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Caregiver's readiness for change as a predictor of outcome and attendance in an intervention programme for children and adolescents with obesity: a secondary data analysis.

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Keywords:	General Paediatrics, Pediatric obesity, Program evaluation, Health Behavior, Childhood obesity intervention, Readiness for change

SCHOLARONE™ Manuscripts Caregiver's readiness for change as a predictor of outcome and attendance in an intervention programme for children and adolescents with obesity: a secondary data analysis.

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Running title: Caregiver's readiness for change does not predict obesity intervention outcome

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Abstract

Objective/design: It remains unclear as to the efficacy of readiness for change (RFC) measurements in child and adolescent obesity intervention programmes. This observational study aimed to determine whether the accompanying family member's stage of change (SOC) could predict outcome and adherence to treatment in an intensive intervention programme for children and adolescents with obesity.

Setting: Participants were from the Whānau Pakari randomised clinical trial, a community based multi-disciplinary intervention programme in Taranaki, New Zealand.

Participants: Eligible participants (recruited January 2012 to August 2014) were aged five to 16 years, and had a body mass index (BMI) ≥98th centile or BMI >91st centile with weight-related comorbidities.

Interventions: This study only assessed participants randomised to the high-intensity intervention programme (6-monthly assessments with weekly group sessions for 12 months) given attendance data were required (n=96).

Primary and secondary outcome measures: Primary trial outcome was BMI standard deviation score (SDS). At baseline assessment, participants (if >11 years old) and their accompanying adult were assessed for readiness to make healthy lifestyle change.

Results: Regression analyses showed that a quantitative measure of SOC in accompanying adults was not a predictor of primary (change in BMI SDS precontemplation/contemplation -0.08, 95% CI -0.18, 0.03, action -0.16, 95% CI -0.27, -0.05, p=0.27) or secondary outcomes, or overall attendance in the weekly activity sessions (p=0.55) in the child or adolescent. The quantitative questionnaires

showed a Cronbach's alpha of 0.62 child/adolescent and 0.65 accompanying adult respectively.

Conclusions: SOC was not a predictor of success in this multi-disciplinary intervention programme for children and adolescents with obesity. Future research needs to determine participants' factors for success.

Strengths and limitations of this study:

- Utilisation of both qualitative and quantitative assessments to assess readiness for change.
- High representation from indigenous populations and those from the most deprived households allowed for robust analysis in terms of ethnicity and deprivation.
- Analysis of readiness for change as a dichotomous and continuous variable.
- The assessment tool has not been used previously, and sample size was also relatively small. It is possible that the study was underpowered to detect an association between the two groups.
- Preparation and action groups were merged as both were offered intervention in clinical practice. However, it could be argued that these stages of change should not be merged.

Introduction

Assessing a participant's psychological "readiness" to make lifestyle change is part of any consultation in clinical practice regarding changes in health. However this is an ill-defined process, and usually qualitative in nature. 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.[1] When deciding to undertake behavioural change, an individual moves through defined stages at different rates and not always in a linear fashion. *Pre-contemplation* is the stage where an individual can be described as feeling they "do not have a problem". *Contemplation* is when the individual acknowledges they "may have a problem". *Preparation* — the individual acknowledges they "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".[1]

The transtheoretical model has been used to assess individual's motivation for smoking cessation.[2] Various tools based on the original RFC questionnaire directed towards excessive alcohol use have been trialled in the obesity setting.[3-5] However, the utility of RFC for obesity services remains unclear, and it is too simplistic to expect that every individual would move through these stages in a similar fashion. Little has been reported about the efficacy of RFC assessment in relation to outcome in children/adolescents with obesity, and whether an individual's readiness in the 'snapshot' situation of an assessment translates to persistent motivation to make lifestyle change over time. However, previous studies have highlighted the importance of tailoring interventions to the individual stage of change (SOC) rather

than treating all participants as if they are in preparation or action stages.[4] A Brazilian study of children and adolescents aged 10 to 18 years found that baseline SOC was associated with anthropometric outcomes after a short (16-week) intervention for weight (maintenance stage of change being favourable).[6] Nonetheless, there was no association between adolescents' adherence to treatment and their baseline SOC. Past international clinical practice guidelines and reviews have recommended the importance of health care professionals assessing readiness and barriers to change prior to implementing any healthy lifestyle plan for weight management.[7-9]

A parent's readiness is a key factor in a child or adolescent's success in making and maintaining lifestyle changes. Factors associated with being at a greater degree of RFC in one study were having a child that was overweight, or older (≥8 years) child, believing their own weight or their child's weight was above average, and perceiving that their child's weight was a health problem.[5] Parental confidence in their ability to do well in a treatment programme was cited as the strongest predictor of treatment completion and early treatment response in an Iceland study of an 18-week intervention for 7.5- to 13.6-year-old children.[10] Importantly however, this variable was not associated with child outcome at 1-year follow-up. Parental recognition of child overweight has been found to be a predictor of behavioural intentions, but these intentions are not always translated into behaviours.[11] A high parental readiness does not necessarily imply their readiness to engage in lifestyle interventions for their child affected by overweight/obesity.[12]

A recent systematic review of barriers and facilitators to initial (and continued) attendance in childhood weight management programmes for primary school-aged children found that parents provide the motivation for programme initiation, largely driven by their concern for their child's psychological health and wellbeing.[13] Non-modifiable predictors of initial and continued attendance included gender (programmes favoured females), ethnicity (favoured ethnic majority), family structure (favoured two-parent families), and socioeconomic background (favoured lower level of deprivation).[13] Body mass index (BMI) or age at entry were not associated with attendance. In the New Zealand context, engagement for Pacific Island parents/caregivers in a weight-management programme was attractive when it was family-based - providing support for each other, highlighting the importance of recognising cultural appropriateness in programmes.[14] Moreover, parents can be in differing stages of change for varying aspects of healthy lifestyle change; one study demonstrated different parental stages of change for modification of their children's dietary versus physical activity behaviours.[15]

Clinician assessment of SOC is usually qualitative. However, if a quantitative tool could determine the likelihood of healthy lifestyle change at initial assessment, this would potentially allow prioritisation of health resources where they are most likely to lead to positive outcomes.[16] Given the complexity of behaviour change as it relates to obesity, the original RFC questionnaire[3] 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 consideration.

A previous audit of a healthy lifestyle initiative in New Zealand (NZ) found there was a need to assess SOC of families prior to programme commencement, as it was not uncommon for the coordinator to visit an empty house, impacting on the use of valuable resource.[17] A new model was created, which incorporated assessment of readiness to make healthy lifestyle change.[16] The service, created and named 'Whānau Pakari', is a multi-disciplinary intervention programme children/adolescents with obesity, with a randomised clinical trial (RCT) embedded within the service to assess outcomes.[16] The results of the RCT showed a mean change in body mass index (BMI) standard deviation score (SDS) at 12-months from baseline of -0.12 in the low intensity control group (6-monthly assessments and advice), and -0.10 in the high intensity intervention group (weekly group sessions with 6-monthly assessments and advice) [18] However, if $\geq 70\%$ attendance was achieved in the high intensity intervention, the effect was doubled (-0.22 SDS).[18] Baseline SOC in the accompanying adult in both groups was not different (control group: preparation/action (n=54, 56%), vs. precontemplation/contemplation (n=43, 43%) 44%); intervention preparation/action (n=43)group: VS. precontemplation/contemplation (n=57; 57%); p=0.075).

The purpose of this study was twofold: first, to investigate whether the accompanying family member's stage of change (SOC) at baseline using a standardised measure of RFC[3] (adapted to focus on attitudes towards eating habits, weight and physical activity) predicted our primary outcome (BMI SDS) and/or the secondary outcomes in the Whānau Pakari 12-month intervention; and second, to determine whether SOC was predictive of adherence to treatment. It was hypothesised that those accompanying family member's expressing a higher SOC (i.e. preparation and action)

would see greater improvements in their children/adolescents in terms of primary and secondary outcomes, and demonstrate greater programme adherence.

Methods

Participants

Taranaki has a population of approximately 23,139 children aged 0-15 years, of whom 81% identify as NZ European (NZE), 28% as Māori, and 1% as other ethnicity (multiple ethnicities possible).[19] Eligible participants (recruited January 2012 to August 2014 as part of the Whānau Pakari trial) were aged five to 16 years, and had a BMI ≥98th centile or BMI >91st centile with weight-related comorbidities.[20] BMI percentile and BMI SDS were calculated as per UK Cole normative data, using the KIGS auxology software (Pfizer Endocrine Care TM).[21] One aspect of eligibility was being pre-contemplative or above on the RFC scoring. We purposely set the bar low (i.e. below the pre-contemplative level) to assess whether degree of RFC predicts outcome;[16] only those classed as not ready for change on SOC assessment were excluded.

The rationale and study design for the Whānau Pakari trial have been previously reported, as have 12-month outcomes.[16, 18] In brief, the RCT compared a 12-month intensive intervention with assessments and weekly activity sessions with a minimal intensity control with assessments only, including 6-monthly follow-up, conducted in Taranaki, NZ. For the purposes of the study, given we were interested in SOC in relation to outcome, only participants in the intensive intervention arm were included.

Assessments

Whānau Pakari was a novel home-based 'demedicalised' model (no hospital visits, with a comprehensive weight-related medical assessment in the home) that was family-centred. The assessment included dietary, physical and psychological review, with evaluation of SOC. Secondary outcomes included waist circumference, number of breakfasts eaten per week; servings of fruit and vegetables per day; consumption of sweet drinks per day (ml); 550-m walk/run time (minutes);[22] actual steps per day and actual time spent on moderate-intensity to very vigorous physical activity per day — measured using accelerometers (ActiGraph wGT3X-BT; Actigraph LLC, Pensacola, Florida, USA); total reported activity per day (minutes); reported screen time per day (minutes); total generic scaled score (child); total generic scaled score (parent) — both from Pediatric Quality of Life (PedsQL)TM questionnaire;[23] Achenbach Child Behavior Checklist (CBCL) internalising, externalising and total raw scores;[24] as well as glycated haemoglobin (HbA1c) and fasting insulin (pmol/L).

At the end of the baseline assessment, two assessments of RFC were undertaken. The healthy lifestyle coordinator's qualitative judgement of SOC, ranked precontemplation, contemplation, and preparation/action for child (if >11 years of age) and committed family member was recorded first. The trial-designed questionnaire was completed by the child (if >11 years of age) and another version of the questionnaire for the family member (in every participant). For comparative analysis, preparation was merged with action, resulting in three possible stages of change. This was a pragmatic decision based on clinical grounds; if SOC was found to be a predictor of outcome, a family that demonstrated preparation or action ratings for

SOC would be likely to be offered a place in the intensive intervention in the "real-world", fiscally constrained setting outside of an RCT; whereas those that were precontemplative or contemplative were more likely to be offered motivational interviewing, and a follow-up assessment at a later date.

RFC as a dichotomous measure

The RFC questionnaire was based on Rollnick et al.'s original readiness to change questionnaire,[3] which we modified to focus on beliefs around weight, eating habits, and physical activity levels. A 5-point Likert scale was used. Given the complexity of obesity, additional questions were added to the original questionnaire, resulting in a 21-item child/adolescent questionnaire and a 27-item questionnaire for the family member, with 6 extra questions related to attitudes/behaviour of the wider family unit. The questionnaire was tested for understanding and comprehension in a randomly selected cohort of clinic patients prior to trial commencement, who were underweight, normal weight, and overweight. This pilot testing found the questionnaire was acceptable for use (i.e. underweight children were scored pre-contemplative).

Questions were reverse keyed in their language to negate the need to reverse the precontemplative scaled score when comparing the three scores for each SOC with each other. Scoring was undertaken, which calculated the sum totals for each SOC (precontemplation, contemplation or preparation/action), divided by the number of questions asked to obtain an adjusted score for each SOC. The highest adjusted score was then designated as the SOC of the child/adolescent or family member. If there were two equal scores, the stage furthest along the scale was taken as the designated SOC as per the original RFC questionnaire.[3]

RFC as a continuous variable

For RFC, we undertook analysis both assigning a SOC as per the Prochaska and DiClemente Stages of Change Model,[2] and also utilising the scores as a continuous RFC variable for the family member questionnaire.[25] The same model for obtaining the continuous score has been previously used.[26] The scores were then summed for each subscale.

Attendance

Attendance was calculated as a percentage based on the number of weekly activity sessions offered to each individual family over the 12-month period of their involvement in the programme.

Ethics

Ethics approval for the trial was granted by the Central Health and Disability Ethics Committee (NZ) (CEN/11/09/054). Written and verbal informed consents were obtained from all participants or their guardians. Trial registration was with the Australian NZ Clinical Trials Registry (ANZCTR: 12611000862943).

Data analyses

Cronbach's alpha was used to establish the reliability of the quantitative RFC questionnaire. The agreement between qualitative and quantitative assessments was examined using Spearman's rank (ρ) and Kendall's (τ) correlation coefficients. Generalised linear regression models were used to compare study outcomes (as described above and in Table 2) in the children according to the family member's

SOC (pre-contemplation/contemplation vs preparation/action). Models were adjusted for child/adolescent's ethnicity, gender, age at assessment, level of socioeconomic deprivation, as well as the respective parameter at baseline. Statistical analyses were performed in Minitab v.16 (Pennsylvania State University, State College, PA, USA) and SAS v9.4 (SAS Institute, Cary, NC, USA). All statistical tests were two-tailed with a significance level maintained at p<0.05.

Results

A total of 102 participants were randomised to the intense intervention arm. The flow of participants through the trial has been previously reported.[18] Two participants were excluded after randomisation; due to new medical diagnoses likely to affect weight status. Of the remaining 100, one participant relocated, never attending a session, and three had longer attendance than offered in the intervention, leaving 96 participants with complete attendance data. Table 1 shows the baseline characteristics of the participants.

Table 1. Baseline characteristics of the 96 intervention participants with complete attendance data. Age and body mass index (BMI) data are means and standard deviations.

		Intervention
n		96
Age (years)		10.7 (3.07)
Sex ratio females (n, %)		48 (50.0%)
Ethnicity (n, %) [†]	Māori	45 (46.9%)
	New Zealand European	40 (41.7%)
	Other	11 (11.5%)
Anthropometry	BMI (kg/m^2)	29.6 (6.11)
	BMI SDS	3.11 (0.59)
	BMI SDS	3.11 (0.59)

Deprivation index (quintile) ‡	1 (least deprived)	14 (14.6%)
	2	19 (19.8%)
	3	17 (17.7%)
	4	22 (22.9%)
	5 (most deprived)	24 (25%)
Accompanying adult	Mother	74 (77.1%)
	BMI (kg/m^2) [§]	32.6 (7.26)
	BMI \geq 30 kg/m ² (obese) §	56 (61.5%)
Living arrangements [¶]	Two-parent household	52 (55.9%)
	One-parent household	37 (39.8%)
	Other	4 (4.3%)

Abbreviations: BMI, body mass index.

Reliability

Reliability of the RFC questionnaire (family member and child/adolescent) using Cronbach's alpha was 0.62 for the child/adolescent questionnaire, and 0.65 for family member questionnaire.

Statistically, there was no evidence of an agreement found between the family member's and child/adolescent's questionnaires as per Kendall's correlation coefficient (τ =0.60; p=0.11). However, scores from the family member's questionnaire and qualitative assessment were positively correlated (ρ =0.28; p=0.005) and showed moderate agreement (τ =0.64; p=0.033). Similarly, the child/adolescent's questionnaire and qualitative assessment scores were also correlated (ρ =0.38; p=0.012), with some evidence of moderate agreement (τ =0.69; p=0.051).

Attendance

[†]Prioritised ethnic group.

[‡]Quintiles of level of household deprivation based on the NZ Deprivation Index 2006.[27]

[§] Parameter was measured where consented to (n=91), otherwise not included.

n = 93

Median attendance at the weekly activity sessions was 35% (IQR 66%). The quantitative RFC questionnaire for the family member was used for all analyses of outcome, as these were available for the entire cohort. In multivariate analyses, there was no association between quantitative SOC of the family member and attendance overall in the intervention (n=96, p=0.55).

