be in the obese range than children living in the least deprived areas.³ In the United States,
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33 85 whilst rates of children with obesity are not readily available for American Indian populations,
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35 86 rates of Type 2 diabetes mellitus (a known weight-related comorbidity) are higher.²
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44 88 Globally, indigenous populations that have experienced historical trauma secondary to
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46 89 colonisation, are over-represented in socioeconomic household deprivation, and both experience
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48 90 the resultant health disparities.² The social determinants of health, such as poverty, limited
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50 91 educational attainment, and critically the loss of a traditional diet all contribute to the impact on
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52 92 these population groups in terms of health and well-being.² Overweight and obesity in
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54 93 adolescence have been shown to be strongly associated with medical complications, including an
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3 94 increase in cardiovascular mortality in adulthood.⁴ Emerging evidence suggests that obesity also
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5 95 affects the emotional health and well-being of children and adolescents, commonly referred to as
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8 96 health-related quality of life (HRQOL).⁵ However, little is known about the HRQOL of
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11 97 indigenous children and adolescents, especially as it pertains to weight. Previous research has
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13 98 found that Sami (the indigenous people of Sweden) children experience lower HRQOL in some
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15 99 domains compared with Swedish children in general.⁶ In relation to HRQOL as it pertains to
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17 100 weight, and the impact of ethnicity, it is acknowledged that information about the relationship
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20 101 between HRQOL and weight may not have transferability from one cultural context to another,
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22 102 given differing perceptions of body image cross-culturally.^{7, 8}
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27 104 Quality of life is a broad construct that encompasses various aspects pertaining to health and
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29 105 well-being.⁹ The assessment of HRQOL is increasingly recognised as a necessary component of
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31 106 health and well-being evaluation, assessing physical, emotional, and social health dimensions.¹⁰
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34 107 ¹¹ Measurement of HRQOL has been shown to have utility in paediatric healthcare settings
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36 108 encompassing numerous chronic health conditions¹²⁻¹⁴ and in the assessment of health in young
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38 109 adults.⁹
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43 111 Obesity during childhood is associated with impaired HRQOL. In one United States (US) study,
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45 112 106 children and adolescents with severe obesity attending an obesity clinic reported
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48 113 significantly lower HRQOL than 401 healthy weight comparison children recruited through
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50 114 private practice paediatrician offices and health clinics, and similar HRQOL to 106 children and
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52 115 adolescents undergoing chemotherapy for cancer.¹⁵ The HRQOL of 9 to 12-year-old children
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55 116 enrolled in an Australian community-based longitudinal study was significantly lower among
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3 117 those with obesity versus those without obesity, with the differences not as marked as in the US
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5 118 study, but more likely to represent those of children with obesity not being seen in a specialised
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7 119 clinic setting.¹⁶ Pooled results from 22 cross-sectional and population-based studies report that
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9 120 children and adolescents with obesity have reduced overall HRQOL compared with normal
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11 121 weight counterparts, with 12 of these studies demonstrating an inverse relationship between
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13 122 overall HRQOL and weight status.⁵ Potential factors contributing to HRQOL in child and
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15 123 adolescent populations with obesity include treatment seeking versus community counterparts,
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17 124 gender, age, and weight-related comorbidities.⁵
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24 126 Alongside, and likely to be contributing to lower HRQOL, children and adolescents with obesity
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26 127 are at increased risk of behavioural and emotional difficulties. In addition to differences in
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28 128 HRQOL, studies have found concerning levels of internalising (anxiety/depression, social
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30 129 withdrawal, and somatic complaints) and externalising behaviours (delinquency and rule-
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32 130 breaking behaviours) in children and adolescents with obesity.^{17, 18} Others have identified higher
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34 131 rates of depression, behavioural problems, and low self-esteem in adolescents with obesity
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36 132 attending obesity clinics compared to affected counterparts in the community.¹⁹ Children who
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38 133 are overweight and obese have also been shown to be at risk for psychosocial difficulties such as
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40 134 body image concerns, and emotional, social, and school difficulties.²⁰
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48 136 Currently there are no published data on the HRQOL of children and adolescents with obesity in
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50 137 New Zealand. To our knowledge, there has only been quality of life data published on oral
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52 138 quality of life as it relates to dental caries,²¹ and Type 1 diabetes in New Zealand.¹⁴ In addition,
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54 139 there is an absence of cross-cultural evaluation of obesity and HRQOL. In this study, we aimed
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3 140 to describe the HRQOL (parent and child reports) and behavioural and emotional problems of
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5 141 children and adolescents with obesity at enrolment in a multi-disciplinary obesity intervention
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8 142 programme. In addition, we compared this cohort to other populations or to normative data, and
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10 143 also examined potential ethnic differences between indigenous and non-indigenous children and
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12 144 adolescents. It was hypothesised that obesity is associated with lower HRQOL in New Zealand
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14 145 children and adolescents with obesity.
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19 20 147 **METHODS**

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24 149 Children and adolescents were recruited into “Whānau Pakari”, a community-based, unblinded
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27 150 randomised controlled trial of a multi-disciplinary obesity intervention programme,²² based in
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29 151 Taranaki (New Zealand). This region has a population of 23,139 children aged 0-15 years, of
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31 152 whom 81% identify as New Zealand European, 28% as Māori, and 1% as other ethnicity.²³
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34 153 Eligibility was defined by residence in Taranaki, being aged 4.8 to 16.8 years, and either in obese
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36 154 [body mass index (BMI) \geq 98th centile], or overweight (BMI $>$ 91st centile) categories with
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39 155 weight-related comorbidities.²⁴ However, only obese participants were included in the study
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41 156 reported here. Referrals were received between January 2012 and August 2014 from a wide
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43 157 range of health professionals (including paediatricians, primary care providers, and public health
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46 158 nurses), Māori health workers, school counsellors and self-referrals. This study examines
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48 159 elements of the baseline demographic data.
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53 161 Ethics approval for the programme was granted by the New Zealand Health and Disability Ethics
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55 162 Committee (CEN/11/09/054). Written and verbal informed consents were obtained from all
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3 163 participants or their guardians. The trial was registered with the Australian New Zealand Clinical
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5 164 Trials Registry (ANZCTR: 12611000862943).
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8 165
9 166 **Assessments**

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11 167 Participants underwent a baseline assessment at home, which included taking anthropometric
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13 168 measurements, a medical history and weight-related physical examination, dietary history,
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15 169 physical activity questionnaire, and completion of psychometric questionnaires. Questions
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17 170 pertaining to family structure, developmental history, presence/absence of headaches, difficulty
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19 171 getting to sleep, and presence/absence of breathing pauses were all included in the weight-related
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21 172 medical history. Randomisation into 6 monthly assessments and advice or the intervention arm
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23 173 occurred if the participants indicated willingness to make healthy lifestyle change.²² The
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25 174 intervention consisted of weekly sessions delivered by a multi-disciplinary team for 12 months
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27 175 including physical activity, dietary advice, and psychology sessions (for example, self-esteem,
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29 176 the importance of sleep, how to make and persist with healthy lifestyle change).
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37 178 **Measures**

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39 179 BMI percentile and standard deviation score (SDS) were calculated using UK Cole normative
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41 180 data²⁵ with the KIGS auxology software (Pfizer Endocrine Care TM). Socioeconomic
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43 181 deprivation was measured at the household level using the New Zealand Deprivation Index 2006.
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45 182 ²⁶ This area level deprivation index is a well-validated measure of socioeconomic deprivation in
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47 183 New Zealand, which is derived from national census data on nine socioeconomic characteristics.
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52 185 Quality of life was measured using the Pediatric Quality of Life Inventory (PedsQL)TM, which
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54 186 has been specifically designed to evaluate HRQOL in children and adolescents. The PedsQL
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3 187 questionnaire has both parent-proxy and child self-report versions, which take approximately 5
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6 188 minutes to administer. It consists of a 23-item Generic Core Scale that assesses problems over
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8 189 the preceding month related to Physical, Emotional, Social and School functioning.^{11, 13} The
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11 190 reliability of this instrument has been demonstrated in ages 2-16 years as excellent ($\alpha = 0.89$
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13 191 child; 0.92 parent report) with acceptable construct validity, in a large population survey in the
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15 192 US (n=10,241), with white, Hispanic/Latino, black/African American, Asian/Pacific Islander,
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17 193 American Indian and Native Alaskan participants.²⁷ A meaningful cut-off to identify those at
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19 194 risk of impaired HRQOL has been proposed as one SD below the population mean.²⁷ Individual
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21 195 questions for each area are reverse scored and linearly transformed into a 0-100 scale, where
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23 196 higher scores indicate better HRQOL.
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29 198 The existence of behavioural difficulties was assessed using the Achenbach Child Behaviour
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31 199 Checklist (CBCL) ages 1.5-5 and ages 6-18 (parent report) and Youth Self Report (YSR) for
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33 200 ages 11-18.²⁸ The CBCL/YSR generate ratings of behavioural, emotional, and social problems.
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35 201 The CBCL can be completed by parents, caregivers, or others who see children in family
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37 202 contexts, or by the young person themselves in the case of the youth self-report (YSR). When the
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39 203 young person completed the YSR, no parent CBCL report was obtained in order to reduce the
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41 204 burden of assessment on the family. Subscale scores for the YSR and the CBCL are calculated
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43 205 for a number of behavioural and psychological problems such as aggressive behaviour, and
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45 206 somatic complaints. Subscales are then combined to obtain overall *T*-scores for *internalising* and
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47 207 *externalising* problems. Aggregate scores that represent *normal*, *borderline*, or *clinical* behaviour
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49 208 are based on quartiles from a normative sample.²⁸ The normative data for the CBCL/YSR has
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51 209 been derived from the 1999 National Survey of Children, Youth and Adults, a US population
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3 210 survey of 2,029 children and adolescents of four ethnic groups (60% Latino white, 20% African
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5 211 American, 12% Mixed other, and 9% Latino), of mixed socioeconomic status (33% “upper”,
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8 212 16% “lower”), equal gender split, and ranging in age from 6-18 years.²⁹
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12 13 214 **Data analyses**

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15 215 PedsQL scores from the children and adolescents enrolled in this study were compared to three
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17 216 populations using 2-sample t-tests. These comparison populations were:

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20 217 1) A predominantly normal weight cohort of children from the Taranaki region (n=42) with a
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22 218 long-term chronic condition (Type 1 diabetes), with a mean age of 11.5 years (range 2-17 years),
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24 219 who were predominantly of New Zealand European [71%] or Māori [19%] ethnicity, and with
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27 220 representation from all levels of household deprivation.¹⁴ This cohort was utilised as they were
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29 221 resident in the same region as Whānau Pakari participants, and the only group of New Zealand
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31 222 children for which published HRQOL data using PedsQL exists. Recruitment period was May-
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34 223 July 2013.

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36 224 2) A cohort of Australian children (n=63) from the Health of Young Victorians Study (follow-up
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38 225 data collected in 2000), who were identified as having obesity (from the total cohort of n=1456).
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40 226 ¹⁶ We utilised Australian data due to the lack of New Zealand data available.

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43 227 3) A cohort of Australian children from the above study (follow-up data collected in 2000),
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45 228 identified as having normal weight (n=1099, from the total cohort of n=1456). The children in
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47 229 the entire Health of Young Victorians cohort were aged 10.4 years (range 9-12 years), with
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50 230 representation from all quintiles of socioeconomic disadvantage, but ethnicity of participants was
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52 231 not reported.¹⁶ Given that developmental stage may be a contributing factor to HRQOL scores,^{5,}
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55 232 ³⁰ the Whānau Pakari cohort comparison was limited to 9-12 years (n=91).
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6 234 Exploratory analyses of the PedsQL data examined potential associations between a number of
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8 235 sociodemographic and clinical parameters with parental and child's generic scaled scores
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10 236 separately, using simple linear regressions and one-way ANOVA. Further, multivariable models
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12 237 were used to examine possible associations between either parental or child's generic scaled
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14 238 score and important confounding factors, namely age, sex, ethnicity, and socioeconomic
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16 239 deprivation.
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22 241 CBCL and YSR T-scores were utilised. One-tailed one-sample proportion tests were used to
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24 242 compare the rates of participants classified as borderline clinical or clinical in each CBCL/YSR
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26 243 subscale to the normative data (i.e. expected to be $\leq 7\%$ of the population). Exploratory analyses
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28 244 using generalized linear regression models also examined the likelihood of displaying
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30 245 behavioural and emotional problems (i.e. having CBCL/YSR scores in the borderline or clinical
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32 246 ranges) in association with certain demographic parameters, adjusting only for source of test
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34 247 scores (i.e. parent or youth). A similarly constructed multivariable model was also run adjusting
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36 248 for age, sex, ethnicity, and socioeconomic deprivation. These results are provided as relative
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38 249 risks (RR) and respective 95% confidence intervals (CI). Data were analysed in Minitab v.16
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40 250 (Pennsylvania State University, State College, PA, USA) and SAS v.9.4 (SAS Institute, Cary,
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42 251 NC, USA). All statistical tests (except one-sample proportion tests) were two-tailed. Significance
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44 252 level was maintained at $p < 0.05$, with no adjustments for multiple comparisons.
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52 254 **RESULTS**

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3 256 After exclusion of 6 participants who were in the overweight category, enrolled participants
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6 257 (n=233) had a mean age of 10.6 years (range 4.8-16.8 years), 52% were females, and the sample
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8 258 were predominantly either of Māori (45%) or New Zealand European (45%) ethnicity. Nearly a
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10 259 third (30%) resided in households among the most deprived quintile (compared with 15%
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12 260 amongst the population of Taranaki).^{26, 31, 32} Forty-two percent of Māori participants were from
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14 261 the most deprived quintile of household deprivation, compared with 20% of New Zealand
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16 262 European participants (p<0.001). BMI SDS at enrolment was 3.12 (SD=0.57, range 2.01-5.34
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18 263 SDS). Demographics of family and medical history have been previously reported for the total
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20 264 cohort.³³ In brief, among our 233 participants, living arrangements included a two-parent
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22 265 household for half of the participants (n=119, 52%), one-parent household (mother) for 38%
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24 266 (n=87), one-parent household (father) for 4% (n=10), and other arrangement for 6% (n=14).
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26 267 Headaches were prevalent in 32% (n=75), 32% of participants had difficulties getting to sleep
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28 268 (n=75), 20% had breathing pauses (n=47), and 9% had developmental concerns (n=20).
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36 270 *Quality of life*

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38 271 The PedsQL scores of our study's participants and those of another study population in Taranaki
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40 272 are shown in Table 1. There was a moderately positive correlation between overall quality of life
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42 273 scores derived from child compared with parental reports (r=0.55; p<0.001). However, for all
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44 274 three PedsQL measures, parents scored their children's HRQOL as being lower than that reported
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46 275 by the participants themselves (Table 1).
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53 277 **Table 1.** Unadjusted PedsQL total generic scaled scores, as well as psychosocial and physical
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55 278 scaled scores (out of 100) for Whānau Pakari participants compared to other Taranaki children
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279 with Type 1 diabetes (predominantly normal weight).¹⁴ Whānau Pakari data are mean ± SD
 280 (95% confidence interval of the mean), while other data are mean ± SD.

		Whānau Pakari	Type 1 diabetes
Location		Taranaki, New Zealand	Taranaki, New Zealand
Source		This study	Mills et al. 2015
n		233	42
Age range		4.8-16.8 years	2-17 years
Child	Total generic scaled score	72.2 ± 16.2 (70.1, 74.3)†††	74.6 ± 15.3
	Psychosocial scaled score	69.4 ± 18.6 (67.0, 71.8)†††	71.2 ± 17.1
	Physical scaled score	76.9 ± 16.7 (74.8, 79.1)†††	80.8 ± 15.3
Parent	Total generic scaled score	65.1 ± 16.0 (63.0, 67.1)	75.9 ± 13.4***
	Psychosocial scaled score	64.1 ± 17.3 (61.9, 66.3)	73.7 ± 13.1***
	Physical scaled score	66.3 ± 20.3 (63.6, 68.9)	79.9 ± 17.9***

281 ***p<0.001 for comparison with Whānau Pakari; †††p<0.001 for a difference between child and parental scores

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283 The Whānau Pakari participants reported similar HRQOL scores to Taranaki youth who were
 284 predominantly normal weight but with a chronic condition¹⁴ (Table 1). However, youth with
 285 obesity in Whānau Pakari had consistently lower HRQOL scores than normal-weight Australian
 286 children (p<0.001; Table 2), and a community sample with obesity.¹⁶ Whānau Pakari parents
 287 reported that their children had lower HRQOL than those reported by the parents of all three of
 288 the comparison groups (p<0.001; Tables 1 and 2).

289

290 **Table 2.** Unadjusted PedsQL total generic scaled scores, as well as psychosocial and physical
 291 scaled scores (out of 100) for Whānau Pakari participants aged 9 to 12 years, compared to
 292 children and adolescents of two reference populations with a matching age range.^{14, 16} Whānau
 293 Pakari data are mean ± SD (95% confidence interval of the mean), while other data are mean ±
 294 SD.

		Whānau Pakari	Normal weight	Obese
Location		Taranaki, New Zealand	Victoria, Australia	Victoria, Australia
Source		This study	Williams et al. 2005	Williams et al. 2005
n		91	1099	63

Age range		9-12 years	9-12 years	9-12 years
Child	Total generic scaled score	69.0 ± 15.9 (65.7, 72.3)†††	80.5 ± 12.2***	74.0 ± 14.2*
	Psychosocial scaled score	65.8 ± 18.4 (61.9, 69.6)†	77.7 ± 14.1***	72.1 ± 14.1*
	Physical scaled score	74.9 ± 15.7 (71.6, 78.2)†††	85.7 ± 12.4***	77.5 ± 17.9
Parent	Total generic scaled score	63.4 ± 14.0 (60.5, 66.3)	83.1 ± 12.5***	75.0 ± 14.5***
	Psychosocial scaled score	61.5 ± 15.1 (58.4, 64.7)	77.6 ± 14.5***	73.9 ± 15.3***
	Physical scaled score	66.7 ± 17.7 (63.0, 70.3)	87.8 ± 14.3***	76.3 ± 17.6**

*p<0.05, **p<0.01, and ***p<0.001 for comparison with Whānau Pakari; †p<0.05 and †††p<0.001 for a difference between child and parental scores

Exploratory analyses showed consistent associations between child and parent total generic scaled scores, and certain sociodemographic and clinical parameters, indicating worse overall quality of life with participants who had breathing pauses (p=0.0439 child and p<0.001 parent respectively), reported difficulty getting to sleep (p=0.019 and p<0.001), history of headaches (p=0.023 and p=0.022), developmental problems (p<0.001 and p<0.001), and a father being identified as the sole/primary caregiver as opposed to children living in two-parent families (p=0.010 and p=0.031). In multivariable models, there was evidence that child and parental generic scaled scores decreased in older children (β =-0.70 and p=0.031, β =-0.64 and p=0.047, respectively), but there were no apparent associations with sex, ethnicity, or household deprivation within our cohort.

Child Behaviour Checklist

Of the total cohort for this study, 232 participants/parents completed the CBCL/YSR. The median CBCL/YSR total score was 58 (interquartile range =15.0). The distribution of participants' scores is shown in Figure 1.

314 **Figure 1.** The frequency distribution of participants according to the Child Behaviour Checklist
 315 (CBCL) and Youth Self Report (YSR) total scores.

316
 317 Just over half of the participants had CBCL/YSR total scores in the normal range (56.5%), while
 318 the remaining 43.5% had scores in the borderline clinical (15.5%) and clinical (28.0%) ranges
 319 (Figure 1; Table 3). From US normative data previously described, the overall proportion of
 320 population falling into the borderline clinical or clinical range is $\leq 7\%$.²⁹ This means that
 321 children in our study had a prevalence of emotional and behavioural problems that was more
 322 than 6 times higher ($p < 0.001$) than normative populations.

323
 324 The classification of participants according to individual CBCL/YSR subscales (both parent
 325 report and youth report) are shown in Table 3. Missing data on subscales for parent report are
 326 due to the absence of these subscales in the questionnaire for 1.5-5-year-olds. Based on
 327 CBCL/YSR findings, children and adolescents in our cohort were significantly more likely to
 328 display emotional and behavioural difficulties than those in the general population. Compared to
 329 normative data, the proportion of participants in borderline clinical or clinical ranges was
 330 considerably greater for all subscales (Table 3).

331
 332 **Table 3.** Proportion of participants with T-scores from Child Behavior Checklist (CBCL)/Youth
 333 Self Report (YSR) falling into normal, borderline clinical, and clinical ranges at baseline, as per
 334 parental and youth assessments. Data are n (%).

Assessment	CBCL/YSR subscale	n	Normal ^a	Borderline clinical ^b	Clinical ^c
Parent	Anxious	128	110 (85.9%)*	8 (6.3%)	10 (7.8%)
	Withdrawn	128	92 (71.9%)*	26 (20.3%)	10 (7.8%)
	Somatic complaints	128	98 (76.6%)*	20 (15.6%)	10 (7.8%)

	Social difficulties	100	70 (7.0%)*	20 (20.0%)	10 (10.0%)
	Thought problems	100	80 (80.0%)*	7 (7.0%)	13 (13.0%)
	Attention difficulties	128	110 (85.9%)*	9 (7.0%)	9 (7.0%)
	Rule breaking	100	76 (76.0%)*	16 (16.0%)	8 (8.0%)
	Aggressive	128	102 (79.7%)*	18 (14.1%)	8 (6.3%)
	Internalising	128	68 (53.1%)*	22 (17.2%)	38 (29.7%)
	Externalising	128	72 (56.3%)*	24 (18.8%)	32 (25.0%)
	Total	128	71 (55.5%)*	19 (14.8%)	38 (29.7%)
Youth	Anxious	104	88 (84.6%)*	12 (11.5%)	4 (3.9%)
	Withdrawn	104	79 (76.0%)*	16 (15.4%)	9 (8.7%)
	Somatic complaints	104	79 (76.0%)*	15 (14.4%)	10 (9.7%)
	Social difficulties	104	84 (80.8%)*	11 (10.6%)	9 (8.7%)
	Thought problems	104	93 (89.4%)*	8 (7.7%)	3 (2.9%)
	Attention difficulties	104	81 (77.9%)*	15 (14.4%)	8 (7.7%)
	Rule breaking	104	86 (82.7%)*	16 (15.4%)	2 (1.9%)
	Aggressive	104	91 (87.5%)*	7 (6.7%)	6 (5.8%)
	Internalising	104	62 (59.6%)*	15 (14.4%)	27 (26.0%)
	Externalising	104	76 (73.1%)*	10 (9.6%)	18 (17.3%)
	Total	104	60 (57.7%)*	17 (16.4%)	27 (26.0%)

335 *Note.* ^a< 65 which is below 93rd centile

336 ^b65-70 which is 93-98th centile (apart from internalising/externalising/total 60-63)

337 ^c>70 which is 98th centile (apart from internalising/externalising/total >63)

338 ***p<0.001 for comparison with normative data (i.e. expected ≤7% of participants in borderline clinical or clinical
339 ranges combined)

341 Exploratory analyses showed a higher probability of behavioural and emotional problems (as per
342 CBCL/YSR total scores) in those who experienced breathing pauses (RR 1.52 [95% CI 1.13–

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3 343 2.04]) or displayed developmental problems (RR 1.59 [95% CI 1.11–2.27]). Multivariable
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5 344 analyses showed that older age at assessment was associated with higher CBCL/YSR total scores
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7 345 (i.e. worse scores) ($\beta=0.89$; $p=0.011$), while males were more likely to display behavioural and
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9 346 emotional problems than females (RR 1.43 [95% CI 1.06–1.94]).
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14 15 348 **Ethnic comparisons**

16
17 349 There were no differences between Māori and New Zealand European participants with obesity
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19 350 with respect to the child's reported overall PedsQL scores ($p=0.09$) or PedsQL psychosocial
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21 351 ($p=0.14$) scores, but Māori children reported higher PedsQL physical scores (80.1 versus 74.7,
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23 352 respectively, $p=0.019$). With respect to parental report, there were no ethnic differences in total
24
25 353 quality of life ($p=0.81$), psychosocial ($p=0.76$), or physical ($p=0.53$) scores. There were no
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27 354 differences between Māori and New Zealand European participants on CBCL/YSR total
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29 355 ($p=0.25$), internalising ($p=0.12$), or externalising ($p=0.71$) scores.
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34 356 35 36 357 **DISCUSSION**

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41 359 The main findings of this study were that children and adolescents with obesity in this region of
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43 360 New Zealand had lower HRQOL on parent report measures when compared with those with a
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45 361 chronic condition (i.e. diabetes that requires daily testing and treatment), and other samples with
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47 362 and without obesity. In addition, a large proportion (43.5%) obtained CBCL/YSR scores in the
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49 363 clinical and borderline range for experiencing psychological problems. The parent report quality
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51 364 of life scores were not dissimilar to those described in children with obesity attending a specialist
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53 365 clinic, and were similar to children and adolescents diagnosed with cancer.¹⁵ The degree to
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3 366 which HRQOL appeared to be affected in our cohort was not surprising, given that treatment-
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5 367 seeking parents of children with obesity are more likely to perceive their child as having a poorer
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8 368 HRQOL and more psychological difficulties when compared with parents of children with
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10 369 obesity in the community not seeking treatment.^{5,34} Our cohort consisted of participants referred
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12 370 to an obesity intervention programme, so were not a true community-based sample. Nor were
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14 371 they directly comparable to a hospital outpatient clinic population given that Whānau Pakari was
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16 372 specifically designed to address barriers to access which exist for hospital-based outpatient
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18 373 clinical care, particularly for indigenous children.²² Allowing for this not being a complete non-
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20 374 referred sample, the difference in HRQOL scores in our cohort compared with a large population
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22 375 based study (n=10,241) of predominantly normal weight children aged 2-16 years (mean score
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24 376 65.4 vs. 81.3) is considerable.³⁵
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29 378 Differences between parent-proxy and child self-report on PedsQL questionnaires have been
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31 379 previously reported. A systematic review of the relationship between parents and children's
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33 380 HRQOL scores found better agreement among parents and chronically sick children than
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35 381 between parents and their healthy children.³⁶ It was argued that both parent and child reports
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37 382 should be obtained as they provide different perspectives. A further review noted differences in
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39 383 parent-child agreement in HRQOL across four different instruments.³⁷ The authors suggested
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41 384 that the disagreement was a consequence of varying individual beliefs about the child's health
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43 385 and well-being, rather than parent or child reports being wrong or right.³⁷ A Norwegian study
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45 386 reviewed this in relation to children and adolescents seeking treatment for obesity versus a
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47 387 community sample of children of any BMI.³⁴ Parents reported the quality of life of the children
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49 388 with obesity seeking treatment as lower than those in the community, which was not seen with
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3 389 the child self-report.³⁴ Pooled analyses however showed that paediatric HRQOL can be
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5 390 accurately predicted from parent proxy reports with moderate to strong linear relationships
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8 391 between the two methods of report.⁵
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12 393 We observed that psychological difficulties were prevalent in our cohort. Our participants aged
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14 394 11 to 18 years reported a mean total YSR score of 55.9 (SD=10.6), which is similar to a small
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16 395 non-clinical group of adolescents with obesity from Turkey (n=30) with a total problem score of
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18 396 58.2 (SD=7.7).¹⁹ We have no national data for comparison with CBCL/YSR, but there is nothing
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20 397 to suggest that scores in the Taranaki region would be higher than those nationally, and there is
21
22 398 no known biological or environmental reason for this cohort to have higher rates of mental health
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24 399 problems outside of their obesity. The absence of Paediatric psychology services are a notable
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26 400 issue in the region (child and adolescent mental health services are available), and it is unclear if
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28 401 this may contribute to these findings. The randomised clinical trial we are undertaking will be
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30 402 able to assess if the intervention can address the relationships between these variables over time.
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37 404 Obesity in childhood is a major health concern in New Zealand, with the third highest prevalence
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39 405 of overweight and obesity in the OECD (Organisation for Economic Co-operation and
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41 406 Development).³⁸ Recent studies in this cohort of children and adolescents with obesity have
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43 407 found suboptimal eating behaviour,³⁹ suboptimal physical activity,⁴⁰ and a high prevalence of
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45 408 weight-related comorbidities, including hypertension and obstructive sleep apnoea.³³ We were
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47 409 not surprised that breathing pauses were associated with poorer HRQOL and higher total scores
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49 410 on the CBCL/YSR. Breathing pauses in children and adolescents with obesity are associated
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51 411 with obstructive sleep apnoea,⁴¹ and children and adolescents with obesity with this condition
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3 412 have reported lower HRQOL total scores than peers with obesity without the condition.¹⁵
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5 413 Moderate to severe obstructive sleep apnoea is associated with increased rates of aggressive
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7 414 behaviour, attention problems, and internalising problems on the CBCL.⁴² These observations
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9 415 are important, given the considerable prevalence of breathing pauses reported in this cohort with
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11 416 obesity,³³ and the wider impact of obstructive sleep apnoea on a child's health, cognitive and
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13 417 behavioural functioning.⁴³
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20 419 Strengths of this study are that it is the first to report HRQOL in children and adolescents with
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22 420 obesity in the New Zealand population. Due to the high participation rate from Māori, we were
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24 421 also able to undertake evaluation of the impact of ethnicity. What was interesting and important
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26 422 about our findings in terms of ethnicity was the lack of disparity in HRQOL scores. This was
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28 423 despite a larger proportion of Māori participants being from the most deprived quintile of
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30 424 households. It therefore appears that obesity itself rather than factors such as deprivation is the
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32 425 main identified factor in our participants contributing to lower HRQOL scores. This finding is in
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34 426 contrast to previous research in Fiji and Kuwait, where there was no meaningful negative
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36 427 association between increased weight and HRQOL in children aged 12-18 in Fiji, irrespective of
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38 428 ethnicity, or Kuwaiti nationals, aged 10-14 years old.^{7,8} The discrepancies in results may be
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40 429 explained by this study reviewing a treatment-seeking group, rather than population-based
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42 430 sample, and the different cultural values assigned to body size in Fiji and Kuwait compared with
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44 431 New Zealand (a westernised society).
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53 433 A limitation of this study, as with all HRQOL assessments, is the use of an assessment tool to
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55 434 extrapolate one's psychological health and well-being. Comparisons of our study have been
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3 435 made with population groups of varying age ranges, which may have affected results. Another
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5 436 limitation of this study is that this was a referred cohort, which means our findings are not
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8 437 necessarily representative of the general population. We compared our data with the Health of
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10 438 Young Victorians cohort from Australia, as this was the most comparable group we had access
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13 439 to. However, the data were collected in 2000, and the differences noted may have been impacted
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15 440 by the difference in dates of data collection. Mean BMI SDS for the Victorian cohort with
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17 441 obesity was not available, which would be important if it was considerably lower than the
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20 442 Whānau Pakari participants. Lastly, we made no adjustments for multiple comparisons in our
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22 443 statistical analyses, so that the findings (particularly from exploratory analyses) need to be
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24 444 interpreted accordingly.
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29 446 In conclusion, this study highlights a lower HRQOL and a higher prevalence of psychological
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31 447 difficulties for this referred community-based group of children and adolescents with obesity
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33
34 448 compared with normative population data. No differences were found between Māori and New
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36 449 Zealand Europeans. This is despite Māori being represented in greater numbers in the more
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39 450 deprived households of the region compared with their non-Māori counterparts, suggesting that
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41 451 obesity itself rather than deprivation is the main contributor to lower HRQOL scores. This study
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43 452 highlights the importance of psychologist involvement and screening in the child and adolescent
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46 453 population with obesity as part of any multi-disciplinary team. Improvement in HRQOL should
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48 454 be considered a goal of all child and adolescent obesity intervention and management. Further
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50 455 research is required to ascertain how to maximise improvements in what is now recognised as an
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53 456 important health outcome.
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4

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27
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34 471 **Competing interests**
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39
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41
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45
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47
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55 480 **Contributorship statement**
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3 481 YCA designed the study, was involved with data interpretation, and drafted this manuscript.
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6 482 LEW recruited participants, and undertook assessments and data entry. KFT provided
7
8 483 psychologist oversight and analysis of patient data. CCG is secondary supervisor for the research
9
10 484 team, and assisted with the interpretation of the study. JMS was involved in study design. TLC
11
12 485 assisted with data entry and analysis. TAW was involved in interpretation of data. JGBD
13
14 486 analysed the data and drafted the manuscript. WSC contributed to study design. PLH contributed
15
16 487 to study design and supervises the research team. All authors critically revised the manuscript,
17
18 488 gave final approval for the version to be published, and are accountable for all aspects of the
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20 489 work.
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27 491 **Data sharing statement**

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29 492 Data cannot be made available in a public repository due to the strict conditions of the ethics
30
31 493 approval of this study. Nonetheless, anonymised and de-identified data will be made available to
32
33 494 other investigators upon request. Interested readers should contact the senior author Prof Paul
34
35 495 Hofman (p.hofman@auckland.ac.nz) to obtain the data.
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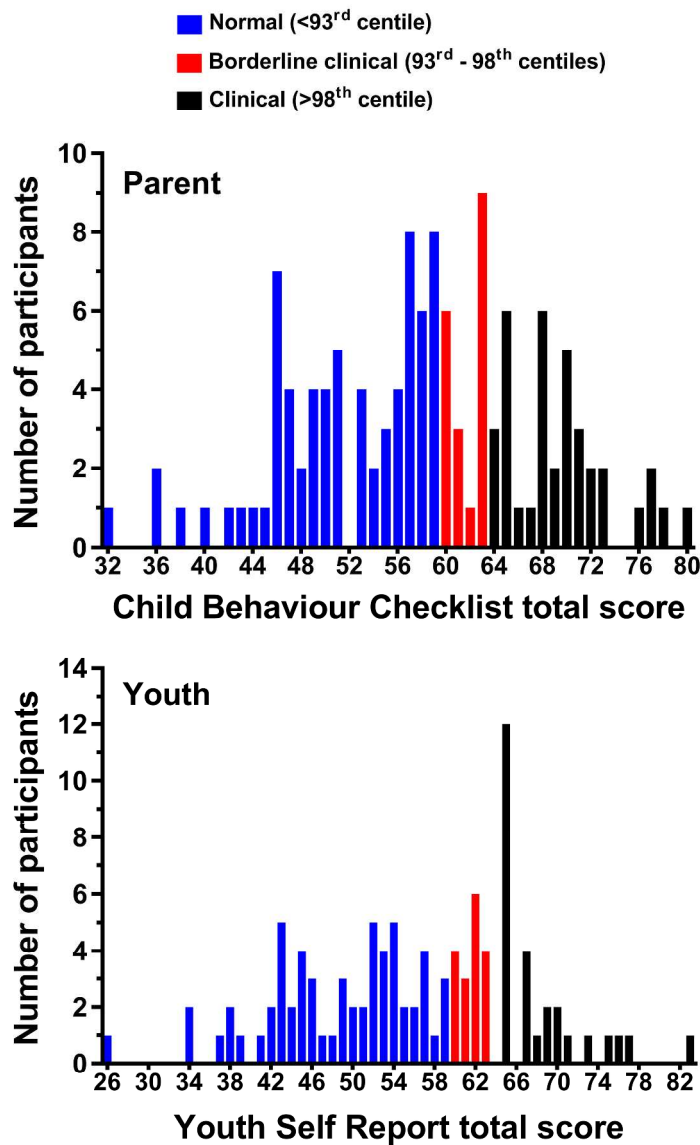


Figure 1. The frequency distribution of participants according to the Child Behaviour Checklist (CBCL) and Youth Self Report (YSR) total scores.

268x387mm (300 x 300 DPI)

STUDY PROTOCOL

Open Access



The effect of a multi-disciplinary obesity intervention compared to usual practice in those ready to make lifestyle changes: design and rationale of Whanau Pakari

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Abstract

Background: Child obesity internationally has been identified as one of the major threats to future population health. Indigenous people and those from lower socio-economic backgrounds are over-represented in obesity statistics. There is a need for evidence of effect of interventions for child obesity with long-term follow-up. Whether engaging with those that are more motivated to make lifestyle changes is a useful strategy has not been fully explored. We hypothesise that in obese/overweight children, assessed as psychologically “ready for change”, delivery of a 12-month multi-disciplinary intervention programme results in a significant reduction in body mass index standard deviation score.

Methods/Design: Whanau Pakari is an unblinded randomised controlled clinical trial comparing a 12 month intervention programme with standard practice, with 6 monthly assessments for 2 years, conducted in Taranaki, New Zealand (a region where 15.8 % of the population are indigenous). It specifically targets indigenous people and those in more deprived households.

Obese/overweight children and adolescents aged 5–16 years are eligible. Exclusion criteria are medical/psychological conditions leading to inability to undertake physical activity/participate in group sessions; those not “ready” to make lifestyle changes; and those without a committed family member.

Assessments of health parameters, dietary history, physical activity and overall health-related quality of life/psychological functioning are completed in the participant’s home. Fasting blood tests are obtained at baseline, 12 and 24 months. The primary outcome is body mass index standard deviation score. Secondary outcomes include quality of life, dietary behaviour and physical activity, cardiovascular and metabolic profile (blood pressure, resting heart rate, waist circumference), glycaemic control (fasting glucose and glycated Haemoglobin), fasting insulin, and lipids.

A general linear mixed model will be used to assess change from baseline using the 6, 12, 18 and 24 month measures, adjusting for age, gender, socioeconomic status and ethnicity, and whether at the contemplative or preparation/action stages of readiness for change.

Discussion: This trial will inform the development of management programmes for obese children and adolescents that are appropriate for indigenous populations. It will investigate whether those at the preparation/action stage of “readiness” to make lifestyle changes are more successful in making changes than those who are contemplative.

(Continued on next page)

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Trial registration: Australian New Zealand Clinical Trials Registry (ANZCTR):12611000862943. (Date registered 15/08/2011).

Keywords: Pediatric, Obesity, Research methods, Indigenous people, Whanau Pakari, Intervention studies, Randomised controlled trials, Nutrition, Physical activity, Body mass index

Background

Childhood obesity causes substantial morbidity, mortality and health cost [1, 2]. The rapid increases in the proportion of the population that are overweight and obese are now apparent in children as well as adults in both developed and developing countries [1, 3]. New Zealand has not avoided the global obesity epidemic, with the country now being ranked fourth in the Organisation for Economic Cooperation and Development (OECD) rankings for overweight and obesity (65 % of the population over 15 years are classed as either overweight or obese) [4]. The Health of New Zealand Children Survey 2013/2014 reported 10 % of children aged 5–14 years are obese, up from 8 % in 2006/2007 [5]. Rates of obesity are higher for Maori – New Zealand's Indigenous population (15 %), Pacific Island children (25 %), and children living in the most deprived quintile of households (18 %) [5].

Few children and adolescents struggling with weight issues have access to intervention programmes. In New Zealand, most overweight or obese children and adolescents coming to the attention of medical professionals are either managed by a general practitioner or general paediatrician with minimal intervention programmes being available nationally [6]. No national cohesive approach for managing childhood obesity exists, despite national clinical guidelines being available since 2009 [7]. A recent multi-centre audit showed that, irrespective of type of intervention, a small but significant reduction in BMI SDS was achievable (–0.15 overall), highlighting the importance of health professionals being proactive in identifying and addressing child obesity [8]. However, even when obesity is identified, intervention is infrequently implemented. In Australia, general practitioners were recently shown to provide weight management for <2 % of overweight and obese children attending primary care services [9], and paediatricians reported lacking confidence in the management of obesity in children, with only 37 % reporting training in the management of obesity-related comorbidities [10]. This is also likely to be the situation in New Zealand, although to date, similar surveys remain unpublished.

Past meta-analyses have supported multi-disciplinary intervention programmes for addressing child and adolescent obesity, as they are deemed as having the greatest chance of success [11, 12]. New Zealand's Ministry of Health guidelines support an approach of working with

family to address food habits, increase physical activity and to promote behavioural change [7]. Evolution of the current trial came from these recommendations, findings from an audit of an existing physical activity/nutrition programme [6] and recognition of the need to address accessibility for those most affected by obesity. A trial was deemed necessary to ensure future decision-making with regard to child and adolescent obesity was informed by the most reliable evidence possible. The trial has been designed with consideration of the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement [13].

It was clear in the pre-existing regional programme that the lack of a measure for assessing a participant's psychological "readiness" to make lifestyle changes was affecting interpretation of the outcomes of the programme overall [6]. Whilst most clinical practitioners assess readiness to make lifestyle changes in their patients on a daily basis, this is a poorly defined process. Historically, readiness for change (RFC) has been utilised qualitatively in some obesity services. It is a concept that has developed from the transtheoretical model defining stages of behavioural change around addiction [14]. When deciding to undertake behavioural change, an individual moves through defined stages at different rates and not always in a linear fashion (Table 1). However, an individual's readiness to change may be behaviour-specific, so it is unclear whether a participant's "readiness" may equate to global changes related to improving lifestyle. In the original readiness for change questionnaire directed towards excessive alcohol use, this was somewhat mitigated by the use of multiple descriptive statements across pre-contemplation, contemplation and action [15].

The transtheoretical model has been used to assess individual's motivation for smoking cessation [16], and various tools for readiness for change have been trialled in the obesity setting [17, 18]. The utility of readiness for change remains unclear as it relates to obesity services, and it is too simplistic to expect that every individual would move through these stages in a similar fashion. However, previous studies have highlighted the importance of tailoring interventions to the individual stage of change rather than treating all participants as if they are in preparation or action stages [17]. If there were a quantitative tool that could predict likelihood of success at initial assessment, this would potentially focus health resource where it was most likely to make a difference. Given the complexity

Table 1 Theoretical model of stages of readiness for change [14]

Stage	Description
Pre-contemplation	"I do not have a problem"
Contemplation	"I may have a problem"
Preparation	"I may have a problem and need to do something"
Action	"I will try these changes"
Maintenance	"The changes I have made are now part of what I do"

of behaviour change as it relates to obesity, the original readiness for change questionnaire [15] would require modification and expansion to include questions regarding eating behaviour, attitude towards weight and physical activity behaviour. Confidence to make changes in physical activity and eating behaviour would also need to be considered.

