Interventions to influence consumption of sugar-sweetened beverages

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Intellectual property and Publication Statements

The candidate confirms that the work submitted is her own, except where work which has formed part of jointly-authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

Chapter 2

Vargas-Garcia EJ, EL Evans C, Cade JE. *Impact of interventions to reduce sugar-sweetened beverage intake in children and adults: a protocol for a systematic review and meta-analysis.* Systematic Reviews. 2015;4:17.

EJVG has led the research approach and drafted relevant sections regarding the literature review and the searching strategy (both development and execution). CELE has led the development of the statistical analysis. CELE and JEC have shared responsibility in the research approach. All authors have read and approved the final manuscript.

Chapter 3

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This publication represents an update of the results presented in this chapter and which have not been included as they have not informed later stages of the PhD. EJVG led the research approach, developed and executed the search strategy, determined trial quality, analysed the data, wrote the first draft of the manuscript and contributed to the subsequent drafts; CELE was involved in all statistical analyses, AP contributed to the plans for data extraction and statistical analysis and provided essential guidance for coding and interpretation of BCTs; BJSM was involved in coding of BCTs; JH assisted in searching and screening of articles ; JEC provided essential guidance at all stages of the review. All authors have edited, reviewed and approved the final manuscript.

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Abstract

Introduction Evidence for higher intakes of sugar-sweetened beverages (SSBs) driving the risks of obesity, type 2 diabetes and cardiovascular disease is increasing. As a result, SSBs have been targeted across public health interventions worldwide, including Mexico- which has one of the highest levels of consumption of SSB and alarmingly high childhood obesity rates.

Aim To determine the effectiveness of interventions and intervention's components to reduce consumption of SSBs and to develop and implement an intervention in school-aged children in central Mexico.

Methods A systematic review and meta-analysis was undertaken to examine the impact that interventions have had to reduce SSB intake or increase water intake across all age groups. Identification and analysis of behavior change techniques used in interventions was also undertaken. Exploratory analyses on data from children in central Mexico indicated that 12% of 6 to 15 year olds met criteria for Metabolic Syndrome. Consequently, a 12-week school-based programme was developed to influence consumption of SSB through promotion of water intake. Sixteen classes in four schools were allocated to the intervention group (N= 2 schools, 8 classes) or control group (N= 2 schools, 8 classes). Participants were 337 children aged 7-12 years (222 in intervention and 115 in controls).

Results Pooled estimates from meta-analyses indicated that interventions modestly influence SSB intakes in children (-92 mL/day (95% confidence interval [CI] -145 to -39; 18 studies, P<0.01) but not in adolescents (-52 mL/ day, 95% CI -121 to 17; 4 studies, P = 0.14) or in adults (-23 mL/day, 95% CI -56 to 9; 7 studies, P = 0.16). Pooled estimates of water intakes were only possible for interventions in children and these were indicative of increases in water intake (MD +80 mL/day, 95% CI 6 to 155; 6 studies, P = 0.04). There was some evidence to suggest model/demonstrating the behaviour or parental involvement helped to reduce SSB intake. Results from the study in Mexico highlighted that intervention and control groups achieved reductions in daily intake of SSB by -61 mL/day and -132 mL/day, respectively, with the difference between groups not being statistically significant (71 mL/day; 95% CI: 94 to 236; p=0.4]. Consumption of water throughout the day decreased in both groups (Intervention: -169 mL/day; 95% CI: -275 to -62 vs controls: 235 mL/day; 95% CI: -369 to -102). Information from a process evaluation highlighted difficulties in children and staff to deliver and adhere to activities as planned.

Conclusion Community-level interventions can influence positive changes in consumption of SSB in children but not in adolescents or adults, An educational and environmental approach focusing on the promotion of water intakes in Mexican children was insufficient to improve consumption patterns of SSB and water. Interventions in the future could potentially be benefitted by longer implementation as well as parental involvement.

List of publications and presentations

Publications

Vargas-Garcia EJ, EL Evans C, Cade JE. *Impact of interventions to reduce sugar-sweetened beverage intake in children and adults: a protocol for a systematic review and meta-analysis.* Systematic Reviews. 2015;4:17. doi: 10.1186/s13643-015-0008-4. This data is presented in **Chapter 2**.

Vargas-Garcia EJ, Evans CEL, Prestwich A, Sykes-Muskett BJ, Hooson J, Cade JE. *Interventions to reduce consumption of sugar-sweetened beverages or increase water intake: evidence from a systematic review and meta-analysis*. Obesity reviews 2017. doi: 10.1111/obr.12580. This data is presented in **Chapter 3**.

Vargas-Garcia, E.J., Evans, C.E.L. and Cade, J.E. (2016) Decreasing sugar-sweetened beverage intake in children: a systematic review and meta-analysis. Proceedings of the Nutrition Society 75(OCE3). doi:10.1017/S0029665116001415. This data is presented in **Chapter 3**.

Vargas-Garcia, E.J., Evans, C.E.L. and Cade, J.E. (2016). Improving consumption of sugar-sweetened beverages across populations: lessons learnt from a systematic review and meta-analysis. J Epidemiol Community Health 2016;70: Suppl 1 A34-A35. doi: 10.1136/jech-2016-208064.59. This data is presented in **Chapter 3.**

Vargas-Garcia, E. J., Evans, C. E. L. and Cade, J. E. (2014). *Prevalence of metabolic syndrome in children from central Mexico. 73*(OCE2). doi:10.1017/S002966511400130X. This oral presentation was given an award and data is presented in **Chapter 4.**

Presentations

Society for Social Medicine 60th Annual Scientific Meeting

Oral presentation (York, UK: 13 to 16 September 2016)

Nutrition Society Summer Meeting 2016: New technology in nutrition research and practice

Poster presentation (Dublin, Ireland: 11 to 14 July 2016)

Hot topic: Dietary Sugars, Obesity & Metabolic Risk

Poster presentation (Berlin, Germany: 29 to 30 June 2015)

Institute of Food Science and Technology: Young Scientist Competition 2015

Oral Presentation (Manchester, UK: 29 April 2015). *Finalist student*.

Nutrition Society Irish Section Meeting

Poster presentation (Correlaine, Northern Ireland: 18 to 20 June 2014). *Awarded the FSAI student prize for poster competition*.

School of Food Science and Nutrition Annual PhD Conference

Oral presentation (Leeds, UK: 16 November, 2016, 18 November 2015, 24 September 2014)

Abbreviations

SSB	Sugar-Sweetened Beverage
WHO	World Health Organisation
FAO	Food Agriculture Organisation
I^2	Heterogeneity
BCT	Behaviour Change Technique
RCT	Randomised Controlled Trial
UK	United Kingdom
NGO	Non-Government Organisation
CVD	Cardiovascular Disease
NAFLD	Non Alcoholic Liver Disease
RR	Relative Risk
OR	Odds Ratio
NHS	Nurses' Health Study
HPFS	Health Professionals Follow-Up Study
HR	Hazzard Ratio
HFCS	High Fructose Corn Syrup
TEI	Total Energy Intake
SE	Standard Error
CI	Confidence Interval
BMI	Body Mass Index
Mesh	Medical Subheading
FFQ	Food Frequency Questionnaire
MoE	Ministry of Education
MoH	Ministry of Health
WF	Water fountain
NEG	Nutritional Epidemiology Group
IDF	International Diabetes Federation
ToC	Theory of Change
WTHR	Waist to Height Ration
oz	Ounce
mL	Millilitres

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Chapter 1 : Introduction

1.1 Obesity trends and determinants: consumption of sugar-sweetened beverages

Obesity has become a global health problem affecting individuals of all ages. Projections for 2030 have estimated that there will be 2.16 billion and 1.12 billion overweight and obese adults, respectively, across the world (Kelly et al., 2008). Reducing longevity and quality of life, obesity has placed a great economic burden on governments' healthcare systems, with medical costs amounting from 4% to 10% of their national health budgets in certain developed countries ff. Nevertheless, it has been recognised that financial, social and health consequences will be greater for low and middle-income countries facing nutritional transitions such as those in Northern Africa, the Middle East, Asia and Latin America (Popkin, 2001). Mexico has not been the exception. Indeed, over the last 20 years the Mexican population has experienced a dramatic shift in lifestyle and dietary behaviours which has resulted in higher rates of obesity and its related comorbidities (Rivera-Dommarco, 2001, Rivera et al., 2004). According to the last National Health and Nutrition Survey (ENSANUT) in 2012, 34.4% of children between 5 and 11 years old were obese or overweight and up to 35% of the adolescent population exhibited weight problems (Gutiérrez et al., 2012). Although obesity-related diseases are major causes of morbidity and mortality in Mexican adults (namely coronary heart disease and type 2 diabetes mellitus), the metabolic syndrome as a predisposing condition to the former diseases has been already identified in younger populations (Wei et al., 2011, Zimmet et al., 2007).

Obesity is a complex and multifactorial problem. Swinburn *et al.* (Swinburn et al., 2011) have appointed the changes in the *food system,* namely the higher availability and accessibility to non-expensive, flavoursome and convenient energy-dense foods, forceful marketing campaigns as well as individual responses to changes in the built environment, as main drivers of the global epidemic. The effect of corporations on the environment related to access, cultural acceptance and price of food products has been extensively appraised as a determinant to the ill-health derived from obesity and non-communicable diseases (NCDs) (Kickbusch et al., 2016); the Obesity System Map (Vandenbroeck and Goossens, 2014) from the UK Foresight Programme, provides one of the most thorough frameworks on obesity determinants and interactions. It depicts a comprehensive interconnection between individual, societal and environmental factors related to the obesity problem. Primary domains under this structure include: social psychology, physical activity environment, food consumption, food production, individual physiology, physical activity and psychology. All of these factors connect to a central engine which involves variables related to "homeostasis" or the resulting energy balance between acquisition and preservation of energy (**Figure 1-1**).

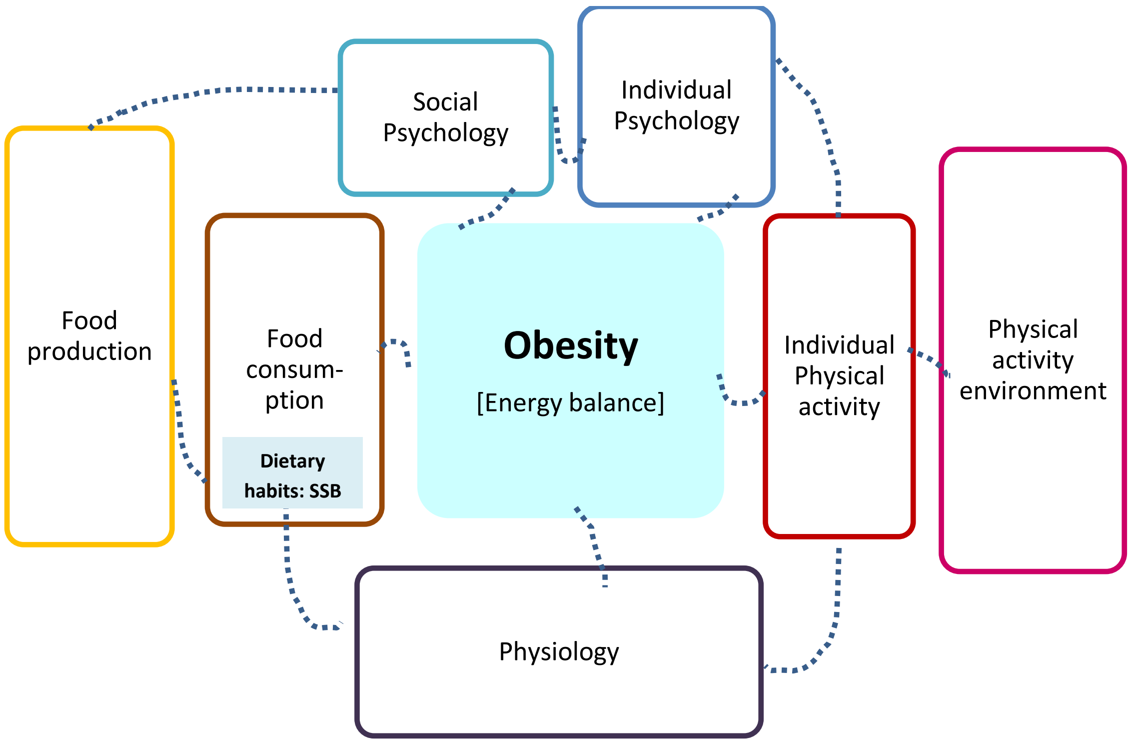

Figure 1-1 Obesity system map (adapted from *(from UK Government's Foresight Programme).*

While the magnitude of effects from these factors will depend on the levels of exposure and individual or population susceptibility (Hu, 2013), ***dietary habits*** (captured under the area of food consumption) have a broad and direct influence to the core system. Modern dietary patterns reflect a transition from traditional foods and cuisines: enlarged portion sizes and increased consumption of processed food products (high-in fat and high-in sugar) which are closely linked to excessive accumulation of energy and thus, obesity. Increased consumption of "free sugars", in particular, has gained much attention as evidence grows to support their association with onset of cardiovascular disease (CVD) and type 2 diabetes via weight gain, increases in adiposity and development of metabolic–risk factors such as non-alcoholic liver disease (NAFLD) (Stanhope, 2016, Moore et al., 2014). Free sugars (often denoted as added sugars) refer to all monosaccharides (glucose, fructose, galactose) and disaccharides (sucrose, lactose, maltose, trehalose) added to foods by the manufacturer, cook or consumer as well as sugars naturally occurring in honey, syrups, fruit juices and fruit concentrates (World Health Organization, 2015b).

In this respect, the role of sugar-sweetened beverages (SSBs) in the obesity problematic has been under scrutiny as they are the leading contributors to sugar intakes across the globe. Data from epidemiological and intervention studies continues to show more implications in the development of ill-health derived from higher intakes of SSBs. Many strategies at local, national and global levels for this reason have been in place to directly seek a reduction in SSB intake (World Health Organization, 2013). Yet, evidence underlying the effect of midstream (behavioural) and upstream (environmental) outcomes remains limited to better understand how this behaviour could be modified in addition to the inherent policy changes that could support these changes (Swinburn et al., 2011).

1.2 Health outcomes from higher intakes and composition of SSB

1.2.1 SSB and body composition (weight, BMI and body fatness)

Though consensus is still needed, sugar-sweetened beverages have been defined by WHO as:

"Drinks containing added caloric sweeteners (sucrose, high-fructose corn syrup, or fruit-juice concentrates). Amongst others, they include carbonates, fruit drinks, sports drinks, energy and vitamin water drinks, sweetened iced tea, and lemonade" (World Health Organization, 2016).

Weight gain and adiposity

Concomitantly to increases in worldwide obesity rates, has been the emerging evidence from epidemiological and intervention studies linking SSBs in the development of weight gain, type 2 diabetes and other cardiovascular risk factors.

Indeed, a recent review by Malik *et al.* (Malik et al., 2013a), has documented that over a year, for every 1- serving/per day increase in SSB (serving size of 12 oz), body mass index (BMI) in children augments by 0.06 kg/m^2 (95% confidence intervals [CI]: 0.02 to 0.10, n=25,745 participants) and adults' weight increases by 0.22 kg (95% CI: 0.09 to 0.34, n= 174,252 participants). This review, which also analysed effects from randomised-controlled trials (RCT) in children, indicated beneficial effects on BMI when SSB were reduced (-0.12 kg/m^2; 95%CI: -0.22 to -0.02, n=2772) which was a common objective across interventions in this age group. Trials in adults on the other hand, focused on assessing changes in body weight followed by an addition of sweetened beverages to the normal diet, and pooled results from meta-analyses highlighted increases by 0.85kg (95% CI: 0.50 to 1.20, n=292) with higher intakes of SSBs. These findings confirmed those by a previous systematic review by this same group in which a positive tendency of weight gain was observed with higher intakes of SSB (Malik et al., 2006).

The effects of dietary sugars on adiposity were systematically reviewed and meta-analysed in longitudinal studies in children in whom higher intakes *versus* lower intakes of SSB (that being intakes of 1-serving/day *versus* no consumption at all) were significantly associated with a 155% greater risk of being overweight (Odds ratio [OR]: 1.55, 95%CI: 1.32 to 1.82). Similar trends were seen in adults, in whom higher intakes of sugars (mainly through consumption of SSB) in comparison to lower or usual intakes, significantly increased weight by 0.75 kg (95% CI: 0.30 to 1.19) (Te Morenga et al., 2013).

Metabolic Syndrome and *Non-alcoholic fatty liver disease*

The impact of SSB consumption on the onset of the metabolic syndrome - as cluster of risk factors (such as dyslipidaemia, hypertension and hyperglycaemia) for cardiovascular disease (Beilby, 2004) has been investigated considering that its aetiology and subsequent therapeutic front lines are connected to obesity management and thus dietary intake. For instance, pooled data from three cohorts in the United States comprising 19,431 adults indicated that consumers in the highest quantiles (approximately one SSB-serving per day) in comparison to non-consumers had a 20% higher risk of metabolic syndrome (RR 1.20, 95% CI: 1.02 to 1.42) (Malik et al., 2010b).

Duffey *et al.*, recently examined the metabolic effect between SSB and cardiovascular health (Duffey et al., 2010) Their analysis from the Coronary Artery Risk Development in Young (CARDIA) study showed that as intake of SSB increased (or consumption moved into higher quartiles), so did the incidence of enlarged waist circumference (RR: 1.09; 95% CI: 1.04, 1.14; P for trend , 0.001), hypertriglyceridemia (RR: 1.06; 95% CI: 1.01, 1.13; P for trend = 0.033), high LDL cholesterol (RR: 1.18; 95% CI: 1.02,1.36; P for trend = 0.018) and hypertension (RR: 1.06; 95% CI: 1.01, 1.12; P for trend = 0.023), with remaining risk factors (hyperglycaemia and low HDL cholesterol) showing the same trend, though not statistically significant (Duffey et al., 2010).

In younger populations, Ambrosini *et al.* confirmed that across 1433 adolescents from the Western Australian Pregnancy Cohort study, girls (n=537) moving to the highest quartile of intake of SSB or consuming more than 1.3 servings per day (serving size 8.45 oz) had higher cardiometabolic risk than those in the lowest tertile (no consumption) in their most adjusted statistical model (Odds ratio [OR]: 2.7 (1.3 to 5.6, p for trend 0.008) (Ambrosini et al., 2013). Isolated risk factors for metabolic syndrome, such as triglyceride levels were higher for boys and girls on the top tertile of consumption of SSB (8.4% change, 95% CI: 1.6 to 15.3, P-trend=0.01 and 7 % change, 95% CI: 0.04 to 13.5, p-trend= 0.03, respectively) (Ambrosini et al., 2013).

Growing evidence has also suggested that sugar, and fructose in particular (Lim et al., 2010), might have an effect on the development of NAFLD- considered to be the hepatic marker of the metabolic syndrome (Moore, 2010). Accounting that SSB are an important source of fructose-containing sugars, the hypothesis that greater intake of sugary drinks could lead to greater risk of NAFLD was tested in data from the Framingham Heart and the Third Generation cohort studies in the United States (Ma et al., 2015). Findings showed a 166% higher risk of fatty liver disease with increases in beverage consumption (1 serving per day) which was independent of BMI and abdominal subcutaneous adipose tissue (OR 1.66, 95% CI: 1.07 to 2.58, P for trend=0.03). However, when visceral adipose tissue was entered into the previous models, the association was no longer significant (OR 1.29, 95% CI: 0.8 to 2.06, p-trend = 0.37) and this was suggestive of a disrupted hepatic fat accumulation with excessive sugar consumption in conditions of greater calorie intake (Ma et al., 2015). Certain hypotheses suggest that fructose can be more easily stored in visceral adipose tissue when excess fructose is ingested as there is higher availability of glucocorticoids receptors in VAT in comparison to SAT (Ma et al., 2016).

Type 2 diabetes

Increased risk of type 2 diabetes has also been linked to higher intakes of SSB via weight gain and excessive adiposity (de Koning et al., 2011). Prospective observational studies have shown that, for example, men on the highest quintile of consumption (median intake of 6.5 servings per week) in comparison to those in the lowest quintile (no consumption) had a 25% increased risk of type 2 diabetes, after adjusting for confounders such as energy intake, BMI and physical activity (de Koning et al., 2011). In school-aged children, Ludwig *et al.* also documented increases in BMI (0.24 kg/m^2, 95% CI: 0.1 to 0.39) and higher obesity incidence (OR 1.60, 95% CI 1.14 to 2.24) for every additional 1-serving/day of SSB (Ludwig et al., 2001).

A meta-analysis on the association between SSB and type 2 diabetes found an increased risk of 26% in those individuals within the highest quantile of consumption (1 to 2 servings/day) ([RR 1.26; 95% CI: 1.12 to 1.41) and an increased risk of metabolic syndrome for those individuals within the highest levels of SSB consumption (RR: 1.20; 95%CI: 1.02 to 1.42) (Malik et al., 2010b).

Results from a meta-analysis by Greenwood *et al.* on prospective cohort studies, also confirmed an approximate 20% increase in type 2 diabetes for every additional daily serving of SSB in adults (serving size 330mL/day) (Greenwood et al., 2014) . More recently, Imamura *et al.* pooled data from prospective studies in the UK and the US on over 10 127 000 person years and found that higher intakes of SSB (one extra serving per day or approximately 250 mL/day) were associated with a 13% greater incidence of type 2 diabetes (RR 1.13; 95% CI: 1.06 to 1.21) which was independent of BMI status and adjusted for adiposity (Imamura et al., 2015).

Hypertension

Consumption of SSB has been implicated in the incidence of hypertension and associations, for instance, have been studied in three US cohorts (Nurses Health Studies [NHS] I & II, Health Professionals Follow Up study [HPFS]) involving 18,6531 women and 37,360 men (Cohen et al., 2012). Pooled analysis from the most adjusted models, which included BMI status and total energy intake as covariates, found an overall increased risk in individuals consuming one or more SSBs per day (serving size 12 oz) equating to a 1.13 HR (95% CI: 1.09 to 1.17) in comparison to those consuming these drinks sparingly (less than once per month). Secondary analyses on SSB composition and hypertension incidence revealed a stronger association for higher intakes of cola-containing beverages in comparison to non-cola ones in all but one cohort study (NHS II, P-interaction 0.11); and for carbonated beverages as compared with non-carbonated beverages in all there cohorts (P-interactions <0.001 for NHS I, 0.03 NHS II and 0.009 for HPFS). Also, analyses by Winkelmayer *et al.* from the NHS II found a 28% higher risk of hypertension in frequent consumers of sugared-cola drinks or having more than 4 glasses per day in comparison to consumers of less than one SSB daily (RR 1.28, 95% CI: 1.01-1.62, P for trend <0.001) (Winkelmayer et al., 2005).

In a similar manner, results from a randomised-controlled trial (RCT) in the US involving 810 participants with hypertension and which delivered educational and behavioural components (i.e., enhanced counselling and goal setting cues) found that at post-intervention (18 months), reduction of one portion size of SSB (defined as 12 oz) per day was linked to clinically significant declines of 0.7 mm Hg in systolic blood pressure (95% CI 0.15 to 1.25) and 0.4 mm Hg (95% CI: 0.02 to 0.75) in diastolic blood pressure, after adjusting for changes in body weight and energy intake (both mediators of the effect) (Chen et al., 2010). Clinical and public health implications from this study suggested that decreasing SSB and sugar intakes should be further supported to lower blood pressure (Chen et al., 2010).

Oral health

Another concern from higher intakes of SSB has been their implication in the development of dental caries (Sheiham and James, 2014) considering SSB are a vehicle of sugars, mainly sucrose, glucose and high-fructose corn syrup, all easily fermented by oral bacteria and resulting in elevated acidity and enamel erosion (Marshall, 2013). The former evidence has served as the foundation for recently updated dietary guidelines by WHO on sugar intakes (World Health Organization, 2015a), in which the consumption of free sugars has been recommended to not exceed more than 10% of total energy intake (TEI) and a pragmatic 5% should be encouraged. This last recommendation is currently followed in the UK (Public Health England, 2015).

1.3 Composition of SSB

1.3.1 Differences between liquid and solid foods

Changes in body weight as a result of excessive energy intake from SSB can not only be explained by their highly sugared composition but also by the incomplete compensation (or poor reduction) in energy intake following consumption of liquid calories (Mattes and Popkin, 2009). Biological mechanisms that trigger satiety signals in the gut and the brain do not appear to be as efficient for liquids as they are for solid foods, leading to an impaired satiety more prone to overconsumption (Zheng et al., 2015a, Malik et al., 2010a). Certainly, the lower energy density and osmolarity from liquids may accelerate their pass through the stomach (i.e., gastric emptying), not allowing feeding signals to be evoked (i.e., satiety promoting hormones or peptides), which could perversely lead to greater caloric consumption (DiMeglio and Mattes, 2000). Perceptive influences can also be implicated, as liquids in comparison to solid foods are usually “thought” to have a lower caloric content, and this has been reported to better predict hunger and subsequent food intakes (Wooley et al., 1972).

Though energy intake (EI) stands as a mediator in the relationship between ingestion of sugary drinks and a positive energy balance, the type of sugars present in these beverages appears to be involved in a cascade of other metabolic dysfunctions, independent of weight gain.

Composition of SSB

SSBs are made up of naturally occurring caloric sweeteners such as sucrose, fruit juice concentrates or more frequently high fructose corn syrup (Malik and Hu, 2012, White, 2008). The amount of sugar in drinks varies from 10 to 15 g per 100 mL (Brown et al., 2008) and in most cases no nutritional benefit other than energy is conferred by these drinks. In comparison to the elevated costs of production of sucrose, high-fructose corn syrup (HFCS) has served as a cheaper replacement to use in soft drinks and other foods available in the market, considering that the starch in corn can be easily transformed into glucose and fructose, yielding thus a similar molar mixture to sucrose (Brown et al., 2008, Bray et al., 2004). For this reason, there has been a growing debate towards the direct contribution of HFCS to the obesity epidemic considering it is one of the main sources of dietary fructose, particularly in the United States (Bray et al., 2004, White, 2008).

Fructose as compared to glucose-containing beverages has been documented to pose more detrimental cardiometabolic health effects if given as part of a hypercaloric diet –accounting for fructose's specific metabolism. Fructose produces fatty acids once metabolised in the liver, process which can trigger de *novo lipogenesis,* acute increases in triglycerides levels, low HDL and high LDL concentrations, increased ectopic fat deposition and insulin resistance states, all of them associated to cardiovascular disease (Le et al., 2009, Wang et al., 2014, Moore et al., 2014, Malik et al., 2010a). Fructose can also increase uric acid concentrations and reduce nitric oxide in tissues, contributing to mechanisms for coronary heart disease development (Wang et al., 2012). Studies analysing an inhibition of orexigenic gut hormones (ghrelin) and release of satiating ones (leptin) have suggested an addictive potential of fructose, yet to be investigated (Tappy and Lê, 2015).

Nevertheless, results from short (Raben et al., 2011) and medium-term (Maersk et al., 2012) trials contrasting the impact of sucrose-containing beverages in body composition and metabolic risk factors have also indicated increases in visceral adiposity, blood pressure, cholesterol and triglycerides in comparison to intake of artificially sweetened beverages (Maersk et al., 2012, Raben et al., 2011), milk or mineral water (Maersk et al., 2012).

While clarity will come from longer, blinded-clinical trials that assess the impact of ad libitum high vs low sugar diets (hence SSBs) on energy intake (placing emphasis in particular to ensuring dietary components remain comparable between groups), (Stanhope, 2016) the low nutritional quality of SSBs and overconsumption patterns around the globe can still place them as a target for prevention of cardiometabolic disorders.

1.4 Global & specific intakes of SSB

Estimates from 2010 on global intakes portrayed that individuals consumed on average 0.58 (8 oz) servings a day (or 132 millilitres/day) and that upper-middle and lower-middle income countries had highest levels of consumption (0.80 servings/day or 192 millilitres/day) and (0.59 servings/day or 141.6 millilitres/day), respectively. For instance, SSBs are primary contributors of added sugars within the American diet, accounting for 6.2% and 9.5% of total energy intake (TEI) in children and young adults, respectively (Welsh et al., 2011); whereas the latest UK's National Diet and Nutrition Survey revealed that non-alcoholic beverages contribute to 6% of TEI in children, 4% in young adults and 2% in older adults (Bates B, 2011). Similar trends have been also observed for Australians (Australian Government, 2014).

Data from countries in the Americas such as Mexico, have portrayed that soft drinks contribute to 10% of daily energy intakes both in children and adults, with an estimated consumption of 31.5 gallons per capita in 2010, followed by other Latin American countries such as Argentina (30.6 gallons per capita per year) and Chile (28.8 gallons) (Basu et al., 2013). Further, a recent report from 13 Latin American countries by the Pan American Health Organisation has shown a threefold-steep rise over the past decade in sales of sweetened drinks (Pan American Health Organization, 2015).

1.5 Lines of action

The available evidence on trends of consumption, contributions to energy intake and links to ill health support targeting SSB intake as part of obesity prevention efforts (World Health Organization, 2013).

Interventions addressing obesity behaviours (including a reduction in SSB consumption) tend to be complex and difficult to deconstruct accounting for the multiple targets and determinants interacting around them. Yet, the incorporation of behaviour change techniques (BCTs) has been highlighted to facilitate identifying those exerting better outcomes and potentially lead to better practice and use of resources within clinical and public health sectors (Michie et al., 2011a, Michie et al., 2009b, House of Lords, 2011). Decreasing SSB has been done through several approaches both non-regulatory and regulatory: the latter understood as a higher regulation of the individual and with a higher state involvement (Lord and Unwin, 2007).

Non-regulatory initiatives have encompassed the provision of health promotion and nutritional education seeking to increase awareness of the content of sugar in drinks and the health consequences associated to greater intakes. Changes to the physical environment by making healthier options a default preference (i.e., water coolers or low-sugar beverages available at schools) have also been emphasised. In the case of younger populations, the WHO has recommended member states as part of the 6 global nutrition targets for 2025 (World Health Organization, 2014):

- A higher regulation of the marketing of food and non-alcoholic beverages to children,
- Adoption of nutrient-based standards to facilitate healthy diets and safe *drinking water* accessible in public settings (i.e., preschools, nurseries and schools),
- Stricter regulations that limit fast-food outlets near childcare settings, considering consumption of SSB has been associated to consumption of certain food groups, including fast food items (Mathias et al., 2013) and displacement of other groups such as milk (Keller et al., 2009).

Assessment of the effectiveness of these strategies has illustrated that educational-based interventions, inclusive of follow-up and changes in the environment are effective in reducing consumption of SSB in children (Avery et al., 2015). Further, a systematic review on the impact of school-based programmes on SSB intake in adolescents found a success rate of 70% across them (26 out of 36 studies), with those incorporating a regulatory (legislative) or environmental component more often being effective in comparison to those incorporating educational features only (success rates of 90 % vs 65%) (Vezina-Im et al., 2017). Yet, the need to educate individuals towards the healthier alternatives to SSB in particular, has been emphasised if enhanced effects from taxation of SSB are sought after (Zheng et al., 2015a).

1.6 Substitution of SSB with other suitable alternatives

The effect that replacing SSB with healthier (lower in sugar) options on long-term health outcomes (i.e. body weight composition, type 2 diabetes and stroke) was recently investigated by Zheng *et al.* (Zheng et al., 2015a). Based on their narrative synthesis of available literature (n=10 studies, 6 longitudinal, 4 interventional), a beneficial effect from substituting SSB with low-calorie alternatives (defined as *plain water, artificially sweetened* *beverages, unsweetened coffee and tea, 100% fruit juice and milk*) was clearer and stronger for body weight outcomes in 5 studies (2 cohorts and 3 RCTs) than it was for other cardiometabolic risk factors or conditions. To be noted though, is that the most suitable beverage alternatives could not be clarified as this was related to specific disease outcomes. However, half of the studies in this review showed greater benefits for total energy intake, weight loss and glucose levels in all age groups when SSB were substituted with water rather than with other low-calorie beverages (Zheng et al., 2015a), reinforcing thus current dietary guidelines of recommending water as a preferred choice of beverage (U.S. Department of Health and Human Services and U.S. Department of Agriculture, 2015-2020) .

These findings were also consistent with later research by Zheng *et al.* in which daily substitution of SSB with water or milk was linked to lower gains in body fatness at follow-up (6 years after) in a cohort of 9 year old Danish children (Zheng et al., 2015b). Results were attenuated and no longer significant when adjustments for energy from beverage and non-beverage sources were considered in the statistical model. This emphasises that not only the energy *per se* from SSB but other non-energetic features (i.e., glycaemic load, effects from fructose) could be contributing to the relationship between SSB and changes in body composition (Zheng et al., 2015b). Difficulties in current dietary assessment tools to measure water intake over the whole day has been highlighted as a limitation in the field, and an aspect criticised by other scholars (Vezina-Im et al., 2017, Popkin et al., 2010). Certainly, dietary assessment methods have had a wider focus on capturing energy and macronutrients rather than water *per se* (Popkin et al., 2010). Developments in mobile and web-based tools, for example, could allow for better collection and analysis of food and specifically beverage data (Carter et al., 2015, Subar et al., 2012). Once easily available and accessible for investigators these could greatly enhance surveillance, epidemiologic, and intervention research in different contexts (Subar et al., 2016).

1.7 Literature gap

Causal associations between higher intakes of SSB and deleterious health effects have been widely discussed. Evidence, nevertheless has remained scarce regarding the direct impact that largely individual interventions have had to curb the consumption of SSBs across all age groups and not solely in younger populations (Avery et al., 2015, Martin et al., 2013). Increases in water intake as a better choice of beverage from behaviour-change interventions have also not been quantified.

As depicted in the Obesity Policy Action logic model in **Figure 1-2** *"midstream or behavioural approaches"* are needed to support achievement of health, economic, social, and environmental outcomes in the obesity epidemic (Sacks et al., 2009). This framework recognises that policy actions can influence behaviour directly or indirectly (via changes in the built environment), and therefore in order to gain improvements in physical conditions and disease risk achieving improvements in eating behaviours is needed as a first step (Sacks et al., 2009).

As leading resources to assist evidence and decision making processes for healthcare, including nutrition policy and practice, Cochrane Reviews have usually had a wider scope, focussed on upstream factors related to health: fortification, legislation or interventions implemented by the media, sporting institutions or workfare places to improve healthy eating and physical activity behaviours (Cochrane, 2017). While the nutrition evidence synthesis generated is tightly coupled to WHO research priorities, it has been recognised that Cochrane will not necessarily have all the answers needed by stakeholders (Cochrane Nutrition, 2017), particularly on intermediary outcomes that are often dismissed in their reviews.

Understanding the elements, behaviour change techniques included that are motivating change in individuals is one of the many steps needed to find the best way forward to influence behaviours and attitudes towards SSB. This particularly relevant for countries that have been most affected by nutritional transitions. A vast majority of interventional studies on SSB originates from high income countries in which better understanding, funding, and political interest may facilitate addressing such research gaps. Yet the approaches taken (including dietary methodologies used) could still guide and be adapted to other less-developed contexts, such as in Mexico.

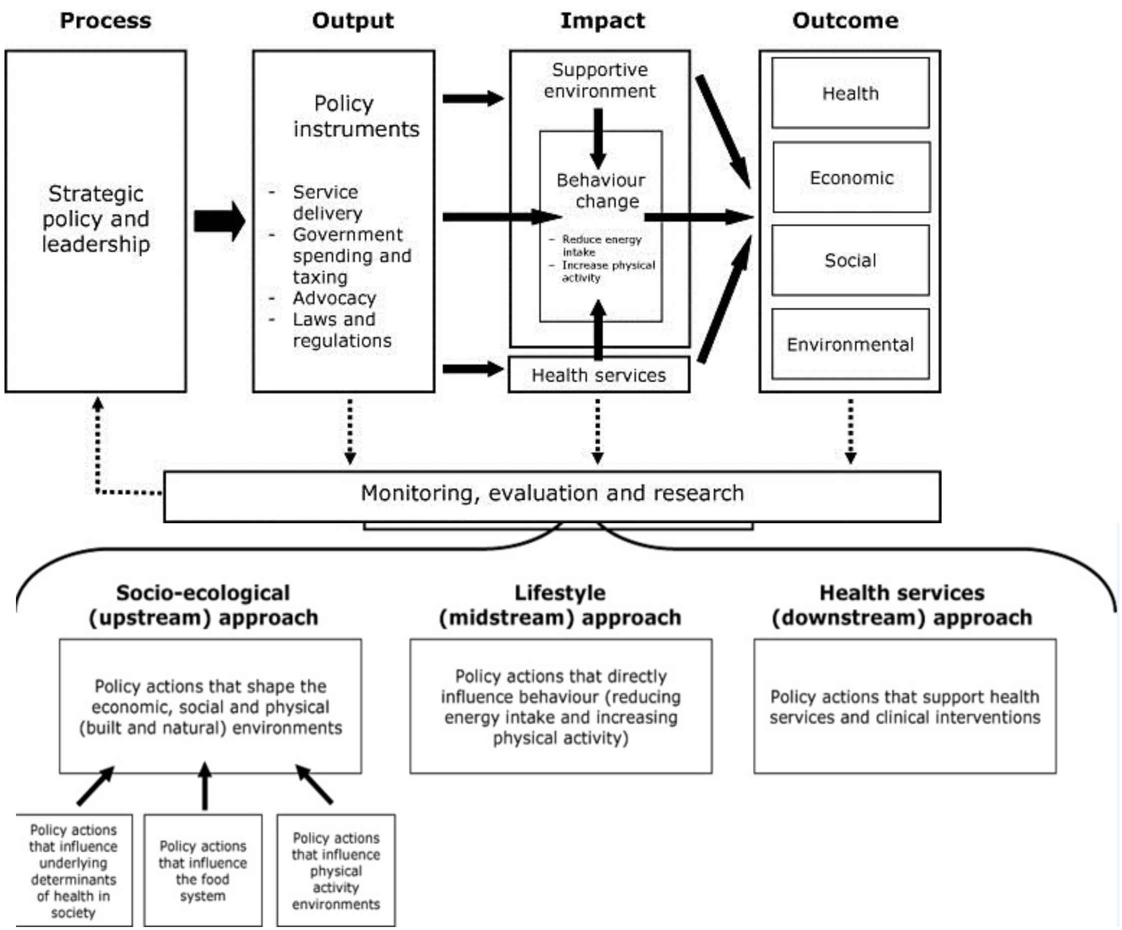

Figure 1-2 Obesity Policy Action framework: breakdown of upstream, midstream and downstream policy targets.

Source Sacks *et al*. (Sacks et al., 2009)

1.8 SSB and the Mexican context in children

1.8.1 Intakes of SSB in Mexico across children and strategies implemented

In 2008, Barquera *et al.* reported that consumption of sweetened drinks (including carbonated beverages, sugar-added juices and sweetened fruit water) accounted for up to 11% of TEI in Mexican school-aged children (Barquera et al., 2010) or approximately 126 kcal/per day [Standard Error (SE) 3.7] (Sánchez-Pimienta et al., 2016). Considering obesity rates in this population, several documents were produced by the federal executive emphasising different lines of action to prevent and control obesity and associated NCDs in the former population (Secretaria de Salud, 2010, Poder Ejecutivo de la Nacion, 2013). Initiatives undertaken in Mexico include the reinforcement of the National Agreement for Healthy Nutrition produced in 2010, which targeted -amongst others: a decrease in SSB by forbidding their expenditure at schools' cafeterias allowing only flavoured sugared water (fruit-based) and plain bottled-water to be sold (Secretaria de Salud, 2010). Stricter guidelines in regards to portion size and specific selling days of SSBs have been additionally incorporated in the latest National scheme for nutrition in schools (Secretaria de Educacion Publica, 2014). Furthermore, potable water supply at schools, responsible marketing by banning misleading food and beverage television advertisements aimed at children, changes in portion sizes of energy-dense food products and enhanced nutritional labelling have all been fostered in the most recent Health Sectorial Program 2013-2018 (Poder Ejecutivo de la Nacion, 2013). Concomitantly, an excise tax to sugar-added beverages (equivalent to 10% or 1 Mexican peso per litre) was introduced in 2014 (Poder Legislativo de la Nacion, 2014).

Following central instructions and initiatives at the local level, in the state of Guanajuato (central Mexico) at the beginning of each academic period, staff from schools' cooperatives receive an annual workshop (approximately 5hrs) by the nutritionists within the ministry of Education on healthy food and beverage preparation; emphasis is placed on lowering content of sugar and fat in handmade/fresh products that can be offered. Though canteen's receive a certificate of participation which facilitates their future sustainability within the schools, unannounced monitoring occurs from time to time by nutritionists along the Ministry (currently there are 6 nutritionists for a total of 1000 schools) to verify that restricted products are not sold. Failure to pass this monitoring can result in the interdiction to the entrepreneur to operate within a given school and direct sanctions to the school by removing their certification as a “healthy promoting school” which also translates in lower global scores across success indicators.

1.8.2 Impact of initiatives targeting SSBs

Though the actions commissioned are relevant to address the current obesity problem in Mexican children, the impact they have had remains unclear, as their enforcement and evaluation have been discretionary and limited to coverage rates: focused on measuring the number of schools complying o technical criteria on healthy eating, hygienic practices and attrition rates/scholar desertion (Secretaria de Educacion Publica, 2014, Rivera-Dommarco et al., 2014). Preliminary results from a study conducted by the National Institute of Public health has revealed a 6% decline in *purchases* of SSB during the first 12 months of implementation of the tax in comparison to the previous year (Colchero et al., 2016). Reports from 1500 individuals surveyed by a Mexican NGO have also indicated a reduction in soft drink intake in 52% of them as a result of the tax (Torres Cruz, 2014). Nevertheless, future evidence will determine whether the tax has curbed *actual* intakes of SSBs and has helped reduce the obesity prevalence. Transparency by regulatory instances in Mexico will determine if the revenues obtained by this fiscal measure have been efficiently earmarked in the promotion of healthier environments and eating initiatives across all populations (particularly in the most deprived).

Information at the school level has not been too promising, as reports by the National Institute of Public Health in 2014 indicated that (Rivera-Dommarco et al., 2014):

- Only **34.1%** of school-aged children seem to bring **plain water** with their lunch boxes,
- **50.2%** still bring **sweetened beverages** such as fruit juices and soft drinks –which actually represent 20.7% of the energy they consume just from items brought from home (most of them receive money to purchase further food items at school)
- Although widely stressed, only one third (1/3) of the primary schools surveyed (n=110 schools representative of 58 041 students) have access to drinking water (water fountains) and their sanitary conditions remain questionable.

Further, an observational study conducted in 2016 across 15 primary schools in the southern part of Mexico (state of Tabasco) assessing the adherence to the National Agreement for Healthy Nutrition also found that SSB were still sold in 73% of them and did not offer potable water as a first choice of beverage (Gallegos Gallegos et al., 2016). Results from another descriptive study in Guanajuato) evaluating differences between schools that had been certified as ”health promoting schools” (n=2), in comparison to those in progress for obtaining this certification (n=2) and those that were not yet certified (n=2), showed no differences in body weight or diet quality (throughout the day) within a subsample of students (N=94 in each setting) under either school’s framework (Morales-Rivera and Granados-Chavez, 2010). Lack of economic and human resources at the school level to adequately manage and deliver this nutritional scheme might be one of the many factors hindering programme’s effectiveness.

1.9 Thesis aim

Research into a broader range of effective strategies to help reduce the consumption of sugar-sweetened beverages should be further supported (Obesity policy coalition, 2014, Rivera-Dommarco et al., 2014). It has been well recognised that schools offer valuable settings for the prevention of overweight and obesity in children, by providing worthwhile opportunities for delivering health education and contributing to the development of desirable eating behaviours. School-based programmes have the potential to reach many children from a range of socioeconomic backgrounds thus making the school environment “an ideal setting to acquire habits, skills and knowledge related to nutrition and healthy diets and provide a framework that may facilitate the sustainability of an intervention over time” (Khambalia et al., 2012).

Considering the momentum that SSB have gained in Mexico and the challenges still faced by the educational system, it becomes feasible to keep addressing the school environment to influence desirable health outcomes (looking for a decrease in SSB and thus impact obesity rates) across a different range of stakeholders (children, school staff, Ministry of Education).

Consequently, the **aim** of this thesis is to determine the effectiveness of interventions and intervention’s components to reduce consumption of sugar-sweetened beverages so as to orientate the development and implementation of a pilot study in school-aged children in central Mexico.

1.10 Structure of the thesis

In order to identify the best evidence available in this area and thus translate it into practice, this thesis has been divided in 7 chapters, the first three relate to the background, planning steps, identification, quantitative and qualitative synthesis of the literature around interventions seeking to decrease sugar-sweetened beverage intake or increase water intake. The following three chapters relate to the health background of children living in central Mexico (Guanajuato State) and the subsequent protocol and findings of the pilot study ("*DrinkSmart"* in schools' project) that was conducted across four public primary schools in the biggest city in Guanajuato state. The final chapter contains the discussion of the overall results, the implications for research and policy, and the concluding remarks. **Figure 1-3** illustrates the thesis framework.

1.11 Study objectives by chapter

Chapter 2: **Impact of interventions to reduce sugar-sweetened beverage intake in children and adults: a protocol for a systematic review and meta-analysis**

- To illustrate the overall development and statistical plan for the systematic review and meta-analysis on interventions to decrease intake of SSB and increase water intake.
- To provide an overview of the definitions, inclusion/exclusion criteria, primary and secondary outcomes considered, the searching strategies executed, statistical analysis plan and tools utilised both for data extraction and quality appraisal.

Chapter 3: **Interventions to reduce consumption of sugar-sweetened beverages or increase water intake: evidence from a systematic review and meta-analysis**

- To qualitative and quantitatively assess the literature meeting inclusion criteria for the systematic review and meta-analysis.
- To investigate the effects of different intervention components on primary and secondary outcomes and heterogeneity.

Chapter 4: **Prevalence of metabolic syndrome in children from central Mexico.**

- To outline the process of data collection, cleaning and statistical analysis for biochemical parameters and BMI.
- To describe and discuss the prevalence of metabolic syndrome in a subsample of children living in Guanajuato state.

Chapter 5: **Design and methods of a non-randomised controlled pilot study to decrease sugar sweetened beverages by promoting water intake in primary schools**

- To outline the methodology that was followed to develop, implement and assess the "*Drink Smart*" in schools' project.

Chapter 6: **Reducing SSB intake through the promotion of drinking water: results from the Drink Smart in schools' project.**

- To discuss the primary outcomes of the *Drink Smart* in schools' project, alongside the findings on the process and formative evaluation.
- To explore the study's delivery process, participant's acceptability as well as satisfaction from activities and information provided throughout the intervention (process evaluation).

Chapter 7: **Discussion and implications for policy**

- To expand on the discussion provided at each chapter as well as situate findings within a broader policy and research context.
- To present the strengths and limitations of the thesis and the implications for future research.

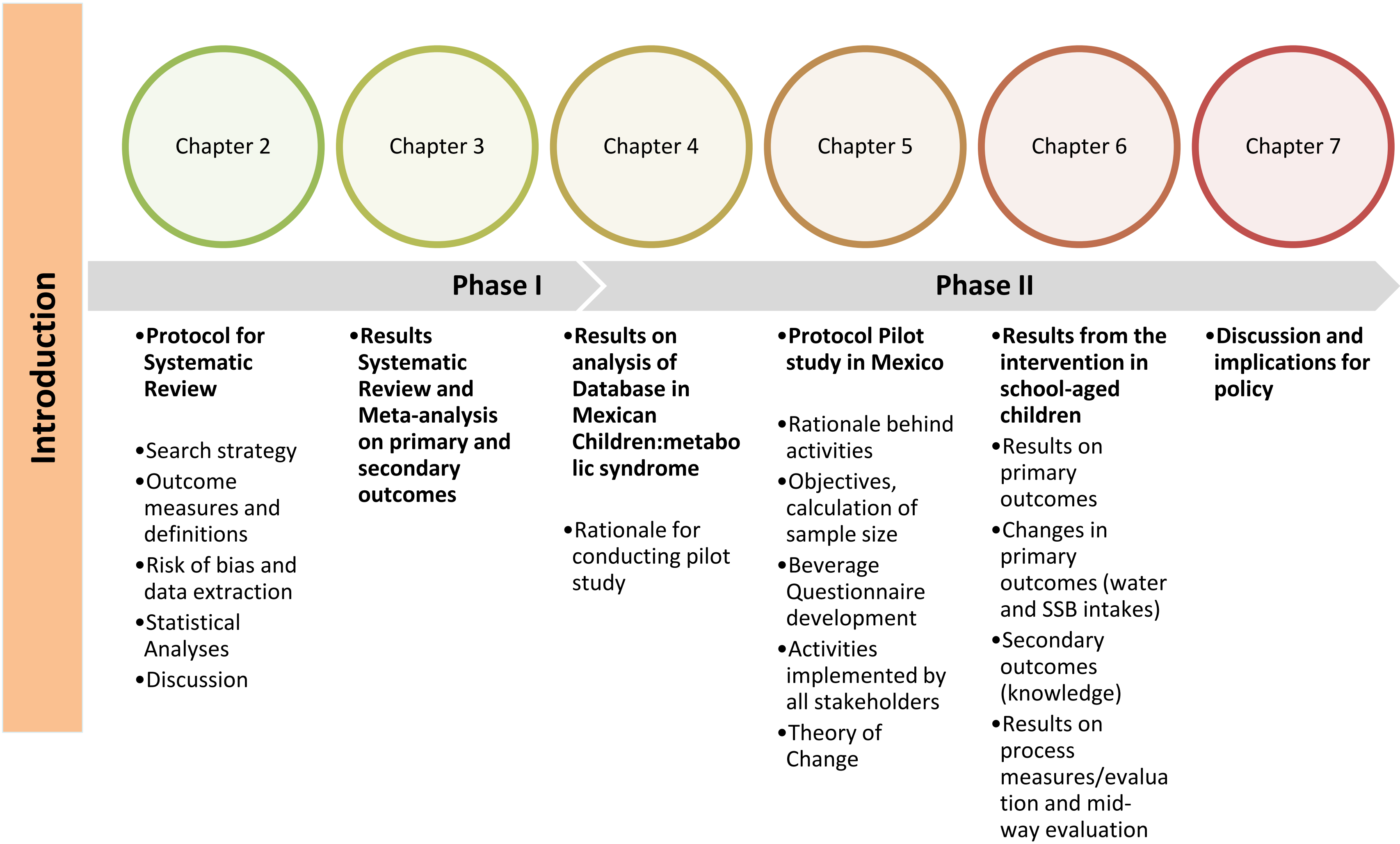

Figure 1-3 Thesis Framework.

Chapter 2 : Impact of interventions to reduce sugar-sweetened beverage intake in children and adults: a protocol for a systematic review and meta-analysis

2.1 Abstract

Introduction Sugar-sweetened beverages have been stressed as relevant targets of public health interventions considering the negative outcomes derived from their excessive intake. Though the evidence from published literature grows to support a cause-and-effect association of SSBs with obesity and other diseases, little is known on the effectiveness that strategies alone or as part of multi-component programmes have had to influence this particular dietary behaviour across all ages. Therefore, this review and meta-analysis aimed to evaluate the effect that interventions have had to decrease their consumption or increase water intake in children and adults so as to guide the design of future programmes and inform policy making.

Methods Included studies in this review were randomised controlled trials and quasi experimental interventions (with a control group) that have reported baseline and post-intervention intakes of SSBs or water and that have been published from 1990 in any language. A thorough search was performed in MEDLINE, EMBASE, Scopus, Web of Science, Cochrane's central register of controlled trials and the Global Health Library. Two independent reviewers conducted initial screening of potentially included articles and later extracted data to analyse domains of intervention design and delivery (with emphasis on behaviour change techniques used as rationale), as well as results in changes on consumption patterns and behavioural determinants. Internal and external validity of each study was also appraised. A random- effects meta-analysis was performed, accounting for the sufficient number of studies meeting inclusion criteria.

Conclusion This systematic review has summarised the current available evidence on characteristics, outcomes and overall effectiveness of largely, community-based interventions targeting consumption of SSB to reduce energy intake. Findings herein, can guide future public health initiatives tackling obesity-related behaviours, in pursuit of meeting dietary guidelines and improving health outcomes in children and adults.

2.2 Introduction

Obesity represents one of the most important public health challenges of the modern era. Several responses have been undertaken to counteract this problem mainly through interventions that have addressed modifiable factors –such as healthy eating and physical activity (Shaw et al., 2006, Ho et al., 2013, Waters et al., 2011, Wadden et al., 2012). Results nevertheless have been inconsistent in the long-term, partly due to a lack of commitment and allocated resources from national levels for evaluation and to guarantee their sustainability (World Health Organization, 2008a).

In the majority of obesity prevention programmes, strategies have focused on discouraging high intakes of fat (mainly saturated and *trans*) and added sugars in food and beverages. Evidence has additionally supported the potential to target individual dietary elements that contribute to higher energy intakes and that increase the risk of developing obesity (Mozaffarian et al., 2011, Hu, 2013). This is the case with sugar-sweetened beverages (SSBs), which are high sources of energy with poor nutritional and satiating values (Stull et al., 2008, Hu, 2013). SSBs are made up of naturally occurring caloric sweeteners such as sucrose (50% glucose and 50% fructose), fruit juice concentrates or more frequently high fructose corn syrup (45% glucose and 55% fructose) (Malik and Hu, 2012). The latter, in particular, has been attributed as one of the main contributors to the adverse health effects from SSBs due to the metabolic pathways of fructose degradation (exacerbating triglyceride synthesis, insulin resistance and uric acid production) (Bray, 2013). However, as the use of any caloric sweetener in beverages appears to have similar acute responses in the body more robust study designs and data are warranted to determine detrimental health outcomes in the longer term (Teff et al., 2009, Wiebe et al., 2011, Rippe and Angelopoulos, 2013, Greenwood et al., 2014, Maersk et al., 2012).

Considering the burden of disease derived by obesity and the financial constraints posed to healthcare systems globally, policy makers and governments around the world have widely supported and joined efforts in improving low- or non-caloric beverage consumption patterns. Actions taken have encompassed interventions to decrease consumption of SSBs or/and increase water intake at community levels, through school policies and media coverage (health campaigns). Political measures like taxation and marketing restrictions have been also implemented.

Nevertheless, there is general recognition about the need for sufficient evidence to help decide the best public health action to decrease sugar-sweetened beverage consumption within populations (Hu, 2013, Malik et al., 2013b). Though literature has particularly highlighted the importance to address behaviour change in interventions so that effective and successful practice can be achieved both in clinical and public health sectors (Michie et al., 2011b), to-date there are no reviews available that have evaluated the content of interventions seeking to modify behaviour of SSB consumption. The reviews that are available have focused on the cause-and-effect association of SSB with obesity and other health outcomes and have advocated the need for successful initiatives to promote a change in SSB consumption (Malik et al., 2006, Schulze et al., 2004, Forshee et al., 2008, Malik et al., 2013a, Greenwood et al., 2014, Malik et al., 2010a).

As an issue of growing interest internationally it is then necessary to inform intervention designers as well as higher levels of authority of the interventions that have most success in reducing SSB intake, in order to improve dietary guidelines, health outcomes and ensure better allocation of health resources.

2.3 Aims

The main purpose of this systematic review and meta-analysis was to evaluate the effect of public health interventions to reduce sugar-sweetened beverage intake or increase water intake in children and adults.

2.3.1 Primary objectives include:

- Evaluation of intervention elements or factors generating a change in SSB behaviour (either on their frequency of consumption or amount consumed) in children and adults.
- Evaluation of intervention elements or factors generating a change in water intake in children and adults.

2.3.2 Secondary objectives:

- Identification and evaluation of the most effective behavioural change techniques targeting SSBs or water intake.
- Evaluation of programme's delivery processes and their contribution to achieving sustainable outcomes.

- Identification of the effectiveness of interventions targeting SSBs or water intake to decrease health inequalities.

2.3.3 How the intervention might work

As portrayed in **Figure 2-1** evidence surrounding the deleterious effects from increased intake of added sugars in the diet (such as those coming from SSBs), has encouraged different initiatives involving a wide range of stakeholders (from children to governmental authorities). By addressing SSB consumption, it is firstly desired to have an impact on participants' awareness, knowledge and beliefs that could increase their motivation to change this dietary behaviour (Michie et al., 2009b). By successfully turning attempts at change into action, weight gain can be prevented and further benefits on a larger scale can be achieved. It should be noted that the macro-environment or context per se may stand as a barrier at primary stages of interventions for enabling the development of desirable skills and behaviours particularly in those from disadvantaged backgrounds (Michie et al., 2009b, Michie et al., 2011b).

2.4 Methods

2.4.1 Research questions

- Can public health interventions reduce the intake of sugar-sweetened beverages in children and adults?
- Can public health interventions increase water intake in children and adults?
- Which intervention components/elements are contributing to reducing SSB intake or increasing water intake in children and adults?
- Which intervention components/elements are hindering or benefiting the implementation/delivery process of programmes targeting consumption of drinking water or SSB?
- Which are the most potentially effective behavioural techniques underpinning changes in SSB or water intake?
- What has been the impact of public health interventions targeting either a reduction in SSB consumption or increase in water intake on reducing health inequalities?

2.4.2 Description of the condition/issue

2.4.2.1 What is a sugar-sweetened beverage?

The range of products that fall into such a category is broad as its characterisation and availability varies from country to country. Language discrepancies also pose a difficulty. The lack of a standard definition across different studies has been previously highlighted (Althuis and Weed, 2013). Yet, major presence of added sugars is the key element to judge or rate overall healthiness and their inclusion under such a term.

Operational definitions

Existing information mainly describes a sugar-sweetened beverage as a non-diet, non-alcoholic and non-dairy cold or warm drink (carbonated or still), with added sugars (derived from energy-yielding sweeteners/sources both natural and processed), including fruit drinks, nectars and cordials with less than 100% fruit juice as well as sports or energy drinks, ready to drink sweetened tea and ready to drink sweetened coffee (Gibson, 2008, Han and Powell, 2013).

In the case of drinking water, this was considered as water that is intended to be ingested or for human consumption. Other terms frequently found in the literature are potable water, plain water or bottled water.

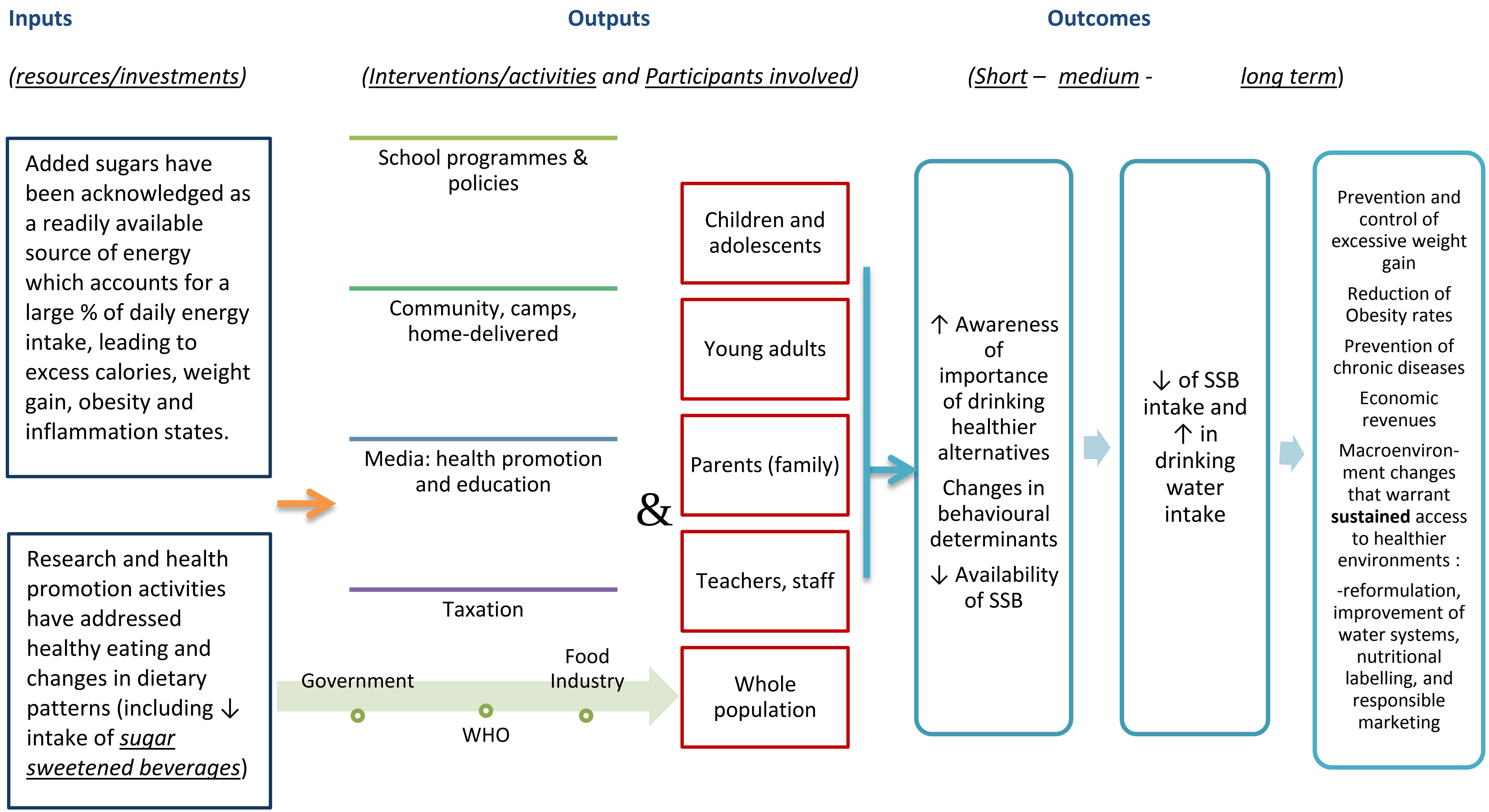

Figure 2-1 Conceptual framework of public health interventions aiming to decrease consumption of SSBs.

2.4.3 Description of the intervention

'Intervention' and 'programme' were interchangeable terms used throughout this review. Public health intervention were understood as a set of actions (within policy, regulatory initiatives, single strategy projects or multi-component programmes) with a coherent objective to bring about change or produce identifiable outcomes seeking to promote health or prevent disease in communities or populations (Rychetnik et al., 2002).

2.4.3.1 Type of studies

This review included:

- Randomised controlled trials (RCTs) reporting a change in sugar-sweetened beverage or water intake throughout the day as part of the intervention targets (even if they were not explicitly designed to address SSB or drinking water alone).
- Quasi-experimental studies and pilot trials (considering the probable lack of RCTs available).
- Studies that have been published from January 1990 in any language.

This review excluded:

- Observational and small studies (e.g. enrolling fewer than 10 people in each arm) (Evans et al., 2012).
- Studies looking at health outcomes (Type 2 diabetes, cardiovascular disease, etc.) as the primary outcome with no measure of intake of SSB or drinking water being reported.
- Studies addressing Gestational Diabetes- if no randomisation took place.
- Studies that did not provide an objective measure of SSB (describing frequency of consumption) derived from a standard-assessment method (24-hour recall, weighed or un-weighed food diary or food frequency questionnaire).
- Studies that did not have baseline and post intervention information on either primary outcomes (SSB or water consumption).
- Studies that did not have a control group or that do not report any measure of variation such as standard deviation, standard error or 95% confidence intervals will not be included in the meta-analysis but may be considered for the review.
- Alcohol interventions (those targeting reduction of alcohol intake).
- Studies addressing sanitation or hygiene aspects.
- Rehydration and subjective appetite trials (those looking at intake of SSB and acute changes in hormonal or appetite intake).

For the purpose of the present review the *control group* will also be referred to as the *comparison group* which should be understood as:

- The arm of a programme that did not receive the planned or active intervention (either no activity was given, a "usual care" approach was taken or an alternative intervention was provided).

2.4.3.2 Type of participants

Participants included were subjects aged 3 years and over. For mixed-aged groups, only studies where more than 50% of the participants were 3 years or over were included.

For interventions targeting individuals with morbid obesity (Body Mass Index ≥ 40 kg/m^2), metabolic syndrome and chronic diseases such as type 2 diabetes, they were only reviewed if they were part of a RCT, as by already having a clinical condition or disease, randomisation would diminish or prevent a more favourable prognosis to one of the groups. This would warrant that they both started with the same opportunities for success or beneficial effects.

Participants suffering from a psychiatric condition (e.g. binge eaters) were excluded.

2.4.3.3 Type of interventions

This review considered public health interventions addressing a reduction in SSB consumption or water increase that had a minimum length of 4 weeks follow-up (from baseline data collection until the first assessment of outcomes) and that were provided mainly at community settings. Studies taking place at clinical locations (e.g. hospital) were only reviewed if participants had been allocated into intervention or control groups by random methods.

Interventions addressing artificially sweetened drinks/diet beverages (those flavoured with non-energy yielding sweeteners such as aspartame, sucralose, saccharin, acesulfame potassium, neotame or stevia) (Mattes and Popkin, 2009) were only included if these were used as alternatives for reducing intakes of SSB and dietary patterns of consumption were reported. Interventions replacing SSB with 100% fruit juice (for a healthier substitution) were not included as it may was difficult to determine the real concentration of natural occurring sugars in such drinks which could have biased results. Interventions targeting an increase in fruit and vegetable juice consumption as the primary outcome were also excluded.

Trials looking at effects of beverage replacement on hormonal response, appetite, and subsequent energy intake were not included.

2.4.3.4 Type of outcome measures

Primary outcomes

- Change in SSB consumption (in millilitres/per day)
- Change in water intake (in millilitres/per day)

Secondary outcomes

- Presence or absence of specific intervention components such as behaviour change techniques.
- Change in knowledge/attitude/beliefs in regard to SSB and water consumption as measured by an existing taxonomy on behaviour-change techniques.
- Changes in physical environments and policies.
- Changes in health inequalities as measured by interactions between socio-demographic characteristics of participants and intervention's effects/outcomes.

2.4.3.5 Search methods for identification of studies

Search strategy

The PICO framework (acronym for patient/ intervention/comparator and outcome) was used as a first tool to identify pertinent terminology for inclusion in the search strategy. Considering the characteristics of this review "setting" was used instead of the "comparator" category. A combination of keywords relating mostly to interventions, settings and outcomes comprised the searching. Medical subheadings (MeSH) and other controlled vocabulary used in indexed journals were considered for the development of the strategy.

The following databases were used to search for relevant articles published from January 1990 in any language, so as to have a wider coverage:

- OVID Medline
- Cochrane central register of controlled trials (CENTRAL)
- EMBASE
- Scopus
- Web of Science
- The Global Health Library
- DARE (Database of Abstracts of Reviews of Effects)
- Clinicaltrials.gov
- The Trials Register of Promoting Health Interventions (TRoPHI)
- International Clinical Trials Registry Platform (ICTRP)
- metaRegister of Controlled Trials (mRCT)

Reference lists were also scanned in order to include missing relevant papers. Selected articles were imported to an Endnote library. An example of the searching strategy designed and executed in Medline (OVID) can be seen in **appendix A**.

2.4.4 Data collection and analysis

2.4.4.1 Selection of studies

Two trained reviewers independently performed an initial screening based on title and abstract (main researcher and assistant). Any disagreements found at this stage was discussed by them and- if required- resolved by discussion and consultation with a third review author.

A copy of full articles was obtained for all potentially relevant studies. For unavailable articles at the University of Leeds, authors were contacted electronically and papers were also ordered from the British Library. Any discrepancies arising at this stage were also be resolved by consulting a third reviewer.

The process of inclusion and exclusion of records at each stage was guided, documented and described using the PRISMA (Preferred reporting items of systematic reviews and meta-analyses) flow-chart which is a recognised tool from a group of reviewers, clinicians, editors and consumers seeking to enhance transparency in published systematic reviews (Moher et al., 2009).

2.4.5 Data extraction and management

Data from the studies meeting the inclusion criteria were entered into Review Manager 5 software and Stata (the latter in duplicate). Characteristics regarding type of study, allocation concealment, sample size, intervention targets, setting, population's age, country and year of study, length of the intervention, primary and secondary outcomes, statistical measures, results as well as attrition rates were fully extracted by the main researcher and a trained assistant using an adapted spreadsheet form available from the Cochrane Collaboration (Higgins, 2011) and then managed with the afore mentioned software.

The following characteristics were summarised and presented in tables from studies meeting inclusion criteria: study details (author, year of publication, trial design, place of study) study objective and aims, study duration, setting of intervention, content, delivery (frequency, duration and intensity of activities), duration of intervention and follow-up, participants' characteristics (mean age, sex and other socio-demographic features available), outcome definition and overall main results on primary outcomes.

Authors were contacted if no definition or description of serving sizes is available within the information of a study. If no response was provided, then a standardised portion or serving of SSB was imputed, that being 8 fluid oz or approximately 240 mL.

When studies had measured intakes of SSB or drinking water at several points across a given intervention, baseline and an average of follow-up measurements were used for analysis. If this was not the case, then baseline and post-intervention measurements was considered. Frequency of consumption of SSBs or water was analysed and transformed –if necessary- into "times per day". For studies reporting more than one group or category of SSBs without the total, in the first instance the authors were contacted to determine whether results for total intake were available.

If this was not possible then the most important type of SSB was entered into the analysis used in the meta-analysis. This was determined by agreement with all those involved in the review.

Additional information-when available-on equity was analysed using the PROGRESS framework (which stands for place of residence, race or ethnicity, occupation, gender, religion, education, socioeconomic status, social status) to identify if the intervention had more positive effects in certain participants or groups.

As one of the main objectives of this review was to identify the behaviour changing techniques that explain intervention effectiveness, two independent reviewers judged and coded these (both in the intervention and control groups) with help of an existing reliable taxonomy of 26 techniques that has characterised the content of interventions addressing healthy eating amongst obese populations (Michie et al., 2009a). Description and examples of techniques can be found in **appendix B** (Michie et al., 2011a).

2.5 Statistical analysis

Random-effects meta-analysis was carried out to produce a pooled estimate of the difference in millilitres (mL) of SSB and drinking water between the intervention and control arms in the studies included in the review. The data was displayed in forest plots, firstly of all studies in the review and secondly in subgroups according to the following age stages of childhood development and adulthood: 3-5 years old, 6-12 years old, 13-18 years old and 19 and above (Waters et al., 2011). If the whole family was targeted, the intervention was allocated under the latter subgroup. The I^2 test was used to check for heterogeneity across studies. Results of heterogeneity-denoted by I^2- between 25- 50% were indicative of moderate heterogeneity, from 50-75% of substantial and above 75% of considerable heterogeneity, respectively (Higgins, 2011). If there were sufficient studies available -more than 10 studies- (Higgins, 2011), a meta-regression was conducted to explore whether heterogeneity was explained by the behaviour-change techniques used in the intervention. This helped determine whether the use of certain techniques was associated with more effective interventions. Potential confounders were also taken into account in the analysis such as age, gender, setting of intervention and randomisation. Mean differences and 95% confidence intervals were used in the analysis of the primary outcome (change in mL of SSBs or water intakes). Reported means together with standard errors were used to determine this.

Cochrane's tool of risk of bias were used to assess quality of studies (both in randomised, non-randomised and cluster-randomised controlled trials) with regards to allocation concealment, sequence generation, blinding, treatment of completers versus non-completers, selective reporting and other bias (Higgins et al., 2011). Cluster RCTs were assessed as low risk of bias if the unit of analysis was considered at the same level as the allocation (either by school, classes, or community) and allocation was carried out on all entities before the intervention had started. In the case of studies that had not accounted for this, then effect estimates and their standard errors from correct analyses of cluster-randomized trials may be meta-analysed using the generic inverse-variance method in RevMan. Reporting bias was identified in studies that included outcomes throughout the methodology but were not presented in the results section or referenced in other peer reviewed publications.

Quantitative synthesis was the desired approach, yet if very small numbers of studies were available and did not allow this or if heterogeneity was found to be too high or unexplained, then a narrative synthesis was sought after.

2.6 Discussion

The magnitude of the obesity epidemic in both children and adults worldwide urgently demands action and better approaches. Both observational and experimental evidence have successfully demonstrated a link between SSB intake, weight gain and its related co-morbidities (that mainly being obesity, metabolic syndrome, CVD and type 2 diabetes). As a result, research has suggested that SSB are a feasible target for public health initiatives in order to reduce the obesity prevalence and other negative consequences (Hu, 2013, Malik et al., 2013b).

There has been a growing debate in regard to a causative link between sugar-sweetened beverages and weight gain in recent years (Hu, 2013, Althuis and Weed, 2013, Kaiser et al., 2013). Nevertheless, much of the attention given has focused solely on the longer health outcomes related to morbidity rather than those related to behaviour change. The former could be the result of the multi-factorial context in which health-related behaviours lie, which pose one of the greatest challenges when seeking to tackle unhealthy dietary patterns (World Health Organization, 2008b).

Despite the fact that the complexity of a problem like obesity does not rely on the reduced consumption of a single food item (in this case sugar-sweetened beverages) it should be recognised that their nutritional composition is poor as they do not provide any real health benefit nor appear to have protective effects in any published study so far. Thus, considering the documented parallel increase in consumption trends and obesity rates in many countries, there is much expectation to know the feasibility of generating a change in SSB intake and whether current resources should be kept or placed elsewhere.

The findings derived from this systematic review and meta-analysis will therefore help in the development of improved public health initiatives tackling obesity, particularly in countries with a magnified consumption of SSB. It will also help identify the pathways and discriminate amongst the array of possibilities available to generate a desirable and sustainable change towards healthier drinking patterns.

While it is likely that the number of papers available addressing the intended research, questions will be limited–as it is a topic that has gained recent momentum-this review will particularly be benefited by including literature in any language. Consequently, it will be possible to detect useful, innovative strategies or elements that could be integrated in upcoming interventions or programmes for future research and policy making.

Chapter 3 : Interventions to reduce consumption of sugar-sweetened beverages or increase water intake: evidence from a systematic review and meta-analysis

3.1 Abstract

Introduction Evidence that links higher intake of sugar-sweetened beverages (SSB) with greater risk ill health continues to grow and supports the need for public health and community action

Methods A systematic review and meta-analysis were conducted to evaluate the effects of interventions to reduce sugar-sweetened beverages (SSB) or increase water intakes and to examine the impact of behaviour change techniques (BCTs) in consumption patterns. Randomised and nonrandomised controlled trials published after 1990 reporting changes in intakes of SSB or water were included. References were retrieved through searches of electronic databases and quality appraisal followed Cochrane's principles. Mean differences (MD) were calculated and data was synthesised using random-effects models.

Results Twenty-nine studies with 10 600 participants were meta-analysed. Interventions significantly decreased consumption of SSB in children by 92 mL/day (95% confidence interval [CI] -145 to -39; 18 studies, $P<0.01$), but not in adolescents (-52 mL/ day, 95% CI -121 to 17; 4 studies, $P = 0.14$) or in adults (-23 mL/day, 95% CI -56 to 9; 7 studies, $P = 0.16$). Pooled estimates of water intakes were only possible for interventions in children, results were indicative of increases in water intake (MD +80 mL/day, 95% CI 6 to 155; 6 studies, $P = 0.04$).

Conclusion There was some evidence to suggest providing general encouragement, model/demonstrating the behaviour, or parental involvement helped to reduce SSB intake. In conclusion, interventions modestly influence SSB and water intakes, with children benefiting most.

3.2 Introduction

Evidence that links higher intake of sugar-sweetened beverages (SSB) with greater risk of tooth decay (The Scientific Advisory Committee on Nutrition, 2015), weight gain (Te Morenga et al., 2013), type 2 diabetes (T2DM) (Malik et al., 2010a) and CVD (Maersk et al., 2012) continues to grow and supports the need for public health and community action. Indeed, it has been highlighted that over a year, for every additional daily serving of SSB, BMI increases by 0.06 kg/m^2 and weight by 0.22 kg in children and adults, respectively (Malik et al., 2013a). Furthermore, in adults the risk of developing T2DM increases by 20% for every daily serving size of SSB, even after adjusting for confounders like adiposity (Imamura et al., 2015, Malik et al., 2010b). This finding is consistent across epidemiological studies, in which consumers of more than a serving per day increase their risk of T2DM by 2-fold in comparison to lower consumers (Schulze et al., 2004, Greenwood et al., 2014) . This evidence has resulted in updated nutritional recommendations by WHO and high-income countries to limit daily intake of free sugars to no more than 10% of total dietary energy, and in the case of the UK to no more than 5%, based on the recognition to reduce risk of dental caries (Public Health England, 2015, U.S. Department of Health and Human Services and U.S. Department of Agriculture, 2015-2020, World Health Organization, 2015b). The term "free sugar" was introduced by the WHO Nutrition Guidance Expert Advisory Group to refer to all monosaccharides and disaccharides added to foods and beverages by the producer, cook or consumer as well as sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates (World Health Organization, 2015b).

Despite these negative impacts on health, SSB consumption has increased across populations worldwide. Estimates from 2010 on global intakes found that adults consumed on average 132 millilitres (mL) per day and that upper-middle and lower-middle income countries had the highest per capita levels of consumption: 192 mL/day and 142 mL/day, respectively (Singh et al., 2015). SSB are primary contributors of added sugars within the American diet, accounting for 6.2% and 9.5% of total energy intake (TEI) in children and young adults, respectively (Welsh et al., 2011). Similarly, the latest UK National Diet and Nutrition Survey revealed that non-alcoholic beverages (soft drinks and fruit juices) contribute to 5.8% of TEI in children, but only 3% in young adults and less than 2% in older adults (Bates B, 2016). These patterns of consumption have also been observed for the Australian population(Australian Government, 2014). However, data from countries in the Americas such as Mexico, have found that soft drinks contribute to 10% of total energy intakes both in children and adults and a recent report from 13 Latin American countries by the Pan-American Health Organisation (PAHO) has shown a steep rise by around threefold in sales of ultra-processed drinks over the past decade: these are high in calories derived mainly from free sugars and are nutritionally poor(Pan American Health Organization, 2015).

Initiatives to reduce consumption of SSB are delivered through a variety of public health interventions and with different approaches taken. Some of these include campaigns to increase public awareness of sugar content in beverages and consequences from heavy consumption, enhanced nutritional labelling of non-alcoholic beverages or the replacement of drinks with low-sugar alternatives (often artificially-sweetened or plain water). Also, policies within educational and working environments restricting the availability of sugary beverages have been enforced. However, SSB intake is recognised as a challenging behaviour to measure and enhanced methodologies for its dietary assessment are warranted (Collins et al., 2010). Whilst behaviour change interventions are considered as fundamental in public health practice (Michie et al., 2011b), evidence remains scarce around the type of interventions most effective in reducing consumption of SSB and increasing water intakes across all age groups (Hu, 2013, Malik et al., 2013a) .

Consequently this review aimed to evaluate the effectiveness of public health interventions to reduce sugar-sweetened beverage intake or increase water intake in children and adults. In addition, study characteristics that could bring about change in consumption patterns were examined.

3.3 Methods

Search strategy and selection criteria

Guided by the PRISMA specifications and following a published protocol (Vargas-Garcia et al., 2015) (registered with PROSPERO, number CRD42014013436), relevant studies were identified through a systematic search in Ovid Medline, Embase, Web of Science, Scopus, Cochrane Central Register of Controlled Trials (CENTRAL), the Global Health Library, Database of Abstracts of Reviews of Effects (DARE), clinicaltrials.gov, the Trials Register of Promoting Health Interventions

(TRoPHI), International Clinical Trials Registry Platform (ICTRP), and metaRegister of Controlled Trials (mRCT) from January 1, 1990, to May 19, 2014. Studies that had been published in any language were included. Guided by the PICO framework (Population/ Intervention/Comparator and Outcome) a combination of keywords (including medical subheadings) related to interventions, settings and outcomes were identified in the final search strategy (Vargas-Garcia et al., 2015), which can be seen in **appendix A**.

This review included randomised-controlled trials (RCTs), cluster RCTs and non-RCTs conducted in participants (no younger than 3 years old) of predominantly community-based interventions with a minimum length of 4 weeks of follow-up (from baseline to final data collection) and with a control group available. The primary outcome was the change in millilitres in SSB or water intakes throughout the day. A SSB was defined as a non-diet, non-alcoholic and non-dairy cold or warm drink (carbonated or still), with added sugars (including fruit drinks, nectars and cordials with less than 100% fruit juice), sports or energy beverages, ready-to-drink sweetened tea and ready-to-drink sweetened coffee (Gibson, 2008, Han and Powell, 2013). If the portion size was not reported or we were unable to obtain the information from authors, we used a portion size per drink of 240 mL. Studies that focused on other outcomes, such as dairy or fruit juice consumption or that did not use a 24-hour recall, food record or food frequency questionnaire (FFQ) as the assessment measure, were excluded. Rehydration, sanitary or trials assessing acute hormonal responses as a result of immediate intakes of SSB were also not included. Interventions on subjects with type 2 diabetes, metabolic syndrome or cardiovascular disease were only considered if randomisation had been conducted in participants before commencement of the study.

3.4 Screening, data extraction and quality assessment

Eligibility was initially verified by 2 independent reviewers based on title and abstract screening, followed by retrieval and evaluation of full texts of studies meeting inclusion criteria. Any discrepancies at both stages were discussed and resolved with two senior reviewers.

Data was extracted on overall study characteristics: study design, risk of bias at the study level using the Cochrane risk of bias tool (Higgins, 2011), number of participants, intervention aims, setting, population's age, country, year of study, length of the intervention, primary and secondary outcomes, statistical measures, main results and attrition rates. Additional information on equity was collated -when available- using the PROGRESS framework (which stands for place of residence, race or ethnicity, occupation, gender, religion, education, socioeconomic status, social status) to identify if the interventions had more positive effects in certain participants or groups (Evans and Brown, 2003). To explore potentially successful components of the interventions, behaviour change techniques (BCTs) associated with interventions' implementation and delivery processes were identified and analysed following a 26-item taxonomy (Abraham and Michie, 2008).

Where available, protocols were obtained and used during data extraction. With the exception of BCTs, data extraction was completed by the main researcher and verified by a second reviewer using an adapted spreadsheet from Cochrane's Public Health Group (Higgins, 2011) which was narrowed to the study designs and specific outcomes of interest in this review. For BCTs, data extraction was completed in duplicate using an established taxonomy (Abraham and Michie, 2008) by two trained reviewers (main researcher and another expert) any disagreements were discussed with a third reviewer. Two further intervention techniques were included: 'environmental support' and "parental involvement". BCTs were coded as '1', '-1' or '0' if present only in the intervention (and not in controls), only in controls (but not delivered to intervention groups) or in both/neither arms, respectively.

Continuous data for primary outcomes were extracted as means and standard deviations or as the adjusted mean difference [MD] and standard error –if presented. Authors of potentially included studies were contacted electronically for further queries and data clarification if needed. When studies reported follow-up data for more than one period, data from the longest follow-up period available was used.

3.5 Statistical analysis

A random-effects meta-analysis was conducted to account for the variation in the magnitude of effect sizes and between-study variance using mean differences in millilitres of SSB or water between groups and standard error of the difference. If these were not reported in studies, then data on changes between baseline and follow-up intakes were used to calculate the difference. The meta-analysis was conducted in Review Manager (version 5.0, Cochrane Library) and Stata 14.0. Results from the most adjusted multivariate models were used whenever these were available. When studies had multiple intervention arms, selection of the most representative group (i.e., having the most BCTs) was discussed and selected by two reviewers. The I^2 test was used to assess heterogeneity across studies; results between 50 to 75% and above 75% were considered to have substantial and considerable heterogeneity, respectively.

Subgroup analyses were conducted to further explore substantial heterogeneity across studies. As per protocol, the effect of participants' age, setting of delivery and randomisation on SSB and water outcomes was examined. Post-hoc analyses were undertaken on the effect of different dietary assessment tools and length of interventions on SSB intakes. Considering the influential effect size of a particular study upon results, sensitivity-analyses were performed excluding this trial which were not originally contemplated in our protocol (Vargas-Garcia et al., 2015). Meta-regression analyses were undertaken to identify if particular BCTs were contributing to greater decreases of SSB by comparing those studies in which the technique was present or absent.

3.6 Results

Study Selection & Characteristics

Figure 3-1 indicates the number of studies considered at each stage of the review. After removal of duplicates (2719) a total of 2747 citations were screened for eligibility, leading to 210 papers identified for potential inclusion. Sixteen authors were contacted at this stage for further information. At the final stage, 34 studies were included in the qualitative synthesis and 29 studies (10 520 participants) published in 27 articles from the USA, Canada, Australia, the Netherlands, Chile, Brazil, Portugal, Belgium, the UK, Malaysia, Germany, Norway and New Zealand, provided information on daily intakes of SSB and 9 of these studies also had available data on water intakes. No studies reporting exclusively water intakes met inclusion criteria. Of the 29 studies, 18 had data on children (7167), 4 on adolescents (2129) and 7 in adults (1224), with a study reporting intakes on both children and adults (Ostbye et al., 2012) and another on adolescents and adults correspondingly (French et al., 2011). Characteristics of all studies (included and not included) can be found in **Table 3-1** and **Table 3-2**, respectively.

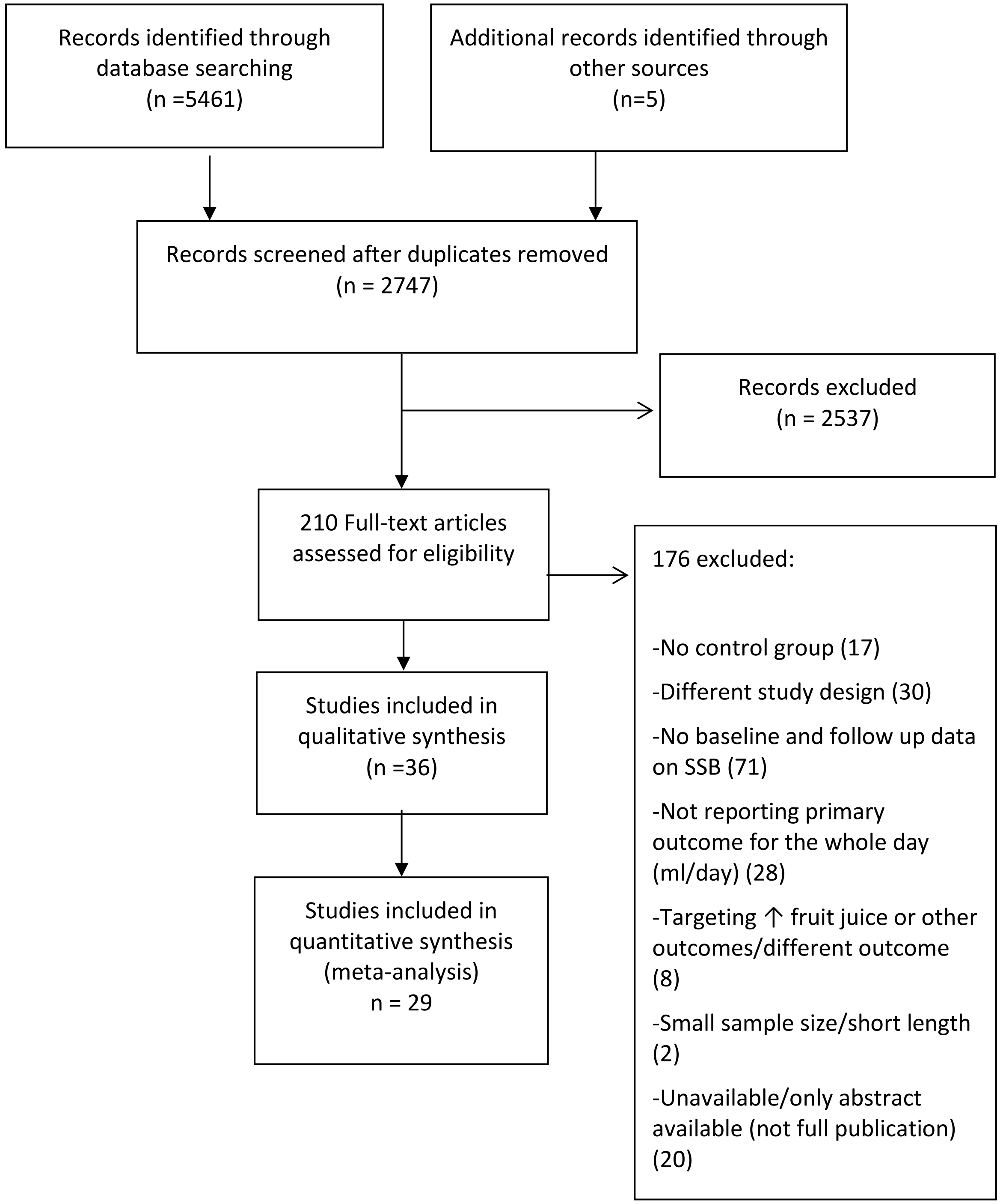

Figure 3-1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow-chart diagram.

Setting of interventions were educational for 10 studies (Shahril et al., 2013, Taylor et al., 2007, Bjelland et al., 2011, Singh et al., 2006, Haerens et al., 2007, Rosario et al., 2013, James et al., 2004, Sichieri et al., 2009, Muckelbauer et al., 2009), home for 6 studies (Ostbye et al., 2012, Albala et al., 2008, Ebbeling et al., 2012, French et al., 2011, Nollen et al., 2014, Shapiro et al., 2008), community centres in 9 studies (Baranowski et al., 2003, Leung et al., 2014, Burrows et al., 2012, Olvera et al., 2010, Klesges et al., 2010, Cunha et al., 2013, Souza et al., 2013, Anand et al., 2007) and clinical in 3 studies (Thompson et al., 2008, Garipagaoglu et al., 2009, Taveras et al., 2011). Duration of interventions varied from 6 weeks to 2 years, with active periods of programme delivery ranging from 3 weeks up to 20 months and follow-up periods ranging from 4 weeks up to 22 months.

Serving sizes of SSB per day varied from 165 to 360 mL across interventions whereas the definition of SSB mainly focused on carbonated beverages and fruit drinks. Frequency of consumption of SSB or water was analysed and transformed into 'servings per day' in 4 studies (Leung et al., 2014, Olvera et al., 2010, Shapiro et al., 2008, French et al., 2011), and response from contacted authors clarified serving sizes in 4 further studies (Shahril et al., 2013, Taveras et al., 2011, Souza et al., 2013, Duncan et al., 2011). Authors of studies reporting intakes for more than one category of SSB were contacted to determine whether results for total intakes were available; this was the case of four studies (Taylor et al., 2007, Taveras et al., 2011, Singh et al., 2009, Duncan et al., 2011). Paired t-tests were conducted in six studies in which only baseline and post-intervention information was available for SSB intake (Leung et al., 2014, Olvera et al., 2010, Garipagaoglu et al., 2009, Thompson et al., 2008, Shapiro et al., 2008, Haerens et al., 2007) and in 2 studies in which only baseline and post-intervention information was available for water intakes (Garipagaoglu et al., 2009, Haerens et al., 2007). The median baseline intake of SSB in intervention groups was obtained in the basis of data available in 26 studies: 612 mL/day in adolescents (IQR [interquartile range] 110 to 744; 3 studies), 310 mL/day in adults (IQR 104 to 464; 6 studies) and 288 mL/day in children (IQR 149 to 432; 17 studies). Median baseline intakes in control groups were similar: 600 mL/day in adolescents (IQR 144 to 612), 323 mL/day in adults (IQR 120 to 495) and 260 mL/day in children (IQR 130 to 400).

3.6.1 Meta-analysis on primary outcomes: SSB and water intakes

Interventions compared with controls, significantly reduced consumption of SSBs in children by 92mL/day (95% CI -145 to -39; P<0.01), but with substantial heterogeneity (I^2= 94%, df=17, *P*<0.01) (**Figure 3-2**). The study of Albala and colleagues (Albala et al., 2008) contributed to estimates for SSBs that were markedly lower in the intervention group and had a larger effect size in comparison to other studies (see **Figure 3-2**). In a sensitivity analysis without this study, which replaced sugary drinks with a milk beverage, results for SSB intakes were similar but attenuated in the intervention group (mean difference -36 mL/day, 95% CI -55 to -18; *P*<0.01) and heterogeneity decreased to 40%.

Studies in adolescents and adults indicated lower intakes of SSB in intervention groups by 52 mL/day (95% CI -121 to 17; *P*=0.14) and by 23 mL/day (95% CI -56 to 9; *P*=0.16) respectively (

Figure 3-3 and **Figure 3-4)**; though differences were not statistically significant. Due to the small number of studies (4 in adolescents and 7 in adults), no further analyses were undertaken in these populations to explore sources of heterogeneity or publication bias.

Data on water intakes were additionally available in 9 studies: one in adults (Anand et al., 2007), two in adolescents (Haerens et al., 2007, Ebbeling et al., 2012), and six in children (Baranowski et al., 2003, Garipagaoglu et al., 2009, James et al., 2004, Klesges et al., 2010, Taylor et al., 2007), thus a meta-analysis was only possible in the child population (3196 participants). Findings suggested that interventions significantly increased water consumption in children by 80 mL/day (95% CI 6 to 155, *P*=0.04), compared with controls (**Figure 3-5**). Heterogeneity was substantial I^2= 79%, but no further testing was possible as a result of the small number of studies.

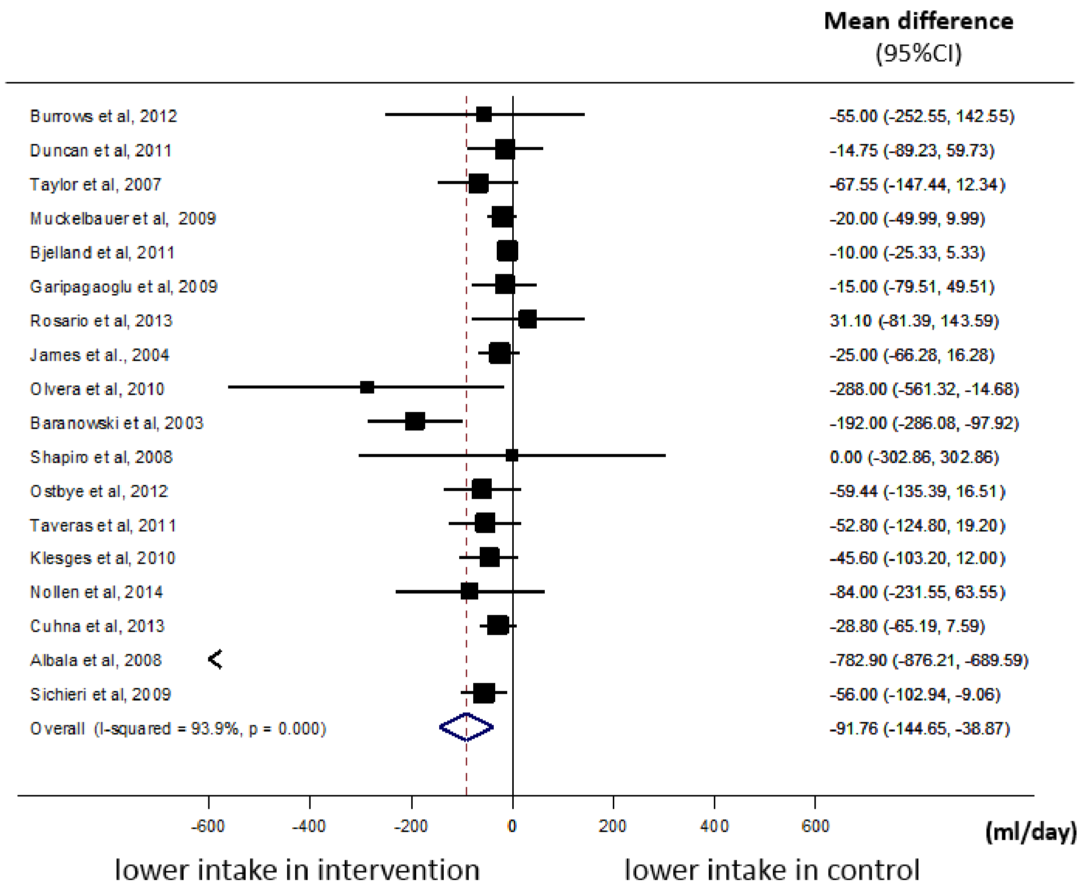

Figure 3-2 Meta-analysis of mean difference in SSB intake (mL) in children, intervention versus controls.

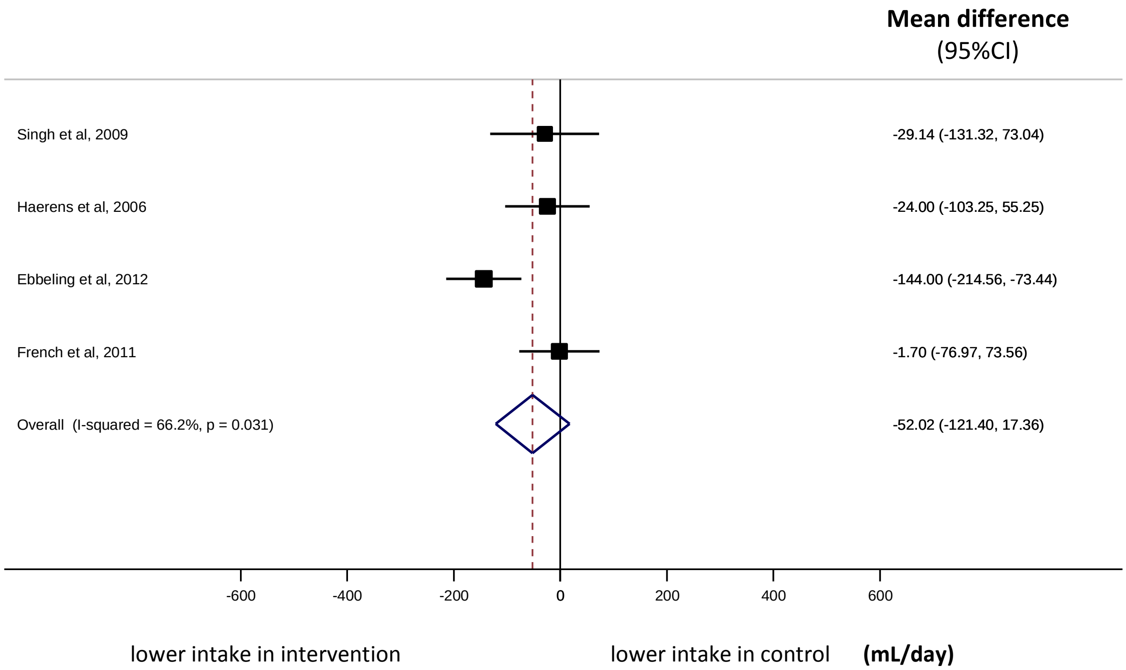

Figure 3-3 Meta-analysis of mean difference in SSB intake (mL) in adolescents, intervention versus controls.

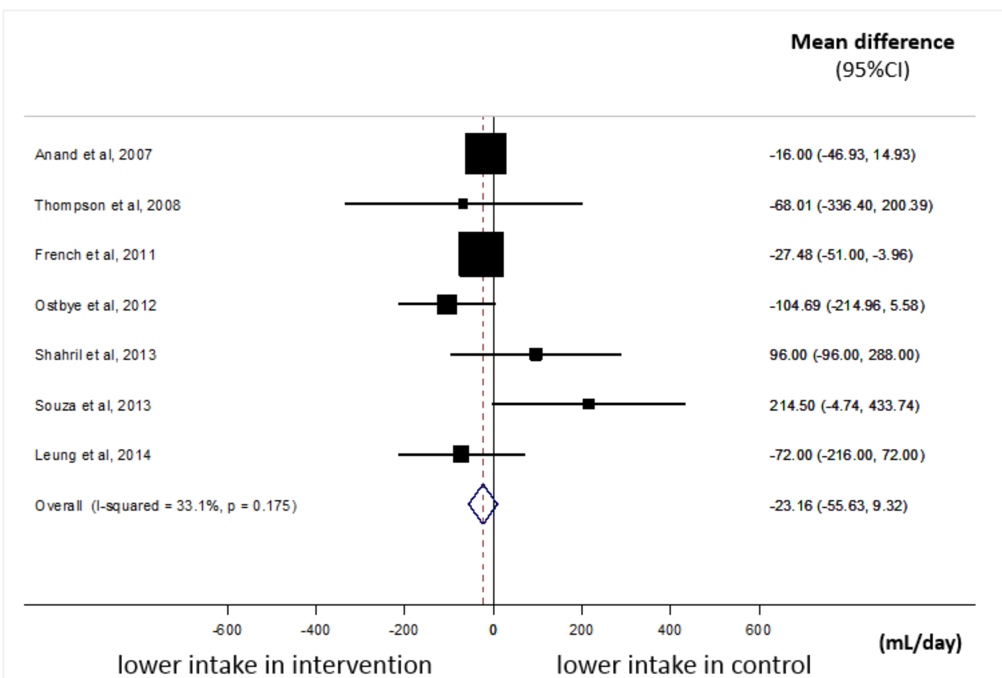

Figure 3-4 Meta-analysis of mean difference in SSB intake (mL) in adults, intervention versus controls.

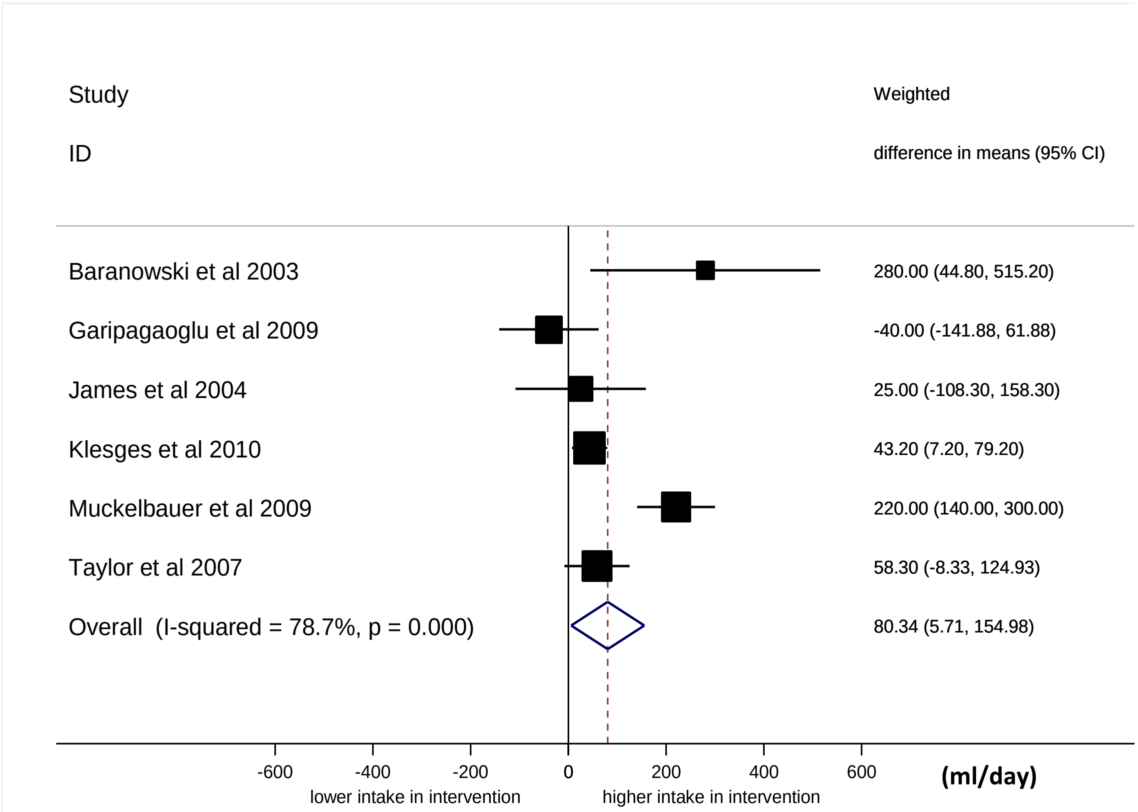

Figure 3-5 Meta-analysis of mean difference in water intake (mL) in children, intervention versus controls.