For the qualitative assessment of RFC of the family member, overall attendance was greater for the pre-contemplation/contemplation group than in the preparation/action group (49.6% vs. 36.5%; p=0.009). In addition, the greater the level of household deprivation, the lower the attendance at the intervention overall (p=0.004), while mean attendance was greater among NZ Europeans compared to non-Europeans (49.5% vs. 36.6%; p=0.003). Further analyses were based on the quantitative measure of RFC.

Outcome

Of the 96 participants, 68 had attendance data and assessment data at 12 months.

Table 2 shows association of quantitative SOC (family member) at baseline assessment and outcome at 12 months.

Table 2. Change at 12 months from baseline in association with the quantitative stage of change of committed family member at baseline (Precontemplation/Contemplation vs. Preparation/Action)

	Pre-contemplation/	Preparation/Action	P-	
	Contemplation*		value [‡]	
N	36	32		
Primary outcome				
BMI SDS	-0.08 (-0.18, 0.03)	-0.16 (-0.27, -0.05)	0.27	

Secondary outcomes			
Waist circumference (cm)	2.7 (0.9. 4.6)	1.5 (-0.54, 3.45)	0.36
Number of breakfasts eaten	0.1 (-0.4, 0.7)	0.2 (-0.5, 0.8)	0.95
Servings fruit/vegetables per day	1.2 (0.6, 1.8)	0.7 (0.03, 1.3)	0.24
Sweet drinks per day (ml)	-126 (-191, -62)	-191 (-261, -121)	0.20
550-m walk/run time (minutes)	-0.46 (-0.65, -0.27)	-0.49 (-0.69, -0.29)	0.84
Actual steps per day	-403 (-1319, 513)	203 (-890, 1296)	0.41
Actual moderate-intensity to very			
vigorous physical activity per day	-9.0 (-17.6, -0.3)	7.2 (-3.1, 17.5)	0.03
(minutes)			
Total reported activity per day (minutes)	19.9 (-7.8, 47.5)	24.7 (-5.5, 54.9)	0.82
Reported screen time per day (minutes)	-21.1 (-53.2, 10.9)	-16.8 (-51.4, 17.8)	0.86
Total generic scaled score - child	7.4 (3.0, 11.8)	8.0 (3.2, 12.7)	0.87
Total generic scaled score - parent	7.7 (1.8, 13.5)	9.2 (2.8, 15.6)	0.74
CBCL internalising raw score	-3.4 (-5.6, -1.2)	-3.2 (-5.5, -0.8)	0.89
CBCL externalising raw score	-2.0 (-4.3, 0.3)	-3.1 (-5.6, -0.6)	0.52
CBCL total raw score	-8.5 (-14.9, -4.8)	-11.7 (-18.5, -4.8)	0.52
HbA1c (mmol/mol) §	-0.29 (-1.69, 1.10)	-0.80 (-2.25, 0.66)	0.63
Fasting insulin (pmol/L) ¶	7.4 (-24.4, 39.1)	-9.45 (-42.4, 23.5)	0.48

^{*}Data are means and 95% confidence intervals adjusted for child/adolescent's ethnicity, gender, level of deprivation, age at assessment and the respective parameter at baseline.

The family member's SOC was not associated with the child/adolescent's ethnicity (p=0.54), gender (p=0.71), level of household deprivation (p=0.88), or age at assessment (p=0.10). This was also seen for the qualitative SOC in the family member (p=0.63; p=0.55; p=0.08; and p=0.59, respectively).

Readiness for change as a continuous measure

Greater scores on RFC in the family member were not associated with changes in

[‡]P-value for a difference in change from baseline between pre-contemplation/contemplation and action 400/ groups.

[§]n=51.

 $^{^{\}P}$ n=56.

primary outcome or with key secondary outcomes assessed (data not shown).

Discussion

This study found that assessment of accompanying family member's SOC on quantitative assessment at baseline was not a predictor of primary or secondary outcomes, or overall adherence in a multi-disciplinary intervention programme for children and adolescents with obesity. This is important, given that attendance was found in the intensive intervention to have a doubling of effect in terms of BMI SDS reduction.[18] Deprivation and ethnicity did not affect SOC in the family member.

It was not surprising that accompanying adult's stage of readiness to make lifestyle changes was not a good predictor of child/adolescent outcome. While readiness models have shown promise in child obesity pilot programmes,[28] it is clear that acknowledgement of child obesity as a problem by the individual and family members is essential for lifestyle change to occur.[5] Our findings are consistent with a previous Icelandic study, which found that parental confidence for doing well in treatment (18-week intervention) was not associated with child outcome at 1-year follow-up.[10] The SOC model is a snapshot in time, and does not necessarily represent future behaviour.[11]

The actions of parents and their SOC are inherently linked to outcomes for a child; a study of 142 families found that changes in parental BMI SDS significantly predicted child's BMI SDS change at 0-6 and 0-24 months in a family-based intervention.[29] However, the situation is complex; a recent study showed that children whose parents perceive them to be overweight are more likely to have negative views about their

own body size, and are more likely to be trying to lose weight. In these children, a counterintuitive association between parents' perceptions of their children as being overweight, and subsequent weight gain in those children was found.[30] It was previously observed that several demographic factors and personal perceptions are associated with a parent's readiness to assist with their child's weight status.[5] These findings highlight that in any multi-disciplinary intervention programme, healthy lifestyle change needs to be the focus, rather than concepts of weight or obesity.

Theoretical weaknesses have been identified when treating RFC scoring as dichotomous variables; therefore a continuous RFC variable has been favoured.[3, 25] However, this approach did not alter our results.

Whilst the transtheoretical model based on RFC offers a comprehensive framework, assessment instruments, such as the URICA, the S-Weight/P-Weight, and the Decisional Balance Inventory (DBI) offer practical applications.[26] Review of these measures found the S-Weight/P-Weight to be the most efficient, providing SOC and the process of change an individual is using.[26] The S-Weight consists of 5 items assessing SOC, with the P-Weight having 34 items measuring four processes of change; emotional re-evaluation, weight management actions, environmental restructuring, and weight consequences evaluation.[26] These were created by international expert consensus.[31] However, to our knowledge, such instruments are not available for use in both parents and children.

Strengths of this study include the use of both qualitative and quantitative assessments of RFC. Due to the high representation from indigenous populations and those from

the most deprived households, robust analysis in terms of ethnicity and deprivation were possible. Limitations of this study include lack of measurement of self-efficacy, and overall confidence to make changes. Confidence in making changes in physical activity and eating behaviour were included in both quantitative questionnaires, however. The assessment tool has not been used previously, and sample size was also relatively small. It is possible that the study was underpowered to detect an association between the two groups. Whilst age may have an impact on attendance of children or adolescents in weight-management programmes, this programme required the attendance of an accompanying adult, irrespective of the age of the child/adolescent. Therefore, findings were not presented separately for varying ages in this cohort. It could be argued that preparation and action should not be merged for the purposes of analysis. However, as outlined previously, this was a decision based on how the outcomes would be used in clinical practice. To ensure this did not affect results, we undertook analysis of RFC as a continuous variable as well.

It had been hoped that, if the RFC measure was predictive of outcome success, then 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 achieve less programme dropout.[16] This would lead to a more efficient and cost effective utilisation of limited resource. However, this was not the case. Further development of a measure of RFC in this context is warranted.

In conclusion, assessment of RFC in this multi-disciplinary intervention for children/adolescents with obesity was not a successful predictor of outcome or attendance. Whilst expert panels are recommending determination of a family's

readiness for change in the overall psychosocial assessment of a child with obesity,[9] this process remains ill defined. Future research needs to determine participants' factors for success in making healthy lifestyle changes.