The question remains as to whether an individual's readiness in the "snapshot" situation of an assessment translates to ongoing motivation to make lifestyle changes over time. In the domain of child and adolescent obesity, parental readiness is a vital factor in a child or adolescent's success in making and maintaining lifestyle changes. If a parent believes their child's weight is a problem, or that they as parents are overweight, they are more likely to be ready to make lifestyle changes for their child [18].

"Whanau Pakari" means "healthy self-assured families that are fully active" in Maori, and was the name gifted to the trial by a prominent Maori community representative. The trial assesses a new mainstream clinical service delivered in an innovative way in order to improve access for Maori, and those from lower socioeconomic backgrounds. Previous child obesity services in the region involved the traditional model of medical referral to a Paediatrician, sometimes with the addition of dietitian input, and physical activity programme input. The physical activity programme, run in the community through the regional sports trust with a maximum number of participants per year, did not specifically target high-risk groups, and was not region-wide [6]. The new programme removes the "hospital visit", but participants continue to receive support and oversight from a Paediatrician. This multi-disciplinary programme incorporates three novel approaches:

1. It provides a trained roving community coordinator to meet families in their homes, enabling improved access to the clinical service, especially for Maori.
2. It assesses "readiness for change" both quantitatively and qualitatively.
3. It provides follow up to 12 months post intervention to assess persistence of lifestyle changes, which is longer than any other multi-disciplinary obesity intervention model trialled in New Zealand.

There is a clear need for evidence-based interventions for child obesity that demonstrate on-going effectiveness [11]. Whether engaging with those that are more motivated to make lifestyle changes is a strategy that warrants further exploration. Our objectives are firstly, to undertake a multi-disciplinary intervention, which is accessible and appropriate for those most affected by child obesity. Secondly, we aim to assess whether a quantitative RFC questionnaire is useful in predicting response to the intervention. We hypothesise that in obese/overweight children, assessed as psychologically "ready for change", delivery of a 12-month multi-disciplinary intervention programme results in a significant reduction in body mass index standard deviation score at 12 months.

Methods/Design

Whanau Pakari is an unblinded randomised controlled clinical trial being conducted in Taranaki, New Zealand (population 23,139 children aged 0–15 years, of which 28 % are Maori) [19]. Ethical approval was granted by the Health and Disability Ethics Committee (Ministry of Health, New Zealand; CEN/11/09/054), and the trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR: 12611000862943). Locality approval has been obtained from Sport Taranaki, and the Taranaki District Health Board.

Participants

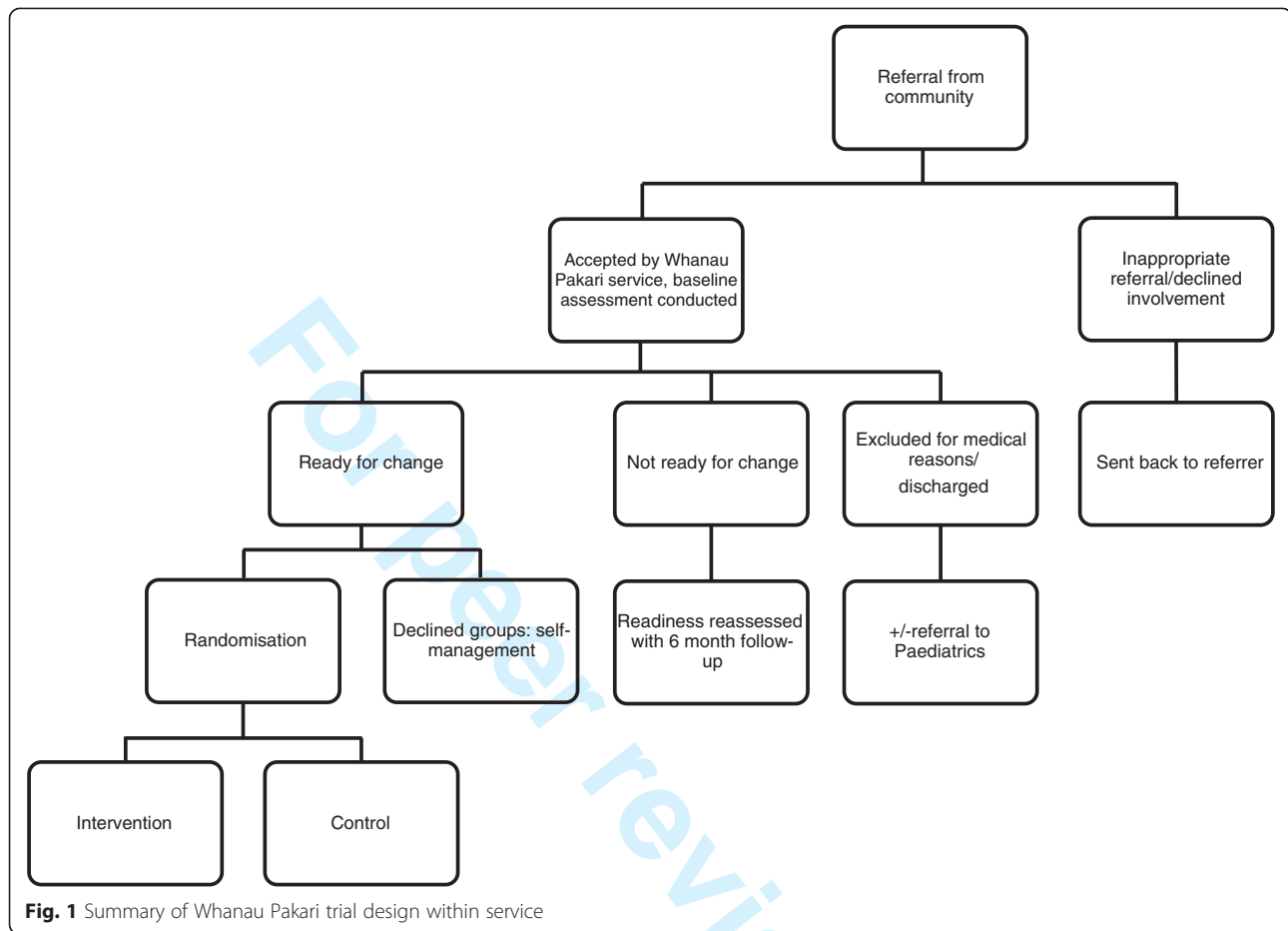
Children from the Taranaki region aged 5–16 years, with a body mass index (BMI) \geq 98th centile, or those $>$ 91st centile with weight related comorbidities will be offered participation in the trial if referred to "Whanau Pakari". These cut-offs are a modification of UK Cole data, and have been chosen as they are nationally accepted for use by the Ministry of Health for defining obesity and overweight respectively in the community for 0–5 years [20, 21]. (There are no nationally accepted growth charts or official cut-offs in use for $>$ 5 year old children currently.)

Exclusion criteria will be significant medical or psychological conditions leading to inability to undertake physical activity or participate in group sessions; those not "ready" to make lifestyle changes; and those without a committed family member (essential to support the family-based approach of the programme).

To optimise accessibility, referrals will be accepted from all health professionals within the community, including public health nurses in schools, and Maori health workers. Self-referrals will also be accepted (Fig. 1).

Recruitment

Recruitment for the trial will be through the service, which is being advertised across Taranaki through multiple channels, including referrer training half-days (training sessions about the service, and how to have conversations about



weight with families), meetings (hui) with all stakeholders, general practice visits, school visits, media releases, pamphlet drops at public places and events, and the Public Health Unit of Taranaki District Health Board.

Whilst the trial will assess a “mainstream” clinical service, the aim is to target Maori and the most deprived in the community. To achieve this aim we will use identified facilitators that enable Indigenous people’s participation such as relationship and partnership building, involvement of Indigenous staff, the use of Indigenous knowledge models (such as He Korowai Oranga: the Maori Health strategy and the Whanau Ora [healthy families] tool) [22, 23], targeted recruitment techniques (such as working with Maori health workers within the community to engage with families) and adapting study material [24].

All children referred will be seen in the family (whanau) home by the Healthy Lifestyles Coordinator (a health professional trained in focussed weight-related assessment, supported by a Paediatrician). This design aspect allows the trial to run as a community-based service yet with a full clinical component to it. Removal of a hospital-based appointment with a specialist was designed to enable access to the service for larger numbers and minority groups,

and to avoid “medicalisation” of the process. Given the service is targeting Maori and those from lower socio-economic areas, ensuring accessibility and appropriateness are crucial to the study design, without compromising clinical care.

Conception and consultation

The multi-disciplinary intervention model was developed after consideration of the national guidelines for implementation of weight management programmes, and the recommendations from the international systematic reviews and meta-analyses [7, 11, 12]. Longer-term follow-up was deemed imperative to determine whether lifestyle changes persisted over time, which has been a deficit of many previous studies. Conceptually, a multi-disciplinary intervention that incorporated dietary, physical and psychological support was considered important, with 12 months the optimal length of intervention. It was necessary for the intervention to be community-based with a strong focus on accessibility to Maori, and those from lower socio-economic areas.

Guidance was sought in the inception stages from the Maori Health Unit of Taranaki District Health Board, who advised appropriate linkages with the community,

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5 identifying the key Maori stakeholders from Maori Health
6 Centres in the region, and tribal representatives. Maori
7 were instrumental in the initial set-up phase, applying a
8 Maori lens to service delivery and curriculum development,
9 and were on the interview panel for all staff members. It
10 was imperative to the researchers that the consultation
11 undertaken helped to:

- 12 1) Build appropriate and positive relationships around
13 the region, particularly in South Taranaki, which has
14 a proportionally larger population of Maori.
- 15 2) Ensure acceptability of the intended research by using
16 a community-based approach.
- 17 3) Provide an opportunity for input and contribution
18 from community stakeholders during the
19 consultation process.
20
21

22 This process ensured that potential barriers for engage-
23 ment for Maori and the most deprived in the community
24 such as lack of access, unfamiliarity with research, distrust
25 and problems with the research material were addressed
26 [24]. The consultation process is ongoing.
27

28 Assessments

29 Assessments will be completed at six monthly intervals
30 for 2 years from enrolment. Information will be gathered
31 regarding ethnicity, past medical history, medical condi-
32 tions and family history. Written informed consent will
33 be obtained to take part in the trial and to share col-
34 lected information between Sport Taranaki (the regional
35 sports trust) and the Health Board. This will be from the
36 participant if age-appropriate, or where the participants
37 are children, a parent/guardian. Table 2 shows the key
38 elements of the assessments undertaken.
39

40 Calculations

41 BMI, BMI percentile and BMI standard deviation score
42 (SDS) will be calculated using UK Cole normative data
43 [25] on the uploadable KIGS auxology software (Pfizer
44 Endocrine Care TM). Height percentile will be calculated
45 using gender specific growth charts for 2–18 years recom-
46 mended by the Australasian Paediatric Endocrine Group
47 for Australian and New Zealand use [26], based on Cen-
48 ters for Disease Control stature for age and weight for age
49 data [27]. To improve accuracy, BP SDS will be calculated
50 using an age-based paediatric blood pressure reference
51 chart calculator based on data from The Fourth Report
52 [28, 29]. BP SDS will then be converted to percentiles.
53 Peak flow percentile will be calculated based on reference
54 New Zealand peak expiratory flow rates [30]. Waist hip ra-
55 tio, and waist height ratio (WHtR) will be calculated.
56 Participants will be deemed pubertal if they are female
57 with breast development \geq B2 or male with pubic hair de-
58 velopment \geq P3 on Tanner pubertal staging [31]. Level
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of household deprivation will be calculated based on
the New Zealand Deprivation Index 2006 [32].

Questionnaires

One aim of this trial is to determine whether there is an
association between reported degree of “readiness” to
make lifestyle changes at baseline assessment, and im-
provements in lifestyle, including BMI SDS. Readiness
for lifestyle change will be based on the transtheoretical
model of stages of change [16], and will be established with
two questionnaires (parent and child/adolescent) and the
best judgement of the Healthy Lifestyles Coordinator at the
end of the baseline assessments. Both questionnaires will
be based on the 12-item Readiness to Change Question-
naire [15] and will use a 5-point Likert scale to assess the
parent’s and child/adolescent’s beliefs, attitudes and behav-
iour about weight, eating behaviour and physical activity.
Given the complexity of obesity, the questionnaires will be
expanded. The child questionnaire will have 21-items and
will be used for children 11 years and older, and a 27-item
parent questionnaire, including 6 questions regarding
family attitudes/behaviour, will be administered to parents.
Whilst self-efficacy/confidence to make changes are not
extensively measured, confidence in making changes in
physical activity and eating behaviour has been included in
both quantitative questionnaires.

Qualitative assessments of readiness for change will be
made by the Healthy Lifestyles Coordinator at the end of
the assessment. This will be the Coordinator’s overall
subjective opinion as a health professional of stage of
change in both the committed family member and child
(if >11 years of age), based on the assessment. A qualita-
tive stage of change will be included as this is what is
undertaken in current clinical practice, and provides a
comparator for the quantitative tool. The quantitative
assessment will be scored at point of data entry by the
Healthy Lifestyles Coordinator. Cronbach’s alpha will be
used to establish the reliability of our readiness for change
lifestyle questionnaire. Confirmatory factor analysis will be
used to examine convergent and discriminant validity.
The questionnaire was tested for understanding and com-
prehension in a randomly selected cohort of clinic patients
prior to trial commencement.