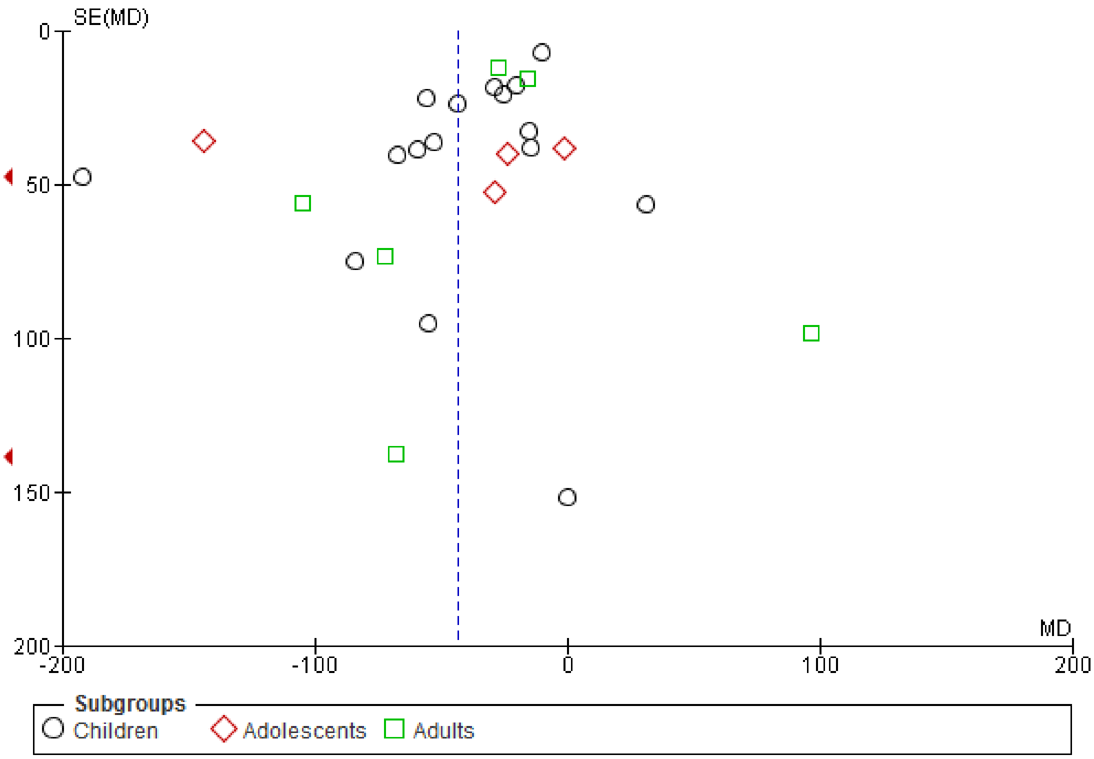

Figure 3-6 Funnel plot of comparison: Consumption of SSB across all studies.

3.6.2 Risk of bias within studies

Assessment of quality of included studies is shown in **Figure 3-7**. Risk of bias across the 29 studies meta-analysed was generally medium to high and unclear judgments were due to insufficient study details for all appraised domains; only two studies were judged to be of higher quality (Klesges et al., 2010, Ebbeling et al., 2012). The risk of bias for allocation concealment was high in 5 studies (19%) and unclear for 16 (59%) as a result of including non-randomised interventions (Taylor et al., 2007, Muckelbauer et al., 2009, Olvera et al., 2010, Leung et al., 2014, Thompson et al., 2008). A high risk of bias was found for outcome assessment in 8 studies (29%) as results were not reported as being adjusted for confounders or attrition rates. Accounting for the nature of interventions, blinding of participants and intervention deliverers was of concern due to a high risk of bias in 19 studies (70%). In other domains, dietary assessment of the primary outcome was classified as high risk of bias in 24 studies (89%) since data were self-reported. Reporting bias was apparent in 4 studies that had available protocols and unclear in 21 (78%).

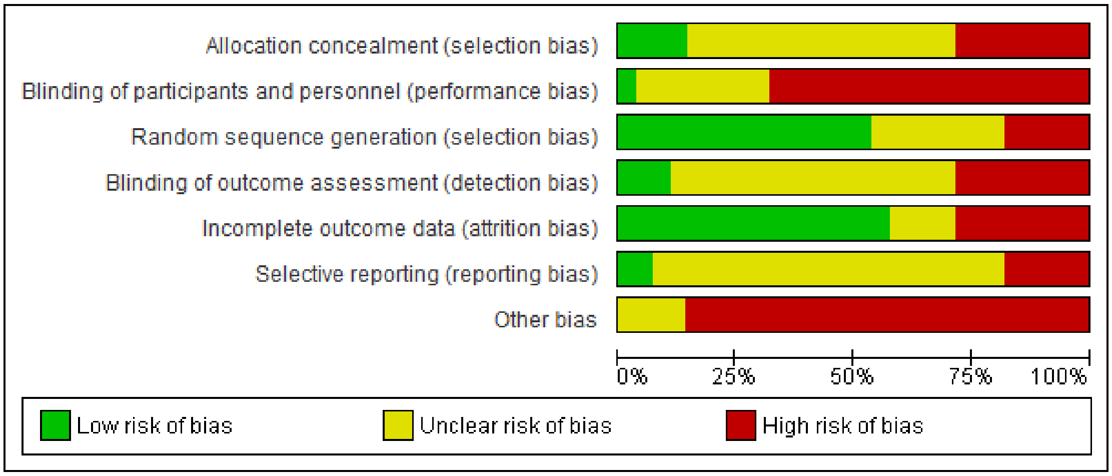

Figure 3-7 Risk of bias of individual studies.

3.6.3 Subgroup analyses on primary outcomes: SSB

All age groups

Results from subgroup analyses are shown in **Table 3-3** and **Table 3-4.** Subgroup analyses were only possible for SSB outcomes, due to the small number of studies on water intakes. Across all populations, subgroup analyses for changes in SSB indicated significant differences in intakes for interventions delivered in the community (MD -53 mL/day, 95% CI -102 to -4; *P* = 0.034) and in educational settings (MD -17 mL/day, 95% CI -29 to -5; *P*<0.01), with the use of 24-hour recall and FFQ as dietary methods (MD -61 mL/day, 95% CI -92 to -30; P<0.01 and MD -85, 95% CI -155 to -14; *P*< 0.01, respectively) but not dietary records; for RCT and cluster RCT (MD -99 mL/day, 95% CI -176 to -28; *P* = 0.01 and MD -17 mL/day, 95% CI -30 to -5; *p*<0.01, respectively) but not non-RCTs, and for studies conducted in North America (MD -63 mL/day, 95% CI -93 to -33; *P*<0.01) and Europe (MD -14mL/day, 95% CI -26 to -1; *P*=0.03) but not those in South America or Australasia. Significant effects emerged in studies judged at medium risk of bias (MD -115 mL/day, 95% CI -182 to -48; *P*<0.01) and in studies at high risk of bias (MD -25 mL/day, 95% CI -40 to -11; *P*<0.01). Studies incorporating intervention periods of more than or equal to 30 weeks or less than 30 weeks in duration both generated significant but similar effects (MD -101 mL/day, 95% CI -187 to -15; *P*=0.02 and MD -39 mL/day, 95% CI -59 to -19, *P*<0.001). Asymmetry was not apparent from funnel plot inspection (**Figure 3-6**) and results from the Egger's test for publication bias were also non-significant (*P*=0.11).

Sensitivity analyses excluding the trial from Albala and colleagues (Albala et al., 2008) had no substantial influence on effect sizes on any of the previously mentioned features, except for place of delivery in which significant differences were also observed for home-based interventions(**Table 3-3**).

<u>Children</u>

Subgroup analyses in studies of children that had intervention periods of more than or equal to 30 weeks (median duration) were suggestive of lower intakes of SSB (MD -22 mL/day, 95% CI -33 to -10; *P* <0.01) but no differences were noted for study design, geographical location (North America vs Europe vs South America or Australasia), measure of dietary intake utilised or delivery mode. There was suggestive asymmetry after funnel plot exploration, although results from the Egger's test were not significant for small-study effects (*P* = 0.10). Sensitivity analyses without the study by Albala and colleagues (Albala et al., 2008) had no influence on any of the previous results (**Table 3-4**).

Meta-analyses on secondary outcomes: BCTs

Regarding the 28 BCTs, all but 2 ("*Provide information about others approval"* and "*prompt self-talk"*) were identified in intervention arms in at least one study. Most commonly delivered techniques given only to experimental groups (without presence in controls) were *provide information on consequences* (n=16), *environmental support* (n=15), *prompt barrier identification* (n=14) and *provide contingent rewards* (n=12). Seven different techniques were identified across control arms of 3 studies, with one using all 7 of these techniques (Nollen et al., 2014), one using two (Souza et al., 2013) and another using one technique (Olvera et al., 2010). The number of techniques used across all included studies varied from 1 to 17. When exploring patterns of techniques used between studies, we did not find two intervention arms using exactly the same techniques, except in a study targeting two different family members (adolescent and parent) (French et al., 2011).

Based on median values, studies were pragmatically classified by total number of techniques incorporated (from the 28-item list) into two categories; using between 1 and 8 (n=15) and using 9 or more (n=14) to explore any differences between studies with higher and lower numbers of

BCTs. No differences were noted between trials using 8 or fewer techniques (MD -73mL/day, 95% CI -143 to -3; *P*=0.04) than in those using 9 or more (MD -48 mL/day, 95% CI -75 to -21; *P*<0.01) after meta-analyses.

The use of any individual technique (from the 28 considered in this review) was not initially associated with greater effectiveness to reduce SSB after univariate meta-regressions were conducted across all age groups (**Table 3-5**). A sensitivity analysis excluding the study from Albala and colleagues (Albala et al., 2008) , however, suggested that studies that incorporated the use of providing general encouragement, model/demonstrating the behaviour, or parental involvement in the intervention groups only were associated with larger reductions in SSB intake compared to studies that did not (MD -75 mL/day [95% CI -148 to -2; *P*=0.04]; MD -41 mL/day [95% CI -81 to -1; *P* =0.04]; (MD -47 mL/day [95% CI -88 to -5; *P*=0.03], respectively); whereas studies that used providing opportunities for social comparison produced increases in SSB consumption (MD +60 mL/day, 95% CI 4 to 116; *P*=0.04).

In the children samples, however, model/demonstrating the behaviour appeared to be particularly effective in reducing SSB intake -196 mL/day (95% CI -378 to -15; *P*=0.04)(**Table 3-6**). When the study from Albala and colleagues was excluded, the use of model/demonstrating the behaviour was no longer significant. However, prompting intention formation, providing contingent rewards and the use of follow-up prompts were beneficial to reduce SSB consumption (-27 mL/day [95% CI -54 to -0.1; *P* =0.049], -45 mL/day [95% CI -85 to 4; *P* = 0.032] and -166 mL/day [95% CI -271 to -61; *P* =0.04], respectively). Studies that incorporated feedback on performance only in the intervention condition produced increases in intakes in SSB than studies that did not (+29.0 mL/day [95% CI 0.28 to 57.7; *P* = 0.048]).

3.7 PROGRESS/Equity

Data on socio-demographic features to identify the effects of interventions on health equity was extracted. All studies indicated the gender of participants at baseline; 6 studies were conducted only in women (Thompson et al., 2008, Baranowski et al., 2003, Ostbye et al., 2012, Olvera et al., 2010, Klesges et al., 2010, Shahril et al., 2013), 7 in low-income populations (Sichieri et al., 2009, Taveras et al., 2011, Cunha et al., 2013, Nollen et al., 2014, Haerens et al., 2007, Leung et al., 2014, Klesges et al., 2010), 14 studies reported a health condition at baseline (being overweight or obese), 14 studies reported race/ethnicity of participants (African-American, Native-Canadian, American-Indian, Hispanic, Caucasian) and 3 studies (Bjelland et al., 2011, Singh et al., 2009, Rosario et al., 2013) analysed results by gender. Only one study reported economic costs of the intervention (Muckelbauer et al., 2009). No further components of the PROGRESS checklist were included for analyses in any other study. Considering the limited information available, it was not possible to evaluate the impact of interventions to decrease health inequalities across populations.

3.8 Qualitative review of studies not included in the meta-analyses

Six studies assessing primary outcomes across different age groups were not included in the meta-analysis due to differences in how outcomes were reported. For instance, 2 studies dichotomised results by establishing a threshold of higher or lower intake (Ezendam et al., 2012, van Grieken et al., 2014), two studies assessed only frequency of consumption as "*times per day*" (Gosliner et al., 2010; Contento et al., 2010), one study measured consumption of SSB through a different dietary method than previously established and did not provide sufficient results of consumption in millilitres for the whole day (de Ruyter et al., 2012). One further study was excluded due to a lack of measures of variation (i.e., SE or CI) (Johansen et al., 2010). Across these studies, 4 studies (one in children, one in adolescents and two in adults) supported the direction of the meta-analysis by achieving significant decreases in SSBs across intervention conditions, whilst two studies (one in children and one in adolescents) did not find any difference between groups.

An online school-based study delivered to Dutch adolescents (Ezendam et al., 2012) aiming to decrease obesity-related behaviours found that intervention groups versus controls (under a regular curriculum) were less likely to report higher intakes of SSB in the short term, yet effects no longer persisted long-term (at 2 years). An intervention in adolescents across low-income schools in New York City, found a significant decrease in the frequency of consumption and portion sizes of SSB in intervention sites yet no changes where seen for water outcomes in either group. This study placed emphasis in goal setting, monitoring and reviewing (Contento et al., 2010).

The only studies in children that were not included in the meta-analysis were both conducted in the Netherlands. One of them involved the evaluation of a cluster-RCT which assessed the effect of parental counselling on obesity prevention and which was delivered through well-child visits (van Grieken et al., 2014). Results 2 years post-intervention found no significant differences across intervention or control groups, as self-reported parental outcomes indicated that both conditions were drinking less than two-serving sizes of SSBs per day. The other study consisted of a blinded RCT which evaluated the effect of replacing SSB with artificially sweetened beverages on children's BMI and this was conducted exclusively during the school time (de Ruyter et al., 2012). This high quality trial, showed at post-intervention (after 18 months) that weight gain was reduced in the intervention group (0.02 SD units) in comparison to controls (0.15 SD units), with the difference in means being statistically significant (MD 0.13 SD, 95% CI -0.21 to -0.05).

Two studies were conducted in adults that did not meet inclusion for meta-analysis. One of them was conducted amongst Pakistani women with overweight and at higher risk of developing type 2 Diabetes living in Norway (Johansen et al., 2010). The culturally tailored programme seeking to enhance self-regulation processes (through goal setting and monitoring), found significant decreases in consumption of soft drinks in comparison to the control group (which only received usual care), however, under-reporting was emphasised by authors as potential source of bias (Johansen et al., 2010). Gosliner *et al.* delivered wellness programme to staff at child care centres in California, US to influence their behaviour towards a better diet (less consumption of SSB) and influence changes in their working environment to sustain healthy eating (Gosliner et al., 2010). Results after 9-monhts of implementation portrayed that the intervention was effective in decreasing the frequency in which SSB were consumed in intervention sites in comparison to controls, yet no differences were retrieved for changes in water consumption between groups.

No adverse events were documented by any of these excluded studies and the overall quality was low in two studies and medium in three.

3.9 Discussion

Summary of evidence

This systematic review and meta-analyses show that public health interventions are moderately effective in decreasing consumption of SSB and increasing water intakes, particularly in young populations. Although results for SSB outcomes in adolescents and adults were not statistically significant, the direction of the effect was consistent. Heterogeneity was considerable for both primary outcomes despite utilising random-effects models to account for the difference in effect sizes across interventions. The inclusion of the study by Albala and colleagues, which generated much larger reductions in SSB relative to the other studies included in the review, was partly accountable for this difference. Exploration of sources of heterogeneity through subgroup analyses on SSB outcomes indicated that interventions delivered within larger groups (communities and schools) inclusive of randomisation could yield better results as well as explain some of the variation between studies, yet a large proportion of the heterogeneity remained unexplained.

Consumption levels of SSB remain high in children and initiatives have been broadly prioritised in this population, as found in this review. In studies of children, it was identified through subgroup analyses that longer interventions could be more effective in improving intakes of SSB. Evidence from childhood obesity-prevention programmes (Stice et al., 2006), has highlighted increased duration of delivery as an important feature leading to superior effects when compared to briefer strategies, as theoretically, participants are provided with more opportunities to gain information, plan, enact and reflect on the desired behaviour (Stice et al., 2006, Waters et al., 2011). Schools, for this reason could represent valuable settings to address and reinforce healthier dietary practices as well as reach disadvantaged populations (Sichieri et al., 2009, Haerens et al., 2007).

The use of specific dietary assessment tools was noted to explain heterogeneity in SSB outcomes across all age groups. While the 24-hr recall is a common method in intervention studies, due to its ability to capture more information on different type of beverages in comparison to the FFQ, it is predominantly paper-based, incorporation of innovative features from new technologies (such as those using image-based capture) could improve the estimation of liquid intakes, which is needed. Despite the emerging interest in water and SSB intakes, very few included studies have reported consumption of water which may relate to the lack of specific and validated tools available to measure beverage intake, as opposed to those existing for assessing food intake (Carter et al., 2015).

Consistent with other reviews (Michie et al., 2009a, Michie et al., 2009b, Dusseldorp et al., 2014, Dombrowski et al., 2012) it was hypothesized that the use of specific behaviour change techniques could also explain heterogeneity and may be associated with greater intervention effectiveness. For instance, the most commonly found techniques across all studies were “prompt intention formation” and “provide opportunities for social comparison”. Considering that the majority of the interventions were group-led and that larger settings appeared to be more effective, findings emphasise the importance of social support via encouragement and parental/family involvement when targeting obesity-related behaviours such as SSB and water consumption. Mechanisms underlying this mode of delivery include strengthening the enactment of the targeted behaviour when seen performed/modelled in others (e.g. drink water instead of SSB) and building capacity through experience sharing, development of social links (such as friendships) as well as increased feelings of social cohesion and efficacy (i.e. working towards a fixed goal) (Cleland et al., 2012). Baranowski and colleagues (Baranowski et al., 2003) piloted a summer camp initiative in African-American girls at higher risk of obesity. Whilst changes in SSB and water intakes were discrete, their extensive process evaluation found “interactive learning” a promising feature for participant’s engagement and involvement which was also documented in a trial carried out subsequently in a similar population (Klesges et al., 2010).

Encouraging people to set a behavioural objective has been highlighted as a key element of any given intervention (Dusseldorp et al., 2014) as it constitutes an initial step for individuals on deciding to change and subsequently acting on a behaviour. Prompting intention formation, as a frequently used technique in the available literature, was marginally associated with greater reductions in SSB intake in children but not across all age groups. In adult populations, this technique is shown to be more effective in increasing healthful eating when in combination with other techniques such as self-monitoring (Michie et al., 2009a) or providing information about a behaviour and health link (Dusseldorp et al., 2014); therefore, and as highlighted by previous research (Michie et al., 2009b, Michie et al., 2009a, Dusseldorp et al., 2014), it is possible that interactions between BCTs are accounting for differences in intervention’s effectiveness. Martin and colleagues (Martin et al., 2013) assessed the impact of BCTs in childhood obesity prevention and management trials, whilst other techniques were described as more efficacious (i.e. environmental restructuring, prompt practice, prompt identification as role model, etc.), they were unable to determine if a BCT was individually effective or if it was a cumulative effect with other techniques.

Providing feedback on performance has also been documented as an essential component of health-related interventions (Dusseldorp et al., 2014, Prestwich et al., 2014) and current technologies provide innovative ways in which this could be achieved. Nevertheless, interventions involving this technique were few, and those that did, showed no evidence for greater benefits and usually emphasised higher respondent burden (Shapiro et al., 2008, Baranowski et al., 2003)

Greater reductions in SSBs from individual use of BCTs was found for modelling/demonstrating the behaviour in children and, after exclusion of an outlier study, significant associations were also shown for all age groups combined. The theory of social learning(Bandura A, 1977) appoints this technique as highly influential in the establishment of behavioural changes as participants are more likely to imitate the behaviour when seeing it modelled in someone they like or admire and when seen it modelled by more than one person (Horne et al., 2011) (i.e., both parental figures). It is possible that participants could gain more benefits from establishing a behavioural objective of consuming fewer SSB if demonstrations on how to choose and prepare less-sweetened alternatives are facilitated as part of intervention activities (Klesges et al., 2010, Olvera et al., 2010, Ebbeling et al., 2012, van de Gaar et al., 2014).

The role of the environment as a paramount driver of consumption of sugar and SSB has been thoroughly emphasised by health organisations (World Health Organization, 2015a, Public Health England, 2015). Whilst environmental support as a technique was not significantly associated with greater reductions of SSB, studies included in this review have focused on changes to the proximate built environment whether at school, work or home settings. Previous work, particularly on children (Avery et al., 2015), has advocated targeting the wider environment concomitantly with helping empower individuals in order to more efficaciously manage and transform their behaviour (Hill et al., 2003). Currently there is limited evidence on the contribution of the macro environment (Public Health England, 2015) through government regulations such as taxation and in cooperation with the food industry by reformulation, enhanced labelling, promotion and advertising techniques in shifting populations to consume less-sweetened beverages, and achieving not only short (Colchero et al., 2016) but long term objectives in reducing obesity rates. Indeed, it has been recognised that no single or isolated action can offer a solution to effectively reduce sugar intakes and thus consumption of SSB.

Strengths and Limitations

This is the first systematic review to comprehensively summarise direct changes in sugar-sweetened beverages and water intakes across different age groups and to test whether use of particular behaviour change techniques leads to greater effectiveness. The present work has followed a rigorous published protocol (Vargas-Garcia et al., 2015) with a thorough search strategy and screening process allowing to synthesise data on more studies than previous reviews and meta-analyses in this subject (Avery et al., 2015, Martin et al., 2013, Mazarello Paes et al., 2015). Multi- and single-component programmes were included from a diversity of countries. Findings are limited though, by the overall quality of studies. For instance, there were interventions that reported changes in more than one type of SSB, had unavailable totals or unclear definitions of SSB. It is possible, therefore, that whilst intake of certain SSB decreased, compensation in other sugary drinks or sugar-added products could also have occurred and not been quantified nor reported. Efforts have been made to better categorise SSB but a clearer definition is needed so as to incorporate and differentiate between those offering better nutritional values. Although inclusion criteria was restricted to studies that used standard methods of assessment, measuring beverage intake is challenging and prone to error(Beaton, 1994), particularly from biased or underestimated portion sizes.

Impact of direct changes in sugar intakes by reformulation of beverages was not within the scope of this review but is an aspect that requires further attention. Geographical differences were noted to significantly contribute to the variability across intakes of SSB. The former could be partly attributed to the higher consumption levels reported in the United States and European countries which have resulted in more research publically available, and so generalisability of results herein to populations with lower intakes may be limited. Results indicated better outcomes for studies which included randomisation; yet scarce information and poor descriptions on reported methodologies could have impaired the ability to give higher quality scores to studies that may have gone through adequate randomisation processes.

Heterogeneity was high across analyses in SSB and water outcomes and, while measures were taken *a priori* to reduce this variation, subgroup analyses were only partially able to explain it which is suggestive of other differences between study outcomes not explained by the variables considered in the analyses. However, with and without exclusion of studies, the direction of the effect remained constant towards a reduction of SSB. Finally, considering the small number of studies we were unable to explore any counterbalancing, neutral or masked effects from other BCTs or intervention components (Dombrowski et al., 2012) on primary outcomes; a lack of compliance to original plans –which was not measured- could have also diminished observed effects.

Implications for practice

We have estimated the effects of public health interventions to influence consumption of SSBs and water. Similarly to estimations that have been made from previous meta-analysis on other outcomes such as dietary advice and adverse vascular risks (Rees et al., 2013), a decrease of 92 mL of sweetened drinks by children could represent a reduction of about one-third of a 280 mL portion size (equivalent to 2.5 teaspoons of sugar or 2% of energy intake from free sugars(Public Health England, 2015)) which may translate, if levels are sustained, in a potential reduction of incidence of dental caries, type 2 diabetes and obesity.

3.10 Conclusion

In summary, findings indicate that interventions are achieving moderate reductions in consumption of sugar-sweetened beverages and increases in water intakes, with children benefiting more. Evidence of effectiveness across all populations was found for community-based interventions and children participating in programmes for more than 30 weeks. The use of modelling/demonstrating the behaviour was suggestive of enhanced effects across interventions in children. Reduction of SSB intake was sensitive to the use of providing general encouragement and parental involvement.

Table 3-1 Characteristics of studies reporting changes in SSB and water intake in all age groups included in meta-analysis.

Author	Study design	Number of participants		Aim	Setting	Age (y)	Length of intervention		Intervention content		Dietary assessment tool	BCTs used		Quality
		Intervention	Control				Intervention	Follow-up	Intervention	Control		Intervention	Control	
Albala *et al.* (2008) Chile	RCT	50	48	Decrease intake of SSB in overweight and obese children	Home	9	16 weeks	-	Weekly home-delivery of flavoured milk beverages.	-	FFQ	4,8,19 Env. Sup	-	medium
Anand *et al.* (2007) Canada	RCT	84	69	Obesity prevention through improvements in dietary and physical activity behaviours	Community	9	6 months	-	Home visits by counsellor, specific dietary and physical activity goal setting for HH members, water cooler provision.	Provision of Canadian dietary guidelines. Children received an after-school program	24-hr recall	4, 8,14,19, 20 Env. sup	-	low
Baranowski *et al.* (2003) USA	RCT	DYADS 26	20	Changes in BMI, decrease intake of SSB, increase intake of fruits, vegetables and water.	Community (*Summer camp)*	8	4 weeks	8 weeks for experimental group	Summer camp designed to address targets (4 weeks) and internet-based programme for follow up involving parental support	Usual camp activities (no nutritional education delivered)	24-hr recall	4,5,8,9,11,14,17,18,19,20 Parental support	-	medium
Bjelland *et al.* (2011) Norway	Cluster-RCT	cluster/ schools: 12 (n=784)	25 (n=1381)	Weight gain prevention through a decreased intake of SSB and screen time.	Educational	11	20 months (2 academic years)	-	School sessions with materials (student booklet), posters and fact sheets for parents.	-	FFQ	1, 2, 8,15,19,20 Env. sup	-	medium
Burrows *et al.* (2012) Australia	RCT	26	24	Weight loss in parents and effects on role modelling "healthy behaviours" to their children.	Community	8	3 months	-	Educational sessions on parental role modeling, goal setting, self-monitoring and relapse prevention. Nutrition and PA	Kept in 6-month waiting list to receive intervention	FFQ	1,2,4,5,7,8,12, 19,20, 21, 23	-	medium

Author	Study design	Number of participants		Aim	Setting	Age (y)	Length of intervention		Intervention content		Dietary assessment tool	BCTs used		Quality
		Intervention	Control				Intervention	Follow-up	Intervention	Control		Intervention	Control	
									information provided, group discussion and practical activities.					
Cuhna *et al.* (2013) Brazil	Cluster - RCT	10 classes (n=293)	10 classes (n=281)	Change in BMI through a decrease intake of SSB, sugar and processed foods.	Educational	11	9 months	-	Ludic sessions (theater sketches, movies, puppet shows, writing and drawing contests), One session on water promotion.	One-hour session of orientation on general health and advice on healthy eating.	FFQ	2, 4,5,8,19, 20 Env. sup	-	low
Duncan *et al.* (2011) New Zealand	Cluster - RCT	4 classes (n=57)	4 classes (n= 40)	Improve PA and 10 dietary behaviours (including fluid intake)	Educational	9-11 years	6 weeks	-	Compulsory homework scheme, learning resource at classes. Printed materials to complete at least 2 out of 3 possible tasks per week.	-	Diet/beverage record	1,2,4,5,7,8,10, 11,13,14,17,19 ,20	-	low
Ebbeling *et al.* (2012) USA	RCT	110	114	Change in BMI by reduction of SSB intake.	Home	15	12 months	12 months	Fortnight provision of non-caloric beverages (water and diet beverages) at home of participants. Motivational phone calls to parents	No information provided. Monetary reward at 4 and 8 months as retention strategy.	24-hr recall	1,2,4,5,6,8, 9,15,20 Env. sup Parental support	-	Medium /high
French *et al.* (2011) USA	Cluster -RCT	45 households (90 adolescents 77 adults)	45 households (90 adolescents 77 adults)	Weight gain prevention through reduction of SSB to ≤ 12 oz per person/day	Home	Adolescents 12-17 Adults 41	6 months	6 months	Group sessions, monthly newsletters provided on SSB, screen time, portion size, pre-packaged snacks, confectionary and fast food products	-	FFQ	4,5,12,14,18,1 9,20 Env. sup	-	low

Author	Study design	Number of participants		Aim	Setting	Age (y)	Length of intervention		Intervention content		Dietary assessment tool	BCTs used		Quality
		Intervention	Control				Intervention	Follow-up	Intervention	Control		Intervention	Control	
Garipagaoglu *et al.* (2009) Turkey	**RCT**	40 child-father dyads	40 child-father dyads	Weight management through improvements in healthy eating and sedentary behaviours	Clinical	10	3 months	-	7 group educational sessions targeting dietary modifications in addition to following a hypocaloric diet	7 individual treatment sessions	Diet/beverage record	1,2,4,5, 8,9,11,19,20 Env. Sup Parental Support	-	medium
Haerens *et al.* (2007) Belgium	Cluster - RCT	1055	655	Obesity prevention through changes in dietary behaviours (healthier food choices and physical activity).	Educational	**13**	12 months	**-**	School policy reorganization: increased number of water fountains, lower prices for water bottled in canteens and vending machines Information given on benefits of drinking water.	-	FFQ for beverages	1,2,4,8,9,19,20 Env. Sup Parental support	-	low
James *et al.* (2004) UK	Cluster -RCT	14 clusters (n= 319)	15 clusters (n=325)	Reduce intake of carbonated drinks	Educational	9	12 months	-	Provision of information on health effects of increased consumption of SSB. Use of ludic activities to reinforce messages.	No information provided	Diet/beverage record	1,2,4,19 Env. sup	-	medium
Klesges *et al.* (2010) USA	RCT	116	127	Obesity prevention through goal setting and positive reinforcement techniques.	Community	9	20 months	-	Group meetings weekly and then monthly (with daughters and parents/caregivers) Behavioural goals setting for decrease consumption of SSB and increase water intakes.	Activities related to building social awareness, self-esteem, social efficacy and community responsibility.	24-hr recall	1,2,4,5,8,9,12, 13,14,19,20 Env. Sup Parental Support	-	medium

Author	Study design	Number of participants		Aim	Setting	Age (y)	Length of intervention		Intervention content		Dietary assessment tool	BCTs used		Quality
		Intervention	Control				Intervention	Follow-up	Intervention	Control		Intervention	Control	
Leung *et al.* (2014) USA	Non-RCT	64	43	Improvements in Dietary quality across beneficiaries of assistance programme	Community	49	3 months	-	Beneficiaries of SNAP can purchase food and other products through monthly instalments on debit card.	-	24- hr recall	Env. sup	-	low
Muckelbauer *et al.* (2009) Germany	non-RCT	17 schools, 85 classes (n=1978)	16 schools, 75 classes (n=1469)	Overweight prevention by increasing water intake	Educational	8	1 academic year (10 months)	-	Installation of water, provision of water bottles , educational sessions on importance of drinking water	-	24-hr recall beverage questionnaire	1,4,13,19 Env. sup	-	medium
Nollen *et al.* (2014) USA	RCT	26	25	Improve dietary behaviours (F&V, SSB, screen time).	Home	11	4 weeks	8 weeks	Smartphone provision for goal setting and planning; self-monitoring, feedback, reinforcement and rewards system available.	Written manuals with information on SSB.	24-hr recall	4,12,13,14,15	-	low
Olvera *et al.* (2010) USA	Non-RCT	26	20	Obesity prevention through increased PA and improvements in dietary intakes of high fat foods, SSB, fruits and vegetables	Community	10	12 weeks	-	Nutritional education, behavioural counseling and sessions of aerobic exercise.	Printed educational materials, group discussions and sessions of aerobic exercise.	FFQ	1,2,4,5,8, 9,12,14,15,19, 20,21.	19	low

Author	Study design	Number of participants		Aim	Setting	Age (y)	Length of intervention		Intervention content		Dietary assessment tool	BCTs used		Quality
		Intervention	Control				Intervention	Follow-up	Intervention	Control		Intervention	Control	
Ostbye *et al.* (2012) USA	RCT	Mothers 143 Children 156	Mothers 140 Children 152	Improvement in dietary intakes (both in recent post-partum mothers and toddlers, targeting among others - decrease intake in SSB)	Home	Mothers 18-35; Children > 3 years	8 months	22 months	Mailed materials and motivational phone interviewing sessions. Building up parenting skills (managing stress, role modelling, barrier identification).	Delivery of monthly information on pre-reading skills.	24-hr recall	**Mothers** 4,5, 8,14,19,21,24, 25 ,26 **Children** 4,5, 8,14,19,21,24 ,26	-	medium
Rosario *et al.* (2013) Portugal	Cluster -RCT	3 schools (n=233)	4 schools (n=231)	Obesity prevention through promotion of healthy eating and active lifestyles	Educational	8	6 months	1-3 months	Class-based sessions on healthy eating and being more physically active	-	24-hr recall	1,2,4,8,19	-	low
Shahril *et al.* (2013) Malaysia	Cluster -RCT	8 classes 178	8 classes 202	Improve dietary intakes and quality in university students	Community	19	10 weeks	-	Class-based lectures, written information and text messaging reminders.	-	FFQ	4, 8, 19	-	low
Shapiro *et al.* (2008) USA	RCT	13	11	Efficacy of SMS in affecting dietary behaviour change in children (target SSB)	Home	9	3 weeks	8 weeks	Group sessions on targeted behaviours: screen time, SSB and PA. Use of SMS to self-monitor dietetic and PA goals	Attended educational sessions but did not self-monitored behaviours.	Diet/beverage record	1,4,6,8,9,10,12 ,13,19,20 Parental support	1,4,8, 9,10, 19,20	low
Sichieri *et al.* (2009) Brazil	Cluster -RCT	23 clusters (n=526)	24 clusters (n=608)	Prevention of weight gain/obesity through decrease intake of SSs	Educational	11	7 months	-	Educational sessions, information on negative health consequences of SSB consumption, water bottle provision.	General session on health issues and printed advice on healthy dieting	24-hr recall	1,2,4,19 Env. sup	-	medium

Author	Study design	Number of participants		Aim	Setting	Age (y)	Length of intervention		Intervention content		Dietary assessment tool	BCTs used		Quality
		Intervention	Control				Intervention	Follow-up	Intervention	Control		Intervention	Control	
Singh *et al.* (2009) Netherlands	Cluster -RCT	10 schools (n=632)	8 schools (n=476)	Behaviour change on energy intake and energy output. Targeted consumption of SSB.	Educational	13	8 months	12 months	Educational programme on biology and physical education with support from school-canteens agreeing to rearrange products	-	FFQ	1,2,4, 5,6,7,8,12,13,15,17,18,19,20 Env. sup	-	medium
Gomes de Souza *et al.* (2013) Brazil	RCT	40	39	Reduce sugar intake in school lunch cooks	Educational	46	7 months	-	Nutritional education sessions on sugar intake and food labelling.	Discussion segments on healthy eating (3 in total)	FFQ	1,2,4, 8,19	4,19	low
Taveras *et al.* (2011) USA	Cluster - RCT	5 clusters (n=271)	5 clusters (n=204)	Change in BMI. Health system restructuring to enhance achievements/targets in patients	Clinical	5	12 months	12 months	Changes to the health care system (defined role of each health team member involved, enhanced electronic medical records, motivational interviewing, input from nurses)	Well-child care visits and follow-up appointments for weight checks with paediatrician.	FFQ	4,8,14,25	-	low
Taylor *et al.* (2007) New Zealand	Quasi-RCT	4 schools (n=384)	3 schools (n= 346)	Obesity prevention by improvements in dietary intakes (including water promotion and reduction of SSB)	Educational	8	12 months	-	Community activity coordinators assignment, **provision of cooled water filters** and nutritional sessions on health consequences of SSB (started at year 2 of intervention)	-	FFQ	1, 2, 4,19,20 Env. sup	-	low

Author	Study design	Number of participants		Aim	Setting	Age (y)	Length of intervention		Intervention content		Dietary assessment tool	BCTs used		Quality
		Intervention	Control				Intervention	Follow-up	Intervention	Control		Intervention	Control	
Thompson *et al.* (2008) USA	Non-RCT	64	71	Improvement in dietary outcomes, including decrease in SSB intake.	Clinical	29	6 months	12 months	Behavioural contracts made, food labelling (for content of sugar), strategies for making healthier choices in and outside home.	Delivery of health magazine, reminders to attend clinic visits.	24-hr recall	1,2,4,5,8, 11,14,16,19,20 ,24	-	low

Table 3-2 Studies not included in meta-analysis.

Author	Study design	Number of participants		Aim	Setting	Age	Length of intervention		Intervention content		Dietary assessment tool	BCTs used		Quality
		Intervention	Control			(years)	Intervention	Follow-up	Intervention	Control		Intervention	Control	
Contento *et al.* (2010) USA	pre-post cluster RCT	20 clusters (n=562)	21 clusters (n=574)	Obesity prevention by improvements in dietary outcomes, including decrease in SSBs and increase in water intakes.	Educational	12	8 to 10 weeks	-	Adapted school science curriculum with educational activities targeting obesity risk behaviours in youth (including water and SSB intakes) through increase in personal agency and autonomous motivation (autonomy & competence). Prompted goal setting.	Kept normal science and biology curriculum	FFQ	1,2,4,5,8,11, 12,13,17,19, 21 Env sup	-	medium
de Ruyter (2012) Netherlands	RCT	225	252	Change in BMI by reduction of SSB intake.	Educational	10	18 months	-	Reception of non-caloric, artificially sweetened at school each week	Received a weekly box with sugar-sweetened beverages	FFQ, biomarker	14 Env sup Parental support	-	high
Ezendam *et al.* (2012) Netherlands	cluster RCT	I: 11 schools (n=485);	C: 9 schools (n=398)	Prevention of weight gain and improvements in dietary behaviours (including a decrease in consumption of SSB)	Educational	12	4 weeks	24 months	Online delivered sessions (8 modules) targeting dietary behaviours, such as decrease in SSB intake	regular curriculum	FFQ	1,4,5,8,10,13,19,20	-	medium

Author	Study desig	Number of participants		Aim	Setting	Age	Length of intervention		Intervention content		Dietary assessment tool	BCTs used		Quality
Gasliner *et al.* (2010) USA	non-RCT	6 clusters (n=50)	7 clusters (n=39)	Improvements in dietary outcomes, including decrease in SSB intake.	Community	25-64	9 months	-	Training of child carers on paediatric nutrition plus participation on wellness programme (including individual health counselling, reinforcing messages of healthy eating, encouragement of physical activity)	Training of child carers on paediatric nutrition and health (providing general information)	FFQ	1,2,4,5,14,18,19	-	low
Johansen *et al.* (2010) Norway	RCT	101	97	Diabetes prevention through reduction of sugar intake (including ↓ in sugary drinks and refined carbohydrates)	Community	41	7 months	-	Nutritional sessions targeting reduction of sugar and complex carbohydrates Personal dietary guidance provided.	usual care by GP	Dietetic history	1,2,4,8,19	-	low
van Grieken (2014) Netherlands		22 clusters (n=349 dyads)	22 clusters (288 dyads)	Obesity prevention in overweighed children (dietary targets included decrease in SSB intakes)	Clinical	6	24 months	-	Health-care professionals and parents chose 1 or 2 of 4 targeted behaviours and an action plan was elicited.	General information on importance of nutrition and PA.to the parents during their regular preventive health care	Child health/Food questionnaire	1,4,9,12,20, 25, Parental support		medium

Table 3-3 Subgroup analyses using random-effects models indicating change in SSB consumption in all studies (n=29).

Variable	Number of studies	Estimate (mL/unit)	95% CI (mL/unit)	P.value	Residual I^2 (%)	P.value after exclusion of outlier study (Albala et al., 2008)	Residual I^2 (%) after exclusion of outlier study (Albala et al., 2008)
Dietary assessment tool							
24 hr recall	12	-60.7	-91.8 to -29.5	<0.001	59	<0.001	59
FFQ	13	-84.6	-155.3 to -14.0	0.02	96	0.01	22
Diet/food record	4	-20.6	-51.9 to 10.8	0.20	0	0.20	0
Geographical region							
North America	14	-62.6	-92.6 to -32.6	0.008	54	0.008	54
Europe	7	-13.6	-25.7 to -1.0	0.03	0	0.03	0
Australasia	4	-30.9	-81.6 to 19.7	0.23	0	0.23	0
South America	4	-172.7	-453.7 to 108.4	0.23	99	0.45	66
Design							
RCT	15	-98.57	-175.5 to -21.7	0.01	95	0.001	57
Cluster-RCT	9	-17.3	-29.6 to -5.1	0.005	0	0.005	0
Non-RCT	5	-45.4	-92.3 to 1.5	0.06	22	0.06	22
Setting							
Community based	8	-52.8	-101.5 to -4.0	0.03	67	0.03	67
Home based	8	-155.9	-312.7 to 0.9	0.05	97	0.006	52
School based	10	-16.8	-28.7 to -5.0	0.005	0	0.005	0
Clinical based	3	-33.0	-80.3 to 14.3	0.17	0	0.17	0
Number of BCTs used							
1-8	15	-72.8	-142.4 to -3.3	0.04	95	<0.001	0
>8	14	-47.8	-75.0 to -20.5	< 0.001	61	0.001	61
Duration of delivery periods							
<30 weeks	15	-101.0	-187.0 to -15.0	0.02	95	0.02	36
>=30 weeks	14	-38.8	-58.7 to -19.0	<0.001	74	<0.001	50

Variable	Number of studies	Estimate (mL/unit)	95% CI (mL/unit)	P.value	Residual I^2 (%)	P.value after exclusion of outlier study (Albala et al., 2008)	Residual I^2 (%) after exclusion of outlier study (Albala et al., 2008)
Risk of bias							
High	16	-25.0	-40.0 to -10.5	0.001	0	0.001	0
Medium	13	-115.1	-182.4 to -47.8	0.001	96	<0.001	66

FFQ=food frequency questionnaire, RCT= randomised controlled trial; BCT= behaviour change technique.

Table 3-4 Subgroup analyses using random-effects models indicating change in SSB consumption in children studies (n=18).

Variable	Number of studies	Estimate (mL/unit)	95% CI (mL/unit)	P.value	Residual I2 (%)	P.value after exclusion of outlier study (Albala et al., 2008)	Residual I2 (%) after exclusion of outlier study (Albala et al., 2008)
Dietary assessment tool							
24 hr recall	7	-54.6	-93.3 to -15.9	0.006	58	0.006	58
FFQ	7	-177.8	-317.4 to -38.3	0.01	98	0.04	34
Diet/food record	4	-20.6	-51.9 to 10.8	0.20	0	0.20	0
Geographical region							
North America	7	-84.1	-134.1 to -34.0	0.001	40	0.001	40
Europe	5	-12.8	-25.5 to -0.23	0.05	0	0.05	0
Australasia	3	-40.4	-92.9 to 12.1	0.13	0	0.13	0
South America	3	-12.85	-25.5 to -0.2	0.08	99	0.008	0
Design							
RCT	8	-160.1	-344.8 to 24.5	0.09	97	0.006	40
Cluster-RCT	7	-17.65	-30.1 to -5.3	0.005	0	0.005	0
Non-RCT	3	-55.4	-130.4 to 19.6	0.15	57	0.15	57
Setting							
Community based	5	-87.2	-158.1 to -16.3	0.02	69	0.02	69
Home based	4	-238.3	-667.2 to 190.6	0.28	98	0.07	0
School based	7	-16.9	-29.1 to -4.9	0.006	0	0.006	0
Clinical based	2	-31.8	-79.9 to 16.2	0.19	0	0.19	0
Number of BCTs used							
1-8	11	-106.8	-196.5 to -17.0	0.02	96	<0.001	0
>8	7	-51.9	-99.2 to -4.6	0.03	68	0.03	68

Variable	Number of studies	Estimate (mL/unit)	95% CI (mL/unit)	P.value	Residual I2 (%)	P.value after exclusion of outlier study (Albala et al., 2008)	Residual I2 (%) after exclusion of outlier study (Albala et al., 2008)
Duration of intervention							
<30 weeks	18	-157.9	-353.4 to 37.6	0.11	96	0.07	56
>=30 weeks	18	-22.7	-33.08 to -10.38	<0.001	1	<0.001	1
Risk of bias							
Medium	10	-121.5	-200.4 to -42.5	0.003	97	0.002	57
high	8	-35.2	-61.6 to -8.8	0.009	0	0.009	0

FFQ=food frequency questionnaire, RCT= randomised controlled trial; BCT= behaviour change technique.

Table 3-5 Univariate meta-regressions on BCTs indicating change in SSB consumption in all studies (n=29).

BCT ‡	**BCT present exclusively in IC**	**BCT present in IC and CC or in neither**	**coef**	**SE**	**95% Confidence intervals**	**P value**	**P value excluding outlier study (Albala *et al.*, 2008)**
(T1) provide information on behaviour–health link	15	1	72.1	59.2	-49.3 to 193.5	0.23	0.68
(T2) provide information on consequences	16	-	70.6	59.2	-50.9 to 192.2	0.24	0.83
(T4) prompt intention formation	22	3	-103.9	92.6	-294.0 to 86.1	0.27	0.11
(T5) prompt barrier identification	14	-	-3.2	60.7	-127.6 to 121.3	0.96	0.12
(T6) provide general encouragement	3	-	-1.7	104.3	-215.7 to 212.3	0.99	0.04*
(T7) set graded tasks	3	-	41.4	100.3	-164.4 to 247.2	0.68	0.77
(T8) provide instruction	19	1	-41.1	64.7	-173.8 to 91.7	0.53	0.83
(T9) model/ demonstrate the behaviour	9	1	-110.3	60.5	-234.4 to 13.7	0.08	0.04*
(T10) prompt specific goal setting	0	1	55.4	159.3	-271.5 to 382.4	0.73	0.69
(T11) prompt review of behavioural goals	4	-	-4.0	89.0	-186.7 to 178.7	0.96	0.42
(T12) prompt self-monitoring of behaviour	8	-	17.8	69.7	-128.1 to 157.7	0.83	0.96
(T13) provide feedback on performance	7	-	50.6	70.0	-93.1 to 194.2	0.48	0.17
(T14) provide contingent rewards	12	-	-4.6	61.6	-130.9 to 121.7	0.94	0.43
(T15) teach to use prompts/cues	5	-	-31.9	81.3	-198.7 to 135.0	0.70	0.50
(T16) agree a behavioural contract	1	-	1.0	207.0	-424.6 to 424.8	1.00	0.83
(T17) prompt practice	3	-	-11.3	97.2	-210.7 to 188.1	0.91	0.23

BCT ‡	BCT present exclusively in IC	BCT present in IC and CC or in neither	coef	SE	95% Confidence intervals	P value	P value excluding outlier study (Albala *et al.*, 2008)
(T18) use of follow-up prompts	4	-	7.8	85.2	-167.0 to 182.7	0.93	0.68
(T19) provide opportunities for social comparison	22	3	-5.8	74.8	-159.2 to 148.6	0.51	0.04*
(T20) plan social support/social change	16	1	-81.6	60.3	-205.4 to 42.2	0.19	0.91
(T21) prompt identification as role model	3	-	-73.3	108.4	-295.8 to 149.2	0.51	0.14
(T23) relapse prevention	1	-	13.5	184.7	-365.5 to 392.5	0.94	0.86
(T24) stress management	2	-	-23.8	130.5	-291.7 to 244.0	0.86	0.30
(T25) motivational interviewing	2	-	-10.5	116.8	-250.2 to 229.2	0.93	0.35
(T26) time management	1	-	-37.9	164.7	-375.9 to 300.0	0.82	0.30
environmental restructuring/support	15	-	-37.3	61.6	-163.8 to 89.2	0.55	0.22
parental support	6	-	-93.3	67.7	-232.2 to 45.5	0.18	0.03*

BCT = behaviour change technique; IC= intervention condition, CC= control condition. No studies involved BCTs number 3 (provide information about other's approval) or 22 (Prompt self-talk). No BCTs were used only in control groups. * $P < 0.05$

‡Appendix B

Table 3-6 Univariate meta-regressions on BCTs indicating change in SSB consumption in children studies (n=18)

BCT ‡	BCT present exclusively in IC	BCT present in IC and CC or in neither	coef	SE	95% Confidence intervals	P value	P value excluding outlier study (Albala *et al.*, 2008)
(T1) provide information on behaviour–health link	11	1	138.1	86.9	-46.1 to 322.3	0.13	0.12
(T2) provide information on consequences	11	-	135.6	87.1	-49.1 to 320.3	0.14	0.25
(T4) prompt intention formation	16	1	-98.9	152.8	-422.9 to 225.0	0.53	0.049*
(T5) prompt barrier identification	8	-	30.9	91.7	-163.5 to 225.4	0.74	0.26
(T6) provide general encouragement	1	-	99.2	243.5	-417.0 to 615.4	0.41	0.85
(T7) set graded tasks	2	-	70.5	147.7	-242.7 to 383.6	0.64	0.75
(T8) provide instruction	12	1	-76.8	95.9	-280.0 to 126.5	0.43	0.90
(T9) model/ demonstrate the behaviour	6	1	-196.1	85.6	-377.6 to -14.5	0.04*	0.12
(T10) prompt specific goal setting	0	1	86.0	193.9	-325.0 to 497.0	0.67	0.68
(T11) prompt review of behavioural goals	3	-	27.8	120.4	-227.3 to 283.0	0.82	0.40
(T12) prompt self-monitoring of behaviour	5	-	8.2	107.8	-220.2 to 236.7	0.94	0.39
(T13) provide feedback on performance	6	-	97.8	94.6	-102.8 to 298.3	0.32	0.048*
(T14) provide contingent rewards	7	-	-0.04	94.1	-199.5 to 199.4	1.00	0.032*
(T15) teach to use prompts/cues	3	-	-12.8	127.2	-282.4 to 256.9	0.92	0.085
(T17) prompt practice	2	-	-7.5	143.1	-310.8 to 295.9	0.96	0.13
(T18) use of follow-up prompts	1	-	-102.2	195.3	-516.2 to 311.9	0.61	0.004*
(T19) provide opportunities for social comparison	16	2	6.0	117.2	-242.6 to 254.5	0.96	0.33
(T20) plan social support/social change	10	1	-109.0	88.5	-296.6 to 78.5	0.24	0.94
(T21) prompt identification as role model	2	-	-70.7	161.9	-413.9 to 272.5	0.67	0.28

BCT ‡	BCT present exclusively in IC	BCT present in IC and CC or in neither	coef	SE	95% Confidence intervals	P value	P value excluding outlier study (Albala *et al.*, 2008)
(T25) motivational interviewing	1	-	45.6	194.5	-366.8 to 458.0	0.82	0.67
environmental restructuring/support	3	-	-38.0	91.3	-231.5 to 156.0	0.68	0.10
parental support	4	-	34.11	111.7	-202.8 to 271.0	0.31	0.21

BCT = behaviour change technique; IC= intervention condition, CC= control condition. No studies in children involved BCTs 3 (provide information about other's approval), 16 (agree a behavioural contract), 22 (prompt self-talk), 23 (relapse prevention), 24 (stress management) or 26(time management). No BCTs were used only in control groups. * P< 0.05.
‡Appendix B

Chapter 4 : Prevalence of metabolic syndrome in children from central Mexico.