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Author's Contributions:

YCA designed the study, coordinated the trial, provided paediatrician oversight, drafted the initial manuscript, and approved the final manuscript as submitted. GMSD created the trial-designed readiness for change quantitative assessment tool. LEW recruited participants and undertook assessments and data entry. KFT provided psychologist oversight and analysis of patient data. TAW assisted with study design, and reliability/validity of the questionnaires. CCG is secondary supervisor for the

research team, and assisted with study design. TLC supervised data entry and cleaning. AJS assisted with data entry and attendance data. JGBD undertook data analysis. WSC contributed to study design. PLH contributed to study design, and supervised the research team. All authors contributed to discussions and critically appraised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Data sharing statement: Anonymised and deidentified data will be made available to other investigators upon request. Interested readers should contact the senior author PH (p.hofman@auckland.ac.nz) to obtain the data.

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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	✓ (1, 3-4)
		abstract	. () - ,
		(b) Provide in the abstract an informative and balanced summary of what was	✓ (3-4)
		done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being	✓ (5-7)
-		reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	√ (8-9)
Methods			
Study design	4	Present key elements of study design early in the paper	✓ (9-12)
Setting	5	Describe the setting, locations, and relevant dates, including periods of	✓ (9-11)
28		recruitment, exposure, follow-up, and data collection	. (/
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of	√ (9)
Turticipants	Ü	selection of participants. Describe methods of follow-up	• (0)
		Case-control study—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	
		Cross-sectional study—Give the eligibility criteria, and the sources and methods	
		of selection of participants	N/A
		(b) Cohort study—For matched studies, give matching criteria and number of	N/A
		exposed and unexposed	
		Case-control study—For matched studies, give matching criteria and the number	
		of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and	✓ (12-
		effect modifiers. Give diagnostic criteria, if applicable	13)
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	✓ (9-10)
measurement		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	✓ (13)
Study size	10	Explain how the study size was arrived at	√ (9)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,	√ (12-
		describe which groupings were chosen and why	13)
Statistical methods	12	(a) Describe all statistical methods, including those used to control for	√ (12-
		confounding	13)
		(b) Describe any methods used to examine subgroups and interactions	√ (12-
			13)
		(c) Explain how missing data were addressed	(13)
		(d) Cohort study—If applicable, explain how loss to follow-up was addressed	N/A
		Case-control study—If applicable, explain how matching of cases and controls	
		was addressed	
		Cross-sectional study—If applicable, describe analytical methods taking account	
		of sampling strategy	
		or sampang sauces	
		(e) Describe any sensitivity analyses	N/A

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially	✓ (13-14)
ranticipants	13.	eligible, examined for eligibility, confirmed eligible, included in the study,	V (13−14)
		completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	✓ (13-14, 15)
		(c) Consider use of a flow diagram	N/A
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and	✓ (13-14)
data		information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	✓ (15)
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures over time	✓ (15-16)
		Case-control study—Report numbers in each exposure category, or summary	N/A
		measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	N/A
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates	✓ (15-16)
		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	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a	N/A
		meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and	✓ (15-17)
		sensitivity analyses	
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	✓ (19)
		imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,	✓ (19)
		multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	✓ (17-19)
Other informati	on		
Funding	22	Give the source of funding and the role of the funders for the present study and, if	✓ (20)
		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.

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Caregiver's readiness for change as a predictor of outcome and attendance in an intervention programme for children and adolescents with obesity: a secondary data analysis.

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Caregiver's readiness for change as a predictor of outcome and attendance in an intervention programme for children and adolescents with obesity: a secondary data analysis.

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Abstract

Objective/design: It remains unclear as to the efficacy of readiness for change measurements in child and adolescent obesity intervention programmes. This observational study aimed to determine whether the caregiver's stage of change could predict outcome and adherence to treatment in an intensive intervention programme for children and adolescents with obesity.

Setting: Participants were from the Whānau Pakari randomised clinical trial, a community based multi-disciplinary intervention programme for obesity in Taranaki, New Zealand.

Participants: Eligible participants (recruited January 2012 to August 2014) were aged five to 16 years, and had a body mass index (BMI) ≥98th centile or BMI >91st centile with weight-related comorbidities.

Interventions: This study only assessed participants randomised to the high-intensity intervention programme (6-monthly assessments with weekly group sessions for 12 months) given attendance data were required (n=96).

Primary and secondary outcome measures: Primary trial outcome was BMI standard deviation score (SDS). Secondary outcome measures included indices such as fruit and vegetable intake, 550-m run/walk time, and quality of life scores. At baseline assessment, participants (if >11 years old) and their accompanying adult were assessed for readiness to make healthy lifestyle change.

Results: A quantitative measure of stage of change in caregivers was not a predictor of primary or secondary outcomes (change in BMI SDS precontemplation/contemplation -0.08, 95% CI -0.18, 0.03, action -0.16, 95% CI -0.27, -0.05, p=0.27), or overall attendance in the weekly activity sessions (40.0% versus 37.1% respectively, p=0.54) in the child or adolescent.

Conclusions: Caregiver's stage of change was not a predictor of success in this multidisciplinary intervention programme for children and adolescents with obesity. Future research needs to determine participants' factors for success.

Strengths and limitations of this study:

- This study utilised both qualitative and quantitative assessments to assess readiness for change.
- This study achieved high representation from indigenous populations and those from the most deprived households.
- This study utilised analysis of readiness for change as a dichotomous and continuous variable.
- Limitations included the utilisation of an assessment tool that has not been used previously, and a sample size that was relatively small and potentially underpowered to detect significant differences in certain outcomes.
- Preparation and action groups were merged as both were offered intervention in clinical practice. However, it could be argued that these stages of change should not be merged, and therefore is a noted limitation.

Introduction

Determining whether a participant is psychologically at a point of "readiness" to make lifestyle change is part of any consultation in clinical practice regarding changes in health. However this is an ill-defined process, and usually qualitative in nature. Readiness for change is a concept derived from the transtheoretical model defining stages of behavioural change related to addiction.[1] When committing to behavioural change, an individual may transition through defined stages at variable rates and the progression is not always a linear process. *Pre-contemplation* is the stage where an individual can be described as feeling they "do not have a problem". *Contemplation* is when the individual acknowledges they "may have a problem". *Preparation* — the individual acknowledges they "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".[1]

Assessment of an individual's motivation for smoking cessation is an example of utilisation of the transtheoretical model.[2] Various tools based on the original readiness for change questionnaire (based on high alcohol use) have been utilised in the obesity setting.[3-5] However, little has been reported about the efficacy of readiness for change assessment in relation to outcome in children/adolescents with obesity, and whether an individual's readiness in the 'moment in time' around an assessment will result in persistent motivation to make lifestyle change. It is too simplistic to treat all individuals the same in terms of moving through stages of change, and tailoring interventions to the individual stage of change rather than treating all participants as if they are in preparation or action stages is considered important.[4] A Brazilian study of children and adolescents aged 10 to 18 years found

that there was an association between baseline stage of change and anthropometric outcomes after a short (16-week) intervention for weight (maintenance stage of change being favourable).[6] Nonetheless, there was no association between adolescents' adherence to treatment and their baseline stage of change. Past international clinical practice guidelines and reviews have recommended the importance of health care professionals assessing readiness and barriers to change prior to implementing any healthy lifestyle plan for weight management.[7-9]

A parent's readiness has been identified as a key consideration in a child or adolescent's ability to make and maintain lifestyle changes. Factors associated with being at a greater degree of readiness for change in one study were having a child that was overweight, or an older child (≥8 years), believing their own weight or their child's weight was above average, and perceiving that their child's weight was a health problem.[5] Parental confidence in their ability to do well in a treatment programme was cited as the strongest predictor of treatment completion and early treatment response in an Iceland study of an 18-week intervention for 7.5 to 13.6year-old children.[10] Importantly however, this variable was not associated with child outcome at 1-year follow-up. Parental perception of their child's weight status is also an important consideration; parents' ability to identify when their child was overweight has been found to be limited.[11] Parental recognition of child overweight has been found to be a predictor of behavioural intentions, but these intentions are not always translated into behaviours.[12] Therefore, high parental readiness does not necessarily equate to being ready to engage in lifestyle interventions for their child affected by overweight/obesity.[13]

A recent systematic review of barriers and facilitators to initial (and continued) attendance in childhood weight management programmes for primary school-aged children found that parents provide the motivation for programme commencement, largely catalysed by their worry surrounding the psychological health and wellbeing of their child.[14] Non-modifiable predictors of initial and continued attendance included gender (programmes favoured females), ethnicity (favoured ethnic majority), family structure (favoured two-parent families), and socioeconomic background (favoured lower level of deprivation).[14] Body mass index (BMI) or age at entry were not associated with attendance. In the context of Aotearoa/New Zealand (NZ), engagement for Pacific Island parents/caregivers in a weight-management programme was attractive when it was family-based - providing support for each other, highlighting the importance of recognising cultural appropriateness programmes.[15] Moreover, parents can be in differing stages of change for varying aspects of healthy lifestyle change; one study demonstrated different parental stages of change for modification of their children's dietary versus physical activity behaviours.[16]

Clinician assessment of stage of change is usually qualitative. However, if a quantitative tool at assessment could determine the likelihood of healthy lifestyle change, this could inform prioritisation of health resources where they are more likely to lead to positive outcomes.[17] A previous audit of a healthy lifestyle initiative in NZ found there was a need to assess stage of change of families prior to programme commencement, as it was not uncommon for the coordinator to visit an empty house, impacting on the use of valuable resource.[18] A new model was created, which incorporated assessment of readiness to make healthy lifestyle change.[17] The

service, created and named 'Whānau Pakari', is a multi-disciplinary assessment and intervention programme for children/adolescents with obesity, with a randomised clinical trial (RCT) embedded within the service to assess outcomes.[17] The results of the RCT showed a mean change in body mass index (BMI) standard deviation score (SDS) at 12-months from baseline of -0.12 in the low-intensity control group (6-monthly assessments and advice), and -0.10 in the high-intensity intervention group (weekly group sessions with 6-monthly assessments and advice).[19] However, if $\geq 70\%$ attendance was achieved in the high-intensity intervention, the effect was doubled (-0.22 SDS).[19] Baseline stage of change in the caregiver (committed family member or legal guardian) in both groups was not different - control group: preparation/action (n=54, 56%), vs. pre-contemplation/contemplation (n=43, 44%); intervention preparation/action (n=43:43%) group: VS. precontemplation/contemplation (n=57, 57%; p=0.08).

The aims of this study were twofold: first, to investigate whether the caregiver's stage of change at baseline using a standardised measure of readiness for change[3] (adapted to focus on attitudes towards eating habits, weight and physical activity) predicted our primary outcome of the trial (BMI SDS) and/or the secondary outcomes in the Whānau Pakari 12-month intervention (such as waist circumference, number of breakfasts eaten, servings of fruit and vegetables, sweet drink consumption, 550-m walk/run time, steps per day, indices on quality of life and behaviour checklists, and biochemical markers); and second, to determine whether stage of change was predictive of adherence to treatment. It was hypothesised that those caregivers expressing a higher stage of change (i.e. preparation and action) would see greater

improvements in their children/adolescents in terms of primary and secondary outcomes, and demonstrate greater programme adherence.

Methods

Participants

Taranaki has a population of approximately 23,139 children aged 0-15 years, of which 81% identify as NZ European (NZE), 28% as Māori, and 1% as other ethnicity (multiple ethnicities possible).[20] Eligible participants (recruited January 2012 to August 2014 as part of the Whānau Pakari trial) were aged five to 16 years, and had a BMI ≥98th centile or BMI ≥91st centile with weight-related comorbidities.[21] BMI percentile and BMI SDS were calculated as per UK 1990 growth reference data, using the KIGS auxology software (Pfizer Endocrine Care TM).[22] One aspect of eligibility was being pre-contemplative or above on the readiness for change scoring. We purposely set the bar low for readiness to change (i.e. below the precontemplative level) to assess whether *degree* of readiness for change predicts outcome;[17] therefore, only those classed as not ready for change on stage of change assessment were excluded from this study.

The rationale and study design for the Whānau Pakari trial have been previously reported, as have 12-month outcomes.[17, 19] In brief, the RCT compared a 12-month intensive intervention with home-based comprehensive assessments (medical, dietary, physical activity and psychology screening) and weekly activity sessions (group sessions for 12 months, including physical activity, nutrition and psychology content) with a minimal intensity control with home-based assessments only, including 6-monthly follow-up, conducted in Taranaki, NZ. For the purposes of this

study, given we were interested in stage of change in relation to outcome, only participants in the intensive intervention arm were included.

Assessments

Whānau Pakari was a novel home-based 'demedicalised' model (no hospital visits, with a comprehensive weight-related medical assessment in the home) that was family-centred. The assessment included dietary, physical and psychological review, with evaluation of stage of change. Secondary outcomes included waist circumference; number of breakfasts eaten per week; servings of fruit and vegetables per day; consumption of sweet drinks per day (ml); 550-m walk/run time (minutes);[23] actual steps per day and actual time spent on moderate-intensity to very vigorous physical activity per day – measured using accelerometers (ActiGraph wGT3X-BT; Actigraph LLC, Pensacola, Florida, USA); total reported activity per day (minutes); reported screen time per day (minutes); total generic scaled score (child); total generic scaled score (parent) – both from Pediatric Quality of Life (PedsQL)TM questionnaire;[24] Achenbach Child Behavior Checklist (CBCL) internalising, externalising and total raw scores;[25] as well as glycated haemoglobin (HbA1c) and fasting insulin (pmol/L).

At the end of the baseline assessment, two assessments of readiness for change were undertaken. The healthy lifestyle coordinator's qualitative judgement of stage of change, ranked pre-contemplation, contemplation, and preparation/action for child (if >11 years of age) and committed family member/caregiver was recorded first. The trial-designed questionnaire was completed by the child (if >11 years of age) and another version of the questionnaire for the caregiver (in every participant). For

comparative analysis, preparation was merged with action, resulting in three possible stages of change. This was a pragmatic decision based on clinical grounds; if stage of change was found to be a predictor of outcome, a caregiver that demonstrated preparation or action ratings for stage of change would be likely to be offered a place for their family in the intensive intervention in the "real-world", fiscally constrained setting outside of an RCT; whereas those that were pre-contemplative or contemplative were more likely to be offered motivational interviewing, and a follow-up assessment at a later date.

Readiness for change as a dichotomous measure

The readiness for change questionnaire was based on Rollnick et al.'s original readiness to change questionnaire,[3] which we modified to focus on beliefs around weight, eating habits, and physical activity levels. A 5-point Likert scale was used. Given the complexity of obesity, additional questions were added to the original questionnaire, resulting in a 21-item child/adolescent questionnaire and a 27-item questionnaire for the family member, with 6 extra questions related to attitudes/behaviour of the wider family unit. The questionnaire was tested for understanding and comprehension in a randomly selected cohort of clinic patients prior to trial commencement, who were underweight, normal weight, and overweight. This pilot testing found the questionnaire was acceptable for use (i.e. underweight children were scored pre-contemplative).

Questions were reverse keyed in their language to negate the need to reverse the precontemplative scaled score when comparing the three scores for each stage of change with each other. Scoring was undertaken, which calculated the sum totals for each stage of change (pre-contemplation, contemplation or preparation/action). This was divided by the number of questions asked to obtain an adjusted score for each stage of change. The highest adjusted score was designated as the stage of change of the child/adolescent or family member.

Attendance

Attendance was calculated as a percentage based on the number of weekly activity sessions offered to each individual family over the 12-month period of their involvement in the programme.

Ethics

Ethics approval for the trial was granted by the Central Health and Disability Ethics Committee (NZ) (CEN/11/09/054). Written and verbal informed consents were obtained from all participants or their guardians. Trial registration was with the Australian NZ Clinical Trials Registry (ANZCTR: 12611000862943).

Participant and Public Involvement

This study was designed in response to our discussions working with families, and the need for a more sophisticated form of triage for referred participants wishing to engage with the healthy lifestyle programme. Participants were not officially involved in study design. Results will not be officially disseminated to study participants, however, we ensure that findings are published in open access formats wherever possible so they are freely available to the community.

Power calculation

A total of 68 study participants had attendance data and completed the 12-month assessments. Based on the changes from baseline observed at 12 months in our study population, and with n of 32 and 36 in each group, our study was powered to detect statistically significant differences in change from baseline in BMI of ± 0.21 SDS, in waist circumference of ± 3.5 cm, and in parent's total generic scaled score of ± 11.1 , with $\alpha=0.05$ and 80% power.

Data analyses

Cronbach's alpha (a numerical measure of internal consistency) was used to establish the reliability of the quantitative readiness for change questionnaire. The agreement between qualitative and quantitative assessments was examined using Spearman's rank (ρ) and Kendall's (τ) correlation coefficients. Generalised linear regression models were used to compare study outcomes (as described above and in the quantitative stage of change and outcome measures section of the results) in the children according to the family member's stage of change (precontemplation/contemplation vs preparation/action). Models were adjusted for child/adolescent's ethnicity, gender, age at assessment, level of stage of change, economic deprivation, as well as the respective parameter at baseline.

Subgroup analyses were also performed examining the associations within age groups; specifically among children aged less than 11 years of age and among those aged 11 years or older. Demographic parameters were compared using chi-square tests and non-parametric Kruskal-Wallis tests. Multivariable models were run as described previously, except that age at assessment was no longer included as a covariate.

Statistical analyses were performed in SAS v9.4 (SAS Institute, Cary, NC, USA) and Minitab v.16 (Pennsylvania State University, State College, PA, USA). All statistical tests were two-tailed, with significance level maintained at p<0.05.

Results

A total of 102 participants were randomised to the intense intervention arm. The flow of participants through the trial has been previously reported.[19] Two participants were excluded after randomisation; due to new medical diagnoses likely to affect weight status. Of the remaining 100, one participant relocated, never attending a session, and three had longer attendance than offered in the intervention, leaving 96 participants with complete attendance data. Table 1 shows the baseline characteristics of the participants.

Table 1. Baseline characteristics of the 96 intervention participants with complete attendance data. Age and body mass index (BMI) data are means and standard deviations.

		Intervention
n		96
Age (years)		10.7 (3.07)
Females (n, %)		48 (50.0%)
Ethnicity (n, %)†	Māori	45 (46.9%)
	New Zealand European	40 (41.7%)
	Asian	5 (5.2%)
	Pacific	2 (2.1%)
	Other	4 (4.1%)
Anthropometry	BMI (kg/m ²)	29.6 (6.11)
	BMI SDS	3.11 (0.59)
Deprivation index (quintile) ‡	1 (least deprived)	14 (14.6%)
	2	19 (19.8%)

	3	17 (17.7%)
	4	22 (22.9%)
	5 (most deprived)	24 (25%)
Accompanying adult	Mother	74 (77.1%)
	BMI (kg/m²) §	32.6 (7.26)
	BMI \geq 30 kg/m ² (obese) §	56 (61.5%)
Living arrangements¶	Two-parent household	52 (55.9%)
	One-parent household	37 (39.8%)
	Other	4 (4.3%)

Abbreviations: BMI, body mass index, SDS, standard deviation score.

Reliability

Reliability of the readiness for change questionnaire (caregiver and child/adolescent) using Cronbach's alpha was 0.62 for the child/adolescent questionnaire, and 0.65 for caregiver questionnaire.

Statistically, there was no evidence of an agreement found between the caregiver's and child/adolescent's questionnaires as per Kendall's correlation coefficient (τ =0.60; p=0.11). However, scores from the caregiver's questionnaire and qualitative assessment were positively correlated (ρ =0.28; p=0.005) and showed moderate agreement (τ =0.64; p=0.03). Similarly, the child/adolescent's questionnaire and qualitative assessment scores were also correlated (ρ =0.38; p=0.01), with some evidence of moderate agreement (τ =0.69; p=0.05).

Quantitative stage of change and outcome measures

Of the 96 participants, 68 had attendance data and assessment data at 12 months.

Table 2 shows the stratified association between quantitative stage of change (caregiver) at baseline assessment and outcome at 12 months.

[†]Prioritised ethnic group.

[‡]Quintiles of level of household deprivation based on the New Zealand Deprivation Index 2006.[26]

[§] Parameter was measured where consented to (n=91), otherwise not included.

n=93

Table 2. Change at 12 months from baseline in association with the quantitative stage of change of caregiver at baseline (preparation/action versus precontemplation/contemplation)

	Preparation/	Pre-contemplation/	Difference	P-value‡
	action	contemplation*	Difference	r -value+
N	32	36		
Primary outcome				
BMI SDS	-0.16 (-0.27, -0.05)	-0.08 (-0.18, 0.03)	-0.09 (-0.24, 0.07)	0.27
Secondary outcomes				
Waist circumference (cm)	1.5 (-0.5, 3.5)	2.7 (0.9. 4.6)	-1.3 (-4.0, 1.5)	0.36
Number of breakfasts eaten	0.2 (-0.5, 0.8)	0.1 (-0.4, 0.7)	0.0 (-0.8, 0.9)	0.95
Servings fruit/vegetables per day (n)	0.7 (0.0, 1.3)	1.2 (0.6, 1.8)	-0.5 (-1.4, 0.4)	0.24
Sweet drinks per day (ml)	-191 (-261, -121)	-126 (-191, -62)	-65 (-164, 35)	0.20
550-m walk/run time (minutes)	-0.5 (-0.7, -0.3)	-0.5 (-0.7, -0.3)	0.0 (-0.3, 0.3)	0.84
Actual steps per day (n)	203 (-890, 1296)	-403 (-1319, 513)	605 (-889, 2100)	0.41
Actual moderate-intensity to				
very vigorous physical activity	7.2 (-3.1, 17.5)	-9.0 (-17.6, -0.3)	16.2 (2.2, 30.2)	0.03
per day (minutes)				
Total reported activity per day (minutes)	25 (-6, 55)	20 (8, 48)	5 (-38, 48)	0.82
Reported screen time per day (minutes)	-17 (-51, 18)	-21 (-53, 11)	4 (-45, 53)	0.86
Total generic scaled score – child	7.9 (3.2, 12.7)	7.4 (3.0, 11.8)	0.5 (-6.3, 7.3)	0.87
Total generic scaled score – parent	9.2 (2.8, 15.6)	7.7 (1.8, 13.5)	1.5 (-7.7, 10.8)	0.74
CBCL internalising raw score	-3.2 (-5.5, -0.8)	-3.4 (-5.6, -1.2)	0.2 (-3.1, 3.6)	0.89
CBCL externalising raw score	-3.1 (-5.6, -0.6)	-2.0 (-4.3, 0.3)	-1.1 (-4.6, 2.4)	0.52
CBCL total raw score	-11.7 (-18.5, -4.8)	-8.5 (-14.9, -4.8)	-3.1 (-12.9, 6.6)	0.52
HbA1c (mmol/mol) §	-0.8 (-2.3, 0.7)	-0.3 (-1.7, 1.1)	-0.5 (-2.6, 1.6)	0.63
Fasting insulin (pmol/L)¶	-10 (-42, 24)	7 (-24, 39)	-17 (-65, 31)	0.48

Abbreviations: BMI SDS, body mass index standard deviation score; CBCL, Achenbach Child Behavior Checklist; HbA1c, glycated haemoglobin.

*Data are means and 95% confidence intervals adjusted for child/adolescent's ethnicity, gender, level of deprivation, age at assessment and the respective parameter at baseline.

[‡]P-value for a difference in change from baseline between pre-contemplation/contemplation and action groups.

§n=51.

n=56

There were no differences in BMI SDS change from baseline between groups according to caregiver's stage of change (p=0.27; Table 2). Among secondary outcomes, family members in the stage of preparation/action spent 16.2 minutes more on moderate-intensity to very vigorous physical activity per day compared to those in pre-contemplation/contemplation (p=0.03; Table 2). There were no other differences in secondary outcomes (Table 2).

The caregiver's stage of change was not associated with the child/adolescent's ethnicity (p=0.54), gender (p=0.71), level of household deprivation (p=0.88), or age at assessment (p=0.10). This was also seen for the qualitative stage of change in the caregiver (p=0.63; p=0.55; p=0.08; and p=0.59, respectively).

Age of child

There was no association between changes at 12 months from baseline among children based on age, and caregiver's readiness for change (Supplementary Tables 1 and 2), apart from a between-group difference in the <11-year group for actual moderate to very vigorous activity (p=0.02).

Attendance

Median attendance at the weekly activity sessions was 35% (IQR 66%). The quantitative readiness for change questionnaire for the caregiver was used for all analyses of outcome, as these were available for the entire cohort. In multivariate analyses, there was no association between quantitative stage of change of the caregiver and attendance overall in the intervention; preparation/action 37.1% (n=43) versus pre-contemplation/contemplation 40.0% (n=53); p=0.54).

For the qualitative assessment of readiness for change of the caregiver, overall attendance was greater for the pre-contemplation/contemplation group than in the preparation/action group (49.6% vs. 36.5%; p=0.009). In addition, the greater the level of household deprivation, the lower the attendance at the intervention overall (p=0.004), while mean attendance was greater among NZ Europeans compared with non-Europeans (49.5% vs. 36.6%; p=0.003). Further analyses were based on the quantitative measure of readiness for change.

Discussion

This study found that assessment of accompanying caregiver's stage of change on quantitative assessment at baseline was not a predictor of primary or secondary outcomes, or overall adherence in a multi-disciplinary intervention programme for children and adolescents with obesity. This is important, given that attendance was found in the intensive intervention to have a doubling of effect in terms of BMI SDS reduction.[19] Deprivation and ethnicity did not affect caregiver stage of change.

It was not surprising that caregiver's stage of readiness to make lifestyle changes was not a good predictor of child/adolescent outcome. Indeed, caregiver readiness is one factor in a complex multitude of factors predicting success in achieving reductions in weight status, such as perception of child weight status, and recognition of weight as a problem.[11, 12] Environmental factors, such as access to transport to sessions, food security, and availability of a caregiver to attend sessions also will affect outcome. Such factors are likely to be why the results from this study were not significant. While readiness models have shown promise in child obesity pilot programmes,[27] it is clear that acknowledgement of child obesity as a problem by the individual and family members is essential for lifestyle change to occur.[5] Our findings are consistent with a previous Icelandic study, which found that parental confidence for doing well in treatment (18-week intervention) was not associated with child outcome at 1-year follow-up.[10] The stage of change model is a snapshot in time, and does not necessarily represent future behaviour.[12]

The actions of parents and their stage of change are inherently linked to outcomes for a child; a study of 142 families found that changes in parental BMI SDS significantly predicted child's BMI SDS change at 0-6 and 0-24 months in a family-based intervention. [28] However, the situation is complex; a recent study showed that children whose parents perceive them to be overweight are more likely to have negative views about their own body size, and are more likely to be trying to lose weight. In these children, a counterintuitive association between parents' perceptions of their children as being overweight, and subsequent weight gain in those children was found. [29] It was previously observed that several demographic factors and personal perceptions are associated with a parent's readiness to assist with their child's weight status. [5] These findings highlight that in any multi-disciplinary intervention programme, healthy lifestyle change needs to be the focus, rather than

concepts of weight or obesity.

Whilst the transtheoretical model based on readiness for change offers a comprehensive framework, assessment instruments, such as the URICA, the S-Weight/P-Weight, and the Decisional Balance Inventory (DBI) offer practical applications.[30] Review of these measures found the S-Weight/P-Weight to be the most efficient, providing stage of change and the process of change an individual is using.[30] The S-Weight consists of 5 items assessing stage of change, with the P-Weight having 34 items measuring four processes of change; emotional re-evaluation, weight management actions, environmental restructuring, and weight consequences evaluation.[30] These were created by international expert consensus.[31] However, to our knowledge, such instruments are not available for use in both parents and children.

Strengths of this study include the use of both qualitative and quantitative assessments of readiness for change. Due to the high representation from indigenous populations and those from the most deprived households, analysis in terms of ethnicity and deprivation were possible. Limitations of this study include lack of measurement of self-efficacy, and overall confidence to make changes. Confidence in making changes in physical activity and eating behaviour were included in both quantitative questionnaires, however. The assessment tool has not been used previously, and sample size was also relatively small, and potentially underpowered to detect statistically significant differences for certain outcomes. This programme required the attendance of an accompanying adult, irrespective of the age of the child/adolescent, yet the age of the child did not appear to have an effect on outcome. It could be

argued that preparation and action should not be merged for the purposes of analysis. However, as outlined previously, this was a decision based on how the outcomes would be used in clinical practice.

It had been hoped that, if the readiness for change measure was predictive of success in outcome measures, then creation of paired interventions relating to motivation for change for those in earlier stages of change, superseded by direct interventions for those in later stages could achieve less attrition from the programme.[17] This would lead to efficiency gains and cost effective utilisation of finite health resource. However, this was not the case. Further development of a measure of readiness for change in this context is warranted.

In conclusion, assessment of caregiver's readiness for change in this multidisciplinary intervention for children/adolescents with obesity was not a successful predictor of outcome or attendance. Whilst expert panels are recommending determination of a family's readiness for change in the overall psychosocial assessment of a child with obesity,[9] this process remains ill defined. Future research needs to determine participants' factors for success in making healthy lifestyle changes.

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Author's Contributions:

YCA designed the study, coordinated the trial, provided paediatrician oversight, drafted the initial manuscript, and approved the final manuscript as submitted. GMSD created the trial-designed readiness for change quantitative assessment tool. LEW recruited participants and undertook assessments and data entry. KFT provided psychologist oversight and analysis of patient data. TAW assisted with study design, and reliability/validity of the questionnaires. CCG is secondary supervisor for the research team, and assisted with study design. TLC supervised data entry and cleaning. AJS assisted with data entry and attendance data. JGBD undertook data analysis. WSC contributed to study design. PLH contributed to study design, and supervised the research team. All authors contributed to discussions and critically appraised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Data sharing statement: Anonymised and deidentified data will be made available

to other investigators upon request. Interested readers should contact the senior author PH (p.hofman@auckland.ac.nz) to obtain the data.

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Supplementary Table 1

Changes at 12 months from baseline among children under 11 years of age, in association with the quantitative stage of change of caregiver at baseline (preparation/action vs pre-contemplation/contemplation).

	Preparation/	Pre-contemplation/	Difference	P-value [‡]
	action	contemplation	Difference	P-value+
n	21	18		
Demographic characteristics				
Sex ratio (females)	8 (38%)	7(39%)		0.96
Ethnicity (New Zealand Europeans)	9 (43%)	5 (28%)		0.33
Deprivation index	7 [5, 9]	5 [4, 10]		0.70
Primary outcome				
BMI SDS	-0.19 (-0.32, -0.10)	-0.17 (-0.31, -0.03)	-0.02 (-0.19, 0.16)	0.83
Secondary outcomes				
Waist circumference (cm)	4.2 (1.9, 6.5)	2.8 (0.3, 5.3)	1.4 (-2.2, 5.0)	0.43
Number of breakfasts eaten	-0.1 (-0.7, 0.5)	0.0 (-0.8, 0.7)	0.0 (-0.1, 0.9)	0.90
Servings fruit/vegetables per day (n)	0.7 (0.1, 1.4)	1.4 (0.6, 2.1)	-0.6 (-1.6, 0.3)	0.17
Sweet drinks per day (ml)	-138 (-233, -42)	-99 (-208, 11)	-39 (-178, 100)	0.57
550-m walk/run time (minutes)	-0.3 (-0.6, -0.1)	-0.4 (-0.8, -0.1)	0.1 (-0.3, 0.5)	0.62
Actual steps per day (n)	991 (-158, 2139)	223 (-922, 1369)	767 (-966, 2501)	0.35
Actual moderate-intensity to very vigorous physical activity per day (minutes)	4.2 (-3.1, 11.5)	-9.7 (-17.0, -2.4)	13.9 (2.7, 25.0)	0.02
Total reported activity per day (minutes)	17 (-23, 57)	18 (-29, 64)	0 (-60, 59)	0.99
Reported screen time per day (minutes)	-32 (-63, -1)	-39 (-74, -4)	7 (-39, 52)	0.77
Total generic scaled score – child	5.2 (-0.9, 11.3)	6.3 (-0.5, 13.2)	-1.1 (-10.0, 7.7)	0.80
Total generic scaled score – parent	7.7 (0.9, 14.6)	10.2 (2.5, 17.9)	-2.5 (-12.4, 7.5)	0.62
CBCL internalising raw score	-2.8 (-5.5, -0.2)	-3.9 (-6.9, -0.9)	1.0 (-2.8, 4.8)	0.58
CBCL externalising raw score	-3.6, (-7.0, -0.3)	-2.1 (-5.9, 1.6)	-1.5 (-6.3, 3.4)	0.53
CBCL total raw score	-10.8 (-19.6, -2.1)	-10.2 (-20.1, -0.2)	-0.7 (-13.4, 12.0)	0.92
HbA1c (mmol/mol)	0.6 (-1.8, 3.0)	0.9 (-1.7, 3.6)	-0.3 (-3.7, 3.1)	0.85
Fasting insulin (pmol/L)	-23 (-54, 9)	40 (8, 72)	-62 (-107, -17)	<0.01