Questionnaires that will be administered to the child/
adolescent or parent include the Paediatric Quality of Life
Inventory (PedsQL)[™] – a measurement model designed to
evaluate health-related quality of life in children and ado-
lescents that has been extensively validated [33–38], the
Achenbach Child Behavior Checklist (CBCL) (Child Behav-
ior Checklist for Ages 1½-5: 7–28-00 Edition-601, Child
Behavior Checklist for Ages 6–18: 6-1-01, Edition-201,
Youth Self-report for Ages 11–18: 6-1-01 Edition-501)
[39], children’s physical activity questionnaire (C-PAQ)
[40], modified children’s dietary questionnaire for New

Table 2 Assessment information for all participants

Key assessments	Baseline	6 months	12 months	18 months	24 months
Resting heart rate	✓	✓	✓	✓	✓
Blood pressure ^a	✓	✓	✓	✓	✓
Height ^b	✓	✓	✓	✓	✓
Weight ^c	✓	✓	✓	✓	✓
Waist circumference ^d	✓	✓	✓	✓	✓
Hip circumference ^e	✓	✓	✓	✓	✓
Peak flow ^f	✓	✓	✓	✓	✓
Acanthosis nigricans screen	✓	✓	✓	✓	✓
Ear, nose and throat examination ^g	✓	✓	✓	✓	✓
Self report of Tanner pubertal stage ^h	✓	✓	✓	✓	✓
Accompanying adult's height and weight	✓		✓		✓
Questionnaires ⁱ	✓	✓	✓	✓	✓
Blood sampling ^j	✓		✓		✓

Technical/procedural information: ^ausing Welch Allyn portable sphygmomanometer with flexiport reusable blood pressure cuffs of appropriate size, ^bto 0.1 cm using average of three readings on Seca 213 portable stadiometer, ^cto 0.1 kg using Seca 813 digital scales, ^dSeca 201 standard measuring tape (at mid-point between the lower margins of the rib and the top of the iliac crest to 0.1 cm at end of normal expiration) [52], ^ewidest girth, ^fusing Mini Wright peak flow meter, ^gusing Welch Allyn portable auroscope, ^hor from parent in very young children [31], ⁱapart from RFC questionnaire (only performed at baseline), ^jfasting insulin, fasting glucose, liver function tests, C-reactive protein, glycated Haemoglobin (HbA1c), and fasting lipids

Zealand use (CDQ) [41], 24 h food recall, knowledge of healthy lifestyles questionnaire (modified from the 2008 Nutrition Survey) [42], and our RFC questionnaire. Any participant deemed not ready for change will be reassessed every six months.

Assessment of physical fitness

Physical fitness assessments include the 550 m walk/run [43], and 5 days of ActiGraph wGT3X-BT (Actigraph, Pensacola, Florida, USA) accelerometer wear will be requested (3 weekdays and 2 weekend days), giving an estimated reliability of 0.80 in children and 0.70 in adolescents [44]. These levels of reliability have been questioned in more recent studies [45], however longer wear time is not practical due to resource. Epoch time will be set to 60 s and cut-off time 60 min.

Metabolic markers

Venous blood sampling will be undertaken to assess for metabolic status (Table 2). These biomarkers identify the biochemical comorbidities associated with obesity [46, 47]. Incentivisation for these samples will be provided.

Comorbidities

Weight-related comorbidities will be screened for and referrals will be made where appropriate.

Study arms

Every child entering Whanau Pakari will be discussed at the multi-disciplinary team meeting, allowing a full clinical review and referrals for further investigation where

appropriate, with additional discussion of dietary intake, physical activity, and psychology issues. The assessments and multi-disciplinary meetings will be repeated for each child/adolescent every six months, irrespective of which group they are randomised to.

Intervention

The intervention programme will be a 12-month multi-disciplinary programme with weekly group sessions. It will be administered by a physical activity coordinator, community dietitian, and psychologist: all staff members within the Whanau Pakari team. It will involve:

- 1) Home visits with the dietitian and physical activity coordinator in the initial phase
- 2) Weekly contact in activity sessions of either physical activity OR
- 3) Psychology sessions (covering topics such as bullying, self-esteem, parenting, making lifestyle changes), and dietitian sessions (covering topics such as portion size, virtual supermarket tours, healthy food on a budget, and vegetable gardens) (Table 3).

The participants will be engaged in the programme one hour per week for four school terms (equating to a total of 40 sessions). The same programme will be delivered to all participants, however these will be tailored to meet the cultural requirements of participants, for example, sessions that include traditional Maori games, recipe makeover of dishes from different cultures, and honouring of particular dietary requirements in cooking

Table 3 Support provided to each group of trial participants enrolled in Whanau Pakari

	Control (Current "standard care")	Intervention
6, 12, 18, 24 month assessments with nutrition advice and feedback (blood tests at baseline, 12, 24 months)	✓	✓
Home visit within 1 st month from physical activity coordinator and dietitian		✓
Physical activity coordinator/ Dietitian review of progress at 6 months (seen at group)		✓
Questionnaire review (team), multi-disciplinary team meeting – review and action of alerts	✓	✓
+/- Keyworker		✓
Weekly activity and education sessions for 12 months		✓
Total home visits over 2 years	5	6

sessions. A committed family member will be required to attend to support and learn alongside the child/teenager, as the programme is family-focussed. No incentivisation will be provided for attending sessions. A commitment contract will be signed at entry to the programme, outlining expectations of attendance at a minimum of 70 % of sessions to gain the most out of the programme. After 12 months, families will be linked into local sport centres/aquatic centres/gym facilities.

Non-intervention

The non-intervention (control) group will receive the same home-visit model and assessments as the intervention group, but will not undertake any of the intervention sessions (Table 3). The families will receive feedback from the assessments with dietary and physical activity guidelines. This model was chosen for community acceptability and is very similar to what is currently considered 'standard care'. This group are offered the intervention after 24 months. All participants declining intervention and those who have completed intervention and 12 month follow-up will be discharged back to primary care, with a guideline sheet of what to monitor, and assess with regard to weight-related comorbidities. Any participants withdrawing from the trial before the end of the 24 months will be incentivised to participate in a modified assessment to allow measurement of their progress, thus maximising completeness of data for the intention to treat analysis.

Randomisation

At baseline, there will be 2 assessments of RFC (given it is not known if a quantitative tool will be successful): the clinician's subjective measure (ranked pre-contemplation, contemplation, preparation/action), and a specifically

devised questionnaire using a 5-point Likert scale that is completed by the child (if > 11 years of age) and a second one for the parent. The RFC questionnaire was based on the original readiness to change questionnaire [15], focusing on beliefs and behaviour around three factors: weight, eating habits and activity levels. If the RFC ranking is scored in the contemplative or further along on either scale, then participants will be offered entry into the trial. We purposely set the bar low (i.e. below the preparation/action level) to assess whether degree of RFC predicts outcomes within those contemplative or above.

Patients will be assessed, consented, and entered into the trial prior to randomisation. Randomisation by minimisation (using age and ethnicity) will be conducted using the Minim randomisation computer programme which maintains approximate balance in the 2 arms for age and ethnicity but incorporates a random element so it cannot be predicted which study arm the subject will be allocated to.

Primary outcome

The primary outcome measure is the change in BMI SDS in the intervention group compared with the control group recorded at 6, 12, 18 and 24 months post enrolment.

Secondary outcomes

Secondary outcomes include changes in health-related quality of life; dietary knowledge and behaviour; physical activity (specifically moderate to very vigorous physical activity), sedentary behaviour, knowledge of benefits of physical activity, cardiovascular and metabolic profile (blood pressure, resting heart rate, waist circumference and WHtR) all at 6, 12, 18, and 24 months, and glycaemic control (fasting glucose and HbA1c), fasting insulin and lipids at baseline, 12 and 24 months.

Other aims and outcomes

This study also aims to investigate whether those assessed as ready for change (i.e. preparation/action) experience a greater reduction in BMI SDS compared with those less ready for change (i.e. contemplation). If the intervention is found to be effective, a cost-effectiveness analysis will be undertaken, taking into account multiple outcome parameters.

Data collection

The Healthy Lifestyles Coordinator will collect all data (apart from physical activity assessments) in the home assessments.

All data from assessments will be entered into a specific purpose-built database, which will be reviewed monthly for data validity and completeness. This database includes alerts for data outside acceptable medical

parameters, for example, elevated blood pressure percentiles, for discussion at multi-disciplinary meetings.

Progress will be captured on the multi-disciplinary team meeting database page, so the team can review the results of each 6-month assessment for each participant, and make further recommendations or referrals.

Statistical considerations

Sample size

With 107 participants per group (120 to account for a 10 % dropout rate) there is 80 % power to detect a difference in change in BMI of 0.5 SDS at the 5 % level of significance, with a standard deviation of 1.3 [48]. Of note, only 15/54 lifestyle studies included in a systematic review at the time of study design reported power calculations [11]. Subsequent meta-analysis of interventions has shown that even a change of -0.1 BMI SDS can lead to improvements in cardiovascular and metabolic outcomes [12]. It is hoped that even demonstrating smaller differences as this more recent literature has shown will still be important at a population level.

Data analyses

Statistical analyses will be performed using SAS version 9.3 (SAS Institute Inc. Cary NC). A general linear mixed model will be used to assess change from baseline measured at 6, 12, 18 and 24 months after initiating the intervention adjusting for age, gender, socioeconomic status, and ethnicity and degree of readiness for change. Means and standard deviations of changes from baseline in outcomes of interest, for both the raw and modelled data, will be presented.

Baseline characteristics

Baseline characteristics will be summarised using descriptive statistics. Continuous variables will be described as numbers of observed and missing values, mean, standard deviation, median, minimum and maximum. Categorical variables will be described as frequencies and percentages.

Treatment effects

Analyses will be performed on the intended to treat population. Reporting will adhere to the CONSORT guidelines for reporting parallel group randomised trials [13].

Discussion

Whanau Pakari is expected to provide important new knowledge to the area of child obesity. This will be achieved with its focus on an indigenous group at increased risk for obesity and its resulting comorbidities, and through its engagement with the community to increase acceptability of the programme. It is likely to inform these areas in a robust manner if high participation is achieved and maintained.

This randomised controlled trial is unique in three key ways. First, it is assessing a mainstream multi-disciplinary clinical service that has evolved to specifically ensure accessibility and appropriateness for Indigenous people. Whanau Pakari is a community “real life” intervention programme resulting out of a clinical need, and has the potential to answer critical questions in relation to delivery of interventions in this area. Secondly, Whanau Pakari utilises a home-visit model which replaces hospital medical assessments, therefore “de-medicalising” obesity assessments. The family-based home model is likely to appeal to many ethnic groups who resist the hospital-based mainstream clinical models currently operating in most areas. Thirdly, Whanau Pakari will only include those considered potentially ready for change, and will investigate whether the level of “readiness” to make lifestyle changes predicts improved outcomes in intervention programmes. If the RFC measures provide a reliable and valid measure of outcome success, then the development of paired interventions around motivation for change for those in earlier stages of change followed by direct interventions for those in later stages could result in less programme dropout as well as being a more efficient and cost effective utilisation of limited resource.

A limitation of this study is the use of self-report for Tanner pubertal stage. Previous literature has demonstrated that obese girls tend to overestimate breast size and obese males stage of pubic hair development more than their non-obese counterparts [49]. However, we did not believe it was appropriate to undertake pubertal examination within the home setting, and it was determined this would be a more appropriate cut-off for pre-pubertal and pubertal status than an arbitrary age for males and females.

Weight-related comorbidities are a particular concern in child obesity, given the long-lasting effects of these conditions [50]. Past meta-analysis highlighted that a BMI SDS reduction of -0.1 led to significant improvements in multiple cardiovascular and metabolic outcomes over time [12]. BMI, in conjunction with waist circumference, WHtR, fasting lipids, glucose and insulin, and blood pressure (all being measured at intervals over an extended period of follow-up) will provide a comprehensive assessment of cardiovascular and metabolic outcomes long-term.

Whilst there has been a shifting focus toward early obesity intervention targeting critical periods of human development, there is still a need for an effective intervention programme to provide assistance for those children and adolescents who are already obese. This research aligns with the Ministry of Health’s clinical guidelines for weight management in children and young people [7], and addresses barriers to accessing services and programmes identified by the Office of the Auditor General’s performance audit into child obesity [51].

In summary, this trial will determine if this unique multi-disciplinary intervention will result in improved health outcomes, especially among Maori. It will also investigate whether there is an indication that being at the preparation/action stages of RFC compared to those in the contemplative stage results in improved success in intervention programmes. As translational research, it will inform the New Zealand Ministry of Health regarding ways to combat child and adolescent obesity. It is hoped this study will lead to prevention of the adult associated comorbidities of child obesity into later life for some individuals, thereby reducing morbidity, particularly for those most vulnerable in our population.

Abbreviations

ANZCTR: Australian New Zealand Clinical Trials Registry; OECD: Organisation for Economic Cooperation and Development; CONSORT: Consolidated Standards of Reporting Trials; RFC: Readiness for change; BMI: Body mass index; HbA1c: glycated Haemoglobin; SDS: standard deviation score; WHtR: Waist height ratio; Peds QL: Pediatric Quality of Life; CBCL: Child Behaviour Checklist; C-PAQ: Children's Physical Activity Questionnaire; CDQ: Children's Dietary Questionnaire.

Competing interests

Dr Anderson wishes to declare funding from grants as listed in funding section below.

Authors' contributions

YCA designed the study, will coordinate the trial, provide Paediatrician oversight, and drafted the manuscript. LEW will recruit the participants, undertake the assessments and enter the data. GMSD created the readiness for change quantitative assessment tool. KRM will undertake the fitness assessments. TLC is a research assistant and will assist with data entry. CCG is secondary supervisor for the research team. JMS was involved in study design, and will be involved with data analysis. WSC contributed to study design. PLH contributed to study design, and supervises the research team. YCA, CCG, WSC and PLH have been involved in revising the draft critically for important intellectual content. All authors have given final approval of the version to be published.

Authors' information

Not applicable.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Complete?
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	✓(1-2) 'enrolment' indicates baseline measures
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	✓(2-3)
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	✓(4-7)
Objectives	3	State specific objectives, including any prespecified hypotheses	✓(6-7)
Methods			
Study design	4	Present key elements of study design early in the paper	✓(7)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	✓(7)
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	✓(7)
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	N/A descriptive baseline results of an RCT
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	✓(7-11)
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	✓(7-10)
Bias	9	Describe any efforts to address potential sources of bias	✓(10-11)
Study size	10	Explain how the study size was arrived at	Information provided in the published protocol (Anderson et al. BMC Obesity 2015;2:41)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	✓(10-11)
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	✓(10-11)
		(b) Describe any methods used to examine subgroups and interactions	✓(10-11)
	(c) Explain how missing data were addressed	N/A	
	(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	N/A descriptive baseline results of an RCT	
	(e) Describe any sensitivity analyses	N/A	

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	✓ (12)
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	✓ (12)
		(b) Indicate number of participants with missing data for each variable of interest	✓ (15)
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	N/A
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	N/A
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	N/A
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	✓ (12–16)
		(b) Report category boundaries when continuous variables were categorized	✓ (12–16)
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	✓ (12–16)
Discussion			
Key results	18	Summarise key results with reference to study objectives	✓ (17–18)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	✓ (20–21)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	✓ (21)
Generalisability	21	Discuss the generalisability (external validity) of the study results	✓ (20–21)
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	✓ (22)

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Assessment of health-related quality of life and psychological well-being of children and adolescents with obesity enrolled in a New Zealand community-based intervention programme: an observational study

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Primary Subject Heading:	Paediatrics
Secondary Subject Heading:	Nutrition and metabolism, Mental health
Keywords:	PAEDIATRICS, obesity, adolescent, quality of life, lifestyle intervention, Whānau Pakari

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3 1 **Assessment of health-related quality of life and psychological well-being of children and**
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13 5 Yvonne C Anderson,^{1,2} Lisa E Wynter,¹ Katharine F Treves,¹ Cameron C Grant,^{3,4,5} Joanna M
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8 27 **Keywords:** Paediatric, obesity, adolescent, quality of life, lifestyle intervention, Whānau Pakari

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10 28 **Word count:** 4107

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15 30 **ABSTRACT**

16
17 31 **Objective:** To describe health-related quality of life (HRQOL) and psychological well-being of
18 32 children and adolescents at enrolment in a multi-disciplinary community-based obesity
19 33 programme, and to determine association with ethnicity. This programme targeted indigenous
20 34 people and those from most deprived households. Further, this cohort was compared to other
21 35 populations/normative data.

22 36 **Methods:** This study examines baseline demographic data of an unblinded randomised
23 37 controlled clinical trial. Participants (recruited from January 2012-August 2014) resided in
24 38 Taranaki, New Zealand (NZ), and for this study we only included those with a body mass index
25 39 (BMI) $\geq 98^{\text{th}}$ percentile (obese). HRQOL and psychological well-being were assessed using the
26 40 PedsQL 4.0TM (parent and child reports), and the Achenbach's Child Behaviour Checklist
27 41 (CBCL)/Youth Self Report (YSR). The trial was registered with the Australian NZ Clinical
28 42 Trials Registry (ANZCTR: 12611000862943).

29 43 **Results:** Assessments were undertaken for 233 participants (45% Māori, 45% NZ European,
30 44 10% other ethnicities, 52% female, 30% from the most deprived household quintile), mean age
31 45 10.6 years. The mean BMI standard deviation score (SDS) was 3.12 (range 2.01-5.34). Total
32 46 PedsQL generic scaled score (parent) was lower (mean=63.4, SD=14.0) than an age-matched
33 47 group of Australian children without obesity from the Health of Young Victorians study

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3 48 (mean=83.1, SD=12.5). In multivariable models, child and parental generic scaled scores
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5 49 decreased in older children ($\beta=-0.70$ and $p=0.031$, $\beta=-0.64$ and $p=0.047$, respectively).
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8 50 Behavioural difficulties (CBCL/YSR total score) were reported in 43.5% of participants, with the
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10 51 rate of emotional/behavioural difficulties 6 times higher than reported norms ($p<0.001$).
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12 **Conclusions:** In this cohort, children and adolescents with obesity had a low HRQOL, and a
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14 concerning level of psychological difficulties, irrespective of ethnicity. Obesity itself rather than
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17 54 ethnicity or deprivation appeared to contribute to lower HRQOL scores. This study highlights the
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19 55 importance of psychologist involvement in obesity intervention programmes.
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25 **Strengths:**

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27 58 • This study is the first to report HRQOL in children and adolescents with obesity in New
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29 59 Zealand.
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31 60 • To our knowledge, there are very limited data regarding ethnicity and HRQOL. Due to the
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33 61 high participation rate from Māori, we were able to evaluate the impact of ethnicity on HRQOL.
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39 **Limitations:**

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41 64 • Due to the lack of NZ HRQOL data, comparisons have been made with population groups of
42
43 65 varying age ranges, which may have affected results.
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45 66 • The study participants were a referred cohort, which means our findings are not
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47 67 representative of the general population. The data from the Victorian cohort were collected in
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49 68 2000, and the differences noted may have been impacted by the difference in dates of data
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51 69 collection.
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3 70 • Mean BMI SDS for the Victorian cohort identified as obese was not available, which would
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6 71 be important if it was considerably lower than the Whānau Pakari participants.

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8 72 • There were no adjustments for multiple comparisons in our statistical analyses; due to the
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11 73 inflated likelihood of Type I errors, our findings (particularly from exploratory analyses) need to
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13 74 be interpreted accordingly.

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17 76 INTRODUCTION

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22 78 Obesity in childhood and adolescence is known to be associated with weight-related
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24 79 comorbidities.¹ Indigenous populations often have higher rates of obesity compared with non-
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27 80 indigenous counterparts where this information has been collated.^{2,3} In New Zealand,
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29 81 approximately 11% of New Zealand children aged two to fourteen years are classed as obese,
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31 82 with Māori (New Zealand's indigenous population) being 1.6 times more likely to be in the
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34 83 obese range compared with non-Māori counterparts.³ In addition, children living in households
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36 84 in the most socioeconomically deprived quintile for New Zealand are five times more likely to
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38 85 be in the obese range than children living in the least deprived areas.³ In the United States,
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40 86 whilst rates of children with obesity are not readily available for American Indian populations,
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43 87 rates of Type 2 diabetes mellitus (a known weight-related comorbidity) are higher.²

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48 89 Globally, indigenous populations that have experienced historical trauma secondary to
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50 90 colonisation, are over-represented in socioeconomic household deprivation, and both experience
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53 91 the resultant health disparities.² The social determinants of health, such as poverty, limited
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55 92 educational attainment, and critically the loss of a traditional diet all contribute to the impact on
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3 93 these population groups in terms of health and well-being.² Overweight and obesity in
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5 94 adolescence have been shown to be strongly associated with medical complications, including an
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8 95 increase in cardiovascular mortality in adulthood.⁴ Emerging evidence suggests that obesity also
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10 96 affects the emotional health and well-being of children and adolescents, commonly referred to as
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12 97 health-related quality of life (HRQOL).⁵ However, little is known about the HRQOL of
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14 98 indigenous children and adolescents, especially as it pertains to weight. Previous research has
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16 99 found that Sami (the indigenous people of Sweden) children experience lower HRQOL in some
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18 100 domains compared with Swedish children in general.⁶ In relation to HRQOL as it pertains to
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20 101 weight, and the impact of ethnicity, it is acknowledged that information about the relationship
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22 102 between HRQOL and weight may not have transferability from one cultural context to another,
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24 103 given differing perceptions of body image cross-culturally.^{7,8}
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31 104
32 105 Quality of life is a broad construct that encompasses various aspects pertaining to health and
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34 106 well-being.⁹ The assessment of HRQOL is increasingly recognised as a necessary component of
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36 107 health and well-being evaluation, assessing physical, emotional, and social health dimensions.^{10,}
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38 108 ¹¹ Measurement of HRQOL has been shown to have utility in paediatric healthcare settings
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40 109 encompassing numerous chronic health conditions¹²⁻¹⁴ and in the assessment of health in young
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42 110 adults.⁹
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48 112 Obesity during childhood is associated with impaired HRQOL. In one United States (US) study,
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50 113 106 children and adolescents with severe obesity attending an obesity clinic reported
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52 114 significantly lower HRQOL than 401 healthy weight comparison children recruited through
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54 115 private practice paediatrician offices and health clinics, and similar HRQOL to 106 children and
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3 116 adolescents undergoing chemotherapy for cancer.¹⁵ The HRQOL of 9 to 12-year-old children
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5 117 enrolled in an Australian community-based longitudinal study was significantly lower among
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8 118 those with obesity versus those without obesity, with the differences not as marked as in the US
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10 119 study, but more likely to represent those of children with obesity not being seen in a specialised
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12 120 clinic setting.¹⁶ Pooled results from 22 cross-sectional and population-based studies report that
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14 121 children and adolescents with obesity have reduced overall HRQOL compared with normal
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16 122 weight counterparts, with 12 of these studies demonstrating an inverse relationship between
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18 123 overall HRQOL and weight status.⁵ Potential factors contributing to HRQOL in child and
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20 124 adolescent populations with obesity include treatment seeking versus community counterparts,
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22 125 gender, age, and weight-related comorbidities.⁵
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29 127 Alongside, and likely to be contributing to lower HRQOL, children and adolescents with obesity
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31 128 are at increased risk of behavioural and emotional difficulties. In addition to differences in
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33 129 HRQOL, studies have found concerning levels of internalising (anxiety/depression, social
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35 130 withdrawal, and somatic complaints) and externalising behaviours (delinquency and rule-
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37 131 breaking behaviours) in children and adolescents with obesity.^{17,18} Others have identified higher
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39 132 rates of depression, behavioural problems, and low self-esteem in adolescents with obesity
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41 133 attending obesity clinics compared to affected counterparts in the community.¹⁹ Children who
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43 134 are overweight and obese have also been shown to be at risk for psychosocial difficulties such as
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45 135 body image concerns, and emotional, social, and school difficulties.²⁰
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53 137 Currently there are no published data on the HRQOL of children and adolescents with obesity in
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55 138 New Zealand. To our knowledge, there has only been quality of life data published on oral
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3 139 quality of life as it relates to dental caries,²¹ and Type 1 diabetes in New Zealand.¹⁴ In addition,
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5 140 there is an absence of cross-cultural evaluation of obesity and HRQOL. In this study, we aimed
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8 141 to describe the HRQOL (parent and child reports) and behavioural and emotional problems of
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10 142 children and adolescents with obesity at enrolment in a multi-disciplinary obesity intervention
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12 143 programme. In addition, we compared this cohort to other populations or to normative data, and
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14 144 also examined potential ethnic differences between indigenous and non-indigenous children and
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16 145 adolescents. It was hypothesised that obesity is associated with lower HRQOL in New Zealand
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18 146 children and adolescents with obesity.
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24 148 **METHODS**25
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29 150 Children and adolescents were recruited into “Whānau Pakari”, a community-based, unblinded
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31 151 randomised controlled trial of a multi-disciplinary obesity intervention programme,²² based in
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33 152 Taranaki (New Zealand). This region has a population of 23,139 children aged 0-15 years, of
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35 153 whom 81% identify as New Zealand European, 28% as Māori, and 1% as other ethnicity.²³
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37 154 Eligibility was defined by residence in Taranaki, being aged 4.8 to 16.8 years, and either in obese
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39 155 [body mass index (BMI) $\geq 98^{\text{th}}$ centile], or overweight (BMI $> 91^{\text{st}}$ centile) categories with
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41 156 weight-related comorbidities.²⁴ However, only obese participants were included in the study
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43 157 reported here. Referrals were received between January 2012 and August 2014 from a wide
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45 158 range of health professionals (including paediatricians, primary care providers, and public health
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47 159 nurses), Māori health workers, school counsellors and self-referrals. This study examines
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49 160 elements of the baseline demographic data.
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3 162 Ethics approval for the programme was granted by the New Zealand Health and Disability Ethics
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5 163 Committee (CEN/11/09/054). Written and verbal informed consents were obtained from all
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8 164 participants or their guardians. The trial was registered with the Australian New Zealand Clinical
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10 165 Trials Registry (ANZCTR: 12611000862943).

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14 167 **Assessments**

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16 168 Participants underwent a baseline assessment at home, which included taking anthropometric
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18 169 measurements, a medical history and weight-related physical examination, dietary history,
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20 170 physical activity questionnaire, and completion of psychometric questionnaires. Questions
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22 171 pertaining to family structure, developmental history, presence/absence of headaches, difficulty
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24 172 getting to sleep, and presence/absence of breathing pauses were all included in the weight-related
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26 173 medical history. Randomisation into 6 monthly assessments and advice or the intervention arm
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28 174 occurred if the participants indicated willingness to make healthy lifestyle change.²² The
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30 175 intervention consisted of weekly sessions delivered by a multi-disciplinary team for 12 months
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32 176 including physical activity, dietary advice, and psychology sessions (for example, self-esteem,
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34 177 the importance of sleep, how to make and persist with healthy lifestyle change).

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38 179 **Measures**

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40 180 BMI percentile and standard deviation score (SDS) were calculated using UK Cole normative
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42 181 data²⁵ with the KIGS auxology software (Pfizer Endocrine Care TM). Socioeconomic
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44 182 deprivation was measured at the household level using the New Zealand Deprivation Index 2006.
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46 183 ²⁶ This area level deprivation index is a well-validated measure of socioeconomic deprivation in
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48 184 New Zealand, which is derived from national census data on nine socioeconomic characteristics.

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3 186 Quality of life was measured using the Pediatric Quality of Life Inventory (PedsQL)TM, which
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5 187 has been specifically designed to evaluate HRQOL in children and adolescents. The PedsQL
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8 188 questionnaire has both parent-proxy and child self-report versions, which take approximately 5
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10 189 minutes to administer. It consists of a 23-item Generic Core Scale that assesses problems over
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12 190 the preceding month related to Physical, Emotional, Social and School functioning.^{11, 13} The
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14 191 reliability of this instrument has been demonstrated in ages 2-16 years as excellent ($\alpha = 0.89$
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16 192 child; 0.92 parent report) with acceptable construct validity, in a large population survey in the
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18 193 US (n=10,241), with white, Hispanic/Latino, black/African American, Asian/Pacific Islander,
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20 194 American Indian and Native Alaskan participants.²⁷ A meaningful cut-off to identify those at
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22 195 risk of impaired HRQOL has been proposed as one SD below the population mean.²⁷ Individual
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24 196 questions for each area are reverse scored and linearly transformed into a 0-100 scale, where
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26 197 higher scores indicate better HRQOL.
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34 199 The existence of behavioural difficulties was assessed using the Achenbach Child Behaviour
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36 200 Checklist (CBCL) ages 1.5-5 and ages 6-18 (parent report) and Youth Self Report (YSR) for
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38 201 ages 11-18.²⁸ The CBCL/YSR generate ratings of behavioural, emotional, and social problems.
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40 202 The CBCL can be completed by parents, caregivers, or others who see children in family
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42 203 contexts, or by the young person themselves in the case of the youth self-report (YSR). When the
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44 204 young person completed the YSR, no parent CBCL report was obtained in order to reduce the
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46 205 burden of assessment on the family. Subscale scores for the YSR and the CBCL are calculated
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48 206 for a number of behavioural and psychological problems such as aggressive behaviour, and
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50 207 somatic complaints. Subscales are then combined to obtain overall *T*-scores for *internalising* and
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52 208 *externalising* problems. Aggregate scores that represent *normal*, *borderline*, or *clinical* behaviour
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3 209 are based on quartiles from a normative sample.²⁸ The normative data for the CBCL/YSR has
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5 210 been derived from the 1999 National Survey of Children, Youth and Adults, a US population
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7 211 survey of 2,029 children and adolescents of four ethnic groups (60% Latino white, 20% African
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9 212 American, 12% Mixed other, and 9% Latino), of mixed socioeconomic status (33% “upper”,
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11 213 16% “lower”), equal gender split, and ranging in age from 6-18 years.²⁹
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18 **Data analyses**

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20 216 PedsQL scores from the children and adolescents enrolled in this study were compared to three
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22 217 populations using 2-sample t-tests. These comparison populations were:
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24 218 1) A predominantly normal weight cohort of children from the Taranaki region (n=42) with a
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26 219 long-term chronic condition (Type 1 diabetes), with a mean age of 11.5 years (range 2-17 years),
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28 220 who were predominantly of New Zealand European [71%] or Māori [19%] ethnicity, and with
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30 221 representation from all levels of household deprivation.¹⁴ This cohort was utilised as they were
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32 222 resident in the same region as Whānau Pakari participants, and the only group of New Zealand
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34 223 children for which published HRQOL data using PedsQL exists. Recruitment period was May-
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36 224 July 2013.