4.1 Abstract

Introduction Childhood obesity rates remain alarmingly high in middle-income countries such as Mexico. The metabolic syndrome has been identified as a co-morbidity in obese younger populations which increases the risk of CVD later in life. The aim of the present study was to determine the prevalence of metabolic syndrome according to the International Diabetes Federation Criteria for children in a sample of 6 to 15 year olds living in central Mexico.

Methods The Ministry of Health in Guanajuato State, Mexico in 2009 carried out a survey in 899,000 children to monitor their weight, height and thus BMI. An additional biochemical analysis was later performed in 10,798 children who had been identified to be at greater risk of suffering from metabolic syndrome. Components measured were high triglycerides, high fasting glucose and low HDL-C levels, in addition to the presence of obesity in certain subjects.

Results Data on BMI and biochemical features was available from 6186 children. Overall 12.3% of the children met the criteria for metabolic syndrome. In comparison to UK data, prevalence of metabolic syndrome in both countries was similar for obese adolescent populations (13.6% vs 14.5%). The most frequent metabolic risk factor was low HDL-C (29.5%). Although more prevalent amongst obese children, several children with normal BMI appeared to also fulfil the criteria for metabolic syndrome which could be suggestive of a relationship between abdominal adiposity and impaired metabolic results that has been described in normal-weight adults. Surrogate measures like waist circumference are needed to further explore and confirm this.

Conclusion Management of obesity through better screening activities along with health education campaigns on lifestyle modification are needed to reduce the risk of developing metabolic syndrome in paediatric populations.

4.2 Introduction

Childhood is a dynamic period of growth and development involving physical changes in which environmental factors, particularly housing conditions, education and food choices can have a direct impact on health outcomes. Excessive dietary intakes during childhood can result in obesity which has been associated with earlier onset of metabolic alterations in glucose levels, serum lipids and blood pressure. Indeed, the prevalence of the metabolic syndrome as a cluster of cardiovascular disease risk factors has been a more documented condition in obese children (Rodriguez-Moran et al., 2004, Cook et al., 2003, Lambert et al., 2004).

The current overweight and obesity rates within 5 to 18 year olds, approximately 32% in girls and 37% in boys (Gutierrez et al., 2012) have placed obesity as a priority for health systems in Mexico. Furthermore, the Mexican health legislation has integrated childcare promotion, screening and therapeutic activities within the national framework of nutrition for health, growth and development (Mexican Executive, 2010).

In response to the strategies entrusted by the World Health Organization in their Action Plan for the Global Strategy for the prevention and control of non-communicable diseases 2008-2013 (Alwan, 2009), the Ministry of Health in the state of Guanajuato additionally conducted in 2009 -with the participation of educational and sanitary entities- a weight and height survey in most children living in the state (from 3 to 18 years of age). The former was done to monitor their nutritional status and explore the prevalence of developmental and growth problems. A year later, the department of adolescent's health within the Ministry obtained biochemical parameters in a subsample of children in order to identify the prevalence of metabolic alterations across this young population.

An initial statistical analysis on the first cohort was carried out by the Department of Research within the Ministry in 2012. However, due to technical limitations, matching between children from the second cohort (with biochemical data) and their corresponding body mass index (BMI) to enable the estimation of metabolic syndrome in a population of 6 to 15 year olds living in Guanajuato, Mexico had not been possible.

4.3 Objectives

This chapter aims to:

- Describe the process of data collection, cleaning and statistical analysis for biochemical parameters and BMI.
- Describe the prevalence of metabolic syndrome mainly in children with obesity.
- Discuss the implications for current surveillance activities and for policies embedded within the educational and health systems.

4.4 Data selection and cleaning

The process of data cleaning and selection is shown in **Figure 4-1**. Originally, the database provided measurements and demographic characteristics on 1,177,091 children who were surveyed in the first cohort (which included height and weight measurements exclusively); 722 cases were eliminated due to the lack of recorded information (mainly errors and inconsistencies on dates of birth); 127,766 cases were duplicates and hence were removed. Of 1,048,603 original records a total of 148,759 were excluded due to being children under 6 years of age or due to biologically non-plausible measurements (i.e., implausible height or weight measurements).

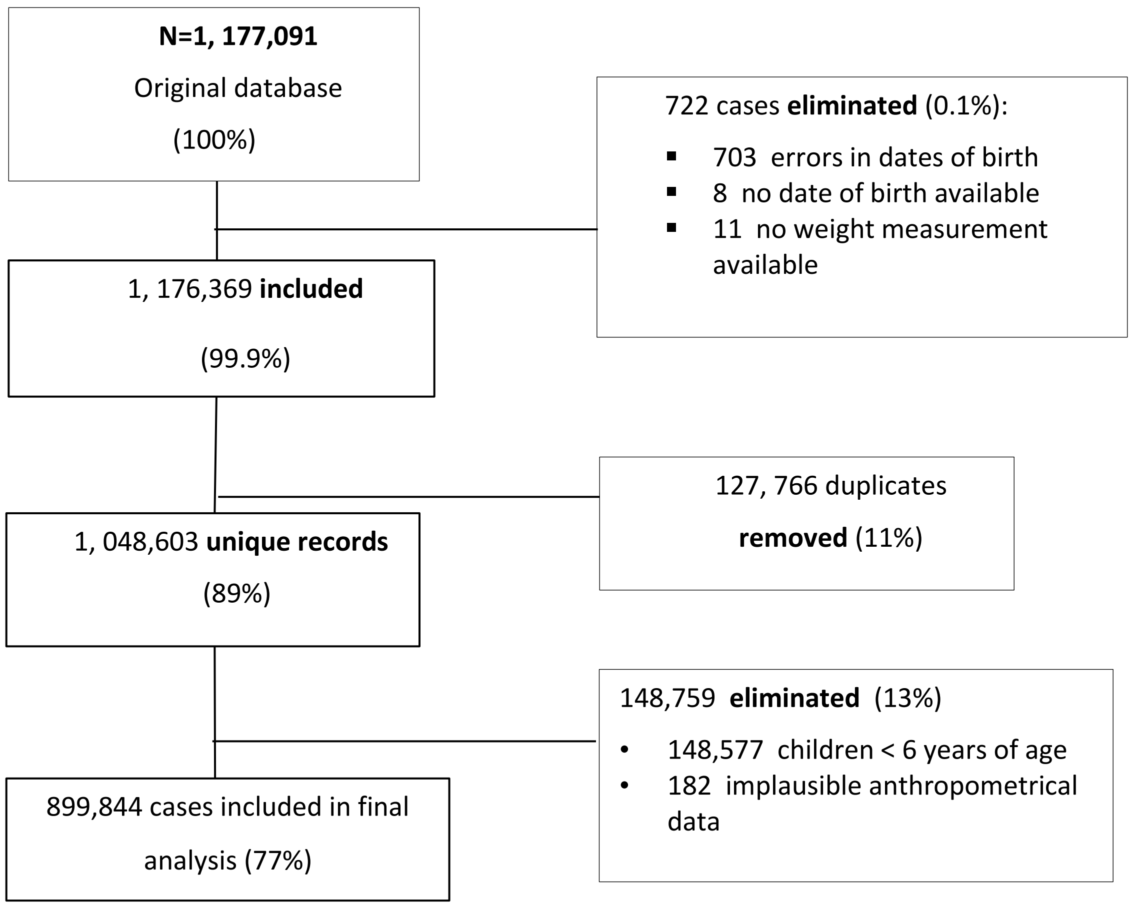

Figure 4-1 Flow chart of children included in anthropometrical analysis.

4.5 Analysis of data

4.5.1 Anthropometrics: BMI

For data analysis purposes, the population was divided into 3 groups. The criteria used for this division by the Ministry was age and pubertal status: 6-9 years (pre-pubertal), 10-13 (pubertal) and 14 and above (adolescent). In order to obtain a sample with normal distribution, 600 children were randomly selected by the Ministry for each age group (300 males, 300 females), in a proportion to that found in each of the 8 sanitary jurisdictions, numbers which were obtained from records by the National Institute of Statistics and Geography (INEGI in Spanish) (Instituto Nacional de Estadistica y Geografia, 2010) . The selection of particular cases was done through the generation of random numbers. Geographical location of the State of Guanajuato and cities in each jurisdiction can be seen in (**Figure 3-2**) and the total number of children by jurisdiction is shown in **Table 4-1**.

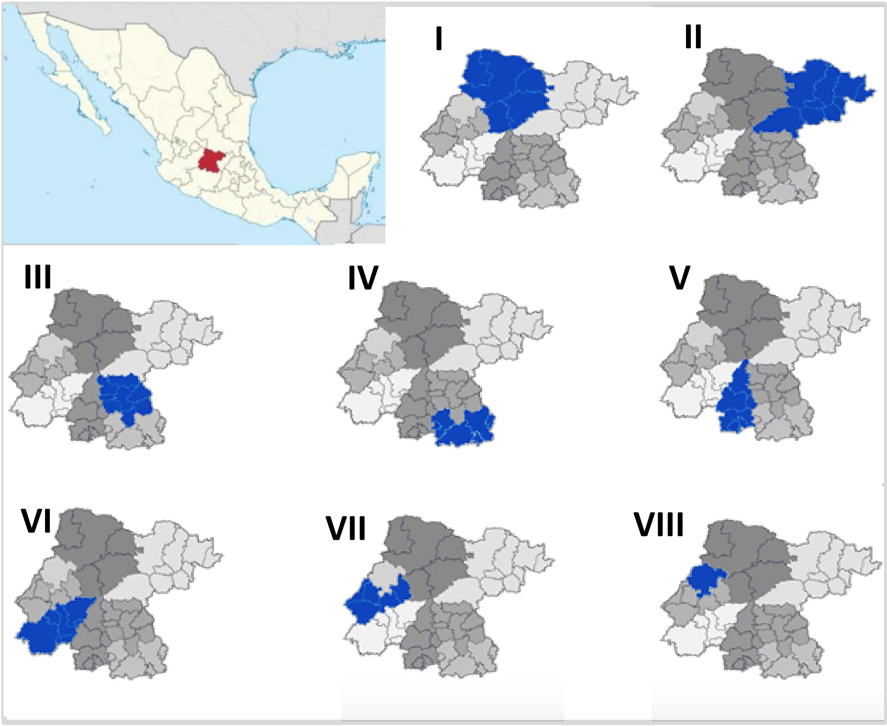

Figure 4-2 Geographical location of Guanajuato and municipalities within each sanitary Jurisdiction.
[Different shadings delimit the 8 different jurisdictions and blue colour indicates the area covering the jurisdiction in concern] Sources: https://es.wikipedia.org/wiki/Guanajuato; http://salud.guanajuato.gob.mx/Directorio-Jurisdicciones.php.

Table 4-1 Total children living across all health jurisdictions in Guanajuato.

	Age group		
Sanitary Jurisdiction	**6-9 years**	**10-13 years**	**≥ 14 years**
	N= 466 807 (100%)	N= 465 487 (100%)	N= 792 482 (100%)
1	43 851 (9.39%)	43 807 (9.41%)	75 994 (9.58%)
2	41 390 (8.87%)	41 517 (8.91%)	68 028 (8.59%)
3	80 082 (17.15%)	78 502 (16.86%)	135 904 (17.15%)
4	21 890 (4.69%)	23 114 (4.96%)	40 104 (5.06%)
5	47 676 (10.21%)	48 292 (10.37%)	83 289 (10.51%)
6	68 051 (14.57%)	70 593 (15.16%)	117 686 (14.85%)
7	122 476 (26.24%)	120 042 (25. 78%)	205 017 (25.37%)
8	40 788 (8.74%)	39 917 (8.51%)	66 505 (8.39%)

Source INEGI 2010

Results from descriptive analysis in the entire population (899,944 children) and general features (i.e., age, gender, weight, height, body mass index, jurisdiction, school shift and type of locality) were retrieved and are presented in **Table 4-2**. Normality tests in data from the whole population indicated that anthropometric variables in the different age groups were broadly normally distributed. Data are reported in means and 95% confidence intervals (**Table 4-2**). For analyses of weight, height and BMI for age by sex, percentiles instead of z scores were used, and the CDC growth charts were followed as these currently serve as reference for anthropometric indicators in several countries, including Mexico(Mexican Executive, 2010). Diagnostic criteria of BMI under this classification are as follows (Centers for Disease Control and Prevention, 2015):

- Malnutrition: <5^{th} BMI percentile
- Normality: ≥5-85 BMI percentile
- Overweight: 85-95 BMI percentile
- Obesity: ≥ 95 BMI percentile

The percentage of children falling into a percentile of weight, height and BMI for age and sex, can be seen in **Table 4-3**. In **appendix C** and **D** offer an insight of the differences found between the referential and registered percentiles of growth (weight/age, height/age and BMI/age) in the sample of 600 children. The former analyses were conducted and were shared by the Ministry of Health.

Table 4-2 General characteristics of all children included in the analyses.

	Number of cases N= 899,944 (100%)	Weight (kg) Mean (95%CI)	Height (cm) Mean (95%CI)	BMI (kg/m^2) Mean (95%CI)
Gender				
Female	445 563 (49%)	37.0 (36.9 to 37.1)	137.2 (137.1 to 137.2)	18.9 (18.9 to 19.0)
Male	454 281 (51%)	37.9 (37.8 to 37.9)	138.5 (138.4 to 138.5)	19.0 (18.9 to 19.0)
Age (years)				
6-9	385 331 (43%)	24.5 (24.4 to 24.5)	120.6 (120.5 to 120.6)	16.7 (16.6 to 16.7)
10-13	364 248 (41%)	40.1 (40.1 to 40.2)	142.3 (142.2 to 142.3)	19.5 (19.4 to 19.5)
≥14	150 265 (16 %)	55.4(55.3 to 55.5)	159.0 (158.9 to 159.0)	21.8 (21.8 to 21.9)
School's shift				
Morning	742 086 (83%)	37.5 (37.4 to 37.5)	137.8 (137.8 to 137.9)	19.0 (18.9 to 19.0)
Afternoon	153 146 (17%)	37.3 (37.2 to 37.4)	138.0 (137.9 to 138.0)	18.8 (18.8 to 18.9)
Mixed (morning and afternoon)	4332 (0.5%)	32.5 (32.2 to 32.8)	132.3 (131.9 to 132.3)	18.2 (18.1 to 18.6)
Only Saturday	280 (0.03%)	22.4 (21.9 to 22.9)	115.9 (115.3 to 116.0)	16.6 (16.3 to 17.2)
Type of locality				
Rural	299 904 (33%)	35.5 (35.4 to 35.5)	136.2 (136.1 to 136.2)	18.4 (18.4 to 18.5)
Urban	599 940(67%)	38.4(38.4 to 38.5)	138.7(138.6 to 138.7)	19.2 (19.1 to 19.3)
Jurisdiction				
1	82 565 (9.2%)	36.3 (36.2 to 36.4)	137.2 (137.1 to 137.3)	18.5 (18.4 to 18.6)
2	104 941 (12%)	33.4 (33.4 to 33.5)	133.2 (133.0 to 133.3)	18.2 (18.1 to 18.2)
3	95 758 (11%)	40.3 (40.2 to 40.4)	140.5(140.4 to 140.6)	19.6 (19.5 to 19.6)
4	52 391 (5.8%)	37.5 (37.4 to 37.6)	138.0(137.9 to 138.0)	18.9 (18.9 to 19.0)
5	117 294 (13%)	38.9(38.8 to 39.0)	139.5 (139.4 to 139.5)	19.2 (19.2 to 19.3)
6	148 678 (17%)	38.3 (38.2 to 38.4)	139.0 (138.9 to 139.0)	19.1 (19.0 to 19.2)
7	211 710 (24%)	37.5 (37.4 to 37.5)	137.9 (137.8 to 137.9)	18.9 (18.9 to 19.0)
8	86 507 (9.6%)	36.7 (36.6 to 36.8)	136.7(136.6 to 136.7)	18.9 (18.8 to 19.0)

Table 4-3 Age-related: weight (kg), height (cm) and BMI (kg/m2) percentiles across children in Guanajuato.

	Female			Male		
	6-9 years	**10-13 years**	**>14 years**	**6-9 years**	**10-13 years**	**>14 years**
	N=165	**N= 154**	**N=151**	**N=135**	**N= 146**	**N=149**
Weight/age*	%	%	%	%	%	%
P3	9.1	12	7.3	17	12	7.4
P5	5.5	7.1	6.6	5.2	8.9	2.7
P10	12	7.8	12	8.1	12	15
P25	19	21	21	20	14	17
P50	22	18	21	16	13	22
P75	0.6	16	15	13	16	17
P90	17	12	8.6	8.1	10	9.4
P95	6.7	1.3	6.6	3	3.4	2.7
P97	1.8	4.5	2.0	9.6	11	6
Height/age*						
P3	20	20	20	24.4	19	17
P5	6.1	5.8	11	8.1	7.6	11
P10	16	14	16	14	12	15
P25	25	16	24	16	23	26
P50	15	23	18	16	19	21
P75	12	13	7.3	12	12	6.0
P90	1.8	5.8	2.7	5.9	6.2	2.7
P95	1.2	1.9	0.7	1.5	0.7	0.7
P97	2.4	0.6	-	2.2	1.4	-
BMI/age*						
P3	5.5	9.7	4.0	11	6.2	3.4
P5	1.2	0.6	2.6	0.7	2.1	4.0
P10	6.1	5.8	6.6	7.4	6.8	8.7
P25	18	14	13	12	19	17
P50	25	22	23	20	14	18
P75	10	18	22	10	12	17
P85	12	9.1	8.6	9.6	9.6	9.4
P90	5.5	7.8	6.6	7.4	10	6.0
P95	6.6	5.2	7.9	10	6.2	8.7
P97	5.5	5.2	5.3	4.4	6.8	4.0
P99	4.8	3.2	0.7	6.7	6.8	4.0

*CDC charts used as reference. Data provided by the Ministry of Health

4.6 Biochemical parameters

The department of Adolescent's health in 2010 at the Health Ministry, followed 10,799 children (approximately 10% of the total cohort) mainly suffering from overnutrition (overweight or obesity) in order to identify possible biochemical/metabolic alterations in this population. Randomisation was not conducted to obtain this sample and little information was provided to better understand how sampling was done; notwithstanding most of the included children were living in Leon as this is the largest jurisdiction (and city) in the whole state. Leon corresponds to Jurisdiction number 7.

Biochemical analyses were performed in which fasting glucose, total cholesterol, triglycerides, HDL and LDL levels, urea, creatinine and uric acid values were obtained as well as those corresponding to blood biometrics (leukocytes, lymphocytes, granulocytes, haemoglobin, haematocrit, erythrocytes, platelets and mean corpuscular volume). The former analyses were seen as "care routine" so that children were instructed to go on one occasion to a specific health centre to provide a blood sample in fasting conditions. Consequently, parental assent was deemed sufficient. Analyses of blood samples were not performed at the central level (that being through the State's Public Health Laboratory in Guanajuato) but through a private company, thus no matching with previous information (anthropometrics) was done. Although biochemical measurements were mainly targeted to those children with obesity (established as BMI ≥ 95^{th} percentile by orders from the head of the Department of Adolescent's health), exploratory analysis by EJVG detected that children with a BMI corresponding to normal and overweight could be also suffering from MS. Resources available (technological, human and time) within the Ministry of Health were limited to match biochemical results with anthropometric information of the initial database; hence facilities and guidance provided by the Nutritional Epidemiology Group (NEG) at the University of Leeds allowed subsequent analyses. Whilst previously available to the main researcher, a letter was provided to the Head of the Department of Research in Health at the Ministry seeking permission to use the data, which was granted.

The main objective of the present analysis was to estimate the prevalence of metabolic syndrome incorporating BMI as another variable to aid in diagnosis; therefore, assessment of other biochemical elements/parameters was not undertaken. The International Diabetes Federation (IDF) criteria (Zimmet et al., 2007) was used to establish the number of children with MS as it matched the information/parameters that had been collected. Components assessed were high triglycerides, high fasting glucose and low HDL-C levels, in addition to the presence of obesity in certain subjects. For the latter variable, BMI ≥ 95^{th} percentile was used as a cut-off point considering this was the parameter followed by the Ministry of Health to determine nutritional status/obesity levels and consequently influenced the identification and enrolment of children in this second cohort.

The criteria of MS in children by IDF are as follows (3 or more components):

HDL < 40 mg/dL or 2.2 mmol/L
Glucose ≥ 100 mg/dL or 5.6 mmol/L
Triglycerides > 150mg/dL or 8.3 mmol/L
Obesity (waist circumference): ≥ 90^{th} percentile

To be noted is that diagnosis of metabolic syndrome should not be done in children from 6 to 9 years of age, but it's has been recommended to make further measurements should family history of metabolic syndrome, T2DM, dyslipidaemia, cardiovascular disease, hypertension and/or obesity exists (Zimmet et al., 2007). For children older than 16 years of age, the existing IDF criteria for adults should be used instead.

4.7 Results

4.7.1 Matching process

In order to pair children from a Master's database (containing 899,944 records) into the biochemical one (containing data on 10,799 children) a thorough electronic process was performed with help from the database manager within the Nutritional Epidemiology Department; matching by name and location –only two similar features available in both databases- retrieved an exact match of close to 6,000 children. This was done through the estimation of a percentage of similarity within the combination of words available (name, middle name and surnames) in addition to municipality. However, due to possible mistyping, many cases were not found and there were others in which the percentage of similarity was high but through direct observation it remained unclear if it corresponded to the child of interest. **Figure 4-3** portrays the flowchart of initial participants taking part in biochemical analyses.

Considering both databases contained sensitive information, access was only allowed to EJVG and NH; moreover, all documents were password protected and for statistical analysis a new ID variable was created for each case included, so that personal details were not longer available. Data were analysed using descriptive statistics in STATA. For the case of children with a diagnosis of obesity, the number of those meeting two additional components was identified through the "OR" (**|**) command in this statistical software, acknowledging the possible combinations:

```
bysort MetSyndrome: tab children_obesity &((high_glucose ==1& high_TAG ==1) |
(high_glucose==1 & low_HDL_ ==1) | (high_TAG==1& low_HDL_ ==1))
```

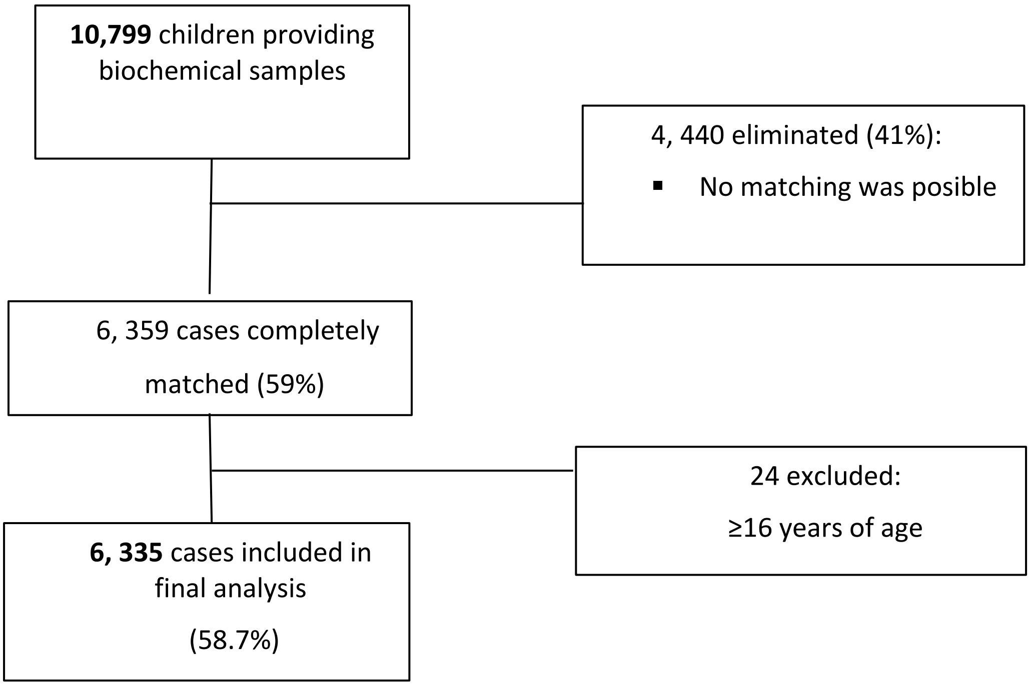

Figure 4-3 Flow chart of children participating in second screening (biochemichal).

Characteristics of children taking part in the second cohort, can be seen in **Table 4-4.** Data on BMI and biochemical features was available in 6335 children, with 4146 (66%) of them being either overweight or obese. The most frequent metabolic risk factor after obesity, was low HDL-C (30%), with close-to a third of the sampled population portraying high triglyceride and high glucose levels.

Table 4-4 General characteristics of children taking part in biochemical analysis.

Baseline characteristics of the study participants		
N= 6335	**n**	**%**
Male	3190	50
Female	3145	50
Age group	**n**	**%**
6 to 9	3245	51
10 to 15	3090	49
BMI (classification)	**n**	**%**
Undernourished	149	2.4
Normal	2050	32
Overweight	1428	23
Obese	2708	43
Abnormal biochemical parameters	**n**	**%**
High triglycerides	1721	27
High glucose	1753	28
Low HDL-cholesterol	1882	30

As portrayed in Error! Not a valid bookmark self-reference., higher abnormal parameters were retrieved for children classified as "obese" with high triglycerides (TAG) being prevalent in 6.6% of the girls and 7.6% in the boys whereas low HDL was prevalent in 7% and 8% of the girls and boys with obesity, respectively. To be noted is that a slightly higher number of boys and girls with normal BMI appear to have more altered risk factors, in comparison to children classified with overweight.

Overall 12.3% of the children met the criteria for MS and were mainly classified as being obese (**Table 4-6**). Children with normal BMI, however, also appeared to fulfil the criteria for metabolic syndrome (approximately 2%) and there were only 2 cases of undernourished children having the syndrome. A higher prevalence, however, was found amongst those above 10 years of age.

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Table 4-5 Metabolic risk factors for the Metabolic Syndrome according to BMI status.

	Female		Male		total	%
Diagnosis	6 to 9 y	10 to 15 y	6 to 9 y	10 to 15 y		
Undernourished	**46**	**24**	**54**	**25**	**149**	**2.4**
High TAG	7	2	7	6	22	
High Glucose	11	5	9	6	31	
Low_HDL	9	6	9	7	31	
Normal	**597**	**496**	**558**	**399**	**2050**	**32.4**
High TAG	127	98	93	90	408	
High Glucose	127	106	164	125	522	
Low_HDL	127	126	102	129	484	
Overweight	**324**	**429**	**339**	**336**	**1428**	**22.5**
High TAG	86	119	74	102	381	
High Glucose	83	102	103	114	402	
Low_HDL	102	119	65	109	395	
Obesity	**591**	**638**	**736**	**743**	**2708**	**42.7**
High TAG	219	198	233	246	896	
High glucose	160	176	203	245	784	
Low_HDL	218	216	230	297	961	
Total	**1512**	**1563**	**1633**	**1478**	6335	100

TAG =triglycerides

Table 4-6 Number and percentage of children that met criteria for metabolic syndrome.

	6-9 year olds (n=3245)		10-15 year olds (n=3090)	
Nutritional Status	3 components of MS (n)	% (95% CI)	3 or more components of MS (n)	% (95% CI)
Undernourished (BMI<5th percentile) n=149	2	0.3 (0.0-3.2)	0	-
Normal (BMI > 5th < 85th percentile) n=2050	16	0.8 (0.4-1.2)	19	0.9 (0.5-1.3)
Overweight (BMI ≥ 85th percentile) n=1428	14	1.0 (0.5-1.5)	34	2.4 (1.6-3.2)
Obese (BMI ≥ 95th percentile) n=2708	324	12.0 (10.7-13.2)	368	13.6 (12.3-14.9)
Total= **6335**	356	**5.6** (5.0-6.2)	421	**6.7** (6.1-7.3)

4.8 Discussion

4.8.1 Summary of the findings

Data shared by the Ministry of Health highlights the double burden of disease affecting children in the state of Guanajuato as both under and over nutrition problems were found across the sampled population. For instance, in 6 to 9 year olds the prevalence of undernourishment (established as a BMI/age $\leq 5^{th}$ percentile) was 7% in girls and 12% in boys, whilst obesity was present in 18% of the girls and 21% of the boys of this same age group (**Table 4-3**). Trends in children between 10 to 13 years of age highlighted that undernourishment was prevalent in 10% of the girls and 8% of the boys, with obesity being present in 14% and 20 % of the girls and boys, respectively, in this age group. Compared to national statistics, obesity in boys was similar across children from 5 to 11 years old (national prevalence being 17.4%) and higher in older children (national prevalence in 12 to 19 year olds being 14.5%) (Gutiérrez et al., 2012). In the female population, obesity rates in Guanajuato remained higher, as the national prevalence in 5 to 11 year olds is 11.8% and in the 12 to 19 year olds is 12.1% (Instituto Nacional de Estadistica y Geografia, 2015). While national results have used BMI Z-scores from WHO cut-off points for classification of nutritional status, which could have been a source of variation, it has been recognised that use of both BMI references (either z-scores or percentiles) are valuable for public health surveillance and screening purposes (Flegal and Ogden, 2011).

Merged information from anthropometrical and biochemical databases indicated that the Metabolic syndrome, is prevalent across 12.3% of 6 to 15 year olds living in Guanajuato. Furthermore, at least one cardio metabolic risk factor (i.e., impaired fasting plasma glucose or lipid/lipoprotein levels) was identified in 3 out of 10 children, with low HDL-cholesterol levels being frequently present. Although the MS was more prevalent amongst those classified as obese, several children with normal BMI appeared to also fulfil the criteria for MS which could be suggestive of the relationship between abdominal adiposity and impaired metabolic results that has been described in normal-weight adults (St-Onge et al., 2004) and adolescents (Rodriguez-Moran et al., 2004). Certainly, the most updated criteria by the IDF highlights the relevance of using the 90^{th} percentile of waist circumference (WC) since central adiposity has been linked to lower insulin sensitivity, dyslipidaemia and altered blood pressure in children and adults (Savva et al., 2000) and thus can be a better predictor of MS and cardiovascular disease (Zimmet et al., 2007, Palaniappan et al., 2004, Savva et al., 2000).

Higher BMI values, whilst indicative of obesity, do not entirely reflect differences in total body fatness across children and adolescents within the same spectrum (Pietrobelli et al., 2008). Indeed, a study conducted in 2014 in Guanajuato estimated the prevalence of MS in 110 exclusively obese children from 8 to 16 years of age and referred to a Paediatric Obesity Tertiary Care Clinic to be 62% (Rodea-Montero et al., 2014). Conclusions from this study indicated that BMI was not the best predictor of MS in comparison to the waist-to-height ratio (WtHR) or waist circumference (WC) – which was found to have a lower sensitivity in comparison to WtHR, but overall better specificity, accuracy and predictive positive and negative values (Rodea-Montero et al., 2014). In order to account for developmental and ethnic variations during infancy, percentiles instead of absolute values of WC have been strongly recommended (Zimmet et al., 2007).

The metabolic syndrome has also been documented in obese and non-obese children from a northern Mexican population of 10 to 18 year olds (Rodriguez-Moran et al., 2004). The presence of the syndrome across the 965 children taking part in the study was 26.1% for those with obesity and 21.3% for those with a normal BMI (7.2% and 6.3%, respectively, of the whole sampled population). Prevalence of metabolic syndrome in the former population was established through the combination of different criteria, including references by WHO, the National Cholesterol Education Programme Adult Treatment Panel III (NCEP ATP III) and the development of a new definition which incorporated a clinical evaluation with data on family phenotype, BMI, blood pressure, in addition to abnormal laboratory values relevant to metabolic syndrome. Results presented in this analysis highlighted a smaller prevalence of metabolic syndrome both for the obese and normal-weight children within the same age range (above 10 years old), potentially due to the diagnostic tool used and the lack of further characteristics such as waist circumference and blood pressure, which could have enabled the detection of other children at higher risk. Demographic differences could account for the variation shown, as the dietary pattern of the northern region of Mexico has been characterised by a higher consumption of animal products and lower intake of whole grains with refined sugars significantly contributing to energy intakes in children (Secretaria de Agricultura, 2011); cultural influence and proximity to the United States has been emphasised as a driver to the former consumption patterns (Secretaria de Agricultura, 2011). Moreover, evidence from Mexican children and adolescents in the highest quantile of the so-called "Western diet" (characterised by higher intakes of processed food, soft drinks and lower intakes of whole grains) has shown that they have 1.92 higher odds (95% confidence interval, 1.08 to 3.43) of exhibiting insulin resistance in comparison to those in the lowest quintile after adjusting for confounders such as BMI (Romero-Polvo et al., 2012).

4.8.2 Prevalence of Metabolic Syndrome in other countries

In comparison with available UK data (St-Onge et al., 2004), prevalence of metabolic syndrome in both countries was similar for obese adolescent populations (13.6% in Mexico vs 14.5% in UK). A study by Bokor *et al.* analysing the prevalence of metabolic syndrome in European obese children from five different countries (France, Greece, Italy and Poland), also found that 16.4% of children between 4.5 and 18 years of age (n= 1241) met diagnostic criteria using the IDF classification (Bokor et al). Similarly, a study in Germany across 1205 overweight children and adolescents (aged 4 to 16 years) exploring metabolic syndrome prevalence using different definitions, found that 14% fulfilled IDF criteria of metabolic syndrome (Reinehr et al). By contrast, the overall prevalence of metabolic syndrome in American adolescents (12 to 19 years old) was 4.2% according to Cook *et al.*, whose definition differs from the IDF in that high triglyceride and high glucose levels are both established as ≥ 110 mg/dL. However, metabolic syndrome affected 28.7% (95% CI 20.7 to 36.7) of adolescents with overweight (Cook et al., 2003).

4.8.3 Limitations of these analyses

Lessons learned from data processing allows to recognise the need to apply more robust methods of data collection (i.e., adequate data entry, consistency in variables measured and producing a unique ID for cases) that could generate smaller losses of information, as it was only possible to match 58% of the biochemical records to the master database.

Furthermore, one of the main criterion for the establishment of metabolic syndrome includes obtaining insulin resistance values which have been shown to provide direct information in assessing the risk of cardiovascular disease in subjects without type 2 diabetes (Karter et al., 2005). Considering measurement of hyperinsulinemia may deem impractical for large screening activities, subsequent assessments in paediatric populations in the state and other regions in Mexico could highly benefit from surrogate measures, such as waist circumference, to distinguish those children at higher risk of health complications as reflected by presence of abdominal obesity. Future interventions and surveillance in these age groups could benefit from establishment of pubertal stage as puberty has been shown to influence fat distribution and consequently decrease insulin sensitivity (Bloch et al., 1987).

4.8.4 Implications for nutritional policy

Early recognition and treatment of the metabolic syndrome during childhood are essential to limit further physical disability and consequences to the psychosocial development of children and adolescents. Lifestyle modifications via dietetic management and increased physical activity stand as the primary line of action in this age group (Zimmet et al., 2007) in order to maintain an adequate weight. Considering the strong association between metabolic syndrome and non-alcoholic fatty liver disease that has been documented in children (Schwimmer et al., 2008), addressing nutritional factors and avoidance of smoking (Moore, 2010) could prevent type 2 diabetes, cardiovascular events or progression to the end-stages of liver disease (Schwimmer et al., 2008). Therefore, health promotion campaigns that emphasise the importance of maintaining a healthy weight and raise awareness that a large waist circumference can be a cardiometabolic risk factor should be further supported and ideally integrated in school's health curriculum.

While the current health sectorial plan 2013-2018 has addressed the current obesity problem in Mexican children (Poder Ejecutivo de la Nacion, 2013) by seeking a decrease in sugar-sweetened beverages, their impact remains to be assessed. In particular, their enforcement and evaluation have been discretionary and limited to coverage rates (Rivera-Dommarco et al., 2014). Furthermore, the need for coordinated activities between the educational and health systems in Mexico is necessary to improve the process of identification, referral and timely management of those children with greater odds of ill health.

4.9 Conclusion

From the analysis of this data, it can be concluded that despite the latent prevalence of undernutrition, boys and girls in the state of Guanajuato have a greater tendency towards overweight and obesity. Figures shared here are in agreement with national statistics. Biochemical data, on the other hand, confirmed the presence of metabolic syndrome in 12.3% of the sampled population, mainly in those suffering from obesity. Nevertheless, a number of children with a normal BMI also appeared to fulfil criteria of metabolic syndrome.

In order to delay the development of cardiovascular and hepatic complications at a young age, strengthening medical surveillance and monitoring systems for detection, referral and treatment should be widely encouraged. Nutritional initiatives in this population, with modifiable factors as targets, could yield promising improvements to their dietary patterns and metabolic profile.

Chapter 5 : Design and methods of a non-randomised controlled pilot study to decrease sugar sweetened beverages by promoting water intake in primary schools

5.1 Abstract

Introduction The magnitude of childhood obesity in Mexico urgently calls for action in order to consolidate robust and sustainable health promotion frameworks within this age group. Amongst the diverse conditions associated with the development of obesity in Mexican children and adults, high caloric beverage intake has been particularly stressed. Schools have been acknowledged as valuable settings to influence dietary behaviours in children.

Methods The *DrinkSmart* in schools' project was a non-randomised controlled feasibility study aiming to assess the effectiveness of an environmental and educational intervention on decreasing consumption of SSB by promoting water intake. Using a "Theory of Change" scheme, the study was tailored to 8 to 12-year-old-children attending public schools in Leon, Guanajuato, Mexico. The study aimed to recruit 500 children from 4 schools in a deprived area (two schools with water fountains functioning and two without). The primary outcome was change in consumption of SSB and water (mL) from baseline to post-intervention (12 weeks after). Secondary outcomes included increased awareness and knowledge on sugar content of beverages and health benefits from drinking water. A beverage questionnaire and other supporting materials were developed and piloted specifically for this project. Multilevel linear modelling and a process evaluation were conducted to learn about intervention's fidelity.

Conclusion This chapter described the methods applied to the feasibility study conducted across four primary schools in Mexico, which was planned following the principles of the Public Health Nutrition Cycle: setting a goal for the nutrition problem of SSB intake, defining objectives for goal, developing, implementing and evaluating the programme's content.

5.2 Introduction

The accumulating evidence on current patterns of consumption, contributions to energy intake and links to ill health (including the metabolic syndrome) support the need to target SSB as part of obesity prevention and management efforts in Mexican children. The previous chapter has highlighted that metabolic abnormalities, such as low-HDL cholesterol and high triglyceride levels, are prevalent in a sample of obese children and adolescents living in Guanajuato State. Clinical progression of the metabolic syndrome into type 2 diabetes and advanced cardiovascular disease prior to adulthood has been documented (Weiss et al., 2004) and this emphasises the call for action in younger populations, as changes in SSB reduction could have future beneficial health and economic effects.

As portrayed by results in chapter 3, schools offer valuable settings for the prevention of overweight and obesity in children, by providing worthwhile opportunities to deliver health education and contribute to the development of desirable dietary behaviours. Indeed, promotion of healthy eating and drinking practices is currently part of the Mexican obesity prevention scheme in childhood (Secretaria de Educacion Publica, 2014, Poder Ejecutivo de la Nacion, 2013). Considering the current health context in Mexico and the promising reductions in SSB intake from child-based interventions (**chapter 3**), it is feasible to keep addressing the school environment to influence desirable health outcomes (looking for a decrease in SSB and thus impact obesity rates) across children and other stakeholders (teachers and parents).

The development of this pilot study was based on systematically reviewing the literature surrounding the topic while the range of potential interventions was categorised using a "*Promise table"* as described by Swinburn and colleagues (Swinburn et al., 2005). This framework aids researchers to grade interventions according to their likely population impact and effectiveness. Collated information for this pilot study can be seen in **Table 5-1.** Additional criteria that were considered to make the former judgements were the feasibility (human and economic resources available), sustainability (addressing barriers that have been already identified for implementation of other activities and policies within the Mexican school system (Rivera-Dommarco et al., 2014), acceptability to stakeholders -accounting for the switch from SSB to plain water and conditions of water fountains- and potential side effects which were considered as minimal as the intervention will seek to comply with the government's health vision and mission (Secretaria de Educacion Publica, 2014)

Table 5-1 Matrix of potential interventions to decrease SSB intake*

Certainty of effectiveness†	Potential population impact‡		
	LOW	**MODERATE**	**HIGH**
QUITE HIGH	School's food policies (banning SSB inside school)	Water fountains at schools	Pricing and economic tools: <u>*Taxation*</u> *(*if revenues are used to promote healthier environments or subsidise healthier alternatives*)*
	(*promising*)	*(very promising)*	(*most promising*)
MEDIUM	Community based programmes (targeting dyad of child/parent, summer camp).	Water coolers	Home delivery of other beverage alternatives (non-calorie yielding drinks)
	(*Less promising*)	(*promising*)	(*very promising*)
QUITE LOW	Self-monitored behaviour either electronically or through diaries Clinically delivered programmes	Isolated information verbally, electronically or other educational materials to parents	Social marketing/health campaigns
	(*least promising*)	(*Less promising*)	(*promising*)

*Adapted **from Swinburn *et al. 2005* according to findings of systematic review in chapter 3.**
†**Effectiveness** understood or judged by the quality of the evidence, strength of programme's logic.
‡**Population impact** considers efficacy (impact under ideal conditions), reach, and uptake.

5.3 Aims

This chapter aims to describe the methodology that was followed to develop, implement and assess the *Drink Smart* in schools' project. The principles behind sections in this chapter have been assigned following the Public Health Nutrition cycle (Gibney et al., 2004) as it identifies, through a logic approach, the key steps for addressing a nutritional problem, and is a tool that aims to solve a public health nutrition problem. It also integrates an ongoing, logic process in which all of the stages of development are based on evidence **Figure 5-1**.

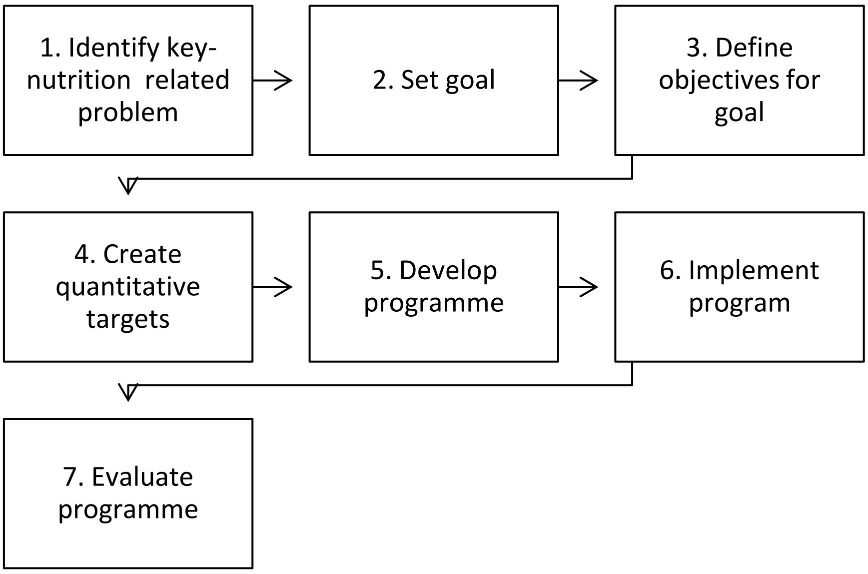


Figure 5-1 Public health nutrition cycle. *Source* (Gibney et al., 2004).

5.3.1 Identification of a key related problem: excess SSB consumption

The identified key-nutrition related problem, as has been described in previous chapters, was the reduction in SSB intake in 8 to 12-year-old children attending elementary schools.

5.4 Goals (long term)

This project aims to:

- Contribute to the reduction of obesity rates in school-aged children from 14.6% to 12% by 2018 (in accordance to National goals) (Poder Ejecutivo de la Nacion, 2013).
- Promote adequate and healthy school environments that prompt children, parents and staff towards healthier non-alcoholic drinking behaviours.
- Contribute to the sustainability of federal strategies to tackle obesity within the school setting.

5.5 Objectives

5.5.1 Primary objectives

To examine the effectiveness of an environmental and educational intervention on decreasing consumption of sugar-sweetened beverages in school-aged children living in Leon, Mexico by promoting water intake.

Hypothesis: Children receiving the intervention will decrease the intake of SSBs by increasing water intake. A reduction in SSBs by half a serving daily (120 mL) and an increase by one to two portions of water daily (240-480 mL) is expected as a result of the intervention.

Rationale for expected outcomes: Considering that daily consumption of SSB in Mexican children (5 to 11 year-olds) has been estimated to be 377 mL (Standard error [SE]=6.6), this would correspond to approximately 1.5 servings a day (1 serving size= 240 mL) (Barquera et al., 2010). Daily water consumption in this group is estimated at 658 mL (SE= 8.9) (Barquera et al., 2010). Results from the meta-analyses (**Figures 3-2 to 3-5**) in children's studies have found reductions about a third of a 240-mL portion of SSB and increases of about 80 mL in water intakes. Thus, the educational and environmental manoeuvre that will be implemented could achieve the desired changes.

5.5.2 Secondary objectives

- To promote the benefits of drinking water through information permanently positioned at a visible site in school.
- To help students recognise visual signs of dehydration through a urine colour chart placed outside toilets.
- To provide further information on the sugar-content of drinks through printed materials (games) that remind students and staff of quantities of sugar in frequently consumed beverages.
- To verify the adequate implementation of school nutritional policies in cafeterias and food concessions as described in the National scheme for nutrition in schools (Secretaria de Educacion Publica, 2014) in terms of sales of SSB.

5.6 Outcomes

<u>Primary</u>

- Change in consumption of SSB (mL/day) from baseline to post-intervention.
- Change in consumption of water (mL/day) from baseline to post-intervention.

<u>Secondary</u>:

- Increased awareness and knowledge on sugar content of most frequently consumed beverages and health benefits from drinking water.

A **SSB** was defined as a:

"Non-diet, non-alcoholic, cold or warm drink (carbonated or still), with added sugars (derived from energy-yielding sweeteners/sources both natural and processed), including fruit drinks, nectars and frappes with less than 100% fruit juice as well as sports or energy drinks"(Vargas-Garcia et al., 2015)

Considering particular beverage items consumed by the Mexican population, the definition also included "sweetened dairy products (yogurts, chocolate milk), fruited –sweetened water (also known as aguas fresca) and 100% fresh juice".

<u>Target group: study population</u>

The intervention targeted public schools with and without a water fountain available. Intervention groups will be considered those having a water fountain, and corresponding targets from the intervention are as follows:

Primary target group *children* attending elementary schools (3rd to 6th graders) from low-socioeconomic areas in Leon, Guanajuato. Selection of this age group has been based on the feasibility to initiate a change during this educational stage rather than at secondary school. Children from the 1st and 2nd year were considered too young to take part in the intervention.

Secondary target group *school's staff* (teachers and principals).

5.7 Ethical aspects

Ethical approval for this study was obtained from the Research Ethics Committee at the Hospital of High Speciality in Guanajuato (HAEB) and the Research Ethics Committee of the Faculty of Mathematics and Physical Sciences (MAPS) at the University of Leeds (**appendix E** and **F** respectively).

Written informed consent was obtained from educational headships at the Ministry of Education (MoE) and verbal agreement was granted from supervisors and head of all schools agreeing to participate in the study. Parental written informed consent was also obtained for children taking part. Potential risks and benefits from participation were provided to schools and parents through an information sheet in which the possibility of withdrawing was highlighted.

5.7.1 Children withdrawal

Considering the environmental and educational elements of this study, for children no longer taking part, data on primary and secondary outcomes was not collected; however, they were not excluded from any activity or resource that was used throughout the intervention.

5.7.2 Good research practice

Guidelines from the Consolidated Standards of Reporting Trials (CONSORT) were used to draft this intervention and present its results in the following chapter(Moher et al., 2001). To document the progress through the phases of the study (that being enrolment, intervention allocation, follow-up, and data analysis), the recommended flow chart diagram by CONSORT was followed –although randomisation was not feasible at the school level (Schulz et al., 2010) (**Figure 5-2**).

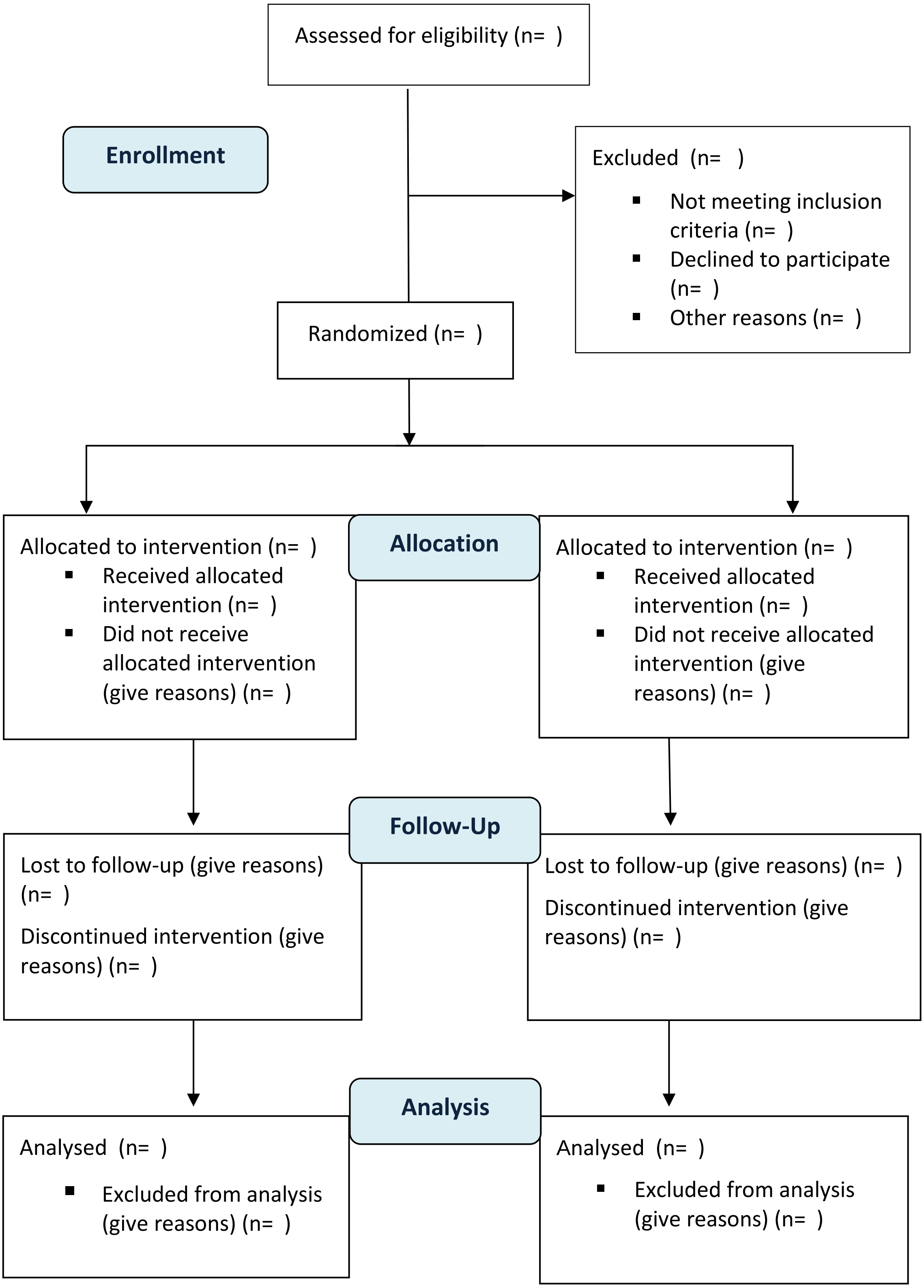


Figure 5-2 Flow diagram of the progress through the phases of a parallel randomised controlled trial of two groups: enrolment, intervention allocation, follow-up, and data analysis. *Source*: (Schulz et al., 2010).

