University of Strathclyde

School of Psychological Sciences and Health

Department of Physical Activity of Health

Adapting an existing preschool-based intervention for use in the Scottish preschool setting to prevent childhood obesity and its co-morbidities

Stephen Malden BSc. (Hons), MPH

Submitted to the University of Strathclyde as a thesis for the degree of Doctor of Philosophy in Physical Activity for Health

August 2020

Declaration of authenticity and author's rights

This thesis is the result of the author's original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.

Signed:

Date: 07/02/2020

Abstract

Background: Scotland has one of the highest rates of childhood obesity in Europe, and efforts to prevent obesity in young children are needed. This thesis aimed to highlight the detrimental health impacts of obesity in younger children and adapt an existing obesity prevention intervention for use in Scottish preschools.

Methods: This thesis presents five manuscripts. The first is a systematic review of the relationship between obesity and co-morbid conditions in childhood (specifically, asthma, vitamin D deficiency, iron deficiency, flat-footedness and allergies). Two methodology manuscripts are then presented, one detailing the steps taken to adapt the ToyBox intervention for use in Scottish preschools, which is followed by a protocol for the feasibility cluster randomised controlled trial (cRCT) of the adapted intervention. Results reporting on intervention fidelity, recruitment rates and secondary outcome measures of the cRCT is first presented, followed by a manuscript detailing acceptability of the intervention using both qualitative and quantitative methods.

Results: The systematic review identified 41 papers which investigated associations between obesity and childhood (defined as <10 years) health conditions. Meta-analysis showed that childhood obesity significantly increased the odds of asthma (OR 1.5; 95% CI: 1.3-1.7), vitamin D deficiency (OR 1.9; 95% CI: 1.4-2.5) and iron deficiency (OR 2.1; 95% CI: 1.4-3.2). There was a lack of high quality longitudinal studies identified in the review. Participant recruitment rates to the cRCT were low (18%), and overall intervention fidelity was high in preschools, but low in the home environment. Barriers to intervention delivery included lack of time, insufficient space and conflicting preschool policies, while the simple layout of materials facilitated delivery.

Conclusions: Obesity is associated with a number of conditions in childhood, although more high quality, longitudinal and experimental research is needed in this area. The ToyBox-Scotland intervention was feasible and acceptable in the Scottish preschool environment. However, more development work is needed to increase recruitment rates, compliance with outcome measures, and acceptability of the intervention in the home environment.

Acknowledgements

I first want to thank my supervisors, Dr Adrienne Hughes, Professor John Reilly, and Dr Ann-Marie Gibson for all their valued support and guidance throughout the entire PhD process. Your critical and encouraging feedback was much appreciated and I enjoyed working with you all over these last three years, and hope there will be opportunities to do so again in the future. Thanks also to the Cunningham Trust for funding my PhD and associated research outputs and conference expenses. I also thank Dr Fiona Muirhead and Dr Ruth Kipping for examining my thesis, and providing helpful feedback that has improved this final submission.

I also thank all staff and postgraduate students within the University of Strathclyde and specifically the Physical Activity for Health department who have offered advice and assistance at various points throughout my PhD. In particular, Dr Xanne Janssen and Aziz Farooq for their help with data analysis, Jenny Gillespie for assisting me with my systematic review screening, Dr Anne Martin for her advice and support on the systematic review, and Dr Farid Bardid for his advice on the intervention materials.

Working on the ToyBox study gave me an opportunity to engage with researchers at sites in UK, Belgium and Greece, and I am particularly grateful to the original ToyBox team for all their advice and guidance. I also want to thank all the staff, parents, teachers and children throughout Glasgow who participated in my research and made it all possible. A special thanks goes to Kay Hamilton and Julie Martin at Glasgow City Council, for helping to coordinate the project and give me the vital contacts needed to get it up and running in the early days.

I want to thank all my colleagues both past and present at SCPHRP, who helped me continue to work in public health research while taking the next step in my career. I especially thank Professor Ruth Jepson, who encouraged me to undertake a PhD, and has been supportive of my development as a researcher for a number of years.

Finally, I want to thank all my family and friends who have been so supportive throughout my PhD. In particular, my wife Esti, who has encouraged me continuously along the way, and my daughter Marina, who's arrival six months into my PhD definitely gave me a more vested interest in health in the early years!

List of abbreviations

BIA = Bioelectrical impedance analysis

BMI = body mass index

CDC = Center for Disease Control & Prevention

CI = confidence interval

cRCT = cluster randomised controlled trial

ES = eating & snacking

FFQ = food frequency questionnaire

GDPR = general data protection regulation

GRADE = Grading of Recommendations Assessment, Development and Evaluation

IOTF = International Obesity Task Force

LDL = low-density lipoprotein

MRC = medical research council

MVPA = moderate-vigorous physical activity

NAP SACC = Nutrition and Physical Activity Self-Assessment for Child Care

NOS = Newcastle-Ottawa Scale

OR = odds ratio

PA = physical activity

PCQ = primary caregiver's questionnaire

PECO = population, exposure, comparison, outcome

PS = Preschool

RCT = randomised controlled trial

SB = sedentary behaviour

SES = socioeconomic status

SIMD = Scottish Index of Multiple Deprivations

UK90 = United Kingdom 1990

WC = water consumption

WHO = World Health Organisation

zBMI = body mass index z score

4H = Healthy Habits, Happy Homes

List of tables

Chapter 2

Table 1. Systematic review database search strategy using PECO framework

Chapter 3

Table 1: Studies reporting on the relationship between obesity and asthma

Table 2: Studies reporting on the relationship between obesity and musculoskeletal disorders

Table 3: Studies reporting on the relationship between obesity and vitamin D deficiency

Table 4: Studies reporting on the relationship between obesity and iron deficiency

Table 5: Studies reporting on the relationship between obesity and allergies

Chapter 5

Table 1: Differences between Scotland and the original population group targeted by ToyBox

Table 2: Intervention mapping protocol

Table 3: Resulting adaptations to the ToyBox-Scotland programme with reasons

Chapter 6

Table 1. CONSORT baseline characteristics table for ToyBox Scotland study sample

Chapter 7

Table 1: Original ToyBox-study intervention structure for classroom and home behaviour focus

Table 2: Adapted ToyBox-Scotland intervention structure

Chapter 8

Table 1: Intervention structure for ToyBox-Scotland

Table 2: Implementation fidelity score logbook items and responses

Table 3: Behavioural and health outcomes at baseline and follow-up

Chapter 9

Table 1: Acceptability scores per item for parental feedback surveys

List of figures

Chapter 3

Figure 1: Prisma flow diagram

Figure 2: Forest plot for random effects meta-analysis of studies investigating relationships between childhood obesity and asthma

Figure 3: Funnel plot for studies reporting on the relationship between obesity and asthma

Figure 4: Forest plot for random effects meta-analysis of studies investigating relationships between childhood obesity and vitamin D deficