Original Research

Investigating the mediators and moderators of child body mass index change in the *Time2bHealthy* childhood obesity prevention program for parents of preschool-aged children

M.L. Hammersley [a,*], A.D. Okely [a], M.J. Batterham [b], R.A. Jones [a]

[a] Early Start, Faculty of Social Sciences, University of Wollongong, Northfields Ave, Wollongong, NSW, 2522, Australia

[b] Statistical Consulting Service, National Institute for Applied Statistics Research Australia, School of Mathematics and Applied Statistics, Northfields Ave, University of Wollongong, NSW, 2522, Australia

ABSTRACT

Objectives: The aim of this study was to explore factors which mediated or moderated the effect of the *Time2bHealthy* online program for parents of preschool-aged children on body mass index (BMI) change.

Study design: Mediation and moderation analyses of data from a two-arm parallel randomised controlled trial.

Methods: Randomisation was conducted after baseline measures. The intervention group received an 11-week online program, and the comparison group received emailed links to information from an evidence-based parenting website. Data on the primary outcome (child BMI), potential mediators (energy intake, fruit and vegetable intake, discretionary food intake, physical activity, screen-time, sleep, child feeding, parent self-efficacy or parent role-modelling) and potential moderators (child age, parent age, parent income, parent education or parent living situation) were collected at baseline, 3 months and 6 months. PROCESS macro for SPSS was used to analyse possible mediators and moderators on BMI outcomes.

Results: Despite significant food-related outcomes in the main analysis of this trial, no significant mediating or moderating effects were found for any hypothesised mediators or moderators.

Conclusions: This study's null results could be explained by the high proportion of children in the healthy weight range, the study period not being long enough to detect change, the multicomponent nature of the intervention or the relatively small number of outcomes measured. Future childhood obesity interventions should continue to explore the effects of mediators and moderators on BMI and consider collecting data on a wide range of mediating and moderating factors to allow for comparison between studies to develop a better understanding of the factors contributing to successful interventions.

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* Corresponding author.
E-mail addresses: mlh965@uowmail.edu.au (M.L. Hammersley), tokely@uow.edu.au (A.D. Okely), marijka@uow.edu.au (M.J. Batterham), rachelj@uow.edu.au (R.A. Jones).

Introduction

Childhood obesity is a major problem worldwide. Childhood obesity tracks from early childhood to adulthood and can result in life-long health issues[1] as well as significant indirect costs.[2] Interventions which aim to treat and/or prevent childhood obesity have been implemented in a range of settings and modes of delivery, some demonstrating success in reducing obesity and/or obesity-related factors, while others have not.[1,3] Although there has recently been a greater focus on investigating the specific mechanisms by which such interventions achieve outcomes, there is still limited research in this area, and it has been recommended that interventions include analyses of mediators and moderators.[4,5] This is particularly important in the early childhood stage where behaviour change is paramount. Studies which explore the mediators and moderators of change are imperative as they assist in gaining a greater understanding of the contributing factors which may have an influence on an intervention achieving desired outcomes. Gaining insight into mediators and moderators that facilitate change can inform the design of more effective interventions, which can be more appropriately targeted.

There have been limited childhood obesity interventions which have explored mediators and moderators of body mass index (BMI), BMI z-score, weight or adiposity change. The few studies conducted in this area have identified mediators such as dietary intake[6] and physical activity–related factors,[7] self-regulation, mood and self-efficacy.[8] Moderators identified include age,[9] baseline weight,[10] baseline dietary intake factors,[11] social and psychological problems[9,12] and the built environment.[13] Only one study has explored mediators of BMI change in an internet-based childhood obesity intervention, which found that parental life and family satisfaction mediated weight loss,[14] and only one study has explored both mediators and moderators of BMI change in childhood obesity interventions targeting preschool-aged children.