5.8 Programme development (methods)

5.8.1 Sample size calculation

In agreement with the recent Health Sectorial Program 2013-2018 (Poder Ejecutivo de la Nacion, 2013), to reduce the obesity prevalence in Mexico, water fountains are being installed in advance across all public elementary schools and should be available for children starting the educational period of 2015-2016 beginning in August. Therefore, assuming a two-sided test, $\alpha = 0.05$ and power of 90%, 231 children were needed per group to detect a difference in water intake of one serving size (240 mL) between intervention and control groups, approximately 4 schools. Considering the study's design and that differences at the school level were not taken into account as well as a dropout rate of 10–15%, a final sample size between 231 and 250 subjects per group (2 schools from intervention and 2 schools from control) was proposed.

The estimated sample size calculation for a two-sample comparison of means can be seen in **appendix G.**

5.8.2 Recruitment of schools and participants: Inclusion criteria

The department of Nutrition at the MoE in Leon was approached by a lecturer from the public state university (Universidad de Guanajuato) to discuss the viability of conducting the study in primary schools. This pilot study was originally conceived to be implemented in schools having newly installed water fountains at the beginning of the academic year in August 2015. However, for administrative convenience, the Nutrition department only provided a list of potential schools from three different educational districts in Leon that had received -in the prior 6 months of the start date of this project- a nutritional course on healthy eating and that fulfilled the following **criteria**:

- Having classes from 3rd to 6th grade,
- Enrolling more than 150 students,
- With or without a water fountain available,
- Located in the urban area of Leon and,
- Having morning and afternoon shifts.

The nutritional sessions delivered by nutritionists at the Ministry of Education in all potentially eligible schools are described in **Table 5-2.**

Table 5-2 Nutritional education and health promotion activities delivered by the Department of Nutrition at the Ministry of Education

	1st session	2nd session	3rd session	4th session
Delivered to **Parents** Duration: 30 minutes	Smart Breakfast	Reading and interpreting food labels	Emotional eating	Diet, love and obesity
Delivered to **Students** Duration: 30 minutes	Sugar content in Sugar-sweetened beverages	Eat well plate	Snakes and ladders of general health	Healthy lifestyle: keeping active
Delivered to **Teachers** Duration: 15 to 30 minutes	Different educational materials	Nutritional activities	Healthy Portfolio	Topics related to overall health (physical exercise, diet)

Nominated schools (n=6) were sent a recruitment letter and were contacted by phone by the main researcher to ask if they were able to participate. Information letters contained details of the objective of the study and the reasons for inclusion (availability of a water fountain). Recruitment of schools was challenging not only due to the administrative process to reach the head of schools (which is portrayed in **Figure 5-3**), but due to limited records to identify schools without a water fountain. Though information for every school in the educational district is accessible online, it is often not updated for the staff at the Ministry nor the general public. Moreover, refurbishment of schools' is done during the summer holidays and thus changes occurring during this period are not easily tracked, which limited the number of schools to be potentially included and any possibilities of randomisation.

All schools approached (6 in total) expressed an interest in participating in the study, nevertheless, final selection was done on the basis of their location (distance from each other) and written approval from corresponding authorities.

Schools agreeing to participate (n=4), delivered classes in the morning and afternoon shifts and were located within the urban area of Leon; however, only the head of schools from morning shifts were approached and invited to take part in the study. In one intervention site, the head of school was in charge of both shifts. Schools in this study were part of the same educational headship but only intervention sites shared the same supervisory chief.

Participating schools were located within considerable distance from each other and were all classified under a “low” level of margination -according to the Ministry’s ranking of educational zones and campuses (Secretaria de Educacion de Guanajuato, 2015)).

One intervention site was bigger in its facilities and had three classes from each grade (from 1st year of primary to 6th grade, a total number of 18 classes) in comparison to the other intervention site. One control school had two classes per academic grade (a total of 12 classes) and the remaining control school had 6 classes in total. Data was collected in children from the 3rd, 4th, 5th and 6th year of elementary education and one group per academic year was randomly selected from each school by flipping a coin.

It was not possible to blind schools to their intervention nature; fieldworkers and the main researcher were also not blinded to the allocation of schools to the intervention and control arms.

5.8.3 Intervention duration

Collection of baseline information was conducted on the 24th of September in intervention groups and on two days later (26th of September) in control groups. The starting and ending dates of intervention were the 1st of October and 16th of December 2015, respectively. Collection of post-intervention information took place on the 16th of December 2015 at the intervention groups and on the 17th of December at the control groups.

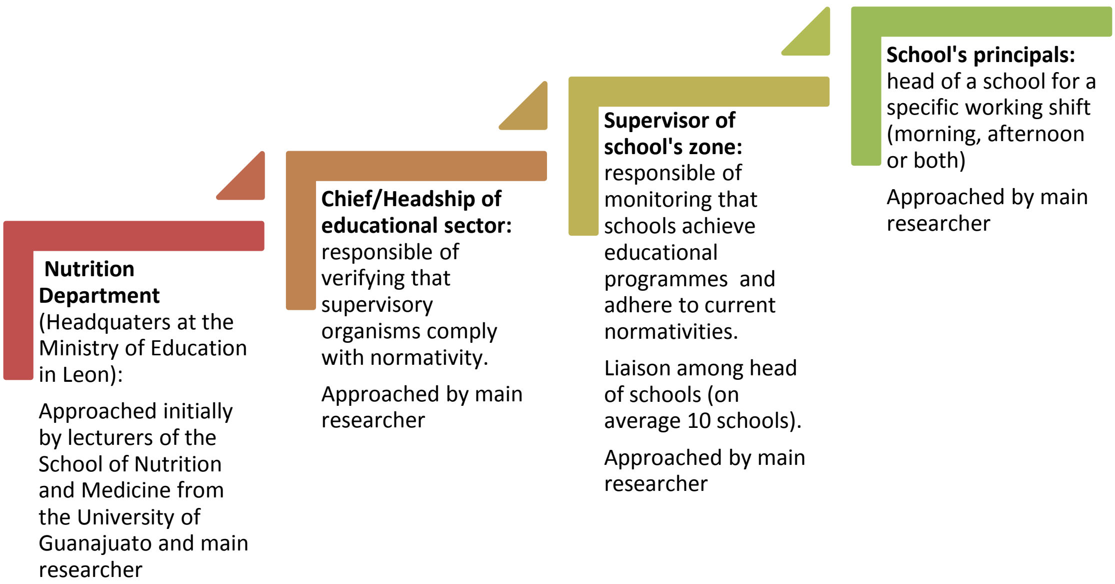


Figure 5-3 Administrative structure of Ministry of Education in Leon, Guanajuato and process to reach schools.

5.8.4 Study design and definitions

As previously mentioned, for administrative convenience this was a non-randomised controlled study.

- *Intervention groups* were considered those that had a working water fountain and agreed to participate.
- *Control schools* were considered those pending for implementation of a water fountain.

5.8.5 Location

Public elementary schools from the urban area of Leon, Guanajuato, Mexico. Leon is located within 380 km north of Mexico city and has a population of 1.5 million residents making it the fourth most populated city in the country (Instituto Nacional de Estadistica y Geografia, 2015).

5.8.6 Activities

Core activities and roles of each of the stakeholders (teachers, fieldworkers, and head of schools, main researcher and academic staff from the University of Guanajuato) are portrayed in **Figure 5-4.** Selected pathways of action, and thus selection of activities and materials, were informed through the development of a Theory of Change (**ToC**) that addressed the unique characteristics from this intervention. Activities were tailored to the population in agreement to findings from Chapter 3, in particular to the behaviour change techniques that appeared more promising to decrease consumption of SSB **Table 3-6**.

5.8.7 Theory of Change (ToC)

In comparison to a regular logic model, a ToC is a visual approach portraying existing and expected links between different programme components as well as the channels through which changes are anticipated to occur (De Silva et al., 2014). Components of the ToC are *intermediate outcomes* or specific changes from programme implementation, which are connected to causal pathways portraying the direction of the relationship across these changes and their contribution to long-term outcomes and goals.

Amid intermediate outcomes, *interventions* (programme's activities), *rationale* (scientific evidence behind selected approaches), *assumptions* (uncertainties to be clarified through formative research or implementation) and *indicators* (metrics of change portraying how much of each intermediate outcome has been achieved) can be found. A Theory of change can be seen in **Figure 5-5**. The map was produced after contact and discussion with local education authorities in Leon. These contacts provided more clarity on the indicators, interventions and assumptions to be tested. Though the ToC was explained and shared with local authorities, no comments or suggestions were received. During the implementation of the study it was possible to refine assumptions to be implemented.

5.8.8 Materials

All educational components that were provided to children, teachers and placed across schools as part of this feasibility study were designed and delivered by the main researcher with help of a graphic designer in Mexico. The logo and promotional messages of the project can be seen in **Figure 5-6** which captures a superhero saying "*Aguas si no tomas agua*" (which stands in Spanish for "Careful if you do not drink water") and a child saying "*Tomala: El Habito del Campeon*" (which stands for "Take it!: the habit of champions). The following educational resources were provided to experimental sites only:

- Two printed games (a memory game and snakes & ladders) with information on consequences of excessive drinking of SSB (**BCT 1 and 2: provide information on behaviour– health link, provide information on consequences),** health benefits of drinking water and sugar contents of most commonly consumed SSB were handed out to teachers from each class (refer to **appendix H**). Teachers were instructed to allow children to play with these resources at a convenient timing (i.e., during school recess, activity break, etc.).
- Educational messages highlighting the importance of water intake and the high sugar content of most frequently consumed beverages was made available to parents and children through banners placed at strategic settings (i.e, main entrance of schools, halls) (**appendix I**).
- One of the intervention's objectives was the identification of good hydration; thus, a urine colour chart was designed and placed in toilets as a reminder of drinking more water. The former strategy was found to be effective in previous Mexican studies to raise awareness of water needs in the body (Carriedo et al., 2013, Elder et al., 2014). Refer to **appendix J**.
- A 500 mL plastic water bottle was provided at the beginning of the study to all children in the experimental arm (regardless if they had or not agreed to participate). They were prompted to personalise it and keep it in good hygienic conditions. Teachers instructed them on a daily basis to bring it filled with water from home and refill at the water fountain during the recess break, so as to

progressively set the desirable behaviour (**BCT 4 prompt intention formation; BCT 17 prompt practice**). Teachers assisted by also bringing plain water as their choice of beverage (**BCT 9, model/demonstrate the behaviour**). Whilst it was contemplated that children could leave permanently their water bottle in the classroom, for hygienic reasons it was decided they should bring it every day from home, where appropriate handling could be given to it (i.e., washing). Teachers also assisted in the implementation of a daily "water break" so that children could all have the opportunity to drink water from their bottles and be prompted of keeping an optimum hydration throughout the school's journey. This activity was previously deemed promising in previous studies (Muckelbauer et al., 2009). The format can be found in **appendix K.**

Control schools were asked to keep their current curriculum and were given the materials at the end of the study. Teachers at all sites were also asked to keep a beverage record of drinks that children brought from home (**appendix L**)

Ministry of Education in Leon

- Provide written consent to recruit and work with schools.
- Provision of functional/ready to use water fountains in intervention schools.

Research Team: University of Leeds

- Lead design of intervention, implementation, collection, assessment and analysis of data.
- Compliance with ethical standards for execution of this study.
- Select, design and pilot tools to collect information.
- Provision of a plastic/reusable 500 mL water bottle to every child at the begining of the intervention.
- Lead collection of information at baseline and post-intervention, statistical analysis , documentation and dissemination of results.
- Recruitment and trainning of collaborative team .
- Active liasion with all stakeholders.

Teachers

- Reinforcement of desirable behaviour though implementation of water break. Demonstrate behaviour by drinking plain water inside class. Record in a monitoring sheet the days were the water break was implemented.
- Prompt refilling of bottles from fountain on a daily basis.
- Record, based on an observation exercise,the beverages that children are bringing as part of their lunch.
- Facilitate educational materials to children (memory game and Snakes &Ladders).

University of Guanajuato

- Support with data collection and mid-way assesment Implementation aidance
- Collection of baseline data in regards to current consumption of SSB and help in implementation of protocol by Boston College on auditing SSB and water access. Refer to **appendix N.**
- Monitoring of adequate delivery of intervention at week 6.
- Collection of follow-up data.

Head teachers (principals)

- Facilitate implementation of intervention components.
- Allow delivery of planned activities: collection of baseline and post-intervention information (access to children/classes), audits to school's conditions.
- Ensure educational materials are kept in place throughout the intervention.
- Inform research team of any incident that could arise related to the intervention.
- Collaborate in informative sessions for parents to help explain purposes of the research and facilitate engagement with them- help to build confidence/engagemen .

Figure 5-4 Core activities and roles of all stakeholders.

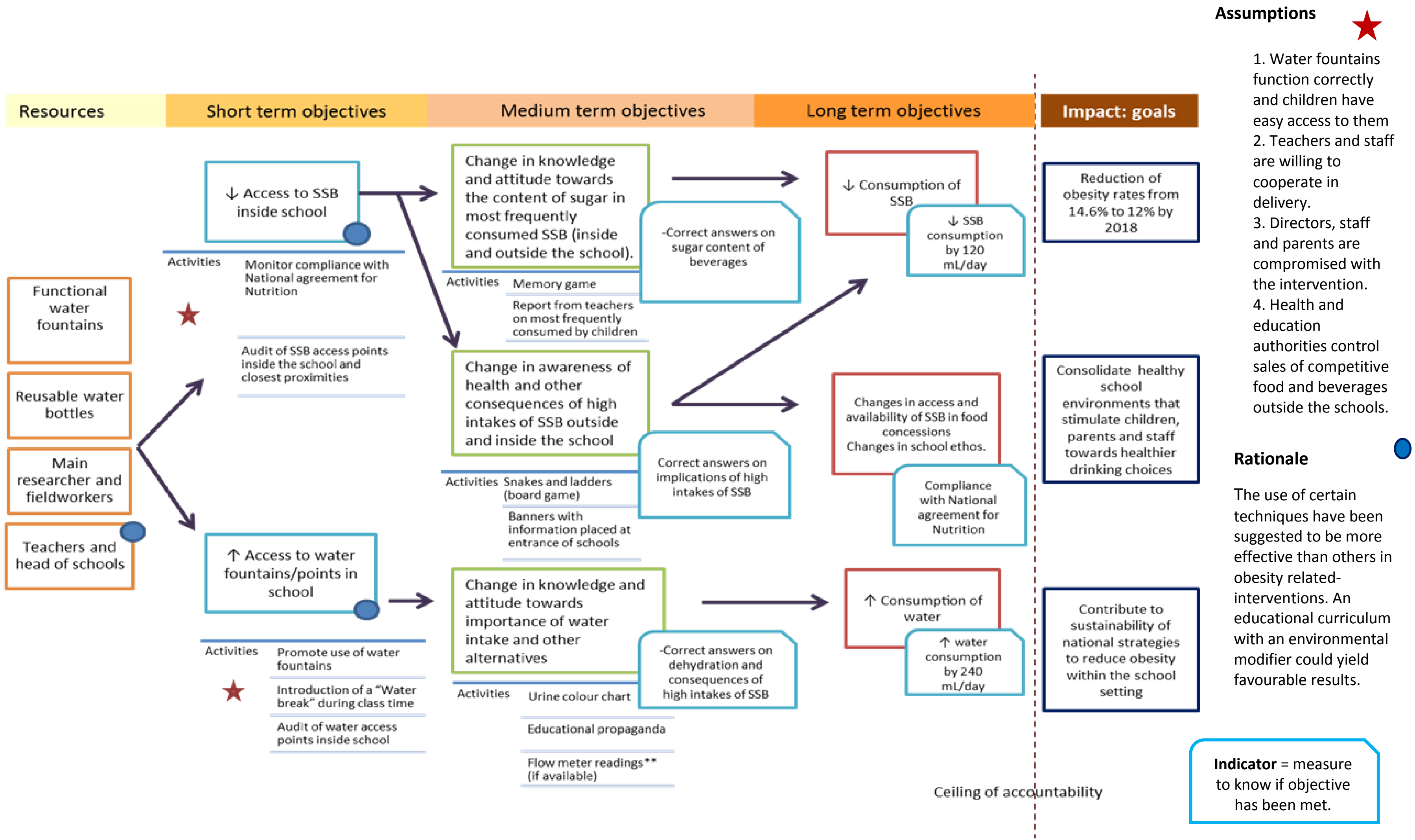


Figure 5-5 Theory of change developed to guide the objectives, indicators, activities and resources in the present feasibility study.

5.8.9 Pre-testing of materials: beverage questionnaire

Results from the systematic review and meta-analysis suggested that differences in intakes of SSB could be partly explained across all age groups by the use of dietary assessment tools, such as the 24-hour recall or the FFQ. Nevertheless, when looking at child studies no significant differences were observed across methodologies.

Figure 5-6 Logo of the *Drink Smart* in schools' project (left) and promotional message (right).

Assessment of food and beverage intake in children is particularly difficult due to their less developed cognitive skills (Collins et al., 2010) and estimation of portion sizes (McPherson et al., 2000) . The selection of a dietary assessment method in childhood should account for the study design and the outcome of interest which should be measured with the greatest possible validity (Rockett and Colditz, 1997). In the case of school trials, however, methods have to additionally consider the time and ease of implementation as well as cost-effectiveness and adequacy to the targeted group (Muckelbauer, 2010). At the planning stages of this intervention, only one dietary assessment tool specifically for Mexican children was identified (Safdie M). Researchers from the National Institute of Public Health in Mexico were contacted to gain permission to use this instrument (a beverage questionnaire) which had been implemented in a similar study in the metropolitan area (Safdie M, 2013). Responses were not favourable as the tool had not been validated and the use of a 24-hr recall was recommended instead.

As the quantitative target of this study was intake of beverages alone and as dietary recalls are often validated with a specific interest in food rather than beverage intake, the development of a self-completion quantitative questionnaire to assess changes in beverage intake across the whole day was considered necessary for the targeted population. Moreover, the 24 hr recall has been recognised as a good estimate for the assessment of group means and not individual data (Nelson and Bingham, 1997).

The instrument for this study was based on the features from the Child and Diet Evaluation Tool (CADET) (Christian et al., 2015) and the beverage questionnaire from the study by Muckelbauer and colleagues (Muckelbauer et al., 2010, Christian et al., 2015). CADET is a UK based diary that integrates a list of more than 100 separate food and drink products into 15 categories (9 items exclusively on beverages) and its completion is done by selecting items which have been consumed under a specific meal time period: 7 periods in total, 3 around school time and 4 around home (**Figure 3-7**). Muckelbauer and colleagues validated a self-completed, pictured, 24-hr recall amongst 7 to 9 year old children in Germany against a weighed record and found good levels of agreement for consumers versus non-consumers of different beverages (Muckelbauer et al., 2010) (**Figure 3-8**).

The combined version of the above tools asked for the number of glasses, bottles or containers from 11 different choices consumed over five time periods during the previous day, (starting from the morning). These periods were described as:

- This morning at breakfast or before school
- During school
- After school and during lunchtime
- In the afternoon (between lunch and supper)
- At supper or before bedtime.

Every period was dealt with on a single page and children were asked to write on the circle the number of containers (glasses, bottles, etc.,) of each beverage category consumed. Selection of categories were informed by Nutritionists within the Department of Nutrition at the State University, visits at schools and available literature (Barquera et al., 2010). The recognition of each category was facilitated by images.

Beverage options included:

- Plain water,
- Yogurt and other sweetened dairy products
- 100% fruit juice
- Chocolate milk
- Milkshake (fruit blend with milk and added sugar)
- Soda

- Bottled juice(less than 100% fruit juice)
- Fruited-sweetened water (also known as “agua fresca”)
- Fruit drinks (not 100% fruit juice)
- Sports drinks
- Frappe.

No validation study was undertaken due to time and resource constraints, but before its implementation, the tool was piloted in an elementary school in Leon with similar characteristics as those included in the study.

Testing of the first draft of the questionnaire (**Figure 5-9, A** and **B**) was carried out in 20 children (8 girls, 12 boys; Median age 10 years) from the 3rd to the 6th grade attending a public school and was done by the main researcher (EJVG). Feedback from children highlighted that the code at the end of the questionnaire (with corresponding portion sizes) was difficult to follow and match to each choice of beverage. Children often drank water from bottles and so an image next to this option could increase clarity; certain products frequently consumed (popular brands of industrialised fruit drinks) were not reflected in the images. The letter size page in which the questionnaire was implemented gave the impression they were under a test whereas the layout of the text and images on the first page did not provide sufficient space to include their personal information.

Consequently, changes implemented to the questionnaire/diary were as follows:

- Inclusion of a front page (similar to that in CADET) where the child could write his/her name, age and academic year.
- As in CADET, page size was formatted to “half a letter” so that the tool would resemble a booklet.
- A bigger instruction of “what did you drink?” at the beginning of each meal time period.
- The inclusion of further images for estimation portion size including a plastic bag and water bottle.
- A label on top of each serving size option with the content in millilitres.

A fragment of the final questionnaire can be seen in **Figure 5-10** and the whole document can be found under **appendix M.**

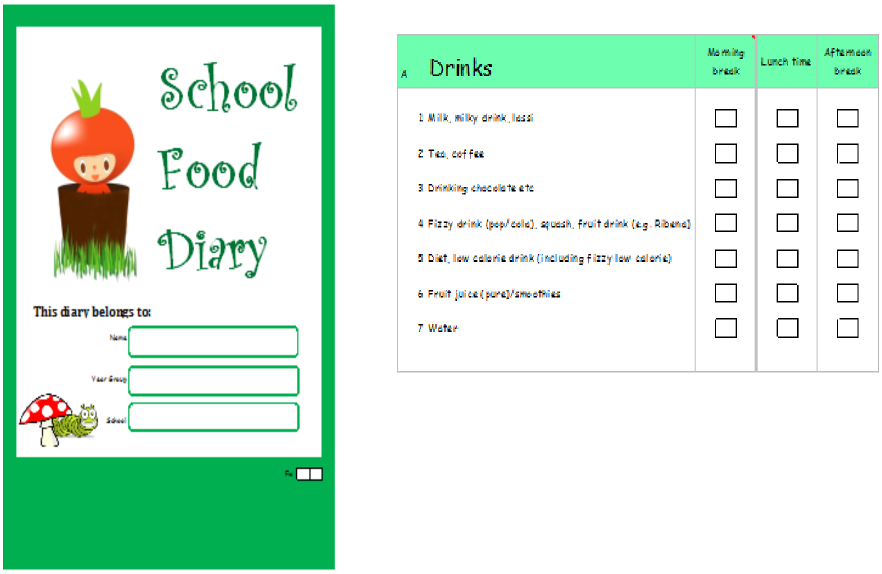


Figure 5-7 Fragment of CADET's food diary.

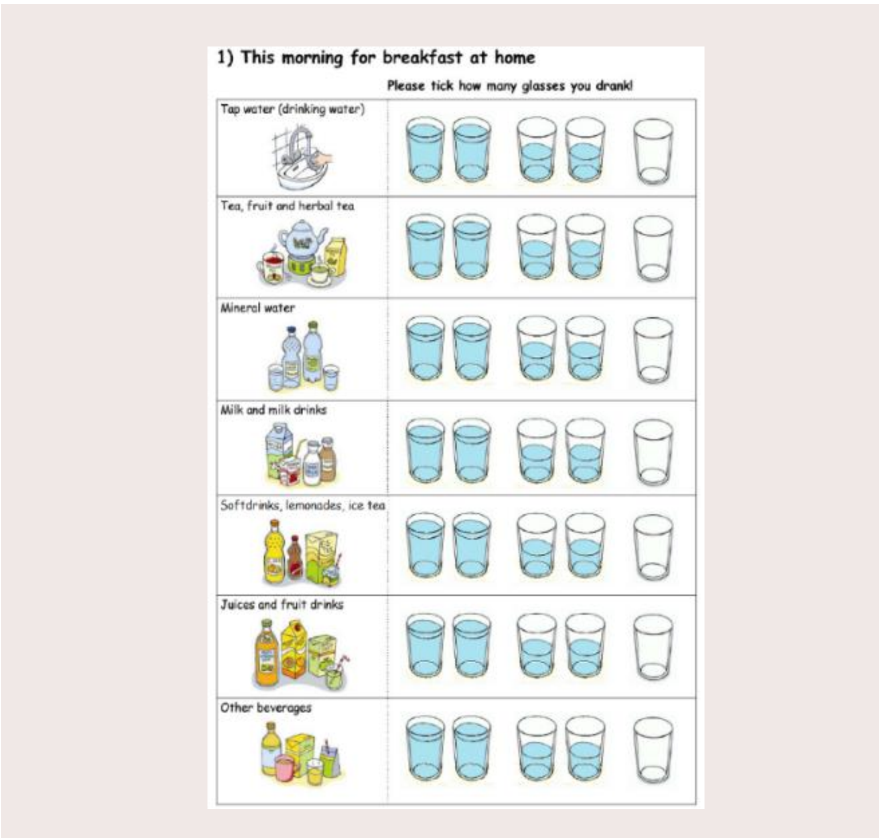


Figure 5-8 Fragment of Muckelbauer and colleagues beverage questionnaire.

Figure 5-9 Draft of piloted questionnaire. Breakfast options (A), code sheet with beverage sizes (B).

Figure 5-10 Fragment of frontal pages of beverage questionnaire.

Tool in Spanish, showing the front page that briefly instructs children on what they had drank, asks for their personal details (left) and includes the breakfast period of beverage consumption (right).

5.8.10 Data collection methods

Baseline and post-intervention data on beverage consumption in children agreeing to participate was collected by four trained Nutrition undergraduate students from the public University (Universidad de Guanajuato) through a piloted beverage questionnaire.

An audit protocol by the Harvard School of Public health and the Boston Public Health Commission (Harvard School of Public Health, 2011) was adapted to identify points of access to SSB and water inside the schools and their nearest surroundings (**appendix N**). This was done at three time points:

- Before commencement of the study (by main researcher)
- At week six (by undergraduate students)
- At the end of the study (by main researcher)

Information on attitudes and knowledge was obtained by the main researcher with a questionnaire at the end of the study at intervention sites only due to time constraints (the format can be found in **appendix O**.

As socioeconomic data was not available at the start of the intervention in any of the schools, this was also requested through a one-page questionnaire based on the rule 8x7 of the "Mexican Association of Market Intelligence and Opinion" (AMAI in Spanish) which is the federal index to group and classify Mexican households in seven levels according to their ability to satisfy needs on housing, health, energy, technology, prevention and intellectual development. Indicators that were measured are as follows:

- Highest level of education of the person that provides most of the household's stipend
- Number of rooms available in the house
- Number of bathrooms
- Number of light bulbs
- Number of cars
- Availability of shower rooms
- Availability of stove
- Type of flooring in the house

A one-page questionnaire was sent to all parents addressing the former information in addition to questions on parental level of education and employment before commencement of the study (refer to **appendix P**).

5.8.11 Training of research assistants- BSc Nutrition students

Recruitment of research assistants was done after a presentation to a group of 4th year students (n=30) from the Department of Nutrition at the University of Guanajuato which took place on the last week of August 2015 and before schools were selected. Four students, with prior experience in working with children, assisted in data collection. Alongside specific details on the beverage questionnaire and standardising instructions for children, research assistants were emphasised to make clear to them that the questionnaire was not a test and that there were no right or wrong answers. They were highlighted to go through each of the time intervals together with the children (particularly those of younger age) as this facilitated the recording of beverage items. Research assistants were also emphasised to help children that were having difficulties to answer the questionnaire and identify if too many responses had been ticked as a reflection of "preferred consumed items" rather than "actual options consumed" on the previous day so as to go verify this data directly with the child.

5.8.12 Data coding and handling

All drinks were coded under their respective beverage category and time period. Each questionnaire was given a unique ID by the main researcher with information on the school and child. Baseline and post-intervention data was entered into an Excel spreadsheet by an independent blinded assistant who was briefly trained to do this activity. Any queries were addressed and discussed with the main researcher (i.e., unclear answers, implausible totals, other beverages consumed). The volume of each beverage was converted to mL. As one of the questions involved the use of the fountain, non-usage was assumed -even if it was not expressly marked as zero on the questionnaire. The volume of each beverage was summed to give a total under their corresponding category and all beverages were summed to give the total 24-hr beverage volume.

Data from both time points (baseline and post-intervention) were transferred from Excel to STATA and were merged by EJVG using the unique ID for the children, therefore, no personal information was included nor visible in the analyses. Original questionnaires were kept locked in the Nutritional Epidemiology Group's office.

5.8.13 Data cleaning

A random sample of the entered questionnaires were checked by EJVG for completeness and accuracy (approximately 10% of baseline and 10% of post-intervention) and the 10 highest and lowest values were checked for error. A threshold of 4000 mL was established a priori as total beverage volume and this was based on the study by Muckelbauer and colleagues (Muckelbauer, 2010). Out of range values were verified against original information to identify entry errors.

Children with missing information on personal characteristics (mainly age) if not obtained directly from schools, were given then mean age of their class group.

From inspection, it was noticed that in the supper time interval, many children included "milk with chocolate", which was only an option for the breakfast period. Thus, an additional column was added to include this option; it was also noted that many children had "plain milk", while it was entered, observations on intakes of milk without chocolate or any other source of added sugar were not considered for analysis.

5.8.14 Evaluation: statistical analysis

The following information was obtained and assessed in both groups (intervention and control) at baseline:

School level:

- Description of beverage and water access points as portrayed in protocol under **appendix M.**

Child level:

- Sex
- Age
- Primary outcomes
- Socioeconomic data

5.8.15 Data analysis plan: objectives

The main outcome of interest for analysis was the difference in consumption of SSBs and water (post-intervention – baseline) between groups and the unit of analysis was the schools.

<u>Beverages were grouped on the following basis:</u>

- Carbonated drinks (soft drinks)

- Sports drinks
- Sweetened flavoured milk products (yogurt, yakult, milkshakes, milk with chocolate)
- Fruit drinks (bottled) and frappes (drinks made from syrups)
- Fresh fruit drinks (100% fruit juice, fruited- sweetened water)
- Plain water

The statistical analysis of the information was focused to meet the following **objectives**:

- To compare the intervention and control groups for baseline characteristics (considering randomisation was not possible):
    - Age
    - Gender
    - Socioeconomic status determined by Mexican index
    - Education level of parents
    - Parental age
    - Parental Occupation
- To assess the distribution of beverage intake at baseline and perform log transformations if found to be substantially not normally distributed.
- To determine the difference in means (post intervention-baseline) in intervention and control group for different beverage categories (including water) through paired t-tests.
- To determine the difference in means (post intervention-baseline) in intervention and control group for water intakes through paired t-tests.
- To determine the difference in means in water and SSB intakes between intervention and control groups through independent t-tests.
- To determine differences in means in water and SSB intakes between intervention and control groups through multilevel modelling, adjusting for imbalances at baseline. The creation of a “change” variable will be potentially used, depending on the most improved data and distribution of residuals.
- To identify differences in SSB and water intakes based on gender, interval periods (either at school or home time) and potential imbalances at baseline through sensitivity analyses.

The following hypotheses were tested:

Ho= There will be no difference in SSB and water intakes between intervention and control groups.

H1= Consumption of SSBs will be decreased in the intervention group in comparison to control.

H1.1= Consumption of water will be increased in the intervention group in comparison to control

5.8.16 Linear and cluster multilevel regression analysis

While linear regression investigates how an outcome or response variable (i.e. change in total intake of water or SSB) can be predicted or explained from other independent or predictor variables (such as gender, socioeconomic level, parental status) (Aiken and West, 1991); multilevel regression analysis is often used for education-based information as it considers the hierarchal structures of school data. Level one, the individual (or children), is considered to be nested within the higher level (level 2), the schools and so provides a means for controlling for both student and school level factors that may affect study outcomes (Raudenbush and Willms, 2014). This approach follows the principle that children's beverage intake within a school is similar; that is, children who have a beverage at school, whether water, bought from the school's canteen or nearby surroundings will have same or very close options on any given day at that particular school. Further, multilevel modelling is not focused on the individual schools within the sample, but on estimating the patterns of variation within the population of schools (Rasbash et al., 2004). Failure to address the hierarchal structure within the data would lead to inaccurate or misleading results (Aiken and West, 1991, Rasbash et al., 2004). Multilevel modelling addresses the associations inside the schools, and therefore allows to compare the beverage intake of students attending the same school (which should not reflect much variation) while also addressing the differences between schools (Raudenbush and Willms, 2014). Technical reasons for applying multilevel regression are that means and standard errors for the different beverages can be calculated adequately (Raudenbush and Willms, 2014) since linear regression would retrieve small standard errors, hence very tight confidence intervals. Further, multilevel regression aims to verify that the observed difference in nested data comes from a genuine association between the intervention's effects and other measured factors whilst assessing the difference expected from chance and all the unmeasured influences differing between students (Raudenbush and Willms, 2014).

5.9 Process evaluation

Process evaluations are important to conduct to ensure programmes are being delivered as planned and to identify any elements concomitantly happening to a programme's implementation that could artificially enhance or weaken its effectiveness (Gibney et al., 2004). Also, they serve to recognise deviations in delivery processes leading to unsuccessful outcomes. Consequently, a mid-way evaluation was conducted on week six of the intervention by research assistants at all study sites. Fieldworkers were handed a questionnaire to learn about the implementation of the intervention's activities and materials. They were instructed to ask teachers and the head of schools on any barriers or difficulties faced to conduct activities, their perception of change in children's behavioural outcomes and the parallel reception of information (through workshops or materials) from external sources (i.e., Ministry of Health) promoting the intervention's objective.

An open-ended questionnaire was designed and given to undergraduate students to address the aforementioned contents. Similarly, changes occurring at the environmental level were captured in this instrument, including an increased availability of convenient stores around the school, adequate functioning of the water fountains (for intervention sites) and the correct implementation of guidelines for schools' cafeterias or concessions in relation to sales of sugar-sweetened beverages (e.g. portion size to be adequate and location of the beverages not to be within the first visible options of purchasing).

At the end of the intervention (week 12) a multiple-choice feedback form was given exclusively to teachers and head of schools at experimental sites to identify the overall perception of the programme's uptake, content and resources, as well as perceived changes made by children and parents across the intervention. Children from experimental schools were additionally asked about the uptake of activities (such as having the opportunity to play with the board games, having a water break, using the water fountain or reading the information placed around the schools). More details on the information collected from process evaluation can be seen in **appendix Q.**

5.10 Summary

This chapter has described the methodology applied to the *Drink Smart* in schools' project, following the principles of the Public Health Nutrition Cycle: setting goals for nutrition problem (decrease consumption of SSB by promoting water intake), defining objectives for goal, creating quantitative targets and developing, implementing and evaluating the programme's content. It has also outlined the rationale behind approaches taken to collect and analyse data.

Chapter 6 : Reducing SSB intake through the promotion of drinking water: results from the *Drink Smart* in schools' project.

6.1 Abstract

Introduction Consumption of sugar-sweetened beverages (SSB) in Mexican children remains one of the highest worldwide with soft drinks alone accounting for 10% of energy intake. Greater intakes of SSB are associated with higher risks of weight gain, cardiovascular disease and metabolic syndrome. Epidemiological data has identified that 12% of 6 to 15 year olds living in central Mexico meet the criteria for metabolic syndrome.

Methods A 12-week programme was developed to determine whether promotion of water intake through an educational component and changes in the school environment was effective to influence consumption of SSB in children. Sixteen classes in four schools were allocated to the intervention group (N= 2 schools, 8 classes) or control group (N= 2 schools, 8 classes). Participants were 337 children aged 7-12 years (222 in intervention and 115 in controls) attending public schools in socially deprived areas in Leon, Mexico. SSB and water intakes were measured using a beverage questionnaire at baseline and post-intervention.

Results Mean baseline intakes of all beverages combined –including water- were 2133 mL (SD = 892mL) for the intervention group and 2250mL (SD =896mL) for the control group. At the end of the study, intervention and control groups achieved reductions in daily intake of SSB by -61 mL/day and -132 mL/day, respectively, with the difference between groups not being statistically significant (71 mL/day; 95% CI: 94 to 236; p=0.4]. Similarly, consumption of water throughout the day decreased in both groups (Intervention: -169 mL/day; 95% CI: -275 to -62 vs controls: -235 mL/day; 95% CI: -369 to -102) and the difference was not statistically significant.

Conclusion The intervention was insufficient to bring about behaviour change in children. Effectiveness may require more intensive approaches with parental involvement and further supportive changes to the built environment.

6.2 Introduction

Preliminary evidence from previous chapters (first meta-analysis conducted) highlighted the potential of the school as a venue to positively impact dietary behaviours in children, especially for SSB intake. The Mexican epidemiological context provides a valuable opportunity to address the prevention and control of noncommunicable diseases –including the metabolic syndrome in children. The implementation of the approach described in chapter 5 was assessed to identify if shifting consumption of SSB towards alternatives that are lower in sugar, such as water, is feasible through simple educational messages and the use of existing nudges, all of them delivered to a captive and easier-to-reach population.

6.3 Study design, participants and schools: baseline characteristics

A non-randomised controlled feasibility study was conducted in 7 to 12 year-old children attending four public elementary schools in the city of Leon, Mexico from September to December 2015. The methods and intervention components have been described in **chapter 5** but briefly comprised the promotion of the school's water fountain, the provision of a 500 mL reusable water bottle, the introduction of a "water break" during class time and the provision of nutritional information through board games to promote drinking plain water and to discourage SSB intake. The study was conducted in two schools in the intervention group and two schools in the control group. Characteristics of each site can be seen in **Table 6-1.** The institutional review board at the hospital of High Speciality in Guanajuato (HAEB) and the Ethics Review committee within the faculty of Mathematics and Engineering Sciences at the University of Leeds approved the study protocol. School and participant flow during the study has been summarised in **Figure 6-1**.Written parental consent was obtained for 485 of the 545 children attending schools (89%). From the 479 children screened at baseline, 429 children had complete data for analysis (90%), but only 337 (70%) were considered to have suitable data for final analyses (those with beverage intakes not exceeding 4,000 mL/day (Muckelbauer, 2010)).

Table 6-1 School's characteristics: Intervention and controls.

School	Total of groups	Class size	Total of students	Hydrosanitary infrastructure
Interventon A	12 groups (2 per year	40-45 students	510 students	Limited, but with working WF
Intervention B	18 groups (3 per year)	40-45 students	780 students	Adequate
Control A	7 groups (one per year, except 6th grade which has 2 groups)	20-31 students	150 students	Limited. Broken water fountain (for over 6 months)
Control B	12 groups	35-45 students	340 students	Deficient. No WF available

WF = water fountain

At baseline, the control and intervention groups were similar in characteristics related to gender, age or socioeconomic characteristics (Table 6-2).

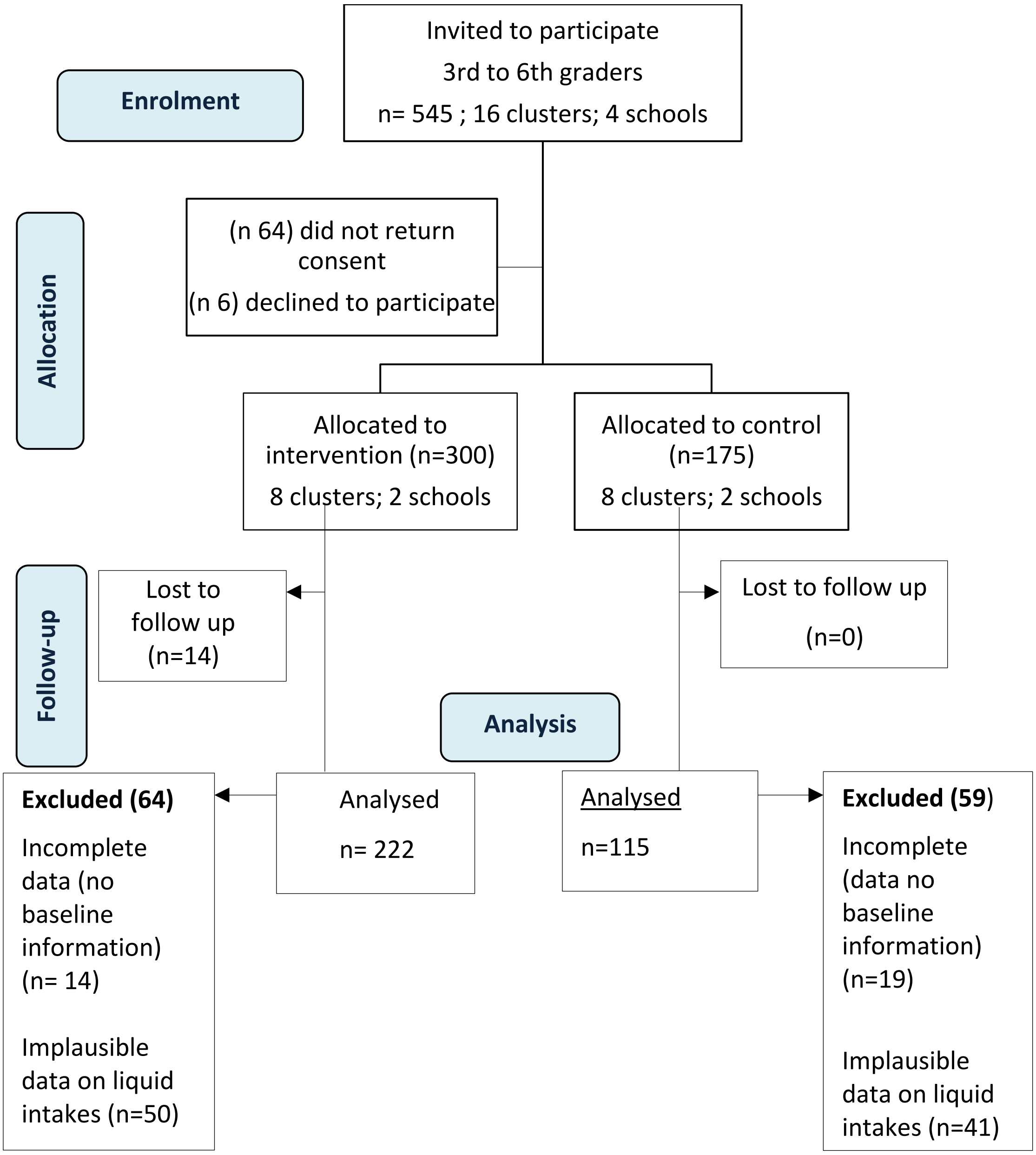


Figure 6-1 Screening, allocation and analysis of schools and study participants.

Table 6-2 Baseline characteristics of analysed participants in both groups (intervention and controls).

	Intervention group	Control group	P value†
N	222	115	
Age, mean (SD), y	9.5 (1.2)	9.6 (1.3)	0.64
Sex – no. (%)			
Male	107 (48.2)	53 (46.1)	0.73
Female	115	62	
Socioeconomic status (%)	n=58	n=36	
AB (higher)	1.7	2.8	0.41
C+	19	8.3	
C	17.2	27.8	
C-	27.6	16.7	
D+	15.5	22.2	
D	19	22.2	
Paternal education (%)	n=55	n=35	
Undergraduate/Postgraduate	5.5	2.9	0.90
Technical career	12.7	8.6	
High School	14.6	8.6	
Secondary	43.6	45.7	
Primary	14.6	22.9	
Incomplete Primary/No studies	9.2	8.5	
Paternal age (%)	n= 55	n=35	
20-29	3.6	8.6	0.16
30-39	63.6	60	
>40	32.7	28.6	
Paternal employment (%)	n=55	n=35	
Blue collar (manual activities)	63.6	77.1	0.44
Commerce	14.6	2.9	
Professional	5.5	2.9	
Technician	9.1	8.6	
Unemployed	7.3	-	
Maternal education (%)	n=56	n=36	
Undergraduate/ Postgraduate	5.4	-	0.70
Technical career	17.9	11.1	
High School	14.3	19.4	
Secondary	42.9	38.9	
Primary	16.1	25.0	
Incomplete Primary/No studies	3.6	5.6	
Maternal age (%)	n=56	n=36	
20-29	14.3	22.2	0.58
30-39	60.7	58.3	
>40	25.0	19.4	
Maternal employment (%)	n=56	n=36	
Blue collar (manual activities)	19.6	22.2	0.50
Commerce	7.1	2.8	
Professional	8.9	-	
Technician	5.4	2.8	

	Intervention group	Control group	P value†
Home (housekeeping)	55.4	61.1	
Domestic help	3.6	11.1	

†Based on Fisher's exact test.

Socioeconomic data had a very small response rate from participating schools (25-30%), potentially because of the unfamiliarity of parents with providing information on characteristics of housing and employment. Moreover, some of the questionnaires were unable to be matched to a particular child due to missing personal information. Nevertheless, matched records did not seem to significantly differ between groups in any of the reported characteristics. The educational system in Mexico usually enrols children from their corresponding living area or nearest surroundings, thus it is unlikely that many children taking part in the study would come from more deprived or affluent zones in Leon.

6.4 Outcome measures

The primary outcomes were the change in consumption of water and SSB in millilitres per day. Intakes were assessed before the start of the intervention (baseline measurements) and at the end of the intervention (post-intervention measurements) through a piloted beverage questionnaire (refer to **appendix M**). A process and formative evaluation were also undertaken to gain understanding on delivery processes during the trial (**appendix Q**).

Considering that behavioural outcomes were the main interest in this study, no anthropometric measure was collected and was unavailable at the Ministry of Education.

6.5 Statistical analysis

Evaluation of continuous outcomes in non-randomised trials is not without limitations and statistical procedures aim to increase precision, and thus provide a more accurate estimation of the treatment effect between study groups. Statistical comparisons can be done in different ways, with trials commonly using either a change score (follow-up minus baseline scores) or the follow-up (post-intervention) measurements. For adequately randomised trials, the distribution of baseline outcomes will be similar in each group and either method will provide the same estimated treatment effect (Vickers and Altman, 2001); when randomisation has been compromised or not conducted at all, imbalances at baseline are a common event. The correlation between baseline and follow-up scores will then direct the statistical significance of the intervention's effect (Vickers and Altman, 2001). When correlation is poor, the use of change scores will introduce variation and follow-up scores will be more prone to show statistical significance; whereas when correlation is high, using follow-up measurements will lead to information losses (by ignoring baseline imbalances) and change scores will be more likely to show statistically significant findings. This last approach was taken; the reasons and full explanation are as follows.

6.5.1 Multilevel analysis: regression assumptions and change in scores

Multilevel analysis was the methodology used to assess the effects of the intervention considering the nested nature of the data. Levels defined were: 1) student 2) school. A random-effects linear regression model was implemented as it is generally recommended for combining continuous outcomes (such as volume intakes) as it considers the correlation between intakes of beverages of children from the same school (within-school variation) (Fu R, 2015).

A change score approach was followed rather than adjusting for baseline measurements to meet regression assumptions (Christian et al., 2014)-which will be further described later in this chapter. The formula that was used for the main multilevel model analysis was:

$$\mathbf{Change_{ij} = ß_0 + \mu_{oj} + e_{ij}}$$

Equation 1 Change variable used in multilevel model analysis

$Change_{ij}$ reflects the mean change in participants' beverage intake (such as in water, carbonated drinks, sweetened milk products, etc.) from post-intervention to baseline of **i** pupil from a particular school **j; $ß_0$** represents the overall mean from all study sites in the model, **μ_{oj}** stands for the school level residuals and **e_{ij}** represents the pupil level residuals (Christian et al., 2014).

The **xtmixed** command was used to conduct the former analyses as it takes into account clustering and allows the calculation of total variance (both between and within-school variation). Subgroup analyses were carried out to identify any variations in the primary outcome, particularly differences in consumption at home and school times. Intraclass correlation coefficients (ICC) were produced for each beverage category. ICC is a measure of the relatedness in responses amongst clustered data (Killip et al., 2004) with values ranging from 0 to 1, values closer to 1 imply that children in the same school relate more like each other than children over all schools, hence their responses will be highly correlated (Killip et al., 2004).

Confidence intervals and p-values were based on the number of study groups (school clusters) rather than the number of children. Analyses were conducted in Stata IC version 14.1 following the intention-to treat-principle, thus no data imputation was performed.

To mathematically calculate the ICC the equation 1.2 was used (Killip et al., 2004):

$$\text{ICC} = \frac{S_b^2}{S_b^2 + S_w^2}$$

Equation 2 Intraclass correlation coefficient

<u>Which stands for :</u>

$S_{b=}^2$ variance between schools (macro-units)

S_w^2 = variance within schools

An example of the output from Stata where the former information was retrieved can be seen in **Figure 6-2.**

```
. xtmixed  change_water_total  school_code ||  School :, mle variance

Performing EM optimization:

Performing gradient-based optimization:

Iteration 0:   log likelihood = -2721.0775
Iteration 1:   log likelihood = -2720.9804
Iteration 2:   log likelihood = -2720.9789
Iteration 3:   log likelihood = -2720.9789

Computing standard errors:

Mixed-effects ML regression                     Number of obs      =       337
Group variable: School                          Number of groups   =         4

                                                Obs per group:
                                                              min =        57
                                                              avg =      84.3
                                                              max =       111

                                                Wald chi2(1)       =      0.56
Log likelihood = -2720.9789                     Prob > chi2        =    0.4551

------------------------------------------------------------------------------------
change_water_total |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------------+----------------------------------------------------------------
       school_code |   66.66197   89.24806     0.75   0.455    -108.261    241.5849
             _cons |  -235.1304   72.43697    -3.25   0.001   -377.1043   -93.15657
------------------------------------------------------------------------------------

------------------------------------------------------------------------------
  Random-effects Parameters  |   Estimate   Std. Err.     [95% Conf. Interval]
-----------------------------+------------------------------------------------
School: Identity             |
                   var(_cons) |   4.41e-15   9.75e-14      6.62e-34    29341.79
-----------------------------+------------------------------------------------
                var(Residual) |   603418.3   46485.61        518853    701766.4
------------------------------------------------------------------------------
LR test vs. linear model: chibar2(01) = 0.00          Prob >= chibar2 = 1.0000
```

Figure 6-2 Example of the output from multilevel modelling in Stata.

In order to obtain the total variance, the estimates for **var (residual)** or within school variation and for **var(_cons)** or between school variation were added (603418.3+ 4.41 e-15) and the variance between schools **var(_cons)** was divided by the former total as follows: 4.41e-15 / 603418.3. The results in this example indicate that less than 1% (7.30e-21) of the variation in changes in water intake are due to the variation between schools and imply that other factors (measured or unmeasured) might be causing the differences observed. Values of ICC close to zero indicate that observations from pupils within schools are not correlated or more similar to those from different schools.

6.6 Results

Distribution of intake of water and SSB

Intakes from different beverage categories were negatively skewed as children would often not consume certain products in a particular day (which translates into having distributions with a large proportion of zeros). Beverage intakes are often not normally distributed and this has been previously documented (Rosario et al., 2013, Sichieri et al., 2009, Duncan et al., 2011). Seeking to improve the distribution of the data and meet assumption criteria for regression models, a natural logarithmic transformation was applied to the follow-up variables with adjustment for baseline intakes, with little success (**Figure 6-3**). Consequently, a **change** between baseline plus follow-up variable for all different beverage categories was created to aid with analysis and account for statistically significant baseline imbalances between study groups for carbonated and processed fruit drink intakes, both of which were found higher in the control groups.

6.6.1 Regression assumptions

Alongside the exploration of the distribution of total water and SSB intakes at post-intervention, the distribution of the residuals was explored to assess whether it would be suitable to conduct regression analyses using post-intervention measurements adjusted for baseline measurements as the primary outcome. As it can be seen in **Figure 6-4**, the distribution of residuals is skewed, both for water and SSB intakes; thus, using post-intervention values would violate regression assumptions and would lead to biased or misleading findings.

