

Time2bHealthy – An online childhood obesity prevention program for preschool-aged children: A randomised controlled trial protocol

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ABSTRACT

Background: The use of parent-focused internet-based programs for the prevention and treatment of childhood obesity has shown promise but there is an acknowledged gap in parent-focused interventions which target the early childhood stage.

Methods: The aim of this study is to determine the efficacy of *Time2bHealthy* - an online healthy lifestyle program for parents of preschool-aged children. The program will be evaluated using a two-arm, parallel, randomised controlled design. The 11-week program is underpinned by Social Cognitive Theory and consists of interactive modules on healthy eating, physical activity, screen-time and sleep. The intervention also involves elements of social media, where participants share ideas and experiences and they can interact and obtain information with experts. *Time2bHealthy* is being compared to a comparison condition. Outcomes include change in BMI (primary outcome), dietary intake, physical activity, sleep, child feeding, parental role-modelling and parent self-efficacy. Process evaluation data, such as adherence and engagement with the online forums, will also be collected.

Discussion: *Time2bHealthy* is the first randomised controlled trial to our knowledge to assess the efficacy of an online parent-focussed healthy lifestyle program for preschool-aged children in changing body mass index. Early childhood is a crucial time for establishing healthy lifestyle behaviours and parents play an important role. This study therefore fills an important gap in the literature. If found to be efficacious, *Time2bHealthy* has potential for broad-reach access and translation into primary health care services.

Trial Registration: The study is registered with the Australian and New Zealand Clinical Trials Registry (12616000119493).

1. Introduction

Overweight and obesity in early childhood is associated with a range of short- and long-term health consequences. Furthermore, overweight children have at least twice the risk of remaining overweight into their adult life compared to children in the healthy weight range [1]. Effective weight management interventions can reduce the likelihood of childhood overweight and obesity continuing into adulthood. Increasing physical activity and improving eating behaviours are recognised cornerstone weight management strategies [1,2]. There is also increasing evidence regarding the importance of limiting screen-time [3], reducing sedentary activities [4–6] and maintaining healthy sleeping patterns [7–9].

Parental influence and role-modelling play a key part in the development of such behaviours [10–12]. Therefore, the role of parents in overweight and obesity prevention and intervention programs is critical. Previous reviews have highlighted the success of interventions

which involve parents compared to those that do not [13–15]. This is particularly true for programs that target young children. Despite the importance of parental involvement in overweight and obesity prevention and treatment programs, there are recognised barriers such as scheduling of appointments/sessions [15], stigma, parental denial [16], childcare for other siblings [17], travel [18] and cost [15] that prevent parental involvement and potentially success of the programs.

The use of the online medium for overweight and obesity prevention and treatment programs offers advantages compared to face-to-face programs in convenience and accessibility. There have been an increasing number of online healthy lifestyle interventions for children in recent years. Systematic reviews have demonstrated that such interventions are efficacious in improving obesity-related behaviours and are cost effective, however the majority of studies have been conducted in the primary- or high-school age groups and most have not involved parents as an agent of change [19–21]. A recent meta-analysis of parent-focussed eHealth obesity interventions found that while there

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was no significant effect found in BMI/BMI z-score change, half of the studies demonstrated significant improvements obesity-related behaviours such as diet or physical activity compared to a control group. In this review there was an absence of studies which included children under the age of five years, an age group where parental influence is probably more profound than older childhood and adolescence [12]. It was therefore recommended that larger, high quality studies are conducted which transform successful components from face-to-face interventions into an eHealth format, particularly those which target younger age groups and focus on parents as agents of change [19]. The aim of this paper is to describe the protocol for the *Time2bHealthy* study. The purpose of the study is to determine the efficacy of the parent-focused *Time2bHealthy* online program in facilitating behaviour change among preschool-aged children who are overweight, or at risk of becoming overweight. The primary hypothesis is that children in the intervention group will demonstrate significantly greater reductions in BMI/BMI z-score compared to the comparison group by the 6-month follow-up. Secondary outcomes including child dietary intake, physical activity, screen-time, sleep and parent self-efficacy will also be assessed.

2. Methods

2.1. Study design

The *Time2bHealthy* study is a two-arm randomised controlled trial involving parent-child dyads (Fig. 1). *Time2bHealthy* is based on formative research with parents of preschool-aged children. This research analysed the content of 300 publicly available websites containing healthy lifestyle information for children of preschool age and found that the websites lacked strategies on how to practically apply the information and set goals to assist in changing behaviours. Focus group results from this research similarly indicated that parents would find information of how to implement changes helpful. Parents also advised that an online program would need to be easy to use and be flexible and highly credible. Personalised feedback from a health professional was also important to parents [22].