This article explores potential mediators and moderators of BMI change in the *Time2bHealthy* study. The *Time2bHealthy* study was a randomised controlled trial (RCT) of a healthy lifestyle program for parents of 2- to 5-year-old children conducted between 2016 and 2017. The main outcomes have been reported previously.[15] Briefly, there was no significant difference in child BMI (the primary outcome) between groups, but there was a significant reduction in BMI within the intervention group. A significant reduction in the frequency of discretionary food intake in the children in the intervention group compared with those in the comparison group was also reported. There was also a greater improvement in 'pressure to eat' child feeding practices and parent nutrition self-efficacy in the intervention group compared with the comparison group. The aim of the current article was to further explore the data from the *Time2bHealthy* RCT to investigate if change in child BMI was mediated by changes in obesity-related variables or moderated by demographic characteristics. The hypothesis was that child BMI change at 6-months postbaseline would be mediated by change in obesity-related variables (energy intake, fruit and vegetable intake, discretionary food intake, physical activity, screen-time, sleep, child feeding, parent self-efficacy or parent role modelling) and/or moderated by demographic characteristics (child age, parent age, parent income, parent education or parent living situation).

Methods

Study design

The *Time2bHealthy* study was a two-arm parallel RCT approved by the University of Wollongong Human Research Ethics Committee (HE15/354) and registered with the Australian and New Zealand Clinical Trials registry (ACTRN:12616000119493) http://www.anzctr.org.au/. All parent participants gave informed written consent. The trial was conducted between January 2016 and December 2017.

Participant recruitment and eligibility

Eligible individuals were 2- to 5-year-old children who were above the World Health Organisation 50th percentile for BMI for their age and sex and their parents. Children were excluded if they were taking medications or had a medical condition that could affect weight or restrict age-appropriate play. Parents were also required to have an existing Facebook account or agree to create one. Provisional eligibility was determined over the phone or via email and eligibility was confirmed at the face-to-face baseline appointment where height and weight were measured. Participants were recruited to the study from the Illawarra and surrounding areas in New South Wales and Melbourne Victoria, Australia. Further details regarding the methods employed for this study have been previously published.[15]

Randomisation

Following baseline data collection, participants were randomised into the intervention or comparison group. A computerised random number generator was used by a data manager who was not otherwise involved in the study to conduct the randomisation. The only individual who was informed of group allocation was the researcher responsible for implementing the intervention. Height and weight measurements were collected by trained and blinded data collectors at the follow-up data collection time-points.

Time2bHealthy intervention

Details of the intervention have previously been published.[15] In brief, the *Time2bHealthy* group received an 11-week online healthy lifestyle program, underpinned by Social Cognitive Theory.[16] The intervention was designed using a backwards intervention mapping process to align the activities to the theory and target behaviours.[17,18] *Time2bHealthy* comprised six modules (introduction, healthy eating [x2], physical activity, screen-time and sleep), followed by a 3-month maintenance period. The modules required participants to read content, watch videos, complete activities and set goals. A dietitian then provided feedback on the goals set. During the

maintenance period, participants received fortnightly emails which revised the key information from each of the modules. Participants also had access to a closed (secret) Facebook group.

Comparison condition

The comparison group received 11 × weekly emails with links to information on similar topics on the evidence-based *Raising Children Network* website. Similar to the intervention group, during the maintenance period, they received fortnightly emails which revised the information sent in the previous emails.

Measures

Data collection was via face-to-face visits with the child/parent dyads conducted at baseline, 3 months and 6 months. Child BMI was calculated using a standardised method.[19] Height was measured to the nearest 0.1 cm using a stadiometer, and weight was measured to the nearest 0.1 kg using a SECA scale. Height and weight measurements were then repeated and the mean taken to calculate BMI. Where height measurements differed by more than 0.5 cm and/or weight measurements differed by more than 0.5 kg, a third measurement was taken.