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39 225 2) A cohort of Australian children (n=63) from the Health of Young Victorians Study (follow-up
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41 226 data collected in 2000), who were identified as having obesity (from the total cohort of n=1456).
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44 227 ¹⁶ We utilised Australian data due to the lack of New Zealand data available.
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48 228 3) A cohort of Australian children from the above study (follow-up data collected in 2000),
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50 229 identified as having normal weight (n=1099, from the total cohort of n=1456). The children in
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52 230 the entire Health of Young Victorians cohort were aged 10.4 years (range 9-12 years), with
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55 231 representation from all quintiles of socioeconomic disadvantage, but ethnicity of participants was
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3 232 not reported.¹⁶ Given that developmental stage may be a contributing factor to HRQOL scores,^{5,}
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5 233 ³⁰ the Whānau Pakari cohort comparison was limited to 9-12 years (n=91).
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10 235 Exploratory analyses of the PedsQL data examined potential associations between a number of
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12 236 sociodemographic and clinical parameters with parental and child's generic scaled scores
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15 237 separately, using simple linear regressions and one-way ANOVA. Further, multivariable models
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17 238 were used to examine possible associations between either parental or child's generic scaled
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20 239 score and important confounding factors, namely age, sex, ethnicity, and socioeconomic
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22 240 deprivation.
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27 242 CBCL and YSR T-scores were utilised. One-tailed one-sample proportion tests were used to
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29 243 compare the rates of participants classified as borderline clinical or clinical in each CBCL/YSR
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31 244 subscale to the normative data (i.e. expected to be $\leq 7\%$ of the population). Exploratory analyses
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33 245 using generalized linear regression models also examined the likelihood of displaying
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35 246 behavioural and emotional problems (i.e. having CBCL/YSR scores in the borderline or clinical
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37 247 ranges) in association with certain demographic parameters, adjusting only for source of test
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39 248 scores (i.e. parent or youth). A similarly constructed multivariable model was also run adjusting
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41 249 for age, sex, ethnicity, and socioeconomic deprivation. These results are provided as relative
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43 250 risks (RR) and respective 95% confidence intervals (CI). Data were analysed in Minitab v.16
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46 251 (Pennsylvania State University, State College, PA, USA) and SAS v.9.4 (SAS Institute, Cary,
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48 252 NC, USA). All statistical tests (except one-sample proportion tests) were two-tailed. Significance
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51 253 level was maintained at $p < 0.05$, with no adjustments for multiple comparisons.
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255 RESULTS

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257 After exclusion of 6 participants who were in the overweight category, enrolled participants
258 (n=233) had a mean age of 10.6 years (range 4.8-16.8 years), 52% were females, and the sample
259 were predominantly either of Māori (45%) or New Zealand European (45%) ethnicity. Nearly a
260 third (30%) resided in households among the most deprived quintile (compared with 15%
261 amongst the population of Taranaki).^{26, 31, 32} Forty-two percent of Māori participants were from
262 the most deprived quintile of household deprivation, compared with 20% of New Zealand
263 European participants (p<0.001). BMI SDS at enrolment was 3.12 (SD=0.57, range 2.01-5.34
264 SDS). Demographics of family and medical history have been previously reported for the total
265 cohort.³³ In brief, among our 233 participants, living arrangements included a two-parent
266 household for half of the participants (n=119, 52%), one-parent household (mother) for 38%
267 (n=87), one-parent household (father) for 4% (n=10), and other arrangement for 6% (n=14).
268 Headaches were prevalent in 32% (n=75), 32% of participants had difficulties getting to sleep
269 (n=75), 20% had breathing pauses (n=47), and 9% had developmental concerns (n=20).

271 *Quality of life*

272 The PedsQL scores of our study's participants and those of another study population in Taranaki
273 are shown in Table 1. There was a moderately positive correlation between overall quality of life
274 scores derived from child compared with parental reports (r=0.55; p<0.001). However, for all
275 three PedsQL measures, parents scored their children's HRQOL as being lower than that reported
276 by the participants themselves (Table 1).

277

278 **Table 1.** Unadjusted PedsQL total generic scaled scores, as well as psychosocial and physical
 279 scaled scores (out of 100) for Whānau Pakari participants compared to other Taranaki children
 280 with Type 1 diabetes (predominantly normal weight).¹⁴ Whānau Pakari data are mean ± SD
 281 (95% confidence interval of the mean), while other data are mean ± SD.

		Whānau Pakari	Type 1 diabetes
Location		Taranaki, New Zealand	Taranaki, New Zealand
Source		This study	Mills et al. 2015
n		233	42
Age range		4.8-16.8 years	2-17 years
Child	Total generic scaled score	72.2 ± 16.2 (70.1, 74.3)†††	74.6 ± 15.3
	Psychosocial scaled score	69.4 ± 18.6 (67.0, 71.8)†††	71.2 ± 17.1
	Physical scaled score	76.9 ± 16.7 (74.8, 79.1)†††	80.8 ± 15.3
Parent	Total generic scaled score	65.1 ± 16.0 (63.0, 67.1)	75.9 ± 13.4***
	Psychosocial scaled score	64.1 ± 17.3 (61.9, 66.3)	73.7 ± 13.1***
	Physical scaled score	66.3 ± 20.3 (63.6, 68.9)	79.9 ± 17.9***

282 ***p<0.001 for comparison with Whānau Pakari; †††p<0.001 for a difference between child and parental scores

283
 284 The Whānau Pakari participants reported similar HRQOL scores to Taranaki youth who were
 285 predominantly normal weight but with a chronic condition¹⁴ (Table 1). However, youth with
 286 obesity in Whānau Pakari had consistently lower HRQOL scores than normal-weight Australian
 287 children (p<0.001; Table 2), and a community sample with obesity.¹⁶ Whānau Pakari parents
 288 reported that their children had lower HRQOL than those reported by the parents of all three of
 289 the comparison groups (p<0.001; Tables 1 and 2).

290
 291 **Table 2.** Unadjusted PedsQL total generic scaled scores, as well as psychosocial and physical
 292 scaled scores (out of 100) for Whānau Pakari participants aged 9 to 12 years, compared to
 293 children and adolescents of two reference populations with a matching age range.^{14, 16} Whānau
 294 Pakari data are mean ± SD (95% confidence interval of the mean), while other data are mean ±
 295 SD.

	Whānau Pakari	Normal weight	Obese
Location	Taranaki, New Zealand	Victoria, Australia	Victoria, Australia

Source	This study	Williams et al. 2005	Williams et al. 2005
n	91	1099	63
Age range	9-12 years	9-12 years	9-12 years
Child			
Total generic scaled score	69.0 ± 15.9 (65.7, 72.3)†††	80.5 ± 12.2***	74.0 ± 14.2*
Psychosocial scaled score	65.8 ± 18.4 (61.9, 69.6)†	77.7 ± 14.1***	72.1 ± 14.1*
Physical scaled score	74.9 ± 15.7 (71.6, 78.2)†††	85.7 ± 12.4***	77.5 ± 17.9
Parent			
Total generic scaled score	63.4 ± 14.0 (60.5, 66.3)	83.1 ± 12.5***	75.0 ± 14.5***
Psychosocial scaled score	61.5 ± 15.1 (58.4, 64.7)	77.6 ± 14.5***	73.9 ± 15.3***
Physical scaled score	66.7 ± 17.7 (63.0, 70.3)	87.8 ± 14.3***	76.3 ± 17.6**

*p<0.05, **p<0.01, and ***p<0.001 for comparison with Whānau Pakari; †p<0.05 and †††p<0.001 for a difference between child and parental scores

Exploratory analyses showed consistent associations between child and parent total generic scaled scores, and certain sociodemographic and clinical parameters, indicating worse overall quality of life with participants who had breathing pauses (p=0.0439 child and p<0.001 parent respectively), reported difficulty getting to sleep (p=0.019 and p<0.001), history of headaches (p=0.023 and p=0.022), developmental problems (p<0.001 and p<0.001), and a father being identified as the sole/primary caregiver as opposed to children living in two-parent families (p=0.010 and p=0.031). In multivariable models, there was evidence that child and parental generic scaled scores decreased in older children (β =-0.70 and p=0.031, β =-0.64 and p=0.047, respectively), but there were no apparent associations with sex, ethnicity, or household deprivation within our cohort.

Child Behaviour Checklist

Of the total cohort for this study, 232 participants/parents completed the CBCL/YSR. The median CBCL/YSR total score was 58 (interquartile range =15.0). The distribution of participants' scores is shown in Figure 1.

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3 315 **Figure 1.** The frequency distribution of participants according to the Child Behaviour Checklist
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5 316 (CBCL) and Youth Self Report (YSR) total scores.
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10 318 Just over half of the participants had CBCL/YSR total scores in the normal range (56.5%), while
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12 319 the remaining 43.5% had scores in the borderline clinical (15.5%) and clinical (28.0%) ranges
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14 320 (Figure 1; Table 3). From US normative data previously described, the overall proportion of
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16 321 population falling into the borderline clinical or clinical range is $\leq 7\%$.²⁹ This means that
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18 322 children in our study had a prevalence of emotional and behavioural problems that was more
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20 323 than 6 times higher ($p < 0.001$) than normative populations.
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24 325 The classification of participants according to individual CBCL/YSR subscales (both parent
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26 326 report and youth report) are shown in Table 3. Missing data on subscales for parent report are
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28 327 due to the absence of these subscales in the questionnaire for 1.5-5-year-olds. Based on
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30 328 CBCL/YSR findings, children and adolescents in our cohort were significantly more likely to
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32 329 display emotional and behavioural difficulties than those in the general population. Compared to
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34 330 normative data, the proportion of participants in borderline clinical or clinical ranges was
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36 331 considerably greater for all subscales (Table 3).
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45 333 **Table 3.** Proportion of participants with T-scores from Child Behavior Checklist (CBCL)/Youth
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47 334 Self Report (YSR) falling into normal, borderline clinical, and clinical ranges at baseline, as per
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49 335 parental and youth assessments. Data are n (%).

Assessment	CBCL/YSR subscale	n	Normal ^a	Borderline clinical ^b	Clinical ^c
Parent	Anxious	128	110 (85.9%)*	8 (6.3%)	10 (7.8%)
	Withdrawn	128	92 (71.9%)*	26 (20.3%)	10 (7.8%)
	Somatic complaints	128	98 (76.6%)*	20 (15.6%)	10 (7.8%)

	Social difficulties	100	70 (7.0%)*	20 (20.0%)	10 (10.0%)
	Thought problems	100	80 (80.0%)*	7 (7.0%)	13 (13.0%)
	Attention difficulties	128	110 (85.9%)*	9 (7.0%)	9 (7.0%)
	Rule breaking	100	76 (76.0%)*	16 (16.0%)	8 (8.0%)
	Aggressive	128	102 (79.7%)*	18 (14.1%)	8 (6.3%)
	Internalising	128	68 (53.1%)*	22 (17.2%)	38 (29.7%)
	Externalising	128	72 (56.3%)*	24 (18.8%)	32 (25.0%)
	Total	128	71 (55.5%)*	19 (14.8%)	38 (29.7%)
Youth	Anxious	104	88 (84.6%)*	12 (11.5%)	4 (3.9%)
	Withdrawn	104	79 (76.0%)*	16 (15.4%)	9 (8.7%)
	Somatic complaints	104	79 (76.0%)*	15 (14.4%)	10 (9.7%)
	Social difficulties	104	84 (80.8%)*	11 (10.6%)	9 (8.7%)
	Thought problems	104	93 (89.4%)*	8 (7.7%)	3 (2.9%)
	Attention difficulties	104	81 (77.9%)*	15 (14.4%)	8 (7.7%)
	Rule breaking	104	86 (82.7%)*	16 (15.4%)	2 (1.9%)
	Aggressive	104	91 (87.5%)*	7 (6.7%)	6 (5.8%)
	Internalising	104	62 (59.6%)*	15 (14.4%)	27 (26.0%)
	Externalising	104	76 (73.1%)*	10 (9.6%)	18 (17.3%)
	Total	104	60 (57.7%)*	17 (16.4%)	27 (26.0%)

Note. ^a< 65 which is below 93rd centile

^b65-70 which is 93-98th centile (apart from internalising/externalising/total 60-63)

^c>70 which is 98th centile (apart from internalising/externalising/total >63)

***p<0.001 for comparison with normative data (i.e. expected ≤7% of participants in borderline clinical or clinical ranges combined)

Exploratory analyses showed a higher probability of behavioural and emotional problems (as per CBCL/YSR total scores) in those who experienced breathing pauses (RR 1.52 [95% CI 1.13–