The histogram of mean change (or mean difference from post-intervention minus baseline measurements) in intake of water and SSB throughout the day (**Figure 6-5, A** and **C**) portrays an overall better distribution in comparison to post-intervention measurements. The plots of the standardised residuals of mean change in total water and SSB intake, as depicted in **(Figure 6-5, B** and **D**) are closer to a normal distribution, and thus change is more suitable to be used as the primary outcome for regression analyses.

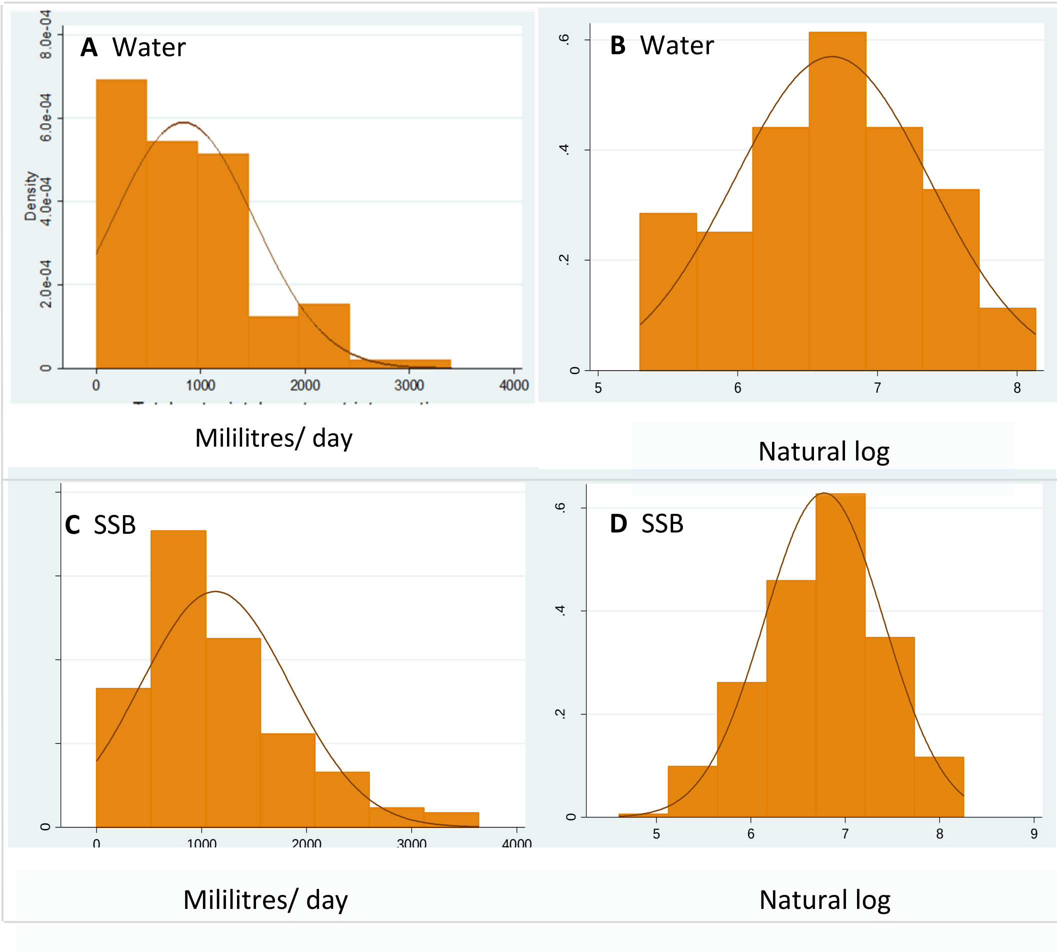


Figure 6-3 Normal distribution and log-transformation of water and SSB intakes at post intervention: Total water intake(A), logarithmic transformation of total water intake (B), total SSB intake (C), logarithmic transformation of SSB intake (D).

.

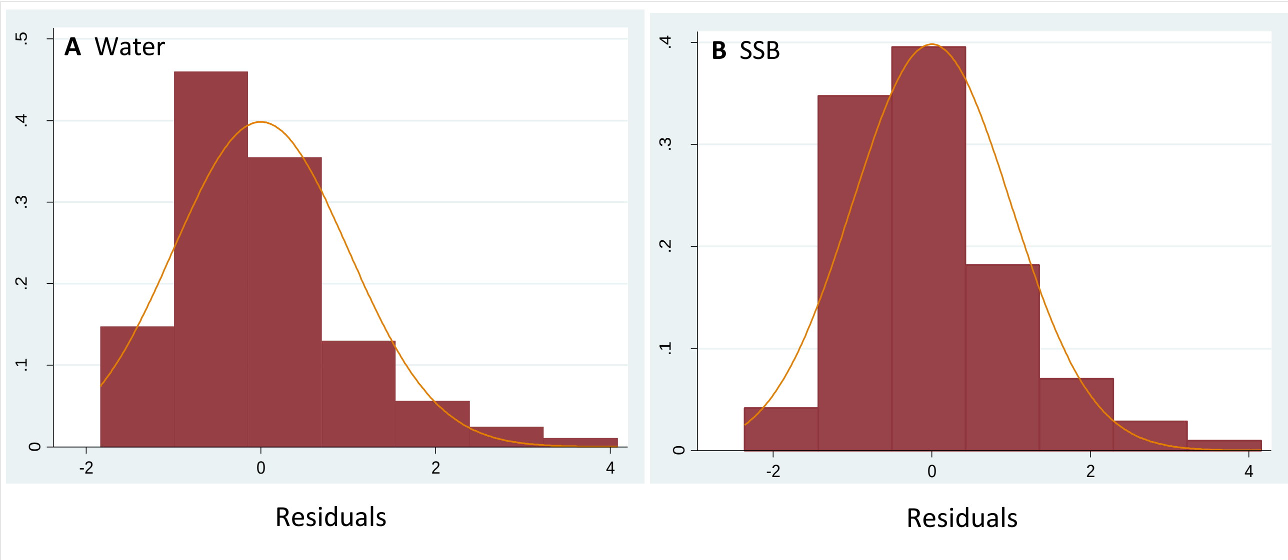


Figure 6-4 Residuals for total water intakes (A) and SSB intakes (B), adjusted for baseline intake.

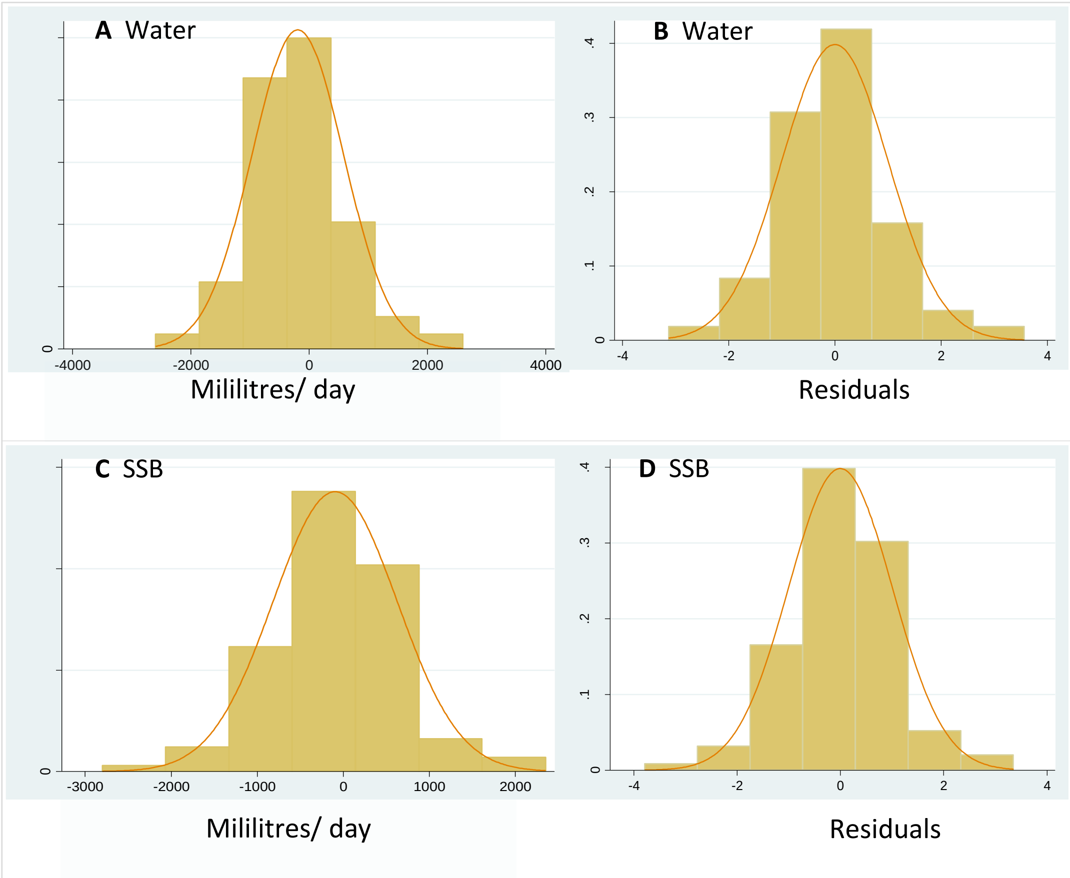


Figure 6-5 Histogram of mean change in intakes of water (A) and SSB (C) and standardised residuals of changes in water intakes (B) and changes in SSB intake (D)

Water and sugar-sweetened beverage consumption levels at baseline from participants completing baseline and post-intervention data collection versus non-completers (with only baseline data available) are illustrated in **Table 6-3.** Results indicate that there was little difference in consumption across beverage categories in both groups. The main difference found was for mean intake of all sugar-sweetened beverages (excluding fruited water and 100% fruit juice), which were on average 34 mL higher in those completing the study (non-completers: 839 mL 95% CI: 780 to 898; completers: 873, 95% CI: 806 to 940; p=0.78). Nevertheless, smaller differences in other beverage categories balanced out results between both groups when combining all sweetened drinks. Water intakes between completers and non-completers were also not significantly different (completers: 1027 mL 95% CI: 951 to 1103; non-completers 1023 mL 95% CI: 948 to 1098, p= 0.53).

Table 6-3 Baseline intakes of beverages of all children who completed the *Drink Smart school's* project vs children who did not complete the study.

Beverage category (mL/day)	**Children not completing post-intervention (baseline data only) n= 364**			**Children completing baseline and follow-up n= 337**		
	Mean	**SE**	**95% CI**	**Mean**	**SE**	**95% CI**
Carbonated drinks	250	19	213 to 287	258	20	219 to 297
Sports drinks	51	9	34 to 69	50	9	32 to 68
Sweetened flavoured milk products	308	13	282 to 33	312	14	286 to 339
All fruit drinks (fruit juice drinks, bottled juice, frappe)	230	16	200 to 261	253	18	217 to 289
Fresh fruit-based drinks (100% fruit juice and agua fresca*)	266	22	223 to 309	258	21	216 to 300
Processed fruit drinks (all drinks except 100% fruit juice and sweetened fruit-based water)	839	30	780 to 898	873	34	806 to 940
All beverages combined (except water)	1105	35	1036 to 1174	1131	39	1055 to 1207
Water	1023	38	948 to 1098	1027	39	951 to 1103
Total	2128	43	2044 to 2212	2158	49	2062 to 2253

*Agua fresca is a combination of fruits blended with sugar and water

6.6.2 Changes in water and SSB throughout the day

6.6.2.1 Water

Overall, 337 (71%) out of 475 enrolled participants at baseline, had plausible data on primary outcomes at both collection points (pre-and post-intervention). At the end of the study a decrease in total beverage intake was found between intervention and control groups, which was not statistically significant (**Table 6-4**). Changes in water intakes from baseline to post-intervention across the whole day were not significantly different in the intervention group compared to the control group. Both groups significantly decreased their water consumption at the end of the study and reductions were higher for the control group (change from baseline -235 mL/day; 95% CI -369 to -102). After adjusting for clustering, however, intervention effects were not significantly different between groups (67 mL/day, 95% CI -108 to 242, p=0.5). As previously illustrated in **Figure 6-2**, less than 1% of the variation for changes in water intake were at the school level, thus 99% of variation were due to students' characteristics.

6.6.2.2 SSB

Changes across all SSB combined did not significantly differ across intervention and control groups (IG-CG) at the end of the intervention with both conditions achieving reductions by -61 mL/day and -132 mL/day, respectively. However, adjustments for clustering indicated greater differences for the control group on all SSBs (71 mL/day [95% CI: -94 to 236, p=0.4]) and particularly on the category of processed fruit drinks (82 mL/day [95%CI: 1 to 163; p=0.049]).

The plot of residuals indicated homoscedasticity for SSB and water outcomes, thus conditions to meet requirements for multilevel modelling were not violated. In addition, there were no correlations highlighting effects of gender, SES or parental education level on intakes of SSB or water. Thus, no further sensitivity analyses were conducted.

6.6.3 Changes at school time

Table 6-5 displays results of changes in consumption of beverages during school time, which for children in Mexico represents the period from 8.0 am until 12.30 pm, with a 30-minute lunch break usually between 10.30 and 11.0 am.

Water intake decreased within groups, with reductions in controls being more pronounced (*intervention*: -54 mL/day vs *control*: -135 mL/day), yet the difference in change from baseline to follow-up between groups was not statistically significant (81mL/day; 95% CI: -16 to 178;

p=0.1). Whilst change in consumption of all SSB combined was not significantly different between groups, compared to intervention, controls showed a small increase in fruit-based and sweetened milk beverages at post-intervention which was not statistically significant (**Table 6-5**).

6.6.4 Changes in water and SSB intake at home-time/out-of-school hours.

Out-of-school period was considered as time 1 (for breakfast or before school), time 3 (after school and at lunch time), time 4 and 5 (mid-afternoon and dinner periods, correspondingly). Changes in water intake did not differ between groups (IG-CG) after adjustment for clustering (9 mL/day; 95% CI: -164 to 146; p=0.9) (**Table 6-6**).

Conversely, changes in all SSB combined differed significantly between groups after adjusting for clustering which indicated greater increases for the intervention group (149 mL/day; 95% CI: 26 to 273; p =0.02). Similarly, change in processed fruit drinks (that being all sweetened drinks except 100% fruit juice and sweetened fruit water) was significantly different between intervention and control groups, with the latter showing greater reductions (164 mL, 95%CI 45 to 283 p=).

The intraclass correlation coefficient for all SSB combined highlighted that 1.1% of the variation in this outcome was at the school (group) level.

Table 6-4 Intervention effect on changes in water and SSB **throughout the day.**

Beverages(ml/day)	Unadjusted data Mean (SD)		Change from Baseline Mean (SE)	Adjusted difference ‡ (SE) [95% CI]	P value
	Baseline	**Post-intervention**			
Carbonated drinks (soft drinks)					
IG (n=222)	221 (335.1)*	218 (314.6)	-3 (22.8)[-48 to 42]	53 (38.1)[-22 to 127]	0.2
CG (n= 115)	328 (411.1)*	272 (355.5)	-56 (29.6)[-115 to 3]		
Sports drinks					
IG	62(197)	53 (184.1)	-9 (13.7) [-36 to 19]	18 (23.7) [-29 to 34]	0.5
CG	73 (209.2)	47 (161.9)	-26 (19.8)[-65 to 13]		
Sweetened flavoured milk products					
IG	319 (253.6)	311 (273.7)	-8 (19.9) [-47 to 31]	-12 (33.1) [-77 to 53]	0.7
CG	299 (245.3)	303 (253.4)	4 (25.7) [-47 to 55]		
Fruit drinks (fruit juice drinks, bottled juice, frappe)					
IG	239 (316.3)	206 (285.6)	-34(23.5)[-80 to 13]		0.049
CG	279 (369.2)	163 (237.0)	-116(35.5)[-186 to -45]	82 (41.3)[1 to 163]*	
Fresh fruit-based drinks (100% fruit juice and agua fresca)					
IG	275 (400.6)	267 (462.7)	-8 (36.3)[-79 to 64]	-70 (60.6) [-189 to 49]	0.3
CG	225 (376.8)	288 (447.0)	62 (47.2)[-31 to 156]		
Processed fruit drinks (all drinks except 100% fruit juice and sweetened fruit water)					
IG	842(602)*	765(552.2)	-54 (38.3)[-129 to 22]	141 (67.9) [8 to 273]*	0.04
CG	979(698)*	757 (541.6)	-194 (59.1)[-311 to -77]		
All beverages combined (except water)	**Baseline**	**Post-intervention**			
IG	1116 (689.7)	1072(655.05)	-61 (51.2)[-162 to 40]		0.4
Control group	1204(780.5)	1055 (680.9)	-132 (62.8)[-256 to 8]	71(84.0)[-94 to 236]	

Water	Baseline	Post Intervention	Change from baseline Mean (SE)	Adjusted difference‡ (SE) [95% CI]	P value
IG	1017(684.1)	848(692.0)	-169 (54.2)[-275 to -62]	67 (89.2) [-108 to 242]	0.5
CG	1046(764.5)	811 (647.8)	-235(67.3)[-369 to -102]		
Total					
IG	2133(892)	1903 (792.6)	-230 (68.0)[-364 to -96]	138 (114.1) [-86 to 361]	0.2
CG	2250 (896)	1883 (734.1)	-367(89.7) [-544.8 to -189]		

† agua fresca is a combination of fruits blended with sugar and water‡ Adjusted for clustering. * p< 0.05

Table 6-5 Intervention effect on changes in water and SSB at **school time.**

Beverages (mL/day)	Unadjusted data Mean (SD)		Change from baseline Mean (SE)	Adjusted difference‡ (SE) [95% CI]	P value
	Baseline	Post-intervention			
Carbonated beverages					
IG	12 (69.0)	10(65.6)	-3(6.5)[-16 to 10]	6 (11.9)[-18 to 29]	0.6
CG	24 (105.1)	15(73.7)	-8(11)[-31 to 13]		
Sweetened milk					
IG	20(61.5)	19(63.9)	-0.90 (5.5)[-6 to 34)	-15 (11.4)[-37to 8]	0.7
CG	16(84.2)	30(77.3)	14(10)[-12 to 10)		
Fruit drinks (fruit juice drinks, bottled juice, frappe)					
IG	64(140.0)	41(112.0)	-23(10.8)[-44 to -2]	-3(18.7)[-39 to 34]	0.9
CG	60(160.4)	40(114.5)	-20(15.5)[-51 to 11)		
Fresh fruit based drinks (100% fruit juice and agua fresca)					
IG	64(192.7)	47(171.7)	-17 (15.4)[-48 to 13]	-30 (31.3)[-92 to 31]	0.3
CG	83(201)	96(221.2)	13 (25.0)[-37 to 63]		
Sports drinks					
IG	18 (99.0)	14 (89.2)	-4 (8.2)[-21 to 12]	-5 (16.3)[-36 to 27]	0.8
CG	10 (78.8)	10 (78.8)	0.0 (10.5)[-1 to 21]		
Processed fruit drinks (all drinks except 100% fruit juice and agua fresca)					
IG	114 (181.8)	83 (163.9)	-31 (13.7)[-58 to -4]	-16 (31.5) [46 to 78]	0.6
CG	111 (216.0)	96 (162.7)	-15(20.9)[-56 to 27]		
All beverages combined (except water)					
IG	178 (245.3)	130 (225.8)	-48 (19.3)[-64 to 60]	-47 (34.9)[-115 to 22]	0.2
CG	193 (283.5)	191 (243.3)	-2 (31.4)[-86 to -11]		

Water	Baseline	Post Intervention	Change from baseline Mean (SE)	Adjusted difference‡ (SE) [95% CI]	P value
IG (n=222)	386 (348.7)	332 (381.4)	-54 (23.6)[-111 to 2.5]	81 (49.5) [-16to 178]	0.1
CG (n= 115)	401(393.0)	266 (342.1)	-135 (41.0)[-216 to 54]		

† agua fresca is a combination of fruits blended with sugar and water‡ Adjusted for clustering. * p< 0.05

Table 6-6 Intervention effect on changes in water and SSB at home/out of school time.

Beverages (mL/day)	Unadjusted data Mean (SD)		Change from baseline Mean (SE)	Adjusted difference ‡ (SE) [95% CI]	P value
	Baseline	Post-intervention			
Carbonated beverages					
IG	209 (320.4)	209 (298.7)	-0.4 (21.6) [-43 to 42]	47(35.2)[-22 to 116]	0.2
CG	304 (379.1)	257 (326.0)	-48 (25.8) [-99 to 4]		
Sweetened milk beverages					
IG	300 (242.6)	292 (264.0)	-7 (19.3) [-45 to 31]	3(32.5)[-61 to 67]	0.9
CG	283 (243.4)	273 (235.5)	-10 (25.8) [-61 to 41]		
Fruit drinks (fruit juice drinks, bottled juice, frappe)					
IG	175 (274.3)	169 (262.0)	-6 (18.8)[-43 to 31]	92(32.6)[28 to 156]*	0.005
CG	219 (310.7)	121 (182.3)	-98 (27.3) [-152 to -44]		
Sports drinks					
IG	44 (152.6)	40 (154.2)	-4 (11.5)[-27 to 19]	22 (25.4) [-28 to 72]	0.4
CG	63 (197.1)	37 (144.1)	-26(18.4)[-63 to 10]		
Fresh fruit based drinks (100% fruit juice and agua fresca*)					
IG	211 (343.2)	212 (348.8)	1(7.6)[-14 to 16]	-15(12.5)[-39 to 10]	0.2
CG	143 (287.4)	158 (293.0)	15(9.4)[-3 to 34]		
Processed drinks (all drinks except 100% fruit juice and agua fresca†)					
IG	727 (528.7)	710 (516.2)	-17(34.3) [-85 to 50]	164 (60.7)[45 to 283]	0.01
CG	869 (607.2)	688 (495.0)	-181 (52.7)[-286 to -77]		
All beverages combined (except water)					
IG	938(594.03)	921(602.7)	-16(35.0)[-87 to 53]	149 (62.54)[27 to 272]	0.02
CG	1011 (662.61)	846(592.3)	-166(53.9)[-273 to -59]		

Water at home	Baseline	Post Intervention	Change from baseline Mean (SE)	Adjusted difference‡	P value
IG (n=222)	631 (540.0)	522 (554.3)	-109(704.2)[-202 to -16]	-9 (79.1) [-164, 146]	0.9
CG (n= 115)	645.5 (595.21)	545.2 (520.)	-100.35 [662.52]		

† agua fresca is a combination of fruits blended with sugar and water‡ Adjusted for clustering. * p< 0.05

6.6.5 Baseline environmental characteristics of schools: water and SSB access points

As mentioned in the previous chapter, the school surroundings were surveyed to identify the number and type of points available to children for purchasing or getting water and sugar-sweetened beverages. Through an established protocol, baseline characteristics inside and outside intervention and control sites, were documented and are summarised in **tables 6-7** and **6-8** for water fountains, and in **tables 6-12 to 6-15 (at the end of this chapter)** for SSB.

Table 6-7 Intervention sites: water fountains

Type of water access point	Date collected	Person collecting information	Accessibility	Photo
Water fountain School A	21/09/2015	EJVG	For all students and staff	
Water fountain 1 School B	20/09/2015	EJVG	For all students and staff	
Water fountain 2 School B	20/09/2015	EJVG	For all students and staff	

Table 6-8 Control sites: water fountains.

Type of water access point	Date collected	Person collecting information	Accessibility	Photo
No water fountain School A	22/09/2015	EJVG	For all students and staff	
Broken Water fountain School B	24/092015	EJVG	For all students and staff	

6.6.6 Process evaluation

A process evaluation for the *DrinkSmart* study was conducted at implementation stages and 4 weeks post-intervention to explore the level of adherence and involvement in the intervention group and to identify potential changes occurring at control sites that could have affected primary outcomes. The methodology of the study has been described in chapter 5. Children in the intervention group received a reusable plastic water bottle (**Figure 6-6**) at the beginning of the study and were encouraged by teachers to bring it every day with plain water and to keep refilling it in the school's water fountain. Teachers in the intervention group documented -in a special sheet provided (**appendix K**)- the attainment of a daily water break by signalling the days during a given week where this activity was possible and reasons behind the lack of implementation –if this the case. Alongside printed materials placed around intervention sites, two board games were given to each class (n=8) in the form of a memory game and a snakes and ladders aiming to reinforce consequences of drinking too many SSB and emphasising the importance of drinking water as a first choice of beverage. Teachers from intervention and control schools (n=16) were handed out a beverage record in which they were instructed to discretely observe and note down characteristics (type/description, size and brand) of the beverages consumed by children during school time on one occasion.

Six weeks after the start of the intervention, research assistants conducted a monitoring exercise to learn about compliance to the programme's elements and identify any difficulties or barriers faced by teachers in the delivery of activities (four research assistants in total, two for each condition). Changes in access and/or availability of SSB in the nearest surroundings across all participating sites were also briefly surveyed.

Figure 6-6 Water bottle facilitated to children in intervention sites at the beginning of the study.

6.6.6.1 Data collection

An audit protocol was used to facilitate the identification of changes in points of access of SSB and water in both conditions (intervention and control) at baseline, mid-way and post-intervention evaluations (**appendix N**). Four weeks after conclusion of the intervention, a semi-structured questionnaire was given to head of schools and teachers in the intervention group by EJVG to explore their perception of changes in children's attitudes, school's ethos, intervention highlights and areas of opportunity/improvement. Records of implementation of activities were also collected from all teachers at this stage. Informal chats were established with all head of schools, to learn about their views on the programme and identify any physical or social changes occurring during implementation phase which may have influenced study outcomes (i.e. construction or repair of water fountain).

6.6.6.2 Mid-way assessment: teachers and head of schools

<u>Intervention sites</u>

Interviews were possible with seven teachers (7/8) and one head of school (1/2). Absences on the day the assessment took place in intervention schools (5th of October 2015) meant one teacher and one head of school were not intervened.

An indicator for water consumption was the implementation of a daily water break. In the mid-way assessment conducted by research assistants, records of this activity by teachers were reviewed. Five out of seven teachers implemented the water break as noted in the corresponding record. Reasons for lack of implementation were: being a new teacher (n=1), not understanding how to record the activity (n=1) and not knowing where the recording sheet was kept (n=1). In relation to the conservation of the water bottles provided, half of the classes (4 out of 8) had already lost them or started to bring different bottles/containers (including other beverages such as sodas and fruit drinks). Teachers were instructed to keep the implementation of the water break (and new sheets were provided) regardless of containers brought by children.

Teachers in the intervention group were additionally questioned about the opportunity of exposing children to the board games; three teachers (n=3) declined exposure, main reasons including: insufficient materials to rotate amongst children (only two games were provided per group), being a new teacher and consequently not having knowledge on the intervention's features, lack of time and badly-behaved children (games were seen as a reward for children who had achieved their expected goals).

Intervention and controls

In comparison to intervention sites, all teachers (n=8) and head of schools (n=2) from control schools were available on the above-mentioned date (5th of October) and provided the requested information.

An aspect that was monitored in both conditions was the registry of sweetened drinks that children brought to school. This exercise was found to be the most challenging for teachers at all sites (n=16) with almost half of them (n=7) not being able to document the beverages brought. Unclear instructions on how to complete the record and time constraints were the main reasons for lack of its implementation. At this point, all teachers were re-explained and thoroughly shown how to complete the record. Research assistants also made sure that instructions were clear and verified that teachers were confident by going through this activity via a guided example.

Dose: exposure to information

As mentioned in the previous chapter, control schools received a leaflet containing the same information that was placed across intervention groups on consequences of high intakes of SSB and importance of keeping hydrated throughout the day. In a control site, the teacher of the youngest class (3rd year) read the leaflet together with the children and placed it somewhere visible in the classroom. It should be noted that certain leaflets were returned by children, for no apparent reason.

Perception of change in children's attitudes: Teachers and Principals

Three out of seven teachers in the intervention group mentioned that they had noted changes in children, often seeing them drinking more water than before, bringing their bottles into school and refilling them in the fountain; while the rest of the interviewed (n=4) mentioned little or no achievements since children were still bringing sweetened beverages to school.

Two teachers from control groups expressed noticing that more children would bring water into school and emphasised that this was a requirement for their physical education class (policy also shared at intervention groups).

Head of schools from control sites (n=2), reported positive changes in children (such as drinking less carbonated beverages), yet they both mentioned that children needed to be constantly reminded not to bring them from home. The head of school from one intervention site stated that "… [I suppose] children are drinking more water…".

Environmental changes & functionality of SSB and water points

None of the participating schools had received any training or printed materials (i.e. from the Ministry of Health, or related institution) promoting water intakes and discouraging SSB consumption. Therefore, no parallel activities occurred in either control or intervention sites that could have had an impact on outcomes.

<u>Intervention sites: water fountains and canteens</u>

The adequate functioning of water fountains was monitored at this stage. The fountain at intervention site A was broken (**Figure 6-7, A** and **B**); yet certain children and teachers commented that this was an infrequent event. Conversely, water fountains at the intervention site B were functioning appropriately from all their corresponding faucets and were kept in good conditions (**Figure 6-7**, **C** and **D**).

Teachers and children were asked on the different beverage options that could be purchased at the school's cooperative. Responses from site A indicated that plain water, fruit drinks (sparingly), milk with biscuits -but no soft drinks- were usually available. Responses from site B, revealed that plain water and certain fruit juices were available. Unfortunately, no pictures were possible to document this information.

In relation to new beverage outlets opening within the nearest proximities of the schools, in both sites, these remained the same. There appeared to be no variation on the products or prices on offer from the outlets that had been surveyed at baseline.

Control sites: canteens

At control sites, purchasing options of SSB constituted mainly fruit drinks, plain water for both schools and additionally, fruited water for just one of them. No new beverage outlets/retailers have been opened nearby the schools, with options for purchase and prices remaining constant.

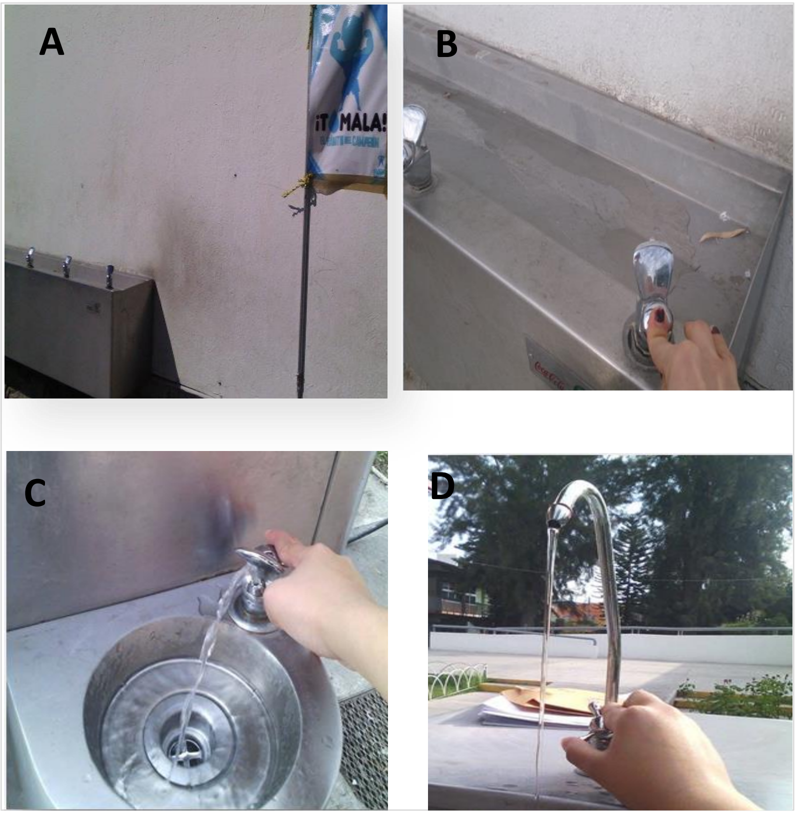


Figure 6-7 Water fountains at intervention sites: not functioning in site A (A,B) and working correctly in site B (C,D).

6.6.6.3 Post-intervention assessment

Similarly to findings from the mid-way evaluation, no changes were found across the products on offer at school's canteens (n=4) as their external entrepreneurs remained constant throughout the intervention's period and an apparent adherence to the food expenditure guidelines by the Ministry of Education (Secretaria de Educacion Publica, 2014) was displayed. From a small survey to the school's proximities and talks with teachers and principals, new shops or stalls had not been opened between mid-way and post intervention evaluation (that being from October 2015 until January 2016). Further, there were no promotional campaigns (nationally or locally) emerging during this time that could have affected prices or inclination to purchase certain products.

Beverage record diaries

All teachers (n=16) were given a specific record (**appendix L**) to observe and document the beverages children usually brought from home (or purchased at school) on a random day, for one occasion only. This activity was intended for monitoring purposes of the type of beverages, serving sizes and popular brands mostly consumed amongst the study population. Completion of this activity was difficult as reflected by a low response rate of 60%, with two classes in intervention site A not conducting the exercise at all. Reasons behind lack of implementation related to time constraints. From the 223 answers collated, mainly fruit juices, sweetened yogurt and sport beverages were still popular products to bring from home at intervention and control sites, fizzy drinks, were not entirely reported. While water appeared to be greatly consumed in both conditions, control groups reported higher volume sizes of containers (most frequently 1 Litre), while at intervention groups serving sizes were mainly reported as 500 mL in addition to comments of using the water fountain **(Figure 6-8).**

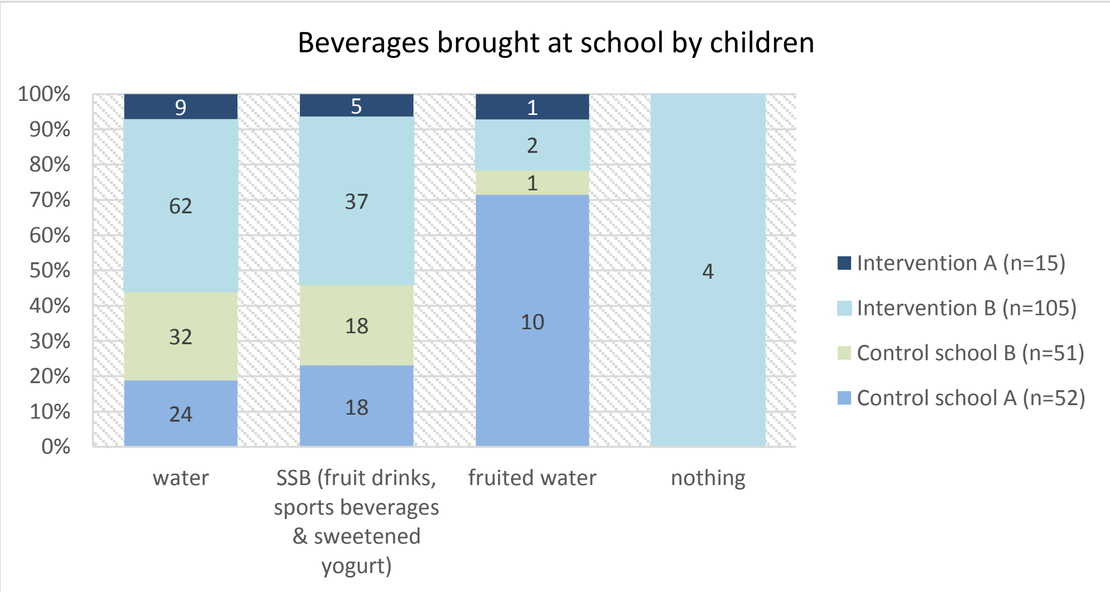


Figure 6-8 Beverages brought by children to school: observation exercise from teachers.

Intervention sites: awareness in children at intervention sites

Evaluation of post-intervention outcomes was conducted four weeks after final data collection of primary outcomes at intervention schools (2nd week of January 2016) through an evaluation sheet (**refer to appendix O**) children were questioned on aspects of exposure and engagement with activities as well as knowledge around the benefits of drinking water and the consequences of higher intakes of SSB. 206 from the 222 analysed children provided answers (97% response rate). The results are portrayed in **Figure 6-9.** Collated results from other process measures can be seen in **Table 6-9** and **Figure 6-10** depicts children playing with materials at intervention sites**.**

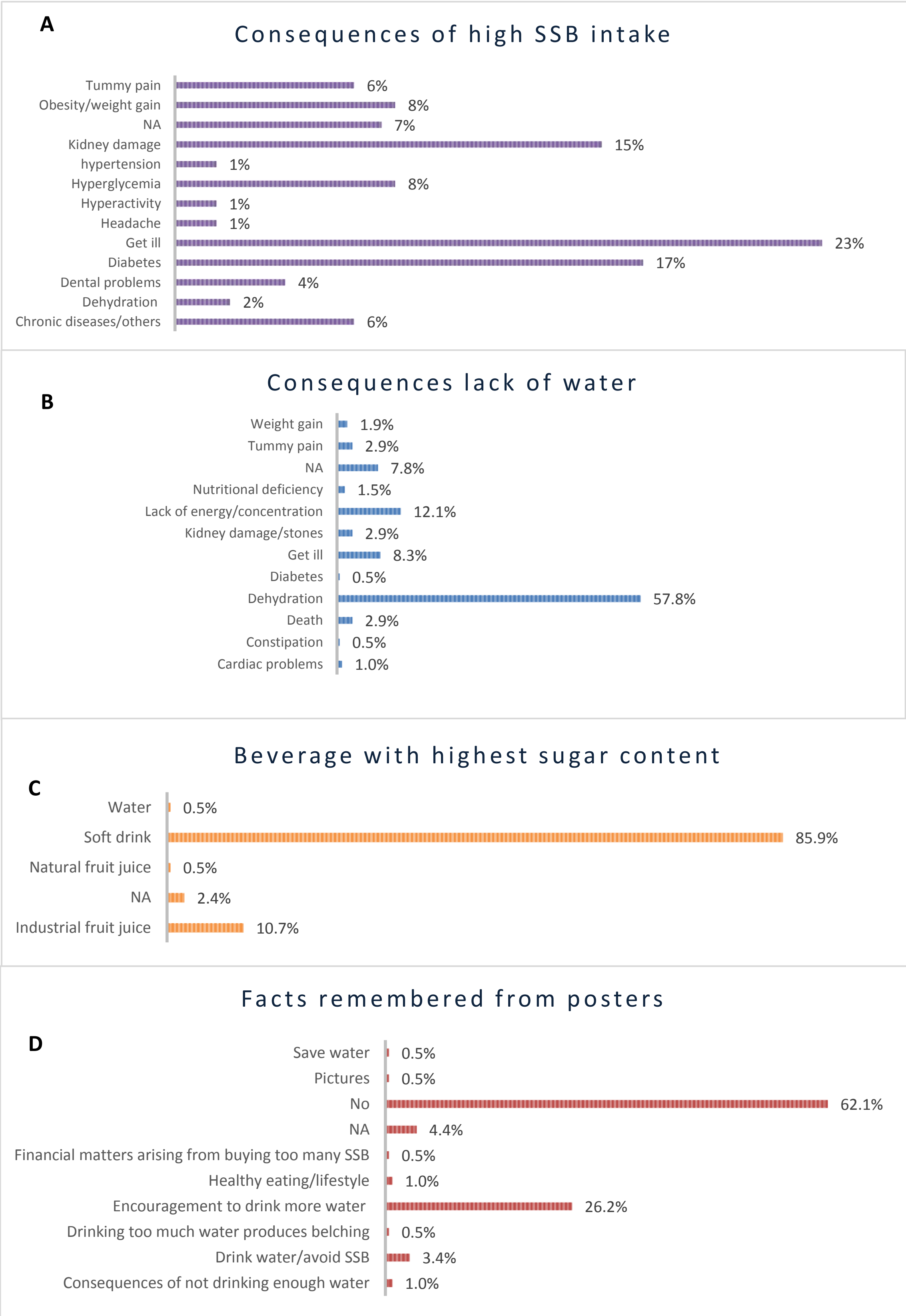


Figure 6-9 Children's answers on: Physical consequences of excessive intake of SSB (A), physical consequences from lack of water (B), rating of beverage with highest sugar content (C) and information remembered from posters allocated around schools (D).

Table 6-9 Children views and opinions towards intervention activities and contextual factors.

Process Measures (n=206)	N	(%)
Did you have a "water break"?		
Yes	176	(86)
No	30	(14)
Do you use the school's water fountain?		
Yes	104	51
No	99	48
Na	3	1
Do you drink more water at school than at home?		
Yes	76	37
No	128	62
Na	2	1
Do you purchase SSBs at the school's canteen?		
Yes	16	8
No	187	91
Na	3	1
Do you believe that there are many places around your school where you can buy SSBs?		
Yes	143	69
No	55	27
Na	8	4
Does your family drink plain water?		
Yes	184	89
No	16	8
Na	6	3
Are SSBs always available at home?		
Yes	59	29
Sometimes	19	9
No	125	61
Na	3	1
How many times did you play "snakes and ladders"		
0	28	14
1	38	19
2	27	14
3	26	13
4	75	38
>4	1	1
Did you like playing "snakes and ladders"?		
Yes	159	77
No	15	7
Na	32	16
How many times did you play the "memory game"		
0	40	19
1	39	19
2	38	18
3	24	12
4	45	22

Process Measures (n=206)	N	(%)
>4	4	2
Na	16	8
Did you like playing the "memory game"		
Yes	139	68
No	25	12
Na	42	20
Correct interpretation of urine colour chart		
Yes	187	91
No	6	7
Na	3	2

NA= not answered

Figure 6-10 Children playing at intervention sites during recess time.

Intervention sites: feedback and views from teachers and heads of school.

Information on process measures was also obtained from teachers and head of schools at experimental schools on the same week that questionnaires were applied to children (January 2016). School staff was questioned on aspects related to the benefits from exposure to the intervention, perceived intermediate impacts in children's behaviour and in school's ethos as well as areas of improvement for the study. Results indicated that all teachers (n=7) and the head of school reported the intervention increased children's knowledge on the favourable effects of drinking more water and on the consequences of drinking too many SSBs whilst becoming particularly benefited from with the provision of the water bottles, although less than half of children kept the bottles by the end of the intervention. Reasons behind children not further bringing the bottles to school were highlighted as: "children may not have liked the design", " not having [personally] the opportunity to approach parents to emphasise importance to keep bringing the bottles", "losses and damages" as well as "having a small capacity (volume in mL)".

Contrasting views between intervention sites were retrieved amongst board games with one school perceiving them as not widely beneficial nor interesting for children and the other school emphasising the opposite. From all resources, both the urine colour chart and banners with information received the lowest ratings.

While implementation of activities was considered as "easy" by 5 out of 7 teachers, the water break was only documented by 5 of them for a median of 7 weeks, with no execution towards the end of the study (around week 10). Further, teachers commented observing children somewhat more interested in drinking fewer SSBs in both intervention sites, with many of the beverage diaries revealing that many children would still bring SSBs (particularly fruit juices/drinks) to school. Other comments from teachers and head of school on existing barriers for children drinking more water at school can be seen in **Figure 6-11.**

Table 6-10 Views of teachers on different aspects of the intervention.

Process Measure	Teachers Intervention site A (n=3)	Teachers Intervention site B (n=4)	Head of School (n=1)
Did your class receive nutritional training before the intervention?			
Yes	3/3	2/4	
No	0/3	2/4	x
Description of nutritional training *received*			
2x 15 minute sessions	1/3	-	
1x 15 minute session	2/3	2/4	
How did the children benefit from exposure to intervention?			
Promoted water intake over SSB	3/3	2/4	x
Increased knowledge on benefits of drinking more water	3/3	4/4	x
Increased knowledge on consequences of drinking too many SSBs	3/3	3/4	x
Fostered positive relationships	2/3	2/4	
Contributed in maintenance/improvement of water fountain	1/3	1/4	x
Contribute in improvement of offering of beverages at school's canteen	0/3	1/4	
To what extent do children seem to be more engaged in drinking water?			
Somewhat interested	2/3	2/4	X
Greatly interested	1/3	2/4	
To what extent do children seem to be more engaged in drinking fewer SSBs?			
Not interested at all	-	1/4	x
Somewhat interested	3/3	2/4	
Greatly interested	-		
In your opinion, which activity was mostly beneficial for children as part of the intervention?			
Snakes and ladders game	1/3	2/4	X
Memory game	1/3	3/4	
Water bottles	3/3	4/4	x

Process Measure	Teachers Intervention site A (n=3)	Teachers Intervention site B (n=4)	Head of School (n=1)
Water break	2/3	2/4	x
Urine colour chart	1/3	2/4	
Posters with information	2/3	0/4	
In your opinion, which activity was mostly interesting/engaging for children as part of the intervention?			
Snakes and ladders game	1/3	2/4	X
Memory game	1/3	3/4	
Water bottles	2/3	3/4	X
Water break	1/3	1/4	
Urine colour chart	0/3	1/4	X
Poster with information	1/3	0/4	
In your opinion, the school's canteen offer of beverages is:			
Adequate	1/3	2/4	X
Inadequate	-	1/4	
NA	2/3	1/4	
Do you consider more children bring water to school as a result of the intervention?			
Yes	1/3	3/4	X
No	1/3	1/4	
NA	1/3		
Estimated % of children bringing water to school			
0-33%	-	1/3	
33-66%	2/3	1/3	
>66%	1/3	2/3	X
Number of children that kept their water bottle			
0-33%	2/3	2/3	
33-66%		1/3	
>66%	1/3	1/3	

Process Measure	Teachers Intervention site A (n=3)	Teachers Intervention site B (n=4)	Head of School (n=1)
Easiness of implementation of activities			
Yes	2/3	3/4	
No	1/3	1/4	

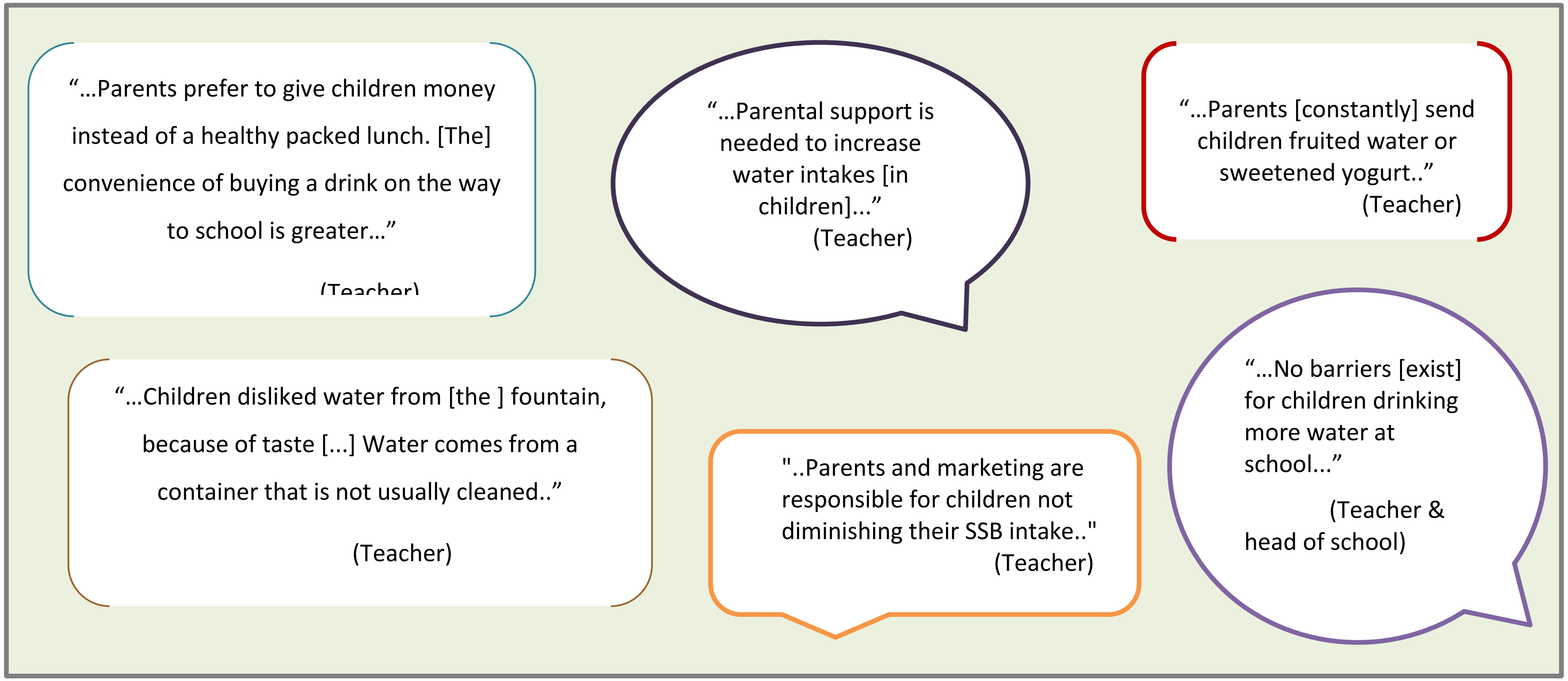


Figure 6-11 Comments from teachers and head of school on existing barriers for children to drink more water at school.

Further comments and suggestions on the intervention from teachers were:

- More activities and of higher intensity will be beneficial.
- More materials are needed.
- Lack of parental support could have potentially resulted in higher intake of SSB.
- Possibility of sending notes to remind parents would have been helpful.
- Difficulty to tackle an established behaviour from home.
- Children need to be constantly reminded of the health consequences of drinking too many SSBs.
- Parents [are] responsible for buying children SSB (Head of school).
- Good programme/initiative to raise awareness about consumption of water"
- "…As part of activities at recess, the school has board games; therefore, initiative was well received and coupled" (Head of school)

Effect of Implementation variability in outcomes: opportunities score

Alongside the analysis of process information on integrity, reach and dose, the integration of process and outcome data can help to understand better how the variation in implementation of activities has affected overall results (Moore et al., 2015) . Therefore, a score was developed to identify if children with higher exposure to the activities implemented and with more environmental support had better intakes of water and SSBs.

The score was developed based on:

- The times that children played with each of the board games:

  0-1 time (or unanswered) = 1 point

  2-3 times= 2 points

  4-5 times= 3 points

  6 or more times= 4 points

  Minimum Score = **2 points/** Maximum score = **8 points**

- The use of water fountain at post intervention

  0 = 0 points

  1-2 times= 2 points

  3-4 times= 3 points

  5 or more times= 4 points

Minimum score= **0 point/** Maximum score = **4 points**

- Having had a “water break” at class, perception of availability of SSB at home, habitual intake of water within the family environment:

  Yes= 1 point

  No = 0 points

  Minimum score= **0 points /** Maximum score= **3 points**

  Overall MINIMUM SCORE= 2 points   MAXIMUM SCORE= 15 points

Based on percentiles and the median (score= 5) a cut-off point of less or equal to 4 was classified as “LOW OPPORTUNITIES” from 5 to 7 as “MEDIUM OPPORTUNITIES” and from 8 and above as “HIGHER OPPORTUNITIES”.

Linear regression was used to compare the effect of having a higher score versus a lower score on the change from baseline to follow-up in consumption of water, processed fruit drinks and all SSB combined in different time points of the day. The reference group in this model was “low opportunity” - meaning those children with fewer exposures to activities and environmental nudges. The results for all children (Table 6-11**)** indicate a negative relationship between a better score and children’s intakes of water and SSBs. For instance, a decrease in water intake and an increase in SSBs across the whole day were retrieved with higher scores. A similar pattern was observed at home time, in which children from the highest category decreased their consumption of water by 118 mL and increased their intake of SSBs by 52 mL in comparison to those children in the lowest category. At school times, however, a higher score was suggestive of a decrease in SSBs of 33 mL and a non-significant decrease in water of 57 mL.

Table 6-11 Mean change in water and SSB intake and higher opportunity scores.

Change in outcome by score level	N	Mean	SE	p-value
Change in water intake throughout the day				
Low opportunity (reference)	90	1		
Medium opportunity	93	-46	120	0.7
High opportunity	39	-161	155	0.3
Change in SSB throughout the day				
Low opportunity (reference)	90	1		
Medium opportunity	93	110	111	0.3
High opportunity	39	235	146	0.1
Change in water intake at school				
Low opportunity (reference)	90	1		
Medium opportunity	93	17	64	0.8
High opportunity	39	-57	82	0.5
Change in SSB at school (mL/day)				
Low opportunity (reference)	90	1		
Medium opportunity	93	-22	43	0.6
High opportunity	39	-33	55	0.6
Change in water intake at home				
Low opportunity (reference)	90	1		
Medium opportunity	93	-76	104	0.5
High opportunity	39	-118	135	0.4
Change in SSB at home				
Low opportunity (reference)	90	1		
Medium opportunity	93	-6	79	0.9
High opportunity	39	52	102	0.6

6.7 Discussion

This chapter has examined the effectiveness of an educational and environmental intervention to influence consumption of SSB through the promotion of water intake in school-aged children. It also has explored the contextual factors -through a process evaluation- that may be mediating its fidelity, dose and reach. Overall, the programme was insufficient to bring about behaviour change in children as consumption of water throughout the day decreased, albeit non-significantly- from baseline to post intervention, with reductions being greater for control groups. Intake of sugar-sweetened beverages throughout the day, on the other hand, was minimally reduced from baseline to post-intervention in both groups, as estimated from the beverage questionnaire and greater reductions were documented for control groups during out-of-school hours. Few Mexican studies have examined the effectiveness of health educational campaigns and environmental changes to schools as a way of promoting water intake and diminishing consumption of SSB in children, all finding mixed results (Carriedo et al., 2013, Elder et al., 2014, Safdie et al., 2013).

For instance, Elder *et al.*, conducted a controlled study in two schools in Mexico city and one school in San Diego, USA – involving a similar population of children- in which water was promoted through an educational campaign that included the distribution of a water bottle, healthier beverage offering at the schools' cafeteria (i.e., plain or aguas frescas as part of cooked meals onsite) and the use of urine colour charts as proxies of hydration (Elder et al., 2014). This 12-week intervention, enrolling more than 1000 participants, documented an increase in water intake at all experimental sites at post intervention. Nevertheless, direct observational measures of the child in the classroom and in the school's grounds were used to assess primary outcomes (water intake) and thus, consumption of water or any other liquid including SSBs over the course of the whole day and especially at home, was not measured. Further, water intake was promoted at Mexican sites through placement of 20 L water containers at each class, which were financed by parents. Therefore, logistics and sustainability to keep this environmental nudge (water containers), would remain challenging for most low-income schools in Mexico considering typical classroom sizes (averaging 30 to 40 students per class) and the unlikely situation of parents to contributing economically, particularly if potable water is also an issue at the household level (Martínez, 2010).

Another cluster-RCT study, which allocated 27-Mexican schools under three different conditions ranging in intensity of activities, showed an effect on increased availability of potable water at experimental schools under the highest programme intensity (n=8) (Safdie et al., 2013). This intervention, which targeted the food environment by reducing the opportunities for children to eat/drink higher-in sugar and higher-in fat products (including SSB), documented an 18.5% decrease on consumption of these products in experimental groups when compared to controls (Safdie et al., 2013). Data, however, was measured through direct observation of children's' intake and was supported by purchasing data from the school's canteens. While the study did not use any other method for dietary assessment and the results presented were not disaggregated by food or beverage categories, it did emphasise how dietary behaviours can be linked to the school's environment and findings were influential in the reinforcement of Mexican school regulations (Safdie et al., 2013).

Similar in length, content and design to this intervention, Carriedo *et al.* sought to increase water consumption and reduce SSB intake in 324 school aged-children in Mexico city through provision and promotion of water containers instead of fountains (Carriedo et al., 2013). Findings from this cluster quasi-experimental study revealed an increase in water intake during school time by 170 mL in intervention groups, when compared to controls: -140 mL, ($p< 0.05$). In a subgroup of children (number not reported) change from baseline (after 12 weeks) showed a decrease in SSB consumption over the whole day in intervention and control groups, by 437mL and 267mL, respectively, with differences between groups being statistically significant ($p<0.05$). This study, which also used a non-validated beverage questionnaire to measure intake, differed on its definition of a SSB as it followed the "*Beverage Consumption Recommendations for the Mexican Population*" developed by the Ministry of Health in 2008 (Rivera et al., 2008). These guidelines categorise beverages into 6 levels depending on their caloric content, nutritional value, and potential health risks from higher intakes. *Carriedo et al.* only assessed beverages from level 6 or the "least healthy" which includes soft drinks and beverages with added sugar like juices, flavoured waters, coffee and tea, whilst other beverages such as sports drinks, fruit smoothies with sugar or sweetened milk were not covered – as they fall under a healthier classification(Rivera et al., 2008). Environmental changes, however, were remarked as effective to entice children into drinking more water and fewer SSB at the end of the study.

6.7.1.1 Potential barriers to changing children's water and SSB intake at the school level

Previous chapters (**chapter 3**) have portrayed that children are a group particularly benefiting from health promotion and education programmes, yet, achieving changes in children's water and sugar-sweetened beverage intake remains challenging. This is particularly true in/for the Mexican context. Highly recommended strategies for reducing SSB intake include ensuring availability of potable water in schools(Commission on Ending Childhood Obesity, 2016). While the Mexican government has succeeded on the elaboration of policy documents targeting nutrition strategies in schools (Secretaria de Educacion Publica, 2014), programme's dose and fidelity widely depend on the willingness of directors, teachers and school staff for its implementation. Similar to findings by other authors (Safdie et al., 2013), sensitivity analyses here suggest that children with higher opportunities to engage in targeted activities were more likely to drink higher volumes of water at school in comparison to those with lower opportunities. Further, process evaluation identified that uptake of educational components started to decline after 6 weeks of implementation, with some of the activities (such as the water break) not being implemented at all by the end of the study. Teachers' busy agenda to complete curricular plans (Knai et al., 2006) as well as their self-perception and influential role towards modifying health behaviours in children (often parent blaming) may stand as barriers for not delivering activities as planned (Clelland et al., 2013).

In contrast to the components of the aforementioned Mexican studies was the promotion of water intake through the school's water fountain in the present study. Certainly, perceptions of tap water and school water fountains in American adolescents have found an inverse association between negative water fountain views and SSB intake, particularly among those of Hispanic origin (OR 2.9, 95 % CI 1.3 to 6.6) (Onufrak et al., 2014). While these views were not associated with water intake *per se*, it was documented that more than a third of the students surveyed (38%) disagreed that their school water fountains were clean and safe. In Mexico for instance, the availability and structure of water fountains mainly depend on the schools' own budget and their ability to effectively coordinate with other educational authorities which can provide funding (such as councils within the educational system). Some funds may also be derived from the revenues of sales of the cafeteria concession. Maintenance (hygienic condition and constant water supply) on the other hand, largely relies on the school's dynamic: agreements and accountability between head of schools from morning and afternoon shifts (Martínez, 2010). For instance, one of the control schools had a broken fountain for more than 6 months prior commencing of the intervention and had not managed to obtain financial resources to fix it by the end of the study; the other control school did not have the built resource and funds were confirmed to be allocated to other needed spaces ("felt needs") such as recreational facilities.

Although acceptability of most activities was found across children's responses, the use of the water fountain varied considerably between intervention sites (**Table 6-9**). As revealed in the midway assessment, possible reasons were that faucets in one of the schools were constantly broken, which could have limited children into drinking more water and potentially (re)filling their water bottles. Also, as portrayed by one teacher's response, water safety could stand as a barrier for staff, parents and children themselves to reinforce greater intakes (**Figure 6-11**).

6.7.1.2 Limitations and Strengths

Regarding the study's strengths, results were obtained following a robust statistical plan consisting of multilevel analysis, which allows for more accurate estimations of the mean and confidence intervals for the different beverages, despite that a higher number of clusters is usually needed to follow this approach. This method also accounts for clustering of participants- as similarity among responses within a group (school) can magnify observed differences in outcomes between groups (intervention *vs* control) (Murray et al., 2004). A change variable was created as residuals followed a more normal distribution than using follow-up results adjusted for baseline data (Fu R, 2015).

Although the instrument used to collect data was not validated, it provided more options on portion size by means of selecting a glass or small bottle, a can or a large bottle (i.e., 200 mL, 330 mL or 600 mL) with inclusion of familiar photographs and images to assist children in portion estimation; application was easy, fast and non-burdensome. Furthermore, to avoid introducing other sources of bias, trained research assistants applied the questionnaires at pre and post-intervention periods and an independent blinded assistant helped with data entry.

Participant engagement and acceptability of activities (board games in particular) were found high throughout the study with formative assessments (at mid-way and post intervention) portraying that children remained interested in most didactic materials. Although a feasibility study, this is the first intervention in the region to assess whether nutritional efforts in combination with environmental nudges could positively affect children´s beverage intake throughout the day. Information retrieved thus, is highly valuable to the educational and health systems in Guanajuato, which currently lack the capacity and resources to conduct any programme evaluation of nutrition schemes in elementary schools.

This feasibility study had several limitations. First, it was targeted to the total child population independent of BMI status, thus detection of an intervention effect on the subgroups of children with normal weight, overweight or obesity was not possible as anthropometrical measurements were beyond the scope and resources of the intervention, nevertheless, it could have been a source of variation in intakes of SSB and/or water as previously documented (Taveras et al., 2011). Also, no other dietary information was collected, thus actual energy intakes, diet quality/adequacy and compensations/replacements in other sugary products were not assessed. Whilst randomisation was considered since designing stages, assignment of participants to each intervention by a formal chance procedure was hindered by educational authorities whom may have provided highly motivated and receptive schools therefore, findings herein cannot be completely generalised to all populations. Caution should be taken to interpret the results as the lack of randomisation resulted in imbalances in beverage intakes between groups at baseline particularly for carbonated beverages and fruit drinks (both higher for control groups). Furthermore, certain classes within the intervention groups had not received any nutritional education by the Ministry, although this was established as an inclusion criterion. While these elements were considered *a priori* to meet "equipoise"/diminish bias, the final choice of schools to take part in this study was limited due to administrative and practical contexts.

Furthermore, the beverage questionnaire was not validated and data was collected for a single day both at pre-and post-intervention times, thus a recommendation for future studies would be the implementation of a multiple 24-h recall/record with a component to prompt adequately participants on missed items (Riordan et al., 2016) and, if possible, in combination with other proxies such as water flow readings from fountains (Muckelbauer et al., 2009, Elder et al., 2014) or other innovative technologies that use image-based or image-assisted approaches for dietary assessment (Boushey et al., 2016). While the ceiling of accountability of the study was the school, it would be important to also explore patterns of beverage consumption during weekends. Considering schools' dynamic in intervention sites, flow-meter readings could have been difficult to obtain as educational settings were shared by two shifts; yet by addressing coordination and logistics between shifts, valuable estimates of water fountain use could be gained.

While access points to water and SSB were identified inside schools and their closest proximities, the present study design was unable (underpowered) to detect potential associations between increased density of convenient stores/food retailers in the local surroundings and higher intakes of SSBs. Available evidence from the UK in 9 to 10 year olds revealed higher consumption of soft drinks with an increased density of supermarkets per square kilometre in the local neighbourhood (Skidmore et al., 2010) whereas an increased number of convenience stores was associated with higher intakes of processed fruit drinks (ß

= 0.25; 95% CI: 0.05 to 0.45). In the *Drink Smart in schools* project, around 70% of children in intervention schools agreed that there were many outlets around the school in which SSB were available (most of them convenient stores) to which educational authorities have no control/regulation, so even if compliance to beverage offering was found across canteens, retailers outside or nearby may be hindering school´s efforts to engage children in healthier dietary practices (Martínez, 2010).

Similarly, to findings from studies in Mexico targeting consumption of water through an educational-based approach (Rodriguez-Ramirez et al., 2015), participants' water intake decreased by the end of the intervention potentially due to a weak intensity programme. Dose of intervention received by certain participants in intervention groups was low as activities were not entirely implemented in some classes and because implementation started to decrease after 6 weeks of study commencement. It should be noted that at the mid-way evaluation more than half of the children stopped bringing the water bottle whereas children at control schools were bringing larger water containers to school, which could have reflected that a bottle with different characteristics (such as a greater capacity, different shape, material) could have been more desirable and beneficial.

The initiative was also brief, and thus, participants may have needed in addition to reinforcing or "booster" sessions, more time to engage in the desired behavior. Changes in seasonality (from September to December temperature usually falls from 30C to 20C)(World Meteorological Organization, 2014) could have also made children drink less water. Further, as documented by analysis of chapter 4, *modeling the behaviour* (i.e., through parental figures) was more effective to reduce SSB intakes in children, however, the ceiling of accountability in this study was the school (**Figure 5-5** from Theory of Change) and no further parental involvement was targeted. While recognised as important in obesity-related interventions (including those targeting SSB intake), parental engagement stands as one of the most challenging elements for effective school-based health promotion (Clelland et al., 2013), future initiatives should address barriers for higher community involvement, for example, through increased social support, crèches, time-management skills which could provide parents with more opportunities to involve in activities and targeted behaviours. Attrition rates were not substantial in the study, yet together with implausible data from children has resulted in a smaller sample size; therefore it is likely that the study had low statistical power to detect a true effect (Button et al., 2013).

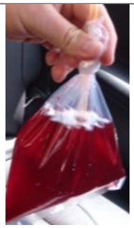
6.8 Conclusion

This school-based intervention combining an educational and environmental approach had little impact on children’s SSB and water intakes. The dose and length of the programme were insufficient to bring about behaviour change in children and mainly raised awareness on the importance of drinking more water throughout the day. Future research should address parental engagement and further changes to the school’s built and proximate environment.

Table 6-12 Access points for water and SSB inside intervention schools.

Type of beverage access point (cafeteria, school canteen)	Date collected	Person collecting information	Brand	Size (mL)	Price	Accessibility	Photo
Cafeteria (School A)	17/09/2015	EJVG	Aqua	620	$3.50	All staff and students	
	17/09/2015	EJVG	Freshly made fruited water	200	$3.0	All staff and students	
Cafeteria (School B)	18/09/2015	EJVG	Aqua	620	$3.50	All staff and students	Picture not available

Table 6-13 Access points for water and SSB outside intervention schools.

Type of beverage access point (beverage outlet)	Date collected	Person collecting information	Brand	Size (mL)	Price	Accessibility	Location	Photo
Intervention site A								
Stall	17/09/2015	EJVG	19 hermanos	200	$2.0	All students, parents, staff, general public	50 mts from school	
Stall	17/09/2015	EJVG	Homemade hibiscus water	200	$2.0	All students, parents, staff, general public	50 mts from school	
Stationary shop	17/09/2015	EJVG	Aqua (plain water)	620	$3.50	All students, parents, staff, general public	50 mts from school	

Stationary shop	17/09/2015	EJVG	Bonafont (fruit juice)	500	$6.50	All students, parents, staff, general public	50 mts from school	
Stationary shop 2	17/09/2015	EJVG	Aqua and Starch: plain water	620 and 600	$3.50, $3.0	All students, parents, staff, general public	Corner of school (75 mts)	See image above
Stationary shop 2	17/09/2015	EJVG	Bida Fruit drink	500	$6.0	All students, parents, staff, general public	Corner of school (75 mts)	
Stationary shop 2	17/09/2015	EJVG	Jumex fruit drink	250	$4.0	All students, parents, staff, general public	Corner of school (75 mts)	
Stationary shop 2	17/09/2015	EJVG	Aqua and Skarch: plain water	620 and 600	$3.50, $3.0	All students, parents, staff, general public	Corner of school (75 mts)	
Stationary shop	17/09/2015	EJVG	Al dia: fruit drink	300	$3.0	All students, parents, staff, general public	Corner of school (75 mts)	Picture not available

Stationary shop	17/09/2015	EJVG	Penafiel: soft drink	355	$3.50	All students, parents, staff, general public	Corner of school (75 mts)	
Stationary shop	17/09/2015	EJVG	Caballitos: soft drink	600	$5.0	All students, parents, staff, general public	Corner of school (75 mts)	
Intervention site B								
Stationary shop 1	18/09/2015	EJVG	Aqua and skarch: plain water	620 , 600 and 330.	$5.0, $3.50, $2.0	All students, parents, staff, general public	25 mts from school	
Stationary shop 1	18/09/2015	EJVG	Caballitos: soft drink	600	$5.0	All students, parents, staff, general public	25 mts from school	See image above
Stationary shop 1	18/09/2015	EJVG	Peñafiel: soft drink	355	$3.50	All students, parents, staff, general public	25 mts from school	See image above

Stationary shop 2	18/09/2015	EJVG	Coca cola products: soft drinks	600, 355	$10.0 - $5.50	All students, parents, staff, general public	25 mts from school	  
Stationary shop 2	18/09/2015	EJVG	Bonafont: flavoured water	1.5 L	$15.0	All students, parents, staff, general public	25 mts from school	
Stationary shop 2	18/09/2015	EJVG	Jugo Jumex: fruit juice	1 L	$19.5	All students, parents, staff, general public	25 mts from school	
Stationary shop 2	18/09/2015	EJVG	Powerade	600 mL	$12.5	All students, parents, staff, general public	25 mts from school	

Stationary shop 2	18/09/2015	EJVG	Nectar Jumex: fruit drink	413 mL	$8.50	All students, parents, staff, general public	25 mts from school	

Table 6-14 Access points for water and SSB inside control schools.

Type of beverage access point (cafeteria, school canteen)	Date collected	Person collecting information	Brand	Size (mL)	Price	Accessibility	Photo
Cafeteria (School A)	22/09/2015	EJVG	Skarch: plain water	600	$5.0	All staff and students	No image available
Cafeteria (School A)	22/09/2015	EJVG	Freshly made fruited water	200	$3.0	All staff and students	
Cafeteria (School B)	24/092015	EJVG	E-pura & ciel: plain water	600	$6.0	All staff and students	

Table 6-15 Access points for water and SSB outside control schools.

Type of beverage access point (beverage outlet)	Date collected	Person collecting information	Brand	Size (mL)	Price	Accessibility	Location	Photo
Control site A								
Stall	22/09/2015	EJVG	Freshly squeezed fruit juice	350	$7.5	All students, parents, staff, general public	20 mts infront of school	  **(350 mL)**
Stall	22/09/2015	EJVG	Aqua: plain water	620 and 300	$3.5; $2.0	All students, parents, staff, general public	20 mts infront of school	No picture available
Stall	22/09/2015	EJVG	Milkshake	350	$7.0	All students, parents, staff, general public	20 mts infront of school	No picture available
Stall	22/09/2015	EJVG	Al dia: Fruit drink	300	$3.0	All students, parents, staff, general public	20 mts infront of school	No picture available

Convenience store	22/09/2015	EJVG	Coca cola products: soft drinks	2L, 600, 355	$24, $10, $7	All students, parents, staff, general public	Corner of school (75 mts)	 
Convenience store	22/09/2015	EJVG	Bonafont (fruit juice)	500	$6.50	All students, parents, staff, general public	Corner of school (75 mts)	
Convenience store	22/09/2015	EJVG	Powerade	600 mL	$12.5	All students, parents, staff, general public	Corner of school (75 mts)	
Convenience store	22/09/2015	EJVG	Ciel: plain water	1.5 L	$12.0	All students, parents, staff, general public	Corner of school (75 mts)	
Convenience store	22/09/2015	EJVG	Danone: sweetened-yogurt	240 mL	$7.0	All students, parents, staff, general public	Corner of school (75 mts)	

Convenience store	22/09/2015	EJVG	Al dia: fruit drink	300	$3.0	All students, parents, staff, general public	Corner of school (75 mts)	No picture available
Control site B								
Food stall	24/092015	EJVG	Coca-cola products	500 mL (glass bottles)	$6.5	All students, parents, staff, general public	20 mts infront of school	 
Food stall	24/092015	EJVG	Agua Kids bonafont: fruited water with concentrated juice	300	$6.0	All students, parents, staff, general public	20 mts infront of school	
Food stall	24/092015	EJVG	Naranjada penafiel: soft drink	600	$7.0	All students, parents, staff, general public	20 mts infront of school	
Convenience store	24/092015	EJVG	Coca cola products: soft drinks	2L, 600, 355.	$24.0, $10.0 $7	All students, parents, staff, general public	75 mts from school	 

Convenience store	24/092015	EJVG	Bonafont (fruit juice)	500	$6.50	All students, parents, staff, general public	75 mts from school	
Convenience store	24/092015	EJVG	Powerade	600 mL	$12.5	All students, parents, staff, general public	75 mts from school	
Convenience store	24/092015	EJVG	Jumex fruit drink	250	$4.0	All students, parents, staff, general public	75 mts from school	
Convenience store	24/092015	EJVG	Ciel: plain water	500 mL, 1.5 L	$6.0, $12.0	All students, parents, staff, general public	75 mts from school	 

Chapter 7 : Discussion and implications for policy

7.1 Summary of findings

Reduction in consumption of sugar-sweetened beverages stands as an important policy option in global action plans addressing the prevention and control of noncommunicable diseases, including obesity (WHO action plan). Acknowledging their association with tooth decay, weight gain, diabetes and cardiovascular disease (**Chapter 1**) and their increasing contribution to total daily energy intakes worldwide, SSBs have become an individual target to achieve lower sugar intakes and thus healthier diets both in emerging and developed economies. The current epidemiological landscape in Mexico has driven national health responses to counteract high obesity rates and the early onset of ill health (i.e., the metabolic syndrome) identified at regional levels (**Chapter 2**). Measures taken to tackle SSB intake in Mexico and in other countries have involved population-based and, most frequently, individual-based approaches encompassing health education, behaviour change and establishment of supportive/enabling environments across different settings. The findings of this thesis have been pioneering to understand how and if these interventions/efforts are being effective to curb consumption of SSB. The systematic review and meta-analysis described in **Chapter 3** has found evidence to support that these frequently called "behaviour change interventions" are indeed achieving desired outcomes in children by means of significantly reducing their SSB intake and increasing water intake (**Chapter 4**).

Across the initiatives implemented by the Mexican government have been modifications to the school environment in ways of facilitating engagement of children in healthier dietary practices. Evidence of their effectiveness, has slowly emerged but been limited to the metropolitan area (Safdie et al., 2013, Rodriguez-Ramirez et al., 2015, Carriedo et al., 2013). Findings from **Chapter 6**, thus, provide a research basis on how feasible it is to nudge young populations at higher risk of metabolic syndrome into drinking more water, the preferred substitution for higher-calorie beverages, (Rivera et al., 2008) using the school as a setting for intervention. Information derived has helped understanding the challenges and barriers within the physical and social school environment that may be driving behaviour change in children.

This chapter aims to expand on the discussion provided at each chapter as well as situate findings within a broader policy and research context. Furthermore, the strengths and limitations of the thesis will be provided.

7.2 Systematic review and meta-analysis

The findings demonstrate that public health interventions are significantly reducing intakes of SSB in children and adolescents, and are being less effective in adults while also increasing water intake only in the children population in whom information was available for meta-analysis. The limited number of interventions targeting increases in water is a surprise considering that evidence from marketing interventions has highlighted that individuals and particularly those in a low income “may be easier to target water rather than diet products (i.e., artificially-sweetened) as a substitution for higher-calorie beverages” (Foster et al., 2014). Further, public health agencies, governments and the WHO have strongly advocated water promotion as a way to discourage sweetened-beverage intake. While much work has been undertaken to measure the impact of water intake prior meals on subsequent energy intake and have assessed changes in body weight (Tate et al., 2012) fewer controlled studies have measured ad libitum water intake in public institutions such as the workplace, hospitals or nursing homes. As discussed elsewhere (Vargas-Garcia et al., 2017) one of the underlying reasons could be that research on SSB and their replacing alternatives (low and noncaloric) has recently emerged concomitantly to the evolution of dietary assessment methods that could effectively capture individual fluid intake –considering most commonly used tools were primarily designed to measure energy content, macro and micronutrients (Popkin et al., 2010). This is a limitation, because current public health efforts may not be entirely captured by available methods.

A range of behaviour techniques were used across those interventions included to enable behaviour change towards SSB consumption. The use of “modelling/demonstrating” was the only technique indicative of significant reductions in intakes of SSB in children, and this was confirmed after removal of outliers. Providing general encouragement together with parental involvement were also associated with decreases in SSB consumption in sensitivity analyses. For instance, work by Mazarello *et al.* on determinants of SSB consumption in younger populations had previously highlighted parental (positive) modelling to be consistently associated with lower SSB intakes in children (Mazarello Paes et al., 2015). The former findings were also documented by Grimm and colleagues who found, in a sample of more than 500

American school-aged youths (Grimm et al., 2004), that children whose parents regularly drank SSB (defined as 3 or more times per week) were 3 times more likely to consume these beverages when compared with those whose parents did not regularly consume them. Grimm *et al.* also found parental influence to be a stronger predictor for SSB intake in comparison to peer pressure (OR: 2.88 [95% CI: 1.76 to 4.72] vs 1.84 [95% CI: 1.17 to 2.88] respectively), reflecting the leverage of the family in obesity-related behaviours (Grimm et al., 2004). Recent work by Tasevska *et al.* on a cohort of 3 to 18 year olds in the United States has also indicated that regular or high parental intakes of SSB in comparison to lower intakes were associated with higher odds of SSB consumption particularly in 6 to 18 year-old children (Tasevska et al., 2016). As a result, evidence-based guidelines for weight management and control have positioned the family system and dynamics as fundamental for successfully engaging children in lifestyle changes (Stewart et al., 2009). Viewed in this context, by exhibiting positive behaviours which could include avoiding availability of SSB at home, drinking water or healthier alternatives to SSB in the presence of other family members, parents may facilitate adoption of the behaviour in children.

Switching populations to drink fewer sweetened beverages has also been done through the provision of artificially-sweetened products as alternative choices. The use of artificially-sweetened beverages in the context of reducing free-sugar intake to combat obesity, while not the scope of the review is an area that merits attention as the marketing and availability of these beverages has steadily increased and so has the evidence questioning a safe and beneficial consumption. Emerging literature from epidemiological studies (Pase et al., 2017, Greenwood et al., 2014) has indicated an association between an increased or cumulative intake of artificially-sweetened drinks and higher incidence of cardiovascular outcomes, including the metabolic syndrome (Hu and Malik, 2010), diabetes mellitus (Greenwood et al., 2014), dementia, and stroke (Pase et al., 2017). In the case of children, longitudinal studies in the UK (Laverty et al., 2015) have shown an association between daily consumption of artificially-sweetened beverages and increases in adiposity by 1.2% kg/m^2 (95% CI: 0.81 to 1.54) at age eleven which remained significant even after adjusting for confounders such as age, gender, BMI classification, socioeconomic status, ethnicity and maternal educational attainment. There is still controversy, however, on the direct or indirect mechanisms in which the association may be taking place and whether reverse causation could be driving documented effects. Indeed, there is still a research gap to understand if people at higher risk of disease or with pre-existing disease risk factors may be substituting normal beverages with artificially-sweetened ones as way for glucose and weight control/management. While inconclusive, the body of literature to date encourages a discretionary and short-term intake of artificially-sweetened drinks since, a) their promotion as healthier alternatives to sugar-sweetened beverages cannot be completely established (Wersching et al., 2017), and b) substitution with water may be more desirable across all age groups (Laverty et al., 2015).

7.3 Feasibility study: current epidemiological context of Mexico

The identified prevalence of Metabolic Syndrome in children in central Mexico (13%) together with the escalating overweight and obesity rates in youth (combined prevalence of 35%) compels the implementation of measures at national and local levels that improve nutritional status in this population by ensuring healthier diets and enabling environments. The data from the secondary analyses in the cohort of Mexican children (Chapter 4), while limited in its scope to identify specific dietary factors or behaviours associated to MS in the sample, was informative in understanding that risk factors for cardiovascular disease can develop at an early age without necessarily being precipitated by the presence of obesity or overweight *per se*. The alarming volumes of SSB intake across Mexican children – greatly associated with MS and other disease conditions – have driven authorities to intervene in areas addressing the exposure of children to irresponsible food marketing as well as school food policies (i.e., endorsement of the Nutrition-Friendly School Initiative by WHO) in ways to eliminate the availability of highly sugared products (including SSBs) in educational settings (Secretaria de Educacion Publica, 2014)

While governmental efforts have resulted in several documents and adoption of policies (Secretaria de Salud, 2010), as previously mentioned, limited evaluation has been conducted on the programme's final reach and effectiveness; mainly due to time, human, and economic constraints. Results from the feasibility study (**Chapter 6**) were not in the desired direction as children in both groups decreased their intake of water while increasing, albeit non-significantly, their consumption of SSB. Findings, nevertheless, served as a "snapshot" of: the difficulties in conducting nutritional research with local authorities; the challenges to assess capacity within the Ministry of Education (i.e., fidelity in the delivery of programmes, quality of data collected, and embedding of nutrition elements into other sectors); and, the complexity for action on a problem that is influenced by bigger determinants beyond the reach of the school level.

The main objective of the feasibility study was the substitution of SSB with water by using *physical resources* (i.e., water fountains), alongside *cues* reminding children to drink water as a first choice of beverage (i.e. urine colour chart and “water break”) and further *educational components* (board games) aimed to have a reinforcing and synergistic effect to those received by schools from the Ministry of Education before the intervention started. Mixed outcomes following a similar environmental approach and data collection methodology have been documented in studies in Mexico (Carriedo et al., 2013) and elsewhere (Muckelbauer et al., 2009, Sichieri et al., 2009, James et al., 2004). Some have shown an increase in water intake in children but not a decrease on SSBs (Muckelbauer et al., 2009), whereas others have seen a decrease in SSB (Sichieri et al., 2009, James et al., 2004) but not an increase in water intakes (Sichieri et al., 2009, Carriedo et al., 2013). Most of these studies have had as choice of architecture either the provision of water bottles, a water container, or a water fountain, and contrasting with the present study have been usually delivered in educational settings over 6 months (Muckelbauer et al., 2009, Sichieri et al., 2009).

While brief contacts such as written information could be a starting point to prompt desirable behaviours such as changes in SSB consumption (Hebden et al., 2014), lengthier interventions may deemed necessary to engage children in other stages of change and sustained action (Dombrowski et al., 2012), as suggested by results from the meta-analysis (**Chapter 3**, section 3.5.2). Further, weak educational components have been emphasised as a reason behind limited outcomes in many of the above studies. Children in the *DrinkSmart* in schools' project enjoyed taking part in the activities delivered; but it wasn't until the outcome evaluation was conducted that certain classes within intervention sites were identified as not having received any Nutritional education sessions by the Ministry in the past. Thus, the messages in the study´s campaign may have been completely new to some children.

Prompting practice and modelling the behaviours as techniques were mainly targeted at children, although certain teachers also adhered to the former techniques. The role of the teacher has been particularly emphasised by government documents in the delivery of obesity-related programmes; however, ethnographic studies conducted in Mexico City have identified an ambivalent attitude by teachers towards the problem (Secretaria de Educacion Publica, 2014, Melendez, 2008). Indeed, in these studies some teachers mentioned using food/drinks as rewards, while others participated actively in the preparation of healthier food/beverages to be served at school's cafeterias (Melendez, 2008). It is important to consider though that teachers in Mexico do not perceive themselves with the moral authority to deliver the intended programmes or information (particularly on topics related to obesity), as they recognise that it is an existing condition in themselves and thus their nutritional practices do not represent the best example to their students. Others also admit that obesity is not their responsibility and that it exclusively relies on the family - particularly on the maternal figure (Melendez, 2008). From comments on the formative evaluation (**section 6.6.6**), this “parent blaming scenario” was shared by teachers and the head of school in intervention sites whom emphasised that as part of the barriers for children´s healthier drink choices were the unhealthy options purchased by parents on the way to the school and giving children money to buy further products in the surroundings of educational sites (comments **Figure 6-11**). According to certain responses there are currently no barriers in the school per se to engage children in drinking more water and fewer SSBs.

In this respect, it is noteworthy that schools appear to comply with national guidelines to limit availability of SSB in canteens – indicator that was true for both, intervention and control schools where only fruited-sweetened water (agua fresca) and plain bottled-water were sold. No data on an individual level is collected (i.e., BMI) as the most important indicators of programme’s success across the Ministry are the number of schools adhering to national codes and those receiving nutritional training (Secretaria de Educacion Publica, 2014) so, little is known on the effect that these policies are having on children´s health.

7.3.1 Water fountains in schools

Water fountains are the main source of potable water in most elementary schools in Mexico and placement of drinking fountains has been prioritised in the government’s framework for tackling obesity (Mexican Executive, 2010, Secretaria de Salud, 2010). Enhanced infrastructure to accessible potable water has been financially feasible not only through the government’s allocated budget for education, but also through revenues gained from recent fiscal measures on taxation of SSB and other highly sugared/fat products (Chamber of Deputies of the Mexican Congress, 2013). Nevertheless, installation of water fountains remains challenging in many Mexican municipalities as infrastructure is often limited to warrant adequate water supply across zones within a city or across whole cities within a State. Indeed, the problem of water distribution in Mexico has been highlighted as one of inadequate political management and governance which surpasses water availability *per se* that is, spatial and temporal distribution (Pineda Pablos, 2002).Inequality in access and consumption to potable water responds to socioeconomic factors (productive activities, social actors, ethnic groups), procurement policies (political decisions) and harmony between private and public sectors seeking to enhance its coverage within territories and not entirely due to scarcity itself.

Consequently, even if educational settings in León and other Mexican cities are interested in making potable water available at schools, barriers related to its supply may hinder their ability to pursue so (Patel and Hampton, 2011). Certainly, and as seen in one of the control sites, there are instances in which schools may not have financial resources to replace old fixtures or broken parts that would allow a constant water supply as well as improve appearance and taste. This is of concern as studies in American children, for example, have documented that students avoided drinking water from fountains when these were broken, dirty and produced unpalatable water (Patel et al., 2010). While children in the feasibility study were not directly asked the reasons for not using the fountains, it is likely that some of these problems/views were shared amongst them, especially when intervention sites held morning and afternoon shifts, thus augmenting the volume of children accessing facilities and posing greater constraints for directors to meet minimum hygiene and maintenance standards (Patel and Hampton, 2011).

7.4 Thesis strengths and limitations

Although each chapter of the thesis has separately covered its strengths and limitations, this section will present the overall strengths and limitations of the project as a whole.

7.4.1 Limitations

The systematic review used a well-established taxonomy for identifying and classifying BCTs relevant for dietary behaviours (Abraham and Michie, 2008), although it is possible that further techniques could have been delivered in the programmes that were not captured in the analyses. Also, and as previously mentioned, the small number of studies did not allow to test interactions between BCTs and other interventions' components, which could enable to potentially determine most effective combination of BCTs with intervention's elements.

There is conflicting evidence surrounding the effectiveness of theory-based versus non-theory based interventions to influence health behaviour change (Prestwich et al., 2014, Glanz and Bishop, 2010, Bartholomew and Mullen, 2011). For instance, it has been argued that the use of theory, such as the theory of planned behaviour (Zoellner et al., 2012), instead of individual BCTs could be more informative when planning and implementing interventions targeting SSB, and thus an analysis based on theory would have deemed more appropriate in the quantitative synthesis. Nevertheless, recent data has highlighted weak associations between the use of theory and intervention effectiveness (Mazarello Paes et al., 2015). Furthermore, within studies included in this review, the type of theory used and exactly how it was implemented was often not reported, limitation of the review as a whole and studies themselves. Consequently, the analyses undertaken have been focused on analysing the effect of specific behaviour change techniques rather than the effect of specific theories.

Heterogeneity remained high and significant across studies in the review, which is partly a reflection of their poor quality and the variation in intervention's content. One of the main challenges during data extraction was identifying the definition used for SSB, which often included either soft drinks, sports drinks or fruit drinks, and with results being presented separately or just for some of the mentioned terms - and not as a whole. While an effort was made to obtain the definition of SSB in all studies and get total volumes, this was not successful and assumptions had to be made in certain cases **(section 3.5).** Therefore, results may be more representative of certain beverages (typically the most consumed ones). Furthermore, one of the main risk of bias observed was reporting of outcomes and, as with any dietary methodology, misreporting and/or recalling bias was likely to be present in studies. Despite improvements in assessment tools for measuring SSB intakes, harmonisation of definitions and a better estimation of portion sizes should be convened so as to increase accuracy in results (Riordan et al., 2016). A recent systematic review of methods to measure SSB intake across European studies has highlighted that self-reported/administered tools should outline what is meant by SSB and provide examples that assist participants in serving sizes (Riordan et al., 2016).

This heterogeneity across SSB definitions together with deficient reporting of primary outcomes also limited the ability to provide estimates based on kcal that could have accurately reflected changes in energy density. Current literature inclines on reporting consumption of SSB based on their direct contribution to energy intake in *kcals per day* so as to translate them into the broader context of sugar intakes, meeting dietary guidelines as recommended by WHO and tracking changes in body composition/weight status. Although the former was not an outcome that the review sought to address, energy values are an aspect that warrants further attention and that should be considered in future reviews or updates.

In relation to the feasibility study, one of its main limitations was the lack of randomisation, which lead to imbalances at baseline for the consumption of carbonated beverages and fruit drinks - both of which were higher in the control group and which have favoured greater effects/reductions in both drink categories for this latter group at the end of the study

(**Chapter 6 section 6.6.2**). Further, as randomisation was not possible, the inevitable presence of unmeasured confounding (or confounding due to exclusion of a confounder from the model) (Fewell et al., 2007) cannot be ruled out. While confounders and the direction of the association between exposures and outcomes were conceived prior implementation of the study, relevant data (such as sociodemographics) from the Ministry of Education (both at central and school levels) was unavailable, and which had to be later obtained and analysed using National standards (López, 2011). The current classification used in Mexico as seen in **Chapter 5**, focuses on measuring the level of satisfaction of basic needs in the family (mainly educational attainment and housing conditions) as a proxy of household quality of life, yet it does not provide information on other aspects related to deprivation such as illnesses or barriers to better housing conditions. The low rate of response obtained from parents due to the unfamiliarity or perceived intrusion from these questions has hindered the possibility to strengthen the statistical analysis in **Chapter 6** to better identify the impact of sociodemographic data and elements of deprivation on consumption of water and SSB in children. Also, from an obesity perspective, the study did not measure total energy intake nor BMI, thus it was unable to explore whether children at higher or lower BMI or with greater calorie intakes could have benefited more from the intervention.

All participating schools, albeit matched in geographic and demographic characteristics, may have been representative of more enthusiastic and highly motivated school communities, facilitating thus, the development and execution of the intervention. Indeed, prior commencement of the study there were certain views by the Nutrition Department at the Ministry linking the intervention to an assessment of their activities *per se.* For this reason, schools that were more responsive and easier to liaise with may have been given preference for participation. This is a limitation, as the successful elements of the intervention may not be transferable to other schools under different circumstances (e.g. those in potentially more socially and economically deprived contexts).

The beverage record used, while piloted in a comparable setting and population to the children in the *DrinkSmart* in schools' project, it was not validated. Before deciding to develop a new dietary assessment tool, Mexican researchers that had conducted similar interventions were approached to gain access to their collection instruments; however, responses in all cases revealed a lack of validation in the tools or recommended the use of the 24-hour dietary recall. Multiple 24 hr dietary recalls are considered to be a reference method to examine *validity* considering they provide detailed dietary information not only on beverages but also foods leading to better estimations of usual energy intakes (Subar et al., 2001). Time and financial constraints from the higher research burden to code data and training required, however, did not make it feasible to use this methodology. Validation in future studies should stand as an essential step towards understanding if information from self-administered instruments has been correctly measured and has captured what they are purported to capture (Livingstone et al., 2004).

Finally, in relation to the biochemical data that has been collected in Guanajuato, it was unfortunate that many cases were lost due to a poor management that failed to match anthropometric data available in these children (BMI, in particular). Also, it remains unclear whether a misclassification of their nutritional status had occurred and that is why children with apparent “undernutrition” were fulfilling criteria for metabolic syndrome (particularly when the objective of the analysis was to follow children with overweight or obesity). For diagnostic purposes of Metabolic syndrome, central adiposity from surrogate measures such as waist circumference should be worth considering in future surveys, as they are more predictive of metabolic disturbances (Savva et al., 2000).

7.4.2 Strengths

Acknowledging that schools are an ideal location for the development of adequate dietary habits and knowledge in young people from all socioeconomic backgrounds, the intervention has targeted a relevant setting and has addressed the documented need of promoting less obesogenic school environments. It has been widely emphasised that the lack of evidence should not stand as a barrier for taking action particularly in a population that was identified to be at higher risk of obesity and NCDs, including the Metabolic Syndrome, and therefore this has been one of the main drivers/foci of this thesis.

The selection of intervention components and the overall design of the intervention followed a logical approach to the best way to go about curbing consumption of SSB and has been guided by the Public health nutrition cycle (Gibney et al., 2004). As a first step, critical appraisal of the literature has adhered to a rigorous protocol in ways to search and identify the best available evidence (Vargas-Garcia et al., 2015) and consequently integrate promising elements (e.g. activities, behavior change techniques) in the feasibility study.

The systematic review is the first of its kind since it has looked at individual based-interventions/ programmes aiming to reduce SSB from the perspective of behaviour change. It has also identified other “ingredients” or intervention components that may drive change. In comparison to existing reviews in the area (Vezina-Im et al., 2017, Mazarello Paes et al., 2015), it has quantified the differences in consumption patterns of SSB and water, and thus, has enhanced understanding on the midstream or behavioural approaches needed to comprehensively address obesity (Sacks et al., 2009), which often are not the narrow outcomes that work well in other reviews, including Cochrane's (Cochrane Nutrition Geneva, Priority setting consultation report 2017).

Statistical analyses in the quantitative synthesis were considered *a priori* and a robust methodology has been used: random effects meta-analysis, which considers the absence of a unique effect size across interventions and thus accounts and seeks to measure the variation between and within studies (Higgins, 2011). The stages of this thesis were informed by an earlier iteration of the review. However, an update was conducted and published recently which did not inform the stages of the thesis. Nevertheless, the direction of the effects did not vary, and additional included studies meeting have added power to statistical analyses and conclusions. Results from these updates can be found elsewhere (Vargas-Garcia et al., 2017).

The foundation and described pathways of effect in the *DrinkSmart* in schools' project were shaped through different frameworks, including a theory of change (De Silva et al., 2014) . Despite that promotion and understanding of this particular model was difficult across stakeholders, it has been documented as valuable way to envisage and construct interventions (De Silva et al., 2014), and therefore it is widely used across other public health entities such as WHO (Cole et al., 2014). In order to learn about the uptake and effectiveness of the intervention, a process evaluation was undertaken which allowed to recognise the barriers for a better response in children taking part, in particular the lack of previous education on the subject, the cessation in activities by teachers over time and the decreased use of water outlets potentially due to poor maintenance and other water quality concerns (Patel and Hampton, 2011).

Although not validated, the beverage record was chosen considering many of the comparable strengths to the FFQ, including its low participant and researcher burden, low cost, simplicity to code and suitability to estimate specific dietary groups (Christian et al., 2015). The provision of portion size images relevant to the children's context (i.e., bottles, cans, "plastic bags") in addition to the format and structure were elements that facilitated its implementation and acceptability.

7.5 Ways forward (Implications for future policy)

Fiscal policies towards SSB

Whilst obesity can be regarded as a medical condition, it is also the symptom of a larger societal problem and cannot be disentangled from commercial determinants (Kickbusch et al., 2016). These determinants are rooted in the political, economic and social contexts in which people live, cope and make decisions about their diets and health. Whether a product of perfect or imperfect knowledge, these decisions have an impact on the actions and policies implemented by governments, industries and other organisations. Like in many other low-income and middle-income countries, the nutritional transition has had an important effect on the Mexican health landscape and subsequent reaction by the government. Efforts to influence people's food choices in Mexico have targeted the broader socioeconomic environment through enhanced front-of package labelling regulations, restricted marketing of unhealthy foods to children, as well as the promotion of healthy food and beverage products at schools. More recently, Mexico has advanced and lead in the implementation of price/fiscal policies – specifically taxation – to reduce demand and shift population-level intakes of non-core foods high in energy and sugar, including SSBs.

Although not the focus of this thesis, population-wide interventions as part of the upstream or socio-ecological approaches towards obesity-related factors have been strongly advocated by WHO and other public health entities(Obesity policy coalition, 2014, Public Health England, 2017) , with many countries now agreeing to their endorsement. Reduction of sugar-sweetened beverages by means of effective taxation is one of the policies encouraged in the global action plan for management of NCDs 2013-2020, and the scenario of Mexico has served to expand the evidence base of the "effectiveness" of such a measure.

Indeed, in 2014 the Mexican congress introduced a specific excise tax on sugar-sweetened beverages. Non-dairy and non-alcoholic beverages with free sugars suffered an increase of 1 peso per litre equivalent to a 10% increase in price. One-year evaluation of this policy highlighted a decrease in purchases by 6% in taxed beverages (-11mL/capita/day) and an increase of 4% in untaxed beverages such as bottled water (36 mL/capita/day) (Colchero et al., 2016). New findings have suggested further reductions after 2 years of implementation, averaging a decrease in taxed beverages by 9.7% in 2015 (Colchero et al., 2017). It should be noted though that these analyses have only used data on household purchasing from stores, therefore they have not covered beverages consumed from street vendors, prepared at home (such as flavoured water), or consumed in restaurants: all of which are highly popular. The nature of the observational design stands as a limitation as causality cannot be determined considering that other regulations were concomitantly implemented by the government which could have also been responsible for documented changes. Whilst optimistic, implementation of the so-called "soda tax" in Mexico has faced many challenges including the strong opposition and interference by the beverage industry: lobbying, aggressive marketing campaigns and changes in product characteristics (particularly in package sizes with consumers having now the possibility of purchasing from 100 mL to 3 litre soft drinks, the latter at a lower cost). All of these channels of operation have confused people about the health gains from the fiscal measure, and may have consequently attenuated its impact. Sustainability and progression of these short-term benefits will hinge upon the availability of data on changes in real intakes of SSB and changes in BMI, in addition to potential substitutions (Colchero et al., 2016)

Revenues from taxed beverages, nevertheless, play a pivotal role in strengthening health benefits if earmarked to fund obesity prevention programmes and address other barriers to behaviour change. In Mexico, for instance, it was not until 2017 (3 years post-tax) that earmarking of tax revenues became "officially" channelled to specific programmes including the implementation of water fountains in schools and public spaces. Consequently, while the tax has favoured desired changes in purchasing patterns of SSB, progress has been slow to tackle environmental factors such as potable water at home, schools and public places (restaurants, streets, parks). Further, the parallel increment in purchases of bottled water should be posited only as a temporary solution to the bigger barriers still needing to be tackled as it is a practice that represents a threaten to the environment considering the high levels of pollution derived from disposal of plastic bottles in the country.

The World Health Organisation has emphasised that whilst *"population-wide interventions, including price policies and environmental changes, show the most potential to decrease inequalities in the prevention and control of noncommunicable diseases, a combination of these and individual interventions is needed to effectively address the complexity of their causes"*. Therefore, the extent in which legally binding norms can and/ or should be used to improve dietary behaviours (such as minimising consumption of SSB), are context-dependent, but the case of Mexico provides an insight of all the social and economic elements that should be considered.

Reformulation of SSB

Another policy option greatly advocated has been **reformulation**. A review by Miele *et al.* (Miele et al., 2017) examined how different combinations of sweeteners (whether natural or artificial) are used to confer beverages their characteristic sweetness. Some difficulties of producing drinks that could have stable sugar profiles while concomitantly meeting commercial appeal in terms of flavour an approved sweetness and other organoleptic properties were addressed. Many natural sweeteners (sucrose included), as opposed to artificial ones, are limited by their poor stability, rapidly extinguishable sweetness and elevated costs. For dairy products in particular, the level of reformulation is often confounded by the presence of fruit and vegetables (Sutherland et al., 2013). This challenges commercial viability to meet consumer and public health demands on developing more natural, healthier yet equally “tasty” beverages (Miele et al., 2017).

A conclusion by Miele *et al*., and other authors (MacGregor and Hashem, 2014, Hashem et al., 2016) is that achieving changes in sensory perceptions of sweetness through newer beverage formulations should be done gradually, as learnt from other cases such as salt reduction in the UK. Strategies to reduce salt intake in the UK were introduced in 2003 and included voluntary product reformulation by the food industry and a health promotion campaign. Findings following a 10-year period indicated a decrease by 1.4 g in mean intakes in adults and a 30% reduction in salt content in processed food (He et al., 2014, Wyness et al., 2012). Success was achieved by stablishing steady increments for certain food groups with explicit deadlines to meet these targets. Such implementation allowed the population to steadily adjust its palate to lower salt concentrations without compromising purchases of reformulated products, thus no significant industry loses were documented and this could have further encouraged corporative/commercial engagement with the programme (Sutherland et al., 2013).

A similar scenario has been put forward in the UK for sugar reduction (Public Health England, 2017), with a proposed 20% decrease in free sugars across top 9 categories of food that contribute most to intakes in younger populations, amongst others biscuits, ice cream, yogurts, breakfast cereals . Reductions can be reached through reformulation, calorie and/or portion size reductions or shifting consumers to lower or no added sugar food products. This approach is sought to be achieved in a period of 3 to 4 years , with a 5% reduction over the first year of implementation (August 2017). It is important to note though that replacement with artificial sweeteners has been discouraged, as well as the introduction of newer products with higher sugar content. Soft drinks and other SSB are not under the scope of this programme *per se* as there are covered in the industry levy under development by the Treasury, which will take effect from April 2018 (HM Revenue and Customs, 2016). The levy on sugary drinks has also been designed to encourage reformulation and reduction in portion size(HM Revenue and Customs, 2016). Evaluation on the effectiveness of reformulation of sugary products on consumer's health and behaviour is currently on its way (Hashem et al., 2016), which will provide better understanding of how this policy could be best adopted and implemented in this and other countries.

7.6 Conclusion

This thesis has aimed to identify whether public health interventions have been effective to curb consumption of sugar-sweetened beverages and improve water intakes across populations and to identify the intervention components (such as BCTs) that could be driving these changes. The former has been done to inform the development and implementation of a feasibility study in Mexican school-aged children, in whom obesity and consumption levels of SSB remain high. Findings of this thesis show that:

- Individual or community-level interventions (mainly through nutritional education and changes to the closer environment) can induce positive changes in consumption of SSB in children but not in adolescents or adults.
- A potential behaviour change technique that appear to be effective to decrease intakes of SSB in children population is modelling/demonstrating the behaviour in addition to lengthier interventions (with a duration of more than 30 weeks).
- Children from central Mexico represent a group at higher risk of cardio metabolic disease as identified by the prevalence of metabolic syndrome, mainly in those suffering from obesity. Yet, children with normal BMI also appear to fulfil criteria of metabolic syndrome. Improvements in data collection by government entities are imperative to draw more robust conclusions.
- A combined educational and environmental approach with a wider focus on promoting water intakes in school-aged children in central Mexico (Guanajuato) was insufficient to improve consumption patterns of SSB and water. Potential reasons for the documented effects may relate to a poor educational component: short in duration and with limited delivery.

- While school cafeterias appear to adhere to national dietary guidelines in relation to available beverages to be sold to children, barriers to guarantee and improve access to free potable water across educational settings remain unattended.
- Interventions in the future could greatly benefit from the use of validated and enhanced dietary methodologies as well as parental involvement.

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Appendix A Example searching strategy in Medline (Ovid)

Searching strategy: Medline	
1	((sugar$ adj2 beverage$) or (sugar$ adj2 drink$) or (carbonated adj beverage$) or (carbonated adj drink$) or (fizzy adj drink$) or (fizzy adj beverage$) or (liquid$ adj carbohydrate$) or cordial$ or (cola adj beverage$) or (cola adj drink$)).tw.
2	("sugar sweetened beverage$" or "sugar-sweetened beverage$").tw.
3	exp Carbonated Beverages/
4	(sugar containing adj (beverage$ or drink$)).tw.
5	(non alcohol$ adj2 (beverage$ or drink$)).tw.
6	("high energy beverage$" or "high energy drink$").tw.
7	(energy adj2 (drink$ or beverage$)).tw.
8	("sweet$ caloric beverage$" or "sweet$ caloric drink$").tw.
9	(sweet$ adj2 (beverage$ or drink$)).tw.
10	((added adj2 sugar$) and (beverage$ or drink$)).tw.
11	(sugar$ rich adj2 (drink$ or beverage$)).tw.
12	(fruit adj2 juice$).tw.
13	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
14	((non calori* sweet* and (beverage$ or drink$)) or (non nutriti* sweet* and (beverage$ or drink$))).tw.
15	(reduced calori* adj2 (beverage$ or drink$ or juice$)).tw.
16	((sucralose adj2 (beverage$ or drink$ or juice$)) or (neotame adj2 (beverage$ or drink$ or juice$)) or (acesulfame adj3 (beverage$ or drink$ or juice$)) or (saccharin adj2 (beverage$ or drink$ or juice$))).tw.
17	((diet* adj2 (beverage$ or drink$ or juice$)) or (low calori* adj (beverage$ or drink$ or juice$))).tw.
18	(artificial$ sweet$ adj2 (beverage$ or drink$ or juice$)).tw.
19	(artificial* sweet$ and (beverage$ or drink$ or juice$)).tw.
20	((intense sweetener$ and (beverage$ or drink$)) or (intense sweet$ adj3 (beverage$ or drink$))).tw.
21	((sweetening agent and (beverage$ or drink$)) or (artificial$ sweet$ adj2 (beverage$ or drink$))).tw.
22	(sugar-free adj2 (beverage$ or drink$)).tw.
23	14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22
24	(sport$ adj2 (drink$ or beverage$)).tw.
25	13 or 24
26	(health$ adj2 behavio#r).tw.
27	exp Health Behavior/ or exp Health Education/ or exp Health Promotion/
28	(health education or health promotion).tw.
29	((community adj2 intervention$) or (media adj2 intervention$)).tw.
30	((community or school) adj2 (intervention$ or program$)).tw.
31	((family adj2 intervention$) or (parent$ adj2 intervention$)).tw.

32	((lifestyle or life style) adj2 (chang$ or intervention$)).tw.
33	(behavio#r adj (chang$ or intervention$ or strateg$)).tw.
34	(health$ adj2 (attitude$ or school$)).tw.
35	exp Health Knowledge, Attitudes, Practice/
36	(diet$ adj (chang$ or education or behavio#r or pattern$)).tw.
37	exp health policy/ or exp nutrition policy/
38	((nutrition$ adj3 polic$) or (food adj polic$) or (school$ adj polic$)).tw.
39	26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38
40	randomi#ed controlled trial.pt.
41	controlled clinical trial.pt.
42	randomi#ed.ab.
43	randomly.ab.
44	trial.ab.
45	groups.ab.
46	exp intervention studies/ or exp pilot projects/ or exp comparative study/
47	40 or 41 or 42 or 43 or 44 or 45 or 46
48	limit 47 to yr=1990-2014
49	exp Drinking Water/
50	(water adj3 provision).tw.
51	(filter$ adj water).tw.
52	(water adj2 (increas$ or intake$ or consum$)).tw.
53	(drinking water adj (increas$ or intake$ or consum$ or decreas$ or reduction$)).tw.
54	(plain adj2 water).tw.
55	49 or 50 or 51 or 52 or 53 or 54
56	exp animals/ not (exp animals/ and exp humans/)
57	exp Veterinary Medicine/
58	exp Animal Experimentation/
59	56 or 57 or 58
60	(25 and 39 and 48) not 59
61	(23 and 39 and 48) not 59
62	(55 and 39 and 48) not 59

Appendix B Behaviour-change techniques used in interventions targeting healthy eating

Number of technique	Technique	Description [43]	Health examples
(T1)	Provide information on behaviour–health link.	Information about the relationship between the behaviour and its possible or likely consequences in the general case usually based on epidemiological data and not personalised for the individual or health education material relevant to the behaviour.	Provide general information about consequences of high intakes of SSB consumption (risk of obesity, metabolic syndrome, type 2 diabetes, coronary heart disease).
(T2)	Provide information on consequences to the individual	Information about the benefits and costs of action or inaction to the individual or tailored to a relevant group based on that individual's characteristics (demographics, clinical, behavioural or psychological information).	Provide information to participants about benefits of reducing SSB intake and the costs of high SSB consumption.
(T3)	Provide information about others' approval	Involves information about what other people think about the target person's behaviour. Clarifies whether others will like, approve or disapprove of what the person is doing or will do.	
(T4)	Prompt intention formation	Involves encouraging the person to set a general goal or make a behavioural resolution e.g., "I will take more exercise next week" would count as a prompt to intention formation. This is directed towards encouraging people to decide to change	Encourage participants to make behavioural resolution such as: - "I will drink less SSB this week"
(T5)	Prompt barrier identification	Presumes having formed an initial plan to change behaviour. The person is prompted to think about	Identify obstacles at particular instances (such as school or workplaces) in which desired

Number of technique	Technique	Description [43]	Health examples
		potential barriers and identify the ways of overcoming them. Barriers may include challenging goals in specified circumstances. Concerns behavioural, cognitive, emotional, environmental, social and/or physical barriers.	behaviour may be compromised (i.e vending machines with unhealthy drinks) and seek potential solutions to face them (i.e increase water intake by bringing and re-filling a reusable bottle every day).
(T6)	Provide general encouragement	Involves praising or rewarding the person for effort or performance without making this contingent on specific behavioural performance; or “motivating” the person in an unspecified manner. This will include attempts to enhance self-efficacy through argument or persuasion (e.g., telling someone the will be able to perform a behaviour).	
(T7)	Set graded tasks:	Breaking down the target behaviour into smaller easier to achieve tasks enabling the person to build on small successes to achieve target behaviour.	Breaking down target behaviour related to SSB or water intake such as: - Get a re-usable bottle to drink more water. - Remember to bring bottle at school/workplace and refill it with water.
(T8)	Provide instruction on how to perform the behaviour:	Involves telling the person how to perform behaviour or preparatory behaviours, either verbally or in written form. Cooking and exercise classes as well as personal trainers and recipes should always be coded as this technique or T9.	
(T9)	Model/demonstrate the behaviour	Involves showing the person how to perform a behaviour e.g through physical or visual demonstrations of behavioural performance, in person or remotely. Participant “observes”	Demonstrate desirable behaviour by showing participants, for example, how to make a healthier drink.

Number of technique	Technique	Description [43]	Health examples
		behaviour being enacted.	
(T10)	Prompt specific goal setting (behaviour)	The person is encouraged to make a behavioural resolution (take more exercise during the week). Encouraging people to decide to change or maintain change. Different from goal setting outcome as It does not involve planning exactly how the behaviour will be done and either when or where he behaviour or action sequence will be performed.	Motivate participants to make resolution on desired/targeted behaviour. Example: - If thirsty, I will only drink plain water instead of soft drinks.
(T11)	Prompt review of behavioural goals	Involves a review or analysis of the extent to which previously set behavioural goals were achieved (i.e take more exercise next week). Follows setting goals' technique and persons' revision/readjustment to achieve them.	
(T12)	Prompt self-monitoring of behaviour	The person is asked to keep a record of specified behaviours as a method for changing behaviour. Should be completely stated as *intervention component* (diary, completing questionnaire on physical activity).	Use of beverage logs to keep track of intake of liquids/fluids throughout the day.
(T13)	Provide feedback on performance	Involves providing the participant with data about their own recorded behaviour or commenting on a person's behavioural performance –or a discrepancy between one's own performance in relation to others.	
(T14)	Provide contingent rewards	Involves the person using praise or rewards for attempts at achieving a behavioural goal. Might include efforts made towards achieving the behaviour or progress made in preparatory steps towards the behaviour, but	Consists of rewarding attempts for behavioural change or improvements achieved. Example: - Entering participants

Number of technique	Technique	Description [43]	Health examples
		not merely participation in intervention. This can include self-reward.	seen drinking water in a drawing for prizes.
(T15)	Teach to use prompts/cues	The person is taught to identify environmental prompts which can be used to remind them to perform the behaviour (or to perform an alternative, incompatible behaviour) in the case of behaviours to be reduced. Cues could include times of day, particular contexts or technologies such as mobile phone alerts which prompt them to perform the target behaviour.	Identification of cues to engage in desired behaviour such as media messages discouraging intake of SSB.
(T16)	Agree a behavioural contract	Involves written agreement on the performance of an explicitly specified behaviour so that there is written record of the person's resolution witnessed by another.	
(T17)	Prompt practice	Prompt the person to rehearse and repeat the behaviour or preparatory behaviours numerous times. Described as "*building habits or routines*" but is still practice so long as the person is prompted to try the behaviour during the intervention or practice between intervention sessions (i.e as homework).	
(T18)	Use of follow-up prompts	Intervention components are gradually reduced in intensity, duration and frequency over time (e.g telephone or letters instead of face to face sessions and/or provided at longer time intervals).	Use of text messaging.
(T19)	Provide opportunities for social comparison	Involves explicitly drawing attention to other's performance to elicit comparisons.	Necessarily involves a comparison of how an individual's performance compares to others- as it relates to opportunities. Any

Number of technique	Technique	Description [43]	Health examples
			group-based approach is coded yes for this technique as it provides an opportunity *per se* for social comparison.
(T20)	Plan social support/social change	Involves prompting the person to plan how to elicit social support from other people to help him/her achieve their target behaviour/ outcome. Includes support during intervention (i.e. *buddy system*) and at follow up, support provided by the individuals delivering the intervention, partner, friends and family (supporting systems).	
(T21)	Prompt identification as role model/ position advocate	Involves focusing on how the person may be an example to others and affect their behaviour. Also includes opportunities for participants to persuade others of the importance of adopting/changing the behaviour.	Stress role of participant in others' behaviour (i.e parents' intake of SSB and consequently their children's intake).
(T22)	Prompt self-talk	Encourage the person to use talk to themselves (Aloud or silently) before and during planned behaviours to encourage, support and maintain action.	
(T23)	Relapse prevention	Identify situations that increase the likelihood of the behaviour not being performed and apply coping strategies to those situations.	
(T24)	Stress management	Behaviours undertaken to reduce stressors or impact of stressors.	
(T25)	Motivational interviewing	Elicit self-motivating statements and evaluation of own behaviour to reduce resistance to change.	

Appendix C Differences between referential (CDC) and registered percentiles of growth in a sample of 300 male children

	Weight (kg)			Height (cm)			BMI (kg/m^2)		
	Reference*	Registered	Difference Ref-Reg**	Reference*	Registered	Difference Ref-Reg**	Reference*	Registered	Difference Ref-Reg**
6-9 years									
P3	20.0	17.0	-3.0	117.3	107.2	-10.1	13.6	12.9	-0.7
P5	20.6	17.6	-3.0	118.6	110.0	-8.6	13.8	13.2	-0.6
P10	21.5	19.0	-2.5	120.6	112.0	-8.6	14.1	13.6	-0.5
P25	23.2	21.0	-2.2	124.0	116.0	-8.0	14.8	15.0	0.2
P50	25.6	24.0	-1.6	127.9	121.0	-6.9	15.8	16.2	0.4
P75	28.7	31.0	2.3	131.8	130.0	-1.8	17.0	18.3	1.3
P85	-	-	-	-	-	-	17.9	20.6	2.7
P90	32.3	36.2	3.9	135.4	138.0	2.6	18.7	21.5	2.8
P95	35.1	45.0	9.9	137.6	140.0	2.4	20.0	23.6	3.6
P97	37.2	45.9	8.7	139.0	141.8	2.8	21.2	24.8	3.6
10-13 years									
P3	29.3	25.0	-4.3	135.4	127.0	-8.4	14.7	13.9	-0.8
P5	30.4	26.0	-4.4	137.1	129.4	-7.7	15.0	14.7	-0.3
P10	32.2	28.0	-4.2	139.7	131.7	-8.0	15.5	15.5	0.0
P25	35.7	32.0	-3.7	144.1	138.0	-6.1	16.4	16.6	0.2
P50	40.5	40.5	0.0	149.1	144.0	-5.1	17.8	19.2	1.4
P75	46.6	51.0	4.4	154.1	152.3	-1.8	19.7	22.4	2.7
P85	-	-	-	-	-	-	21.0	24.9	3.9
P90	53.7	60.3	6.6	158.8	159.0	0.2	22.1	26.1	4.0
P95	59.0	70.7	11.7	161.6	166.0	4.4	24.2	28.1	3.9
P97	63.0	73.3	10.3	163.4	169.0	5.6	26.0	29.1	3.1
14-20 years									
P3	49.3	37.0	-12.3	161.3	148.5	-12.8	17.3	15.4	-1.9
P5	50.8	39.5	-11.3	163.1	149.0	-14.1	17.7	16.4	-1.3
P10	53.3	43.0	-10.3	165.8	152.0	-13.8	18.3	17.0	-1.3
P25	58.2	49.0	-9.2	170.4	158.5	-11.9	19.6	18.3	-1.3
P50	64.7	56.5	-8.2	175.3	164.0	-11.3	21.2	21.0	-0.2
P75	72.8	64.5	-8.3	180.2	169.0	-11.2	23.4	24.0	0.6
P85	-	-	-	-	-	-	24.9	25.8	0.9
P90	82.1	73.0	-9.1	184.5	172.0	-12.5	26.1	26.8	0.7
P95	88.8	83.2	-5.6	187.0	175.0	-12.0	28.3	29.8	1.5
P97	93.8	86.5	-7.3	188.6	177.0	-11.6	29.9	32.9	3.0

*Corresponding median weight matched to age range from CDC growth charts.
**Difference between Reference and registered values

Appendix D Differences between referential (CDC) and registered percentiles of growth in a sample of 300 female children

	Weight (kg)			Height (cm)			BMI (kg/m^2)		
	Reference*	Registered	Difference Ref-Reg**	Reference*	Registered	Difference Ref-Reg**	Reference*	Registered	Difference Ref-Reg**
6- 9 y									
P3	19.5	17.0	-2.5	117.1	108	-9.1	13.3	12.81	-0.49
P5	20.1	17.3	-2.8	118.3	109	-9.3	13.5	13.47	-0.03
P10	21.1	19.0	-2.1	120.3	111.6	-8.7	13.9	14.24	0.34
P25	23.0	22.0	-1.0	123.7	115	-8.7	14.7	15.10	0.4
P50	25.6	25.0	-0.6	127.6	122	-5.6	15.8	16.26	0.46
P75	29.0	30.0	1.0	131.6	129	-2.6	17.3	18.69	1.39
P85	-	-	-	-	-	-	18.3	19.86	1.56
P90	33.0	35.0	2.0	135.3	135	-0.3	19.1	21.26	2.16
P95	36.0	38.0	2.0	137.6	139.7	2.1	20.7	23.02	2.32
P97	38.3	42.0	3.7	139.1	142.1	3.0	21.9	25.24	3.34
10-13 y									
P3	29.9	23.8	-6.1	137.1	125	-12.1	14.5	13.16	-1.34
P5	31.0	25.0	-6.0	138.9	128.5	-10.4	14.8	13.49	-1.31
P10	32.9	27.8	-5.1	141.7	131	-10.7	15.4	14.93	-0.47
P25	36.6	32.0	-4.6	146.2	138	-8.2	16.5	16.49	-0.01
P50	41.6	40.0	-1.6	151.2	144	-7.2	18.1	18.72	0.62
P75	48.1	50.0	1.9	156.1	154	-2.1	20.2	21.67	1.47
P85	-		-	-	-	-	21.7	23.87	2.17
P90	55.7	58.1	2.4	160.6	161	0.4	22.9	24.71	1.81
P95	61.4	64.3	2.9	163.2	163.3	0.1	25.2	28.64	3.44
P97	65.6	75.7	10.1	164.9	166.4	1.5	27.1	29.93	2.83
14-20 y									
P3	43.3	36.4	-6.9	150.7	143.6	-7.1	16.8	15.92	-0.88
P5	44.4	38.0	-6.4	152.3	146.2	-6.1	17.2	16.09	-1.11
P10	46.3	41.0	-5.3	154.6	148	-6.6	17.8	17.01	-0.79
P25	50.0	44.9	-5.1	158.6	151	-7.6	19.1	18.55	-0.55
P50	55.2	50.0	-5.2	162.9	156	-6.9	20.9	21	0.1
P75	62.3	58.0	-4.3	167.3	160	-7.3	23.4	23.74	0.34
P85	-	-	-	-	-	-	25.2	26.1	0.9
P90	71.6	70.0	-1.6	171.2	164	-7.2	26.7	27.08	0.38
P95	79.5	74.8	-4.7	173.6	167.4	-6.2	29.6	29.8	0.2
P97	86.2	76.9	-9.3	175.1	168	-7.1	32.2	31.38	-0.82

*Corresponding median weight matched to age range from CDC growth charts.
**Difference between Reference and registered values

Appendix E Ethical approval HRAEB (Mexico)

CEI-19-15

SALUD
SECRETARÍA DE SALUD

HOSPITAL REGIONAL DE ALTA ESPECIALIDAD
DEL BAJÍO

COMITÉ DE ÉTICA EN INVESTIGACIÓN

Registro ante Comision Nacional de Bioetica:
CNBCEI-11-0001-2009.05.01.

HOSPITAL REGIONAL
ALTA ESPECIALIDAD
B A J Í O

León, Gto. a 10 de septiembre 2015.

Asunto:

Respuesta del Comité de Ética en Investigación a la propuesta de revisión de los documentos del Proyecto "Intervención escolar para disminuir el consumo de bebidas azucaradas en León, Guanajuato."

Dra. Luz Elvia Vera Beccerra
Investigador principal

Estimada Dra.:
Le informo que el Comité de Ética en Investigación del Hospital Regional de Alta Especialidad del Bajío ha evaluado los siguientes documentos:

- Protocolo del proyecto

De acuerdo a lo anterior, ha resuelto emitir la siguiente decisión: **APROBADO**

Se le señalan observaciones que se sugiere corregir antes de iniciar el protocolo:

En el apartado de "Aspectos éticos" se sugiere citar únicamente la versión más reciente de la Declaración de Helsinki, que es la del año 2013.
En los formatos de consentimiento informado, se sugiere mencionar los datos de contacto (dirección y teléfono) de por lo menos dos investigadores que participan en el estudio. En los formatos de consentimiento informado se sugiere que se mencione el hecho de que los investigadores van a revisar las mochilas de los alumnos.

El código asignado por el comité es: **CEI-19-15**. Esté código deberá estar presente en la Carta de Consentimiento y/o el Aviso de Privacidad.

De acuerdo al cronograma de actividades y a los procedimientos internos de este Comité, será necesario que usted presente un reporte de avances cada 6 meses durante el desarrollo y al finalizar el proyecto, así también deberá informar cualquier modificación que realice al protocolo original.

Le reitero el apoyo del CEI para el logro de su proyecto

Dr. Rafal Ludwik Smolinski
Presidente
Comité de Ética en Investigación,
Hospital Regional de Alta Especialidad
del Bajío

María Maldonado Vega
Dra. María Maldonado Vega
Secretario
Comité de Ética en Investigación,
Hospital Regional de Alta Especialidad
del Bajío

Appendix F Ethical approval Leeds

Performance, Governance and Operations
Research & Innovation Service
Charles Thackrah Building
101 Clarendon Road
Leeds LS2 9LJ Tel: 0113 343 4873
Email: ResearchEthics@leeds.ac.uk

UNIVERSITY OF LEEDS

Elisa J. Vargas-Garcia
School of Food Science & Nutrition
University of Leeds
Leeds, LS2 9JT

MaPS and Engineering joint Faculty Research Ethics Committee (MEEC FREC)
University of Leeds

26 February 2018

Dear Elisa

Title of study	**An intervention to decrease sugar-sweetened beverages by promoting water intake in Mexican school-aged children**
Ethics reference	**MEEC 15-002**

I am pleased to inform you that the application listed above has been reviewed by the MaPS and Engineering joint Faculty Research Ethics Committee (MEEC FREC) and following receipt of your response to the Committee's initial comments, I can confirm a favourable ethical opinion as of the date of this letter. The following documentation was considered:

Document	Version	Date
MEEC 15-002 Appendix 7. Aproval letter Ethics Commitee Mexico.pdf	1	21/10/15
MEEC 15-002 Ethical_Review_Form_Elisa Vargas_Garcia.doc	2	21/10/15
MEEC 15-002 Appendix 1. Audit protocol translated.pdf	2	21/10/15
MEEC 15-002 Appendix 2. Parental informed consent intervention.pdf	2	21/10/15
MEEC 15-002 Appendix 2. Parental consent form control.pdf	2	21/10/15
MEEC 15-002 Appendix 3. assent form children translated.pdf	2	21/10/15
MEEC 15-002 Appendix 4. Questionnaire translated.pdf	2	21/10/15
MEEC 15-002 Appendix 5. Urine colour chart translated.pdf	2	21/10/15
MEEC 15-002 Appendix 6. beverage image questionnaire translated.pdf	2	21/10/15
MEEC 15-002 Fieldwork assessment form- low risk.pdf	2	21/10/15

Please notify the committee if you intend to make any amendments to the original research as submitted at date of this approval, including changes to recruitment methodology. All changes must receive ethical approval prior to implementation. The amendment form is available at http://ris.leeds.ac.uk/EthicsAmendment.

Please note: You are expected to keep a record of all your approved documentation, as well as documents such as sample consent forms, and other documents relating to the study. This should be kept in your study file, which should be readily available for audit purposes. You will be given a two week notice period if your project is to be audited. There is a checklist listing examples of documents to be kept which is available at http://ris.leeds.ac.uk/EthicsAudits.

We welcome feedback on your experience of the ethical review process and suggestions for improvement. Please email any comments to ResearchEthics@leeds.ac.uk.

Yours sincerely

Jennifer Blaikie
Senior Research Ethics Administrator, Research & Innovation Service
On behalf of Professor Gary Williamson, Chair, MEEC FREC

CC: Student's supervisor(s)

Appendix G Sample size calculation for pilot trial

. sampsi 657.9 900, sd1(802) a(0.05) power (0.9)

Test Ho: m1 = m2, where m1 is the mean in population 1 and m2 is the mean in population 2

Assumptions:

alpha = 0.0500 (two-sided)
power = 0.9000
m1 = 657.9 (current water intake in mL)
m2 = 900 (expected water intake from intervention)
sd1 = 802 (Standard deviation to the mean of water intake)
sd2 = 802
n2/n1 = 1.00

Estimated required sample sizes:

n1 = 231
n2 = 231

→

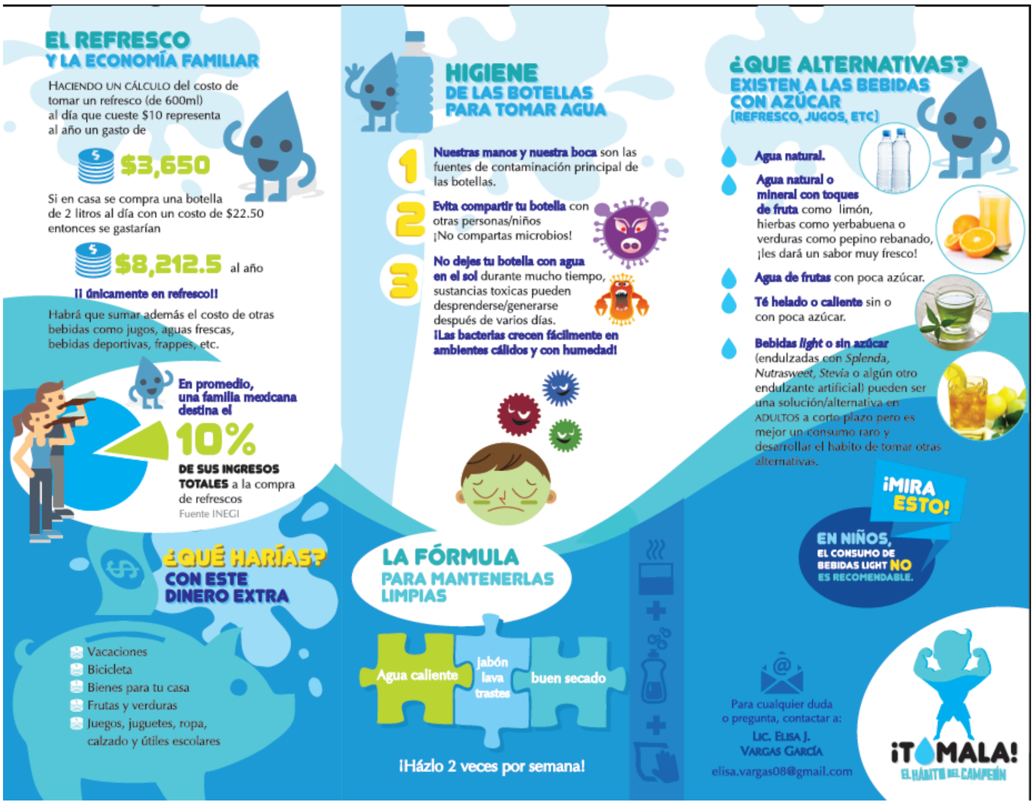
Accounting for 10 % attrition

n1 = 254
n2 = 254

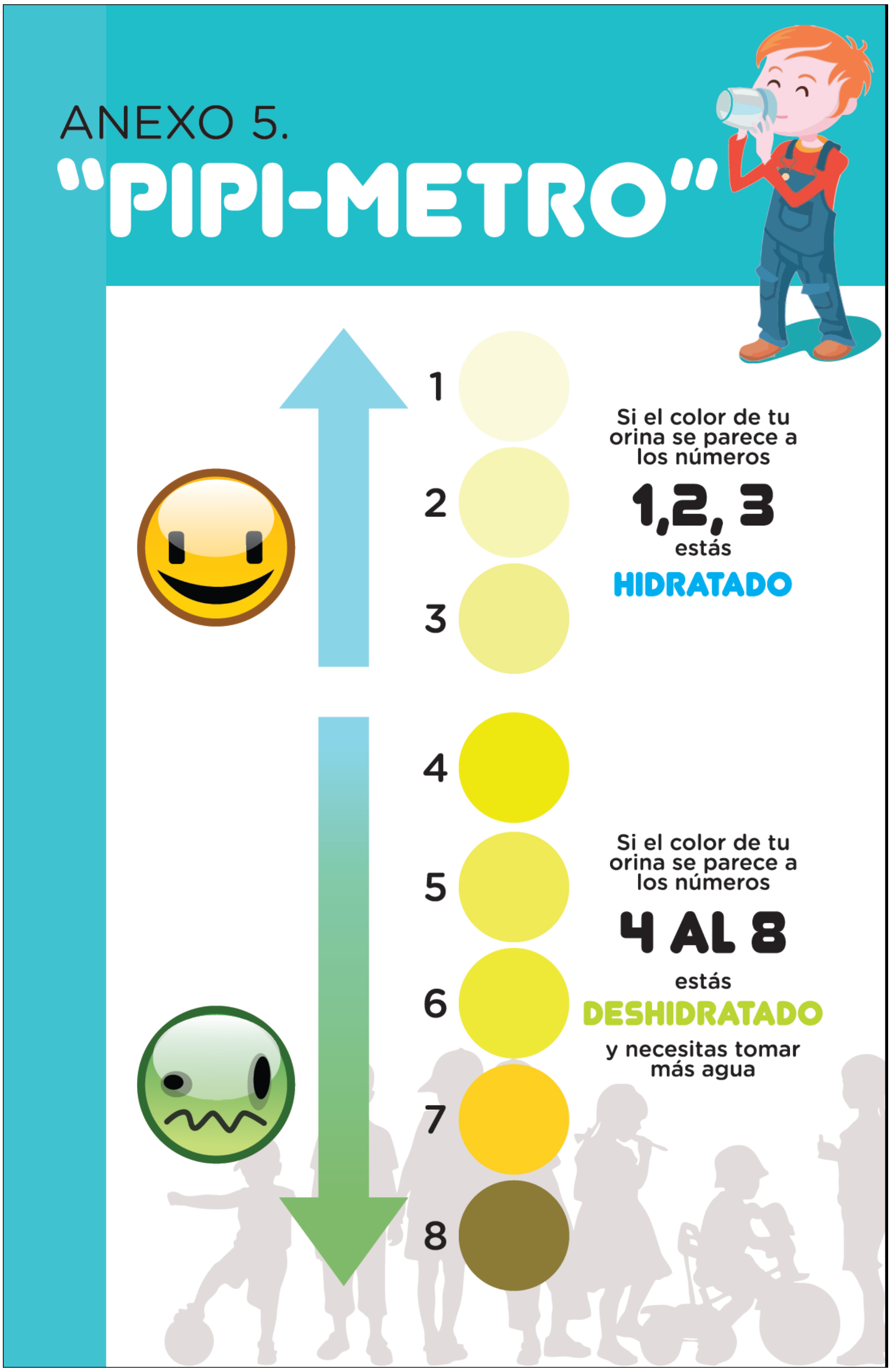
Appendix H Materials for the intervention: Snakes and ladders and Memory game

¡TÓMALA!
LA MEMORIA DE LAS BEBIDAS AZUCARADAS
¡AGUAS! SI NO TOMAS AGUA
LA COCA 12 DE AZÚCAR
EL GUEITOREI 12 DE AZÚCAR
EL FIUZ-TI 9 a 10 DE AZÚCAR
EL YOGUR 5 DE AZÚCAR
EL CHOCOMIL 2 a 3 DE AZÚCAR
EL DELBAYE 5 a 9 DE AZÚCAR
EL LICUADO 2 a 3 DE AZÚCAR
LA NARANJADA 3
EL FRUTCI 6
EL JUMECS 5 DE AZÚCAR
EL AGUA NATURAL SABORIZADA 0 DE AZÚCAR
EL AGÜITA 3 DE AZÚCAR
EL FRAPPÉ 6 DE AZÚCAR
EL YACUL 2 a 3 DE AZÚCAR
EL AGUA 0 DE AZÚCAR
EL AGUA FRESCA 3 DE AZÚCAR
¡TÓMALA! EL HÁBITO DEL CAMPEÓN
¡AGUAS! SI NO TOMAS AGUA
¡TÓMALA! EL HÁBITO DEL CAMPEÓN
¡AGUAS! SI NO TOMAS AGUA
LA COCA 12 DE AZÚCAR
EL GUEITOREI 12 DE AZÚCAR
EL FIUZ-TI 9 a 10 DE AZÚCAR
EL YOGUR 5 DE AZÚCAR
EL CHOCOMIL 2 a 3 DE AZÚCAR
EL DELBAYE 5 a 9 DE AZÚCAR
EL LICUADO 2 a 3 DE AZÚCAR
LA NARANJADA 3
EL FRAPPÉ 6 DE AZÚCAR
EL YACUL 2 a 3 DE AZÚCAR
EL AGUA 0 DE AZÚCAR
EL AGUA FRESCA 3 DE AZÚCAR
EL FRUTCI 6
EL JUMECS 5 DE AZÚCAR
EL AGUA NATURAL SABORIZADA 0 DE AZÚCAR
EL AGÜITA 3 DE AZÚCAR

Appendix I Posters placed at intervention sites


EL REFRESCO
Y LA ECONOMÍA FAMILIAR
HACIENDO UN CÁLCULO del costo de tomar un refresco (de 600ml) al día que cueste $10 representa al año un gasto de
$3,650
Si en casa se compra una botella de 2 litros al día con un costo de $22.50 entonces se gastarían
$8,212.5 al año
¡¡ únicamente en refresco!!
Habrá que sumar además el costo de otras bebidas como jugos, aguas frescas, bebidas deportivas, frappes, etc.
En promedio, una familia mexicana destina el
10%
DE SUS INGRESOS TOTALES a la compra de refrescos
Fuente INEGI
¿QUÉ HARÍAS? CON ESTE DINERO EXTRA
Vacaciones
Bicicleta
Bienes para tu casa
Frutas y verduras
Juegos, juguetes, ropa, calzado y útiles escolares
HIGIENE
DE LAS BOTELLAS PARA TOMAR AGUA
1
Nuestras manos y nuestra boca son las fuentes de contaminación principal de las botellas.
2
Evita compartir tu botella con otras personas/niños ¡No compartas microbios!
3
No dejes tu botella con agua en el sol durante mucho tiempo, sustancias toxicas pueden desprenderse/generarse después de varios días.
¡Las bacterias crecen fácilmente en ambientes cálidos y con humedad!
LA FÓRMULA
PARA MANTENERLAS LIMPIAS
Agua caliente
jabón lava trastes
buen secado
¡Házlo 2 veces por semana!
¿QUE ALTERNATIVAS?
EXISTEN A LAS BEBIDAS CON AZÚCAR
(REFRESCO, JUGOS, ETC)
Agua natural.
Agua natural o mineral con toques de fruta como limón, hierbas como yerbabuena o verduras como pepino rebanado, ¡les dará un sabor muy fresco!
Agua de frutas con poca azúcar.
Té helado o caliente sin o con poca azúcar.
Bebidas light o sin azúcar (endulzadas con Splenda, Nutrasweet, Stevia o algún otro endulzante artificial) pueden ser una solución/alternativa en ADULTOS a corto plazo pero es mejor un consumo raro y desarrollar el habito de tomar otras alternativas.
¡MIRA ESTO!
EN NIÑOS, EL CONSUMO DE BEBIDAS LIGHT NO ES RECOMENDABLE.
Para cualquier duda o pregunta, contactar a:
LIC. ELISA J. VARGAS GARCÍA
elisa.vargas08@gmail.com
¡TOMALA!
EL HÁBITO DEL CAMPEÓN

Appendix J Urine Colour Chart



Appendix K Water Break registry for teachers

Registro "Pausa para tomar agua"

Septiembre

Semana	*Lunes*	*Martes*	*Miércoles*	*Jueves*	*Viernes*	*Dificultades en la implementación? (detallar)*
28 al 30	28	29	30			

Octubre

Semana	*Lunes*	*Martes*	*Miércoles*	*Jueves*	*Viernes*	*Dificultades en la implementación? (detallar)*
1 al 3			1	2	3	
5 al 9	5	6	7	8	9	
12 al 16	12	13	14	15	16	
19 al 23	19	20	21	22	23	
26 al 30	26	27	28	29	30	

Noviembre

Semana	*Lunes*	*Martes*	*Miércoles*	*Jueves*	*Viernes*	*Dificultades en la implementación? (detallar)*
2 al 6	2	3	4	5	6	
9 al 13	9	10	11	12	13	
16 al 20	16	17	18	19	20	
23 al 27	23	24	25	26	27	

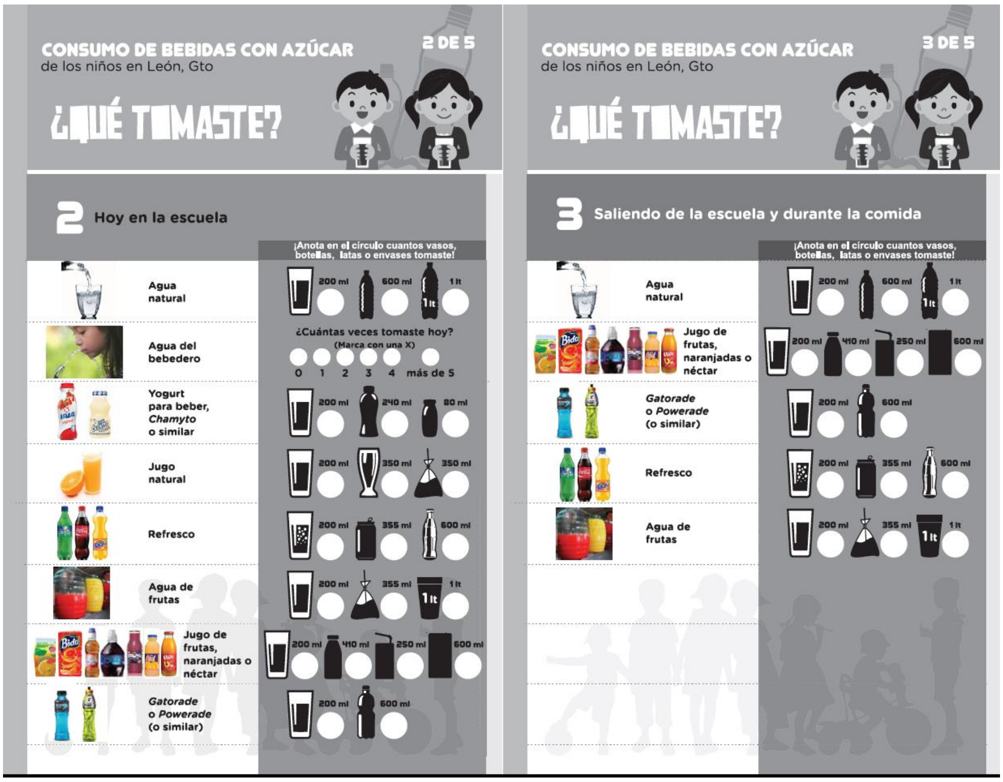
Diciembre

Semana	*Lunes*	*Martes*	*Miércoles*	*Jueves*	*Viernes*	*Dificultades en la implementación? (detallar)*
30 al 4	30	1	2	3	4	
7 al 11	7	8	9	10	11	
14 al 18	14	15	16	17	18	

Appendix L Teachers record of drinks brought from school

ID (No de lista)	**Tipo de bebida** (refresco, jugo, agua natural,agua de frutas, bebida deportiva, bebida saborizada (agüitas), yogurt bebible)	**Presentación de la bebida** (botella, caja, lata, envase de plástico)	**Tamaño de la bebida** (ml)	**Marca de la bebida**	**Dia de registro** (dd/mm/año)
Ejemplo No. 25	***Nectar de frutas***	***Botella vidrio***	***408 ml***	***Del Valle***	***14/09/2015***
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					
16.					

Appendix M Beverage Questionnaire



CONSUMO DE BEBIDAS CON AZÚCAR
de los niños en León, Gto

4 DE 5

¿QUÉ TOMASTE?

4 Por la tarde antes de cenar

¡Anota en el círculo cuantos vasos, botellas, latas o envases tomaste!

Agua natural	200 ml	600 ml	1 lt	
Jugo de frutas, naranjadas o néctar	200 ml	410 ml	250 ml	600 ml
Refresco	200 ml	355 ml	600 ml	
Agua de frutas	200 ml	355 ml	1 lt	
Gatorade o *Powerade* (o similar)	200 ml	600 ml		
Frappe	400 ml			

CONSUMO DE BEBIDAS CON AZÚCAR
de los niños en León, Gto

5 DE 5

¿QUÉ TOMASTE?

5 Durante la cena y antes de ir a dormir

¡Anota en el círculo cuantos vasos, botellas, latas o envases tomaste!

Agua natural	200 ml	600 ml	1 lt
Jugo de caja	200 ml		
Refresco	200 ml	355 ml	600 ml
Agua de frutas	200 ml	355 ml	1 lt
Gatorade o *Powerade* (o similar)	200 ml	600 ml	
Leche con chocolate	200 ml	350 ml	

Appendix N Audit protocol for SSB and water access

1. Mapping location of SSB and water access points (vending machines, water fountains, water coolers, cafeterias) inside schools and outside them (convenience stores, small supermarkets, stalls, bakeries, cafes,.)
2. Assessment of public water available
    a. Identify number of units (both functioning and broken)
    b. Take pictures of conditions of water fountains.
    c. Identify if access of units would be limited to certain people in the school (e.g only staff).
    d. 6Produce/plot information in chart as follows:

Type of water access point	Date collected	Person collecting information	Accessibility

3. Beverage sales assessment
    a. Sample all beverage sale points (inside and outside- if possible)
        i. Inside: School canteens/cafeterias, vending machines –if being the case
        ii. Outside: convenience stores, small supermarkets, stalls, bakeries, cafes, luncheonettes, etc.
4. Point of purchase labelling (baseline and post intervention)
    a. Identify at selling points if there is any signage highlighting healthier drinking alternatives
5. Record beverage sizes, brands and prices at every selling point (photograph if possible)
    a. Produce/plot information in chart as follows:

INSIDE SCHOOL

Type of beverage access point (cafeteria, school canteen)	Date collected	Person collecting information	Brand	Size (mL)	Price	Accessibility

OUTSIDE SCHOOL

Type of beverage access point (convenience stores, small supermarkets, stalls, bakeries, cafes, luncheonettes)	Date collected	Person collecting information	Brand	Size (mL)	Price	Accessibility

Appendix O Questionnaire for children process evaluation

Tacha x la bebida que tiene <u>más azúcar</u> (cross the drink that has most sugar in it)

¿Qué le pasa al cuerpo si <u>no tomamos</u> suficiente <u>agua</u>? (what happens to the body if we don't drink enough water?)

____

____

____

¿Qué pasa si tomamos <u>mucho</u> refresco, jugos y otras bebidas con azúcar? (what happens if we drink too many soft drinks, juices and other SSB?)

____

____

____

Tacha x unarespuesta (**cross an answer)**

1. En clase tenemos una "pausa para tomar agua" (**During class time, "we have a water break")**
   Si No
2. Tomo agua en el bebedero de la escuela (I **drink water at the water fountain**)
   Si No
3. Tomo más agua en la escuela que en casa (I drink more wáter at school than at home)
   Si No
4. En la escuela compro refresco u otras bebidas con azúcar (**I purchase/buy soft drinks at school)** Si No
5. En casa preferimos tomar agua sola en lugar de refrescos o jugos (**at home we prefer to drink plain water instead of soft drinks or juices)**
   Si No
6. En casa siempre hay refresco, jugo u otras bebidas con azúcar(**At home there are always soft drinks, juices and other beverages with sugar)**
   Si No

7. Cerca de la escuela, hay muchos puestos o tienditas que venden bebidas con azúcar (refresco, jugos, licuados, frappes) **Around the school there are many shops or stolls that sell SSB**
   Si No

Tacha x Cuántas veces jugaste con la memoria **(Cross the times you played the memory game)**

Ninguna 1 2 3 4

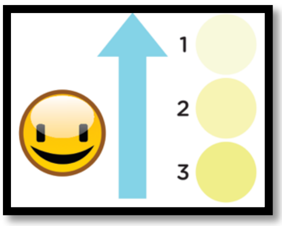
Te gusto? Si ☺☺ No 😐😐

Tacha x Cuantas veces jugaste 'Serpientes y escaleras'? **(Cross the times you played "snakes and ladders")**

Ninguna 1 2 3 4

Te gusto? Si ☺☺ No 😐😐

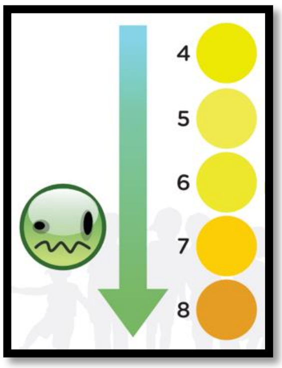
Une los dibujos con una línea (match the drawings)



Si el color de tu orina se parece a estos números estás: **(if the colour of your urine looks like these numbers you are:)**

Deshidratado/dehydrated

Hidratado/hydrated



Recuerdas algún dato de este poster? /**Do you remember any information from this poster?**

Escríbelo aquí/**write it here!**

____

____

____

Appendix P Socioeconomic data questionnaire

Edad del papá

___15 a 19 años ___20 a 30 años ___30 a 40 años ____40 a 60 años ____Mayor de 60 años

Nivel último de estudios del papá

______ Posgrado
______ Licenciatura
______Carrera Técnica o comercial
______Preparatoria/Bachillerato
______Secundaria
______Primaria
______ Primaria incompleta
______Sin estudios

Ocupación/empleo actual del papá

___Profesionista
___Obrero o trabajador en mano de obra
___Empresario
___ Comerciante
___ Técnico
___ No trabaja
Otro: _____________

Edad de la mamá

___15 a 19 años ___20 a 30 años ___30 a 40 años ____40 a 60 años ____Mayor de 60 años

Nivel último de estudios de la mamá

______ Posgrado
______ Licenciatura
______Carrera Técnica o comercial
______Preparatoria/Bachillerato
______Secundaria
______Primaria
______ Primaria incompleta
______Sin estudios

Ocupación/empleo actual de la mamá

___Profesionista
___ Obrera o trabajador de mano de obra
___ Comerciante
___ Técnica
___ No trabaja
___ Ayuda domestica
____ Hogar (ama de casa)
Otro: _____________

Total de personas que habitan en casa : 2 3 4 5 6 7 8 o más

Total de cuartos, piezas o habitaciones con que cuenta su vivienda (no incluir baños, medios baños, pasillos, patios ni azoteas):

1 2 3 4 5 6 7 o más

Número de **baños completos con regadera y W.C**.(excusado) que hay para uso exclusivo de los integrantes de su hogar:
1 2 3 4 5 o más

¿La **regadera** funciona en alguno de los baños**?** SI ___ NO___

Contando todos los focos que utiliza para iluminar su hogar,incluyendo los de techos, paredes y lámparas de buró o piso, ¿cuántos **focos** tiene su vivienda? ____ 0 a 5 focos ____ 6 a 10 focos _____11 a 15 focos ________16 a 20 focos _______21 o más

En casa cuentan con:

- Agua entubada dentro de la vivienda SI ___ NO __
- Sistema de drenaje SI ___ NO ___
- Estufa de gas o electrica SI ___ NO ___

El piso de la vivienda es de: ____ Tierra ____ Cemento o firme ____Madera, mosaico u otro recubrimiento ___ Otro

Número de autmóviles propios (Excluyendo taxis) que tienen en su hogar: 1 2 3 4 o más

Pensando en la **persona que aporta la mayor parte del ingreso** en su hogar, ¿cuál fue el último año de estudios que completó?

______ Posgrado (maestría o doctorado)

______ Licenciatura

______Carrera Técnica o comercial

______Preparatoria/Bachillerato

______Secundaria

______Primaria

______ Primaria incompleta

______Sin estudios

Appendix Q Feedback questionnaire to teachers taking part in intervention groups

Durante los últimos 3 meses, su grupo ha sido partícipe de la Intervención "Aguas si no tomas agua" encaminada a promover el consumo de agua simple y desalentar el consumo de bebidas azucaradas en los niños.

Over the last 3 months, your group has been part of the intervention "Aguas si no tomas agua" which has sought to promote water intake and discourage consumption of SSB amongst children.

¿Podría regalarnos un momento para contestar el siguiente cuestionario? Es importante para nosotros saber qué tan útiles fueron para los niños los diferentes elementos y actividades de la intervención. **Could you give us a moment of your time to answer the following questionnaire?. It is important for us to know how useful were for children the different intervention elements and activities.**

Nombre del profesor:____________

Grupo:_______________

¿Su grupo recibió con anterioridad algún tipo de plática sobre la importancia de tomar agua y las consecuencias de tomar muchas bebidas azucaradas?

Did your group previously receive any talk/session on the importance of drinking plain water and the consequences of drinking to many SSBs?

- ☐ No
- ☐ Si/**yes**

Detallar (número de pláticas/sesiones, duración, actividades principales)

Provide further details (number of sessions, lenght, activities implemented)

____

____

____

1. ¿Cómo se benefició la escuela al ser parte de la Intervención "Aguas si no tomas agua"? (puede elegir más de una)

How did the school beneffited from the intervention (You can select more than one)

- ☐ Logró promover la importancia del consumo del agua simple por encima del consumo de bebidas azucaradas/ **It improved the consumption of water over intake of SSB**
- ☐ Aumentó el conocimiento sobre los beneficios de tomar agua/**It increased knowledge on the bennefits of drinking plain water**
- ☐ Aumentó el conocimiento sobre las consecuencias de tomar muchas bebidas azucaradas/ **It increased knowledge on the consequences of drinking too many SSB**
- ☐ Incrementó el compañerismo en los niños mediante los juegos implementados/**it increased colegiality amongst children through implemented games**
- ☐ Ayudó a conservar y/o mejorar las condiciones del bebedero escolar/**It helped mainteining/improving conditions of the water fountain**
- ☐ Ayudó a conservar y/o mejorar la oferta de bebidas que se venden en la tiendita escolar / **It helped maintaining/improving drinks on offer on the school's canteen.**
- ☐ **Otra_____________________ (others)**
- ☐ Ninguno de los anteriores/**None of the above**

2. ¿Hasta qué punto sus alumnos han mostrado un interés en tomar más agua?

To what extent have your pupils shown an increased interest in drinking more water?

☐ Están **mucho más** interesados /**much more interested**
☐ Están **un tanto más** interesados/ **slightly more interested**
☐ No es evidente el interés/**no evident interest**

3. ¿Hasta qué punto sus alumnos han mostrado un interés en tomar menos bebidas azucaradas (refresco, jugos, "agüitas", etc)?

To what extent have your pupils shown an increased interest in drinking less SSB?

☐ Están **mucho más** interesados /**much more interested**
☐ Están **un tanto más** interesados/ **slightly more interested**
☐ No es evidente el interés/**no evident interest**

4. ¿Cuáles de los siguientes aspectos encontró valioso o benéfico como parte de esta intervención? (Puede seleccioanr más de una opción)

Which of the following intervention elements did you find valuable? (You can select more than one)

☐ Juego de serpientes y escaleras/**Snakes and ladders**
☐ Juego de memoria/**Memory game**
☐ Entrega de botellas reusables/**delivery of water bottles**
☐ Pipimetro/**Urine colour chart**
☐ Pausa para tomar agua/**Water break**
☐ Banners/Posters con información sobre bebidas azucaradas **Posters**
☐ Ninguno de los anteriores **/none of the above**

5. ¿Cuáles de los siguientes aspectos fueron más interesantes para los niños? (Puede seleccionar más de una opción)

☐ Juego de serpientes y escaleras/**Snakes and ladders**
☐ Juego de memoria/**Memory game**
☐ Entrega de botellas reusables/**delivery of water bottles**
☐ Pipimetro/**Urine colour chart**
☐ Pausa para tomar agua/**Water break**
☐ Banners/Posters con información sobre bebidas azucaradas **Posters**
☐ Ninguno de los anteriores **/none of the above**

6. En su opinión, la oferta de bebidas en la cooperativa/tiendita escolar es

☐ Adecuada
☐ Inadecuada
☐ No sé

7. ¿Tomar más agua es considerado importante para sus alumnos y para los padres de familia?

In your opinion, is drinking plain water seen as important by your pupils and their parents?

Para Alumnos/ **Pupils**

☐ Nada importante/**not important**
☐ Un tanto importante/**slightly important**
☐ Muy importante/**very important**

Para Papás /**Parents**

☐ Nada importante/**not important**
☐ Un tanto importante/**slightly important**
☐ Muy importante/**very important**

8. Considera que más niños trajeron agua simple como parte de su lunch/refrigerio escolar?

Do you think more children brought water simple as a result of the intervention?

☐ Sí/**yes**
☐ No/**no**
☐ No sé/**unsure**

9. En promedio, ¿cuántos niños en su grupo traen agua simple a la escuela?

On average, how many children in your class bring plain water with them to school?

______niños/niñas

10. En promedio ¿cuántos niños en su grupo conservaron la botella de plástico entregada al principio de la intervención?

On average, how many children in your class brought the water bottle provided at the beginning of the intervention?

________ niños/niñas

¿A qué cree que se deba lo anterior? /why do you think this was?

____

____

____

11. Las actividades propuestas fueron fácles de implementar/were activities proposed, easy to be implemented?

☐ Si
☐ No

¿Qué resultó fácil o dificil? (what was easy or difficult about it?)

____

____

____

12. En su opinión, ¿cuáles son las principales barreras y/o obstáculos para lograr que los niños tomen más agua dentro de la escuela? /**In your opinion what are the main barriers/obstacles so that children drink more water?**

____

____

____

13. En su opinión, ¿cuáles son las principales barreras y/o obstáculos para que los niños tomen menos bebidas azucaradas?/ **In your opinion what are the main barriers/obstacles so that children drink fewer SSB?**

____

____

____

¿Tiene algun otro comentario sobre la intervención? /**Do you have any further comments about the intervention?**

____

____

Appendix R Quantiles of changes on SSB (A) and water (B) consumption throughout the day between groups against quantiles of normal distribution