Obesity-related behaviour and parent self-efficacy measures were collected from parents via an iPad including parent questionnaires on demographics (baseline only), food intake, screen-time, sleep, self-efficacy, child feeding and role modelling. Questionnaires which had been assessed for validity and reliability were used where possible.

The food questionnaire (modified from the Eating and Physical Activity Questionnaire, which has been validated in the preschool age group[20]) assessed intake of fruit, vegetables and discretionary foods. Daily fruit and vegetable intake was measured on a continuous scale. A set of questions assessed frequency of intake of discretionary foods on an ordinal rating scale from never to 2 or more times per day (Cronbach's alpha = 0.68). Responses to questions on frequency of intake of takeaway or fast food; sugary cereals; potato chips or other salty snacks; sweets; cakes, doughnuts, sweet biscuits or muffins; and sugary drinks were then used to calculate a discretionary food score. A parent-reported 24-h recall of child dietary intake was conducted (using the 'Easy Diet Diary' app [Xyris Software (Australia) Pty Ltd]). Data from the 24-h recall were used to calculate kJ per kg of body weight.

Actigraph GT3X + accelerometers (ActiGraph Corporation, Pensacola, FL) were used to measure physical activity. Monitors were worn by children for 7 days with an elasticised belt around their waist. Data were analysed in ActiLife, version 6 (ActiGraph Corporation, Pensacola, FL). Accelerometers have been previously used in many physical activity studies in children and have been validated for use in preschool-aged children.[21] Categorisation of physical activity was conducted using the following cut-points: sedentary, <100 counts/min; low light-intensity physical activity, 101−800 counts/min; high light-intensity physical activity, 801−1679 counts/min; moderate-intensity physical activity, 1680−3367 count/min and vigorous-intensity physical activity, ≥3368 count/min.[22,23]

Screen-time was measured using a set of questions (based on previously used questions which have been assessed for reliability)[24,25] to ascertain the usual number of hours of screen-time per day on weekends and weekdays, which were then used to calculate overall average time per day. Sleep duration was assessed via accelerometer and parent-reported questionnaire[26] as usual hours per night. Parent-reported sleep duration was used for the purpose of these analyses because of poor compliance with night-time accelerometry. The questions used were modified from a tool which has been previously used in the preschool age group.[26] Child feeding was assessed using the validated 'pressure to eat' and 'restriction' subscales from the validated Child Feeding Questionnaire,[27] and parent role modelling (developed after reviewing other questionnaires as there were no appropriate existing tools[28,29] [Cronbach's alpha = 0.63]) was assessed using a set of questions on a five-point scale. Parent self-efficacy was scored using a set of questions on a 0 to 10 scale which were modified from a previously validated questionnaire[30] (Cronbach's alpha = 0.89). Self-efficacy is a key component of Social Cognitive Theory. Parent self-efficacy has been found to be important in facilitating change in obesity-related behaviours in young children,[31] such as increasing fruit and vegetable intake,[32−34] increasing physical activity[34] and limiting consumption of unhealthy foods.[31,32,34,35]

Statistical analysis

Power calculations for the *Time2bHealthy* study have been published previously.[15] Mediation and moderation complete case analyses were conducted in IBM SPSS Statistics for Windows, version 25 (IBM Corp., Armonk, NY) to explore whether child BMI change at 6 months postbaseline was mediated by changes in obesity-related variables at 3 months postbaseline or moderated by participant demographics at baseline. Baseline values and child age were included as covariates in the models.

Obesity-related variables hypothesised to mediate the effect of BMI change were included in a mediation model *a priori*. Change in fruit and vegetable intake, energy intake (kJ/kg body weight), discretionary food intake, high light, moderate and vigorous-intensity physical activity, screen-time, sleep duration, child feeding (restriction and pressure to eat sub-scales), parent self-efficacy and parent role modelling from baseline to 3 months were hypothesised to mediate change in BMI at 6 months (Fig. 1). For the purpose of this analysis, ordinal data were treated as continuous. Model four of the PROCESS Macro for SPSS version 3.0 was used to calculate the pathways. Mediation procedures outlined by Hayes[36] were used to guide the analysis. The direct effect of the intervention on change in obesity-related variables at 3 months was determined in pathway a. The association between change in the obesity-related variables at 3 months and BMI change at 6 months was determined in pathway b. The direct effect of the intervention on BMI change was determined in pathway c'. The indirect intervention effects were determined via pathway ab. Bootstrapped 95% confidence intervals (CIs) were calculated to test if the indirect effect was significant. Mediation was determined to be significant if the CIs did not include zero.
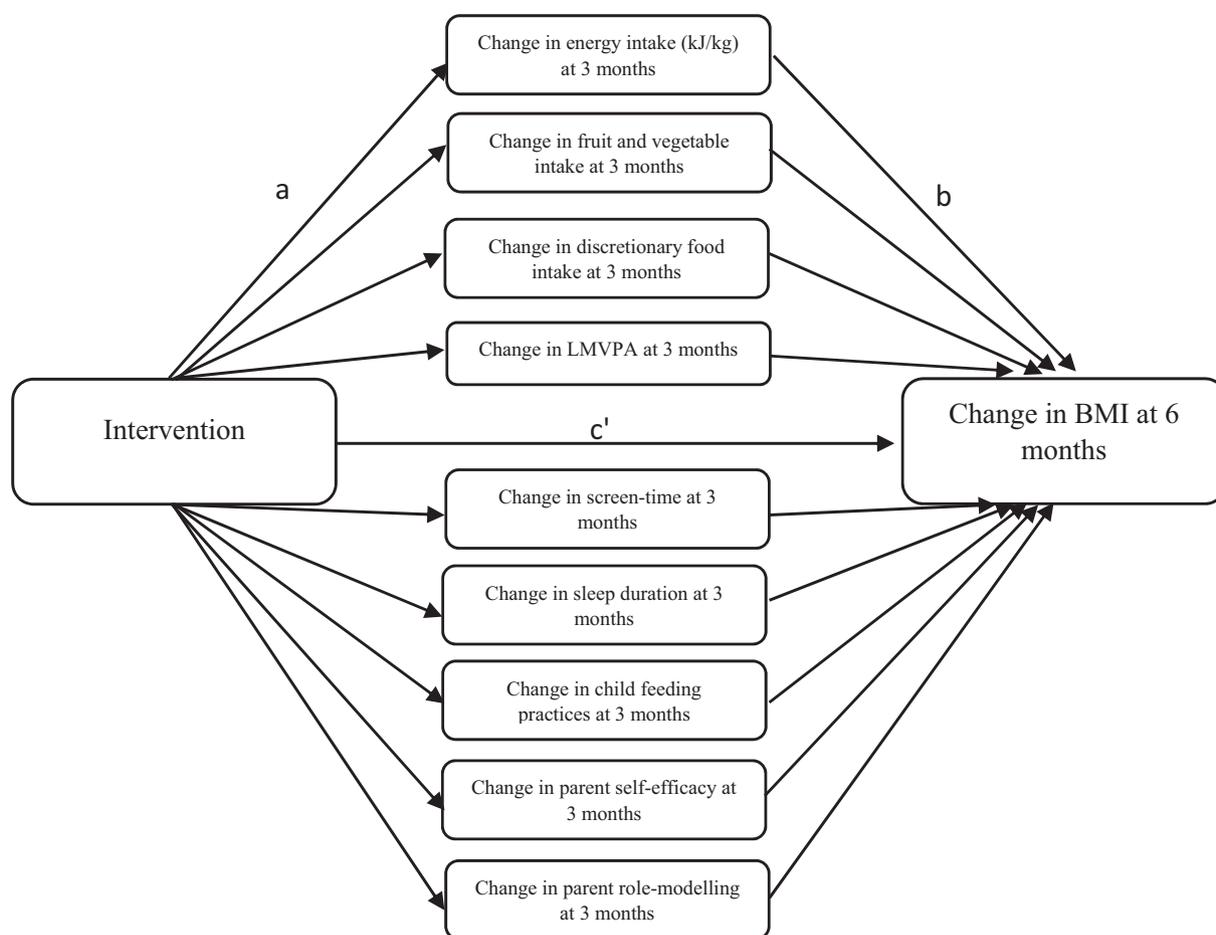
Fig. 1 – **Mediation pathway for obesity-related variables hypothesised to mediate change in BMI 6 months. BMI, body mass index; LMVPA, light, moderate and vigorous-intensity physical activity. a = the direct effect of the intervention on change in obesity-related variables at 3-months, b = the association between change in the obesity-related variables at 3 months and BMI change at 6 months, c' = the direct effect of the intervention on BMI change, ab = the indirect intervention effects.**

Moderation analyses were conducted using model one of the PROCESS Macro for SPSS version 3.0. Moderation procedures outlined by Hayes[36] were used to guide the analyses. Single moderation models were used for the baseline demographic variables of parent age, child age, parent income, parent education and parent living situation (with/without partner) to determine if there was a moderating effect of any of these variables on BMI change at 6 months.

Results

Initial contact was received from 372 parents who enquired about the study and received the information sheet. In total, 159 participants stated that they were interested, and after screening, 104 parent/child dyads were potentially eligible and invited to attend an initial appointment. Ninety-three parent/child dyads attended this appointment, and 86 were confirmed to be eligible. Forty-two dyads were randomised to the

intervention group and 44 to the comparison group. Most participants were in the healthy weight range (91%), 63% had a university degree and 85% were married or with partner. The study had a retention rate of 91%, with one participant withdrawing and seven lost to follow-up. Further information regarding baseline demographics and participant flow have been previously reported by Hammersley et al.[15]

Mediation and moderation analyses

The results of the mediation analyses are displayed in Table 1, and the results of the moderation analysis are shown in Table 2. Despite significant results previously reported in the main outcome analyses for frequency of discretionary food intake, child feeding, pressure to eat and parent nutrition self-efficacy, none of the hypothesised obesity-related variables were significant mediators of BMI change at 6 months. Furthermore, none of the hypothesised participant characteristic variables were significant moderators of BMI change at 6 months.

Table 1 − Results of mediation analysis assessing indirect effects of the *Time2bHealthy* intervention on 6-month postbaseline changes in BMI through hypothesised mediator variables.

Hypothesised mediator	c' path (SE)	a path (SE)	b path (SE)	Bootstrap results for indirect effects (95% CI)		
				ab-mediated path (SE)	Lower bound	Upper bound
Change in energy intake (kJ/kg)	0.023 (0.047)	5.024 (39.384)	0.001 (0.001)	0.003 (0.045)	−0.100	0.092
Change in fruit and vegetable intake	0.023 (0.047)	−0.193 (0.486)	0.011 (0.067)	−0.002 (0.042)	−0.105	0.072
Change in discretionary food intake	0.023 (0.047)	−2.162 (1.038)	−0.002 (0.028)	0.004 (0.075)	−0.143	0.170
Change in LMVPA	0.023 (0.047)	2.032 (1.941)	0.001 (0.015)	0.002 (0.468)	−0.100	0.096
Change in screen-time	0.023 (0.047)	0.514 (0.613)	0.150 (0.046)	0.077 (0.094)	−0.082	0.283
Change in sleep duration	0.023 (0.047)	0.291 (0.261)	0.081 (0.107)	0.024 (0.054)	−0.035	0.170
Change in parent self-efficacy	0.023 (0.047)	−0.101 (0.242)	−0.130 (0.115)	0.013 (0.049)	−0.055	0.148
Change in parent modelling	0.023 (0.047)	0.424 (0.208)	0.056 (0.138)	0.024 (0.074)	−0.117	0.186
Change in child feeding	0.023 (0.047)	−0.115 (0.376)	−0.047 (0.084)	0.005 (0.042)	−0.057	0.118

LMVPA, light, moderate and vigorous-intensity physical activity; CI, confidence interval; BMI, body mass index. a = the direct effect of the intervention on change in obesity-related variables at 3-months, b = the association between change in the obesity-related variables at 3 months and BMI change at 6 months, c' = the direct effect of the intervention on BMI change, ab=the indirect intervention effects.

Discussion

This current article exploring the mediators and moderators of BMI change at 6 months postbaseline found no significant effect of the hypothesised mediators and moderators of the intervention on BMI change. There is an identified need for interventions that explore the mediators and moderators of change in childhood obesity interventions,[4,5] and to date, there have been few studies examining mediating and moderating effects of an intervention on BMI change.[6−14] There is a particular need for these analyses in childhood obesity studies using eHealth (technology-supported health care and health interventions) and those involving preschool-aged children.[7,14] As eHealth is a rapidly growing area of research, the need to investigate the mechanisms by which these interventions work and who they work for is particularly important.

The aim of this article was to explore mediators and moderators of child BMI change at 6 months postintervention in the *Time2bHealthy* RCT. The main outcomes of the RCT indicated that although there was no significant difference between groups in BMI change, there was a significant improvement in BMI within the intervention group.[15] While the original study found no significant difference between groups in BMI change, it is still worthwhile exploring potential

moderators and mediators. The effect of an intervention on a mediator variable can be greater than the direct effect on the outcome variable and therefore may be a stronger indirect effect of the intervention.[6] Mediation results may also indicate the future potential of the intervention to effect the main outcome.[37] Exploring potential moderators in interventions where there is no significant effect of the intervention on the main outcome is useful for uncovering opposing effects of an intervention based on moderating effects of participant characteristics which would not be apparent otherwise.[37]

As the majority of children in the study were in the healthy weight range, there may have been a dilution effect on BMI, which could have impacted on both the null findings in the main outcomes analysis and the null findings in the mediation and moderation analysis. Furthermore, owing to the breadth of content of the *Time2bHealthy* intervention and because there were a limited number of mediators and moderators for which we collected data and included in these analyses, it is possible that other mediators and moderators that we have not assessed were significant in facilitating BMI change. In the only other childhood obesity eHealth intervention which has explored mediators, White et al.[14] found that parent life and family satisfaction were significant mediators of weight loss in a family-focussed eHealth childhood obesity intervention for 11- to 15-year-old children involving nutrition education and behaviour change strategies for adolescents and their parents.

The results of the only two traditionally delivered (i.e. face-to-face) studies have been mixed,[7,38] with only one study reporting a significant mediation and moderation result. zBMI change was moderated by socio-economic status, and targeted sedentary behaviour had a significant mediating effect on zBMI in a study which aimed to reduce television viewing and computer use.[7] The intervention targeted sedentary behaviour only and was therefore quite different to the multiple behaviour intervention design employed in the *Time2bHealthy* study, which also focussed on healthy eating, physical activity and sleep. Unlike *Time2bHealthy*, the study also enforced mandatory sedentary behaviours limits (i.e. capped time spent in sedentary behaviours), provided children with financial incentives for reducing TV and computer

Table 2 − Results of moderator analyses of the *Time2bHealthy* intervention on 6-month postbaseline change in BMI.

Demographic characteristic	Coefficient	95% CI		P-value
		Lower bound	Upper bound	
Child age	0.096	−0.214	0.406	0.539
Parent age	0.000	−0.062	0.063	0.989
Parent income	−0.249	−0.631	0.133	0.198
Parent education	0.206	−0.406	0.817	0.505
Parent living situation (with/without partner)	−0.648	−1.947	0.650	0.323

CI, confidence interval; BMI, body mass index.

use and fitted a device to TVs and computer monitors preventing their use after the screen-time 'budget' was exhausted. The study was also conducted over a 2-year period and therefore much longer than the *Time2bHealthy* intervention. It is possible that more time would be required to demonstrate change in BMI, particularly given the age of the children, and had a longer follow-up period been included in the *Time2-bHealthy* study, perhaps mediators of change would have been detected.

A number of mediators and moderators have been found to have an effect in previous studies of older children which were not included in the mediation and moderation models in our analyses. Factors such as self-regulation, mood, child self-efficacy,[8] aerobic fitness,[39] resistance training self-efficacy, physical activity behavioural change[10] and family factors[14] have mediated BMI effects. Characteristics such as social adjustment/problems,[9,12] anxiety,[9] built environment factors,[13] baseline energy dense food intake, parent concern over own weight, and parent child acceptance[11] have moderated the effect on BMI outcomes. While previous studies have had specific areas of focus, owing to the wide range of mediators and moderators explored in studies, it is difficult to make comparisons, and it is therefore recommended that future interventions investigate a broader range of mediators and moderators to enable results to be compared between studies. The mixed results of the mediating and moderating factors of childhood obesity interventions on BMI outcomes in the current literature demonstrate that more studies which incorporate mediation and moderation analyses are needed, particularly in interventions targeting younger children and eHealth-based studies.

Strengths and limitations

This is one of the first articles to explore mediators and/or moderators of BMI change in a childhood obesity intervention in the preschool age group and the first to explore both mediators and moderators of BMI change in an eHealth childhood obesity study in any age group. There are some limitations of this study. As mentioned, the majority of children (91%) in the study were in the healthy weight range, and there was a possible dilution effect on BMI. Therefore, it could be argued that the eligibility criteria may have been too broad. However, targeting children who are at may be risk of becoming weight is important in long-term obesity prevention. Also, had the eligibility criteria been restricted to children with overweight and obesity, the trial may not have been able to proceed if a minimum sample size had not been achieved. The sample was not perfectly representative of the general Australian population as it contained a higher proportion of participants in the healthy weight range compared with the overall Australian population (where approximately 80% of children aged 2−4 years are in the healthy weight range).[40] Participants were also generally more educated (63% possessing a university degree compared with 23% of the general Australian population)[41] and more likely to be married/with partner (85%) than Australian families with children in general (74%).[42] Heterogeneity was not assessed in this study. It is possible that both response to the intervention and the mediators and moderators of change varied between participants because of individual characteristics, an avenue that could be explored in future studies. The sample size was smaller than planned, despite strategies implemented to enhance recruitment as previously described,[15] which therefore would have affected the statistical power. This mediation and moderation analysis was a complete case analysis. The main outcomes analysis for this study[15] used an intention-to-treat design, and a complete case analysis was also undertaken. Few differences were found between these two analyses of the main outcomes, and we therefore propose that had an intention-to-treat design been used for this mediation and moderation analysis, similar results would have been found. It is possible that questionnaire-based data could be intentionally or unintentionally misreported by parents, a common issue to many other studies.[43,44] Finally, the number of mediators and moderators tested were limited by the data that were collected in the main study.

In conclusion, this exploratory analysis of the mediators and moderators of the *Time2bHealthy* childhood obesity intervention on BMI showed null results. There is a lack of studies in this area, particularly in younger children and in the field of eHealth. Further research is required, exploring a wider range of factors to gain greater insight into the mechanisms by which interventions achieve or do not achieve outcomes, which can be used to better inform policy and the design of more successful interventions.

Author statements

Contributors

M.L.H. contributed to designing the research, conducted the research, analysed data and wrote the paper. R.A.J. contributed to designing the research, conducted the follow-up data collection and edited the manuscript. M.J.B. contributed to designing the research, provided input and advice on the statistical analysis plan, data interpretation, and edited the manuscript. A.D.O. contributed to designing the research and edited the manuscript. All authors read and approved the final manuscript.

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