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3 344 2.04]) or displayed developmental problems (RR 1.59 [95% CI 1.11–2.27]). Multivariable
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5 345 analyses showed that older age at assessment was associated with higher CBCL/YSR total scores
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7 346 (i.e. worse scores) ($\beta=0.89$; $p=0.011$), while males were more likely to display behavioural and
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9 347 emotional problems than females (RR 1.43 [95% CI 1.06–1.94]).
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14 15 349 **Ethnic comparisons**

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17 350 There were no differences between Māori and New Zealand European participants with obesity
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19 351 with respect to the child's reported overall PedsQL scores ($p=0.09$) or PedsQL psychosocial
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21 352 ($p=0.14$) scores, but Māori children reported higher PedsQL physical scores (80.1 versus 74.7,
22
23 353 respectively, $p=0.019$). With respect to parental report, there were no ethnic differences in total
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25 354 quality of life ($p=0.81$), psychosocial ($p=0.76$), or physical ($p=0.53$) scores. There were no
26
27 355 differences between Māori and New Zealand European participants on CBCL/YSR total
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29 356 ($p=0.25$), internalising ($p=0.12$), or externalising ($p=0.71$) scores.
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34 357 35 36 358 **DISCUSSION**

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41 360 The main findings of this study were that children and adolescents with obesity in this region of
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43 361 New Zealand had lower HRQOL on parent report measures when compared with those with a
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45 362 chronic condition (i.e. diabetes that requires daily testing and treatment), and other samples with
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47 363 and without obesity. In addition, a large proportion (43.5%) obtained CBCL/YSR scores in the
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49 364 clinical and borderline range for experiencing psychological problems. The parent report quality
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51 365 of life scores were not dissimilar to those described in children with obesity attending a specialist
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53 366 clinic, and were similar to children and adolescents diagnosed with cancer.¹⁵ The degree to
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3 367 which HRQOL appeared to be affected in our cohort was not surprising, given that treatment-
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5 368 seeking parents of children with obesity are more likely to perceive their child as having a poorer
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8 369 HRQOL and more psychological difficulties when compared with parents of children with
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10 370 obesity in the community not seeking treatment.^{5,34} Our cohort consisted of participants referred
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12 371 to an obesity intervention programme, so were not a true community-based sample. Nor were
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14 372 they directly comparable to a hospital outpatient clinic population given that Whānau Pakari was
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16 373 specifically designed to address barriers to access which exist for hospital-based outpatient
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18 374 clinical care, particularly for indigenous children.²² Allowing for this not being a complete non-
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20 375 referred sample, the difference in HRQOL scores in our cohort compared with a large population
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22 376 based study (n=10,241) of predominantly normal weight children aged 2-16 years (mean score
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24 377 65.4 vs. 81.3) is considerable.³⁵
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29 379 Differences between parent-proxy and child self-report on PedsQL questionnaires have been
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31 380 previously reported. A systematic review of the relationship between parents and children's
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33 381 HRQOL scores found better agreement among parents and chronically sick children than
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35 382 between parents and their healthy children.³⁶ It was argued that both parent and child reports
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37 383 should be obtained as they provide different perspectives. A further review noted differences in
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39 384 parent-child agreement in HRQOL across four different instruments.³⁷ The authors suggested
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41 385 that the disagreement was a consequence of varying individual beliefs about the child's health
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43 386 and well-being, rather than parent or child reports being wrong or right.³⁷ A Norwegian study
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45 387 reviewed this in relation to children and adolescents seeking treatment for obesity versus a
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47 388 community sample of children of any BMI.³⁴ Parents reported the quality of life of the children
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49 389 with obesity seeking treatment as lower than those in the community, which was not seen with
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3 390 the child self-report.³⁴ Pooled analyses however showed that paediatric HRQOL can be
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6 391 accurately predicted from parent proxy reports with moderate to strong linear relationships
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8 392 between the two methods of report.⁵
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12 394 We observed that psychological difficulties were prevalent in our cohort. Our participants aged
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15 395 11 to 18 years reported a mean total YSR score of 55.9 (SD=10.6), which is similar to a small
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17 396 non-clinical group of adolescents with obesity from Turkey (n=30) with a total problem score of
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19 397 58.2 (SD=7.7).¹⁹ We have no national data for comparison with CBCL/YSR, but there is nothing
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21 398 to suggest that scores in the Taranaki region would be higher than those nationally, and there is
22
23 399 no known biological or environmental reason for this cohort to have higher rates of mental health
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25 400 problems outside of their obesity. The absence of Paediatric psychology services are a notable
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27 401 issue in the region (child and adolescent mental health services are available), and it is unclear if
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29 402 this may contribute to these findings. The randomised clinical trial we are undertaking will be
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31 403 able to assess if the intervention can address the relationships between these variables over time.
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35
36 405 Obesity in childhood is a major health concern in New Zealand, with the third highest prevalence
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38 406 of overweight and obesity in the OECD (Organisation for Economic Co-operation and
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40 407 Development).³⁸ Recent studies in this cohort of children and adolescents with obesity have
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42 408 found suboptimal eating behaviour,³⁹ suboptimal physical activity,⁴⁰ and a high prevalence of
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44 409 weight-related comorbidities, including hypertension and obstructive sleep apnoea.³³ We were
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46 410 not surprised that breathing pauses were associated with poorer HRQOL and higher total scores
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48 411 on the CBCL/YSR. Breathing pauses in children and adolescents with obesity are associated
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50 412 with obstructive sleep apnoea,⁴¹ and children and adolescents with obesity with this condition
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3 413 have reported lower HRQOL total scores than peers with obesity without the condition.¹⁵
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5 414 Moderate to severe obstructive sleep apnoea is associated with increased rates of aggressive
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8 415 behaviour, attention problems, and internalising problems on the CBCL.⁴² These observations
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10 416 are important, given the considerable prevalence of breathing pauses reported in this cohort with
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12 417 obesity,³³ and the wider impact of obstructive sleep apnoea on a child's health, cognitive and
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14 418 behavioural functioning.⁴³
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19
20 420 Strengths of this study are that it is the first to report HRQOL in children and adolescents with
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22 421 obesity in the New Zealand population. Due to the high participation rate from Māori, we were
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24 422 also able to undertake evaluation of the impact of ethnicity. What was interesting and important
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26 423 about our findings in terms of ethnicity was the lack of disparity in HRQOL scores. This was
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28 424 despite a larger proportion of Māori participants being from the most deprived quintile of
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30 425 households. It therefore appears that obesity itself rather than factors such as deprivation is the
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32 426 main identified factor in our participants contributing to lower HRQOL scores. This finding is in
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34 427 contrast to previous research in Fiji and Kuwait, where there was no meaningful negative
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36 428 association between increased weight and HRQOL in children aged 12-18 in Fiji, irrespective of
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38 429 ethnicity, or Kuwaiti nationals, aged 10-14 years old.^{7,8} The discrepancies in results may be
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40 430 explained by this study reviewing a treatment-seeking group, rather than population-based
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42 431 sample, and the different cultural values assigned to body size in Fiji and Kuwait compared with
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44 432 New Zealand (a westernised society).
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53 434 A limitation of this study, as with all HRQOL assessments, is the use of an assessment tool to
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55 435 extrapolate one's psychological health and well-being. Comparisons of our study have been
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3 436 made with population groups of varying age ranges, which may have affected results. Another
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6 437 limitation of this study is that this was a referred cohort, which means our findings are not
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8 438 necessarily representative of the general population, and therefore generalisability of findings to
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10 439 wider population groups is reduced. We compared our data with the Health of Young Victorians
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12 440 cohort from Australia, as this was the most comparable group we had access to. However, the
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14 441 data were collected in 2000, and the differences noted may have been impacted by the difference
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16 442 in dates of data collection. Mean BMI SDS for the Victorian cohort with obesity was not
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18 443 available, which would be important if it was considerably lower than the Whānau Pakari
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20 444 participants. Lastly, we made no adjustments for multiple comparisons in our statistical analyses,
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22 445 so that the findings (particularly from exploratory analyses) need to be interpreted accordingly.
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29 447 In conclusion, this study highlights a lower HRQOL and a higher prevalence of psychological
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31 448 difficulties for this referred community-based group of children and adolescents with obesity
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33 449 compared with normative population data. No differences were found between Māori and New
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35 450 Zealand Europeans. This is despite Māori being represented in greater numbers in the more
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37 451 deprived households of the region compared with their non-Māori counterparts, suggesting that
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39 452 obesity itself rather than deprivation is the main contributor to lower HRQOL scores. This study
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41 453 highlights the importance of psychologist involvement and screening in the child and adolescent
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43 454 population with obesity as part of any multi-disciplinary team. Improvement in HRQOL should
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45 455 be considered a goal of all child and adolescent obesity intervention and management. Further
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47 456 research is required to ascertain how to maximise improvements in what is now recognised as an
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49 457 important health outcome.
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16
17 465 PedsQL™, developed by Dr James W. Varni.
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21
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23

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34 472 **Competing interests**
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37
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42
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44
45
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47
48 478 been paid in a fellowship capacity from the Health Research Council of New Zealand, TLC has
49
50
51 479 been paid as a research assistant, JGBD has been paid for data analysis.
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55 481 **Contributorship statement**
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3 482 YCA designed the study, was involved with data interpretation, and drafted this manuscript.
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6 483 LEW recruited participants, and undertook assessments and data entry. KFT provided
7
8 484 psychologist oversight and analysis of patient data. CCG is secondary supervisor for the research
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10 485 team, and assisted with the interpretation of the study. JMS was involved in study design. TLC
11
12 486 assisted with data entry and analysis. TAW was involved in interpretation of data. JGBD
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14 487 analysed the data and drafted the manuscript. WSC contributed to study design. PLH contributed
15
16 488 to study design and supervises the research team. All authors critically revised the manuscript,
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18 489 gave final approval for the version to be published, and are accountable for all aspects of the
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20 490 work.
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492 **Data sharing statement**

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29 493 Data cannot be made available in a public repository due to the strict conditions of the ethics
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31 494 approval of this study. Nonetheless, anonymised and de-identified data will be made available to
32
33 495 other investigators upon request. Interested readers should contact the senior author Prof Paul
34
35 496 Hofman (p.hofman@auckland.ac.nz) to obtain the data.
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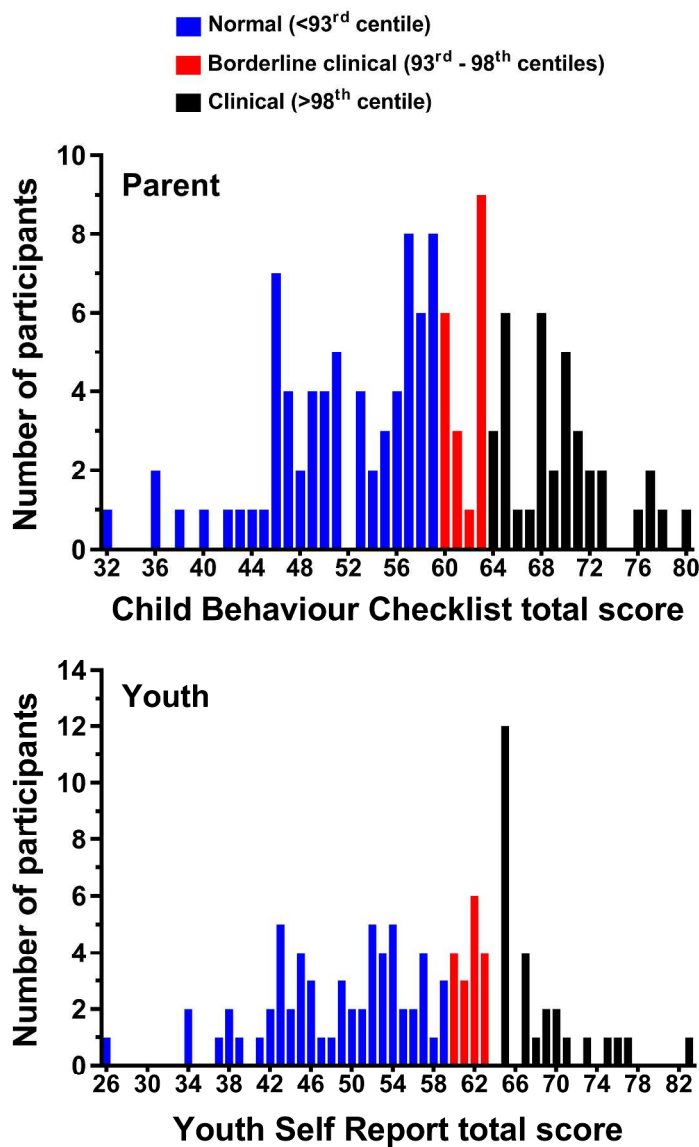


Figure 1. The frequency distribution of participants according to the Child Behaviour Checklist (CBCL) and Youth Self Report (YSR) total scores.

268x387mm (300 x 300 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Complete?
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	✓(1-2) 'enrolment' indicates baseline measures
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	✓(2-3)
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	✓(4-7)
Objectives	3	State specific objectives, including any prespecified hypotheses	✓(6-7)
Methods			
Study design	4	Present key elements of study design early in the paper	✓(7)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	✓(7)
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	✓(7)
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	N/A descriptive baseline results of an RCT
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	✓(7-11)
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	✓(7-10)
Bias	9	Describe any efforts to address potential sources of bias	✓(10-11)
Study size	10	Explain how the study size was arrived at	Information provided in the published protocol (Anderson et al. BMC Obesity 2015;2:41)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	✓(10-11)
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	✓(10-11)
		(b) Describe any methods used to examine subgroups and interactions	✓(10-11)
	(c) Explain how missing data were addressed	N/A	
	(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	N/A descriptive baseline results of an RCT	
	(e) Describe any sensitivity analyses	N/A	

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	✓ (12)
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	✓ (12)
		(b) Indicate number of participants with missing data for each variable of interest	✓ (15)
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	N/A
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	N/A
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	N/A
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	✓ (12–16)
		(b) Report category boundaries when continuous variables were categorized	✓ (12–16)
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	✓ (12–16)
Discussion			
Key results	18	Summarise key results with reference to study objectives	✓ (17–18)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	✓ (20–21)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	✓ (21)
Generalisability	21	Discuss the generalisability (external validity) of the study results	✓ (21)
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	✓ (22)

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.