Sex ratio and ethnicity data are n (%); deprivation index data are median [quartile 1, quartile 3]; all other data are means and 95% confidence intervals adjusted for child/adolescent's ethnicity, gender, level of deprivation, and the respective parameter at baseline.

^{*}P-value for a difference in change from baseline between pre-contemplation/contemplation and action groups.

Abbreviations: BMI SDS, body mass index standard deviation score; CBCL, Achenbach Child Behavior Checklist; HbA1c, glycated haemoglobin.

Supplementary Table 2

Changes at 12 months from baseline among children aged 11 years or older, in association with the quantitative stage of change of caregiver at baseline (preparation/action vs pre-contemplation/contemplation).

	Preparation/	Pre-contemplation/	Difference	P-
	action	contemplation*	Difference	value [‡]
n	11	18		
Demographic				
characteristics				
Sex ratio (females)	8 (42%)	11 (58%)		0.52
Ethnicity (New Zealand Europeans)	4 (36%)	10 (56%)		0.32
Deprivation index	5 [2, 8]	5 [3, 7]		0.96
Primary outcome				
BMI SDS	-0.18 (-0.39, 0.04)	0.02 (-0.13, 0.18)	-0.20 (-0.47, 0.07)	0.14
Secondary outcomes				
Waist circumference (cm)	-1.92 (-5.16, 1.33)	1.15 (-1.24, 3.54)	-3.07 (-7.10, 0.97)	0.13
Number of breakfasts eaten	0.64 (-0.86, 2.14)	0.55 (-0.54, 1.64)	0.04 (-1.73, 1.89)	0.92
Servings fruit/vegetables per day (n)	1.10 (-0.30, 2.49)	1.19 (0.19, 2.19)	-0.09 (-1.76, 1.57)	0.91
Sweet drinks per day (ml)	-253.89 (-334.49, -173.27)	-160.07 (-219.60, - 100.55)	-93.80 (-191.81, 4.20)	0.06
550-m walk/run time (minutes)	-0.69 (-0.99, -0.39)	-0.71 (-0.95, -0.46)	0.02 (-0.37, 0.41)	0.92
Actual steps per day (n)	-403.25 (-2987.79, 2181.29)	-1758.26 (-4225.62, 709.10)	1355.01 (-2137.89, 4847.92)	0.40
Actual moderate-intensity to very vigorous physical activity per day (minutes)	10.72 (-15.40, 36.83)	-16.15 (-43.23, 10.93)	26.87 (-10.54, 64.28)	0.14
Total reported activity per day (minutes)	43.21 (2.65, 83.78)	25.57 (-3.88, 55.03)	17.64 (-33.30, 68.58)	0.48
Reported screen time per day (minutes)	-1.94 (-89.76, 85.87)	21.69 (-42.08, 85.46)	-23.63 (-134.51, 87.24)	0.66
Total generic scaled score - child	3.78 (3.35, 19.06)	6.37 (0.69, 12.05)	4.83 (-502, 14.68)	0.32
Total generic scaled score – parent	13.68 (1.17, 26.19)	2.84 (-6.36, 12.05)	10.84 (-5.17, 26.84)	0.17
CBCL internalising raw score	-4.53 (-9.58, 0.52)	-3.62 (-7.24, 0.00)	-0.91 (-7.31, 5.49)	0.77
CBCL externalising raw score	-3.12 (-7.04, 0.81)	-1.56 (-4.37, 1.27)	-1.57 (-6.46, 3.32)	0.51
CBCL total raw score HbA1c (mmol/mol)	-15.10 (-27.05, -3.15)	-7.58 (-16.26, 1.09)	-7.51 (-22.51, 7.49)	0.31
Fasting insulin (pmol/L)	20.86 (-32.98, 74.70)	-25.84 (-76.39, 24.70)	46.70 (-27.08, 120.49)	0.20

Sex ratio and ethnicity data are n (%); deprivation index data are median [quartile 1, quartile 3]; all other data are means and 95% confidence intervals adjusted for child/adolescent's ethnicity, gender, level of deprivation, and the respective parameter at baseline.

[‡]P-value for a difference in change from baseline between pre-contemplation/contemplation and action groups. Abbreviations: BMI SDS, body mass index standard deviation score; CBCL, Achenbach Child Behavior Checklist; HbA1c, glycated haemoglobin.



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	✓ (1, 3-4
		abstract	
		(b) Provide in the abstract an informative and balanced summary of what was	✓ (3-4)
		done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being	✓ (5-7)
01	2	reported	4(0,0)
Objectives	3	State specific objectives, including any prespecified hypotheses	√ (8-9)
Methods			
Study design	4	Present key elements of study design early in the paper	√ (9-12)
Setting	5	Describe the setting, locations, and relevant dates, including periods of	✓ (9-11)
		recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of	✓ (9)
		selection of participants. Describe methods of follow-up	
		Case-control study—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	
		Cross-sectional study—Give the eligibility criteria, and the sources and methods	
		of selection of participants	
		(b) Cohort study—For matched studies, give matching criteria and number of	N/A
		exposed and unexposed	
		Case-control study—For matched studies, give matching criteria and the number	
		of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and	√ (12-
		effect modifiers. Give diagnostic criteria, if applicable	13)
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	✓ (9-11)
measurement		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	✓ (13)
Study size	10	Explain how the study size was arrived at	✓ (9)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,	√ (12-
		describe which groupings were chosen and why	14)
Statistical methods	12	(a) Describe all statistical methods, including those used to control for	√ (12-
		confounding	14)
		(b) Describe any methods used to examine subgroups and interactions	√ (12-
		• •	14)
		(c) Explain how missing data were addressed	(13)
		(d) Cohort study—If applicable, explain how loss to follow-up was addressed	N/A
		Case-control study—If applicable, explain how matching of cases and controls	
		was addressed	
		Cross-sectional study—If applicable, describe analytical methods taking account	
		of sampling strategy	
		(e) Describe any sensitivity analyses	N/A
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Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially	✓ (14-15)
		eligible, examined for eligibility, confirmed eligible, included in the study,	
		completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	✓ (14-15)
		(c) Consider use of a flow diagram	N/A
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and	✓ (14-15)
data		information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	✓ (15)
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures over time	✔ (15-18)
		Case-control study—Report numbers in each exposure category, or summary	N/A
		measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	N/A
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates	✓ (15-18)
		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	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a	N/A
		meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and	✓ (15-18)
		sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	✓ (18-19)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or	✓ (20-21)
		imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,	✓ (21)
		multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	✓ (18-21)
Other informati	on		
Funding	22	Give the source of funding and the role of the funders for the present study and, if	√ (22)
		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.