Based on the results of this research, a 10-week, five-module online program – *Time2bHealthy* – was developed which covered the areas of healthy meals, healthy snacks and drinks, physical activity and screen-time. The program was piloted with 47 dyads and was found to be

acceptable, potentially efficacious and had a high level of retention [23] and a randomised controlled trial is now required to fully test the efficacy of the intervention. Due to more recent research into the effects of sleep on overweight and obesity in children, an additional module on sleep was added to the program for the current trial. Content of the modules was also updated according to the latest evidence-based recommendations [24–26] and the behaviour change and goal-setting aspects of the program were strengthened.

The study will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement [27]. The study has been approved by the University of Wollongong Human Research Ethics Committee (HE15/354) and is registered with the Australian and New Zealand Clinical Trials Registry (12616000119493).

2.2. Participant recruitment and eligibility criteria

Participants are being recruited from the Illawarra, Southern and South-Western Sydney, Southern Highlands and Shoalhaven areas of New South Wales and Melbourne, Victoria. To assist with recruitment, organisations and individuals such as early childhood education centres, schools, playgroups, general practices, early childhood nurses, preschool swimming and sporting activities are being contacted and asked to distribute flyers and/or display posters. Articles have been placed in university and local health district newsletters, a Facebook page was created to communicate information about the study throughout the recruitment areas and a media release was sent to media agencies.

Potential participants are provided with a participant information sheet and screened for eligibility via phone or email. Participants are eligible if they live in one of the geographical areas described, the child is 2–5 years of age and not yet attending school at the time of recruitment and the child is at or above the WHO 50th percentile for body mass index for their age and sex. Parents are also required to have a Facebook account or be willing to create one for the duration of the study.

Child participants are excluded if they are taking medications or have a medical condition that can affect weight. As such, children are excluded if they are taking any of the following medications: Ritalin or other therapy for attention deficit hyperactivity disorder, long-term steroids, anti-psychotic medication. Furthermore, children are excluded if they have any of the following conditions or disabilities; Prader-Willi Syndrome, Bardet-Biedl Syndrome, Diabetes, Phenylketonuria or other metabolic disorders, Cystic Fibrosis, significant physical or developmental disability (that restricts age-appropriate play) or other conditions associated with overweight/obesity. Children with conditions such as Coeliac Disease or food allergies are able to participate, but parents are informed that some of the healthy eating content of the program will not be entirely appropriate and they will need make their own modifications to some of the information provided to suit their child's specific dietary requirements.

Eligible participants provide informed consent after reading the participant information sheet by completing a written consent form. Eligibility is confirmed at the baseline data collection visit when child height and weight are measured and body mass index is calculated to determine if the child is at or above the WHO 50th percentile for age and sex. Recruitment commenced in January 2016, with participants being recruited into six cohorts on a rolling basis. It is anticipated that recruitment will be completed by June 2017.

2.3. Power and sample size

We expect an effect size of approximately 0.4 for this trial (based on the results of the pilot study). To detect a statistically significant difference between groups ($\alpha = 0.05$ and power = 0.8), 136 participants are required (68 per group) and considering an estimated attrition rate of 15%, 160 participants are planned to be recruited (80 per

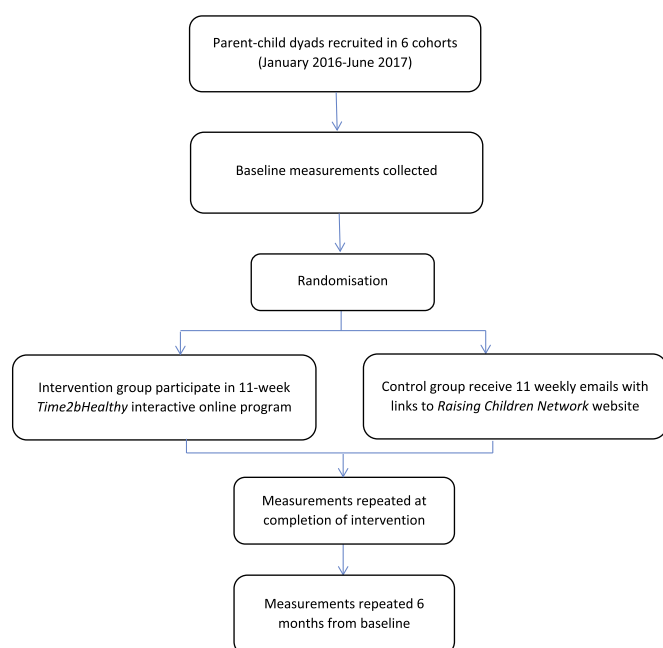


Fig. 1. *Time2bHealthy* study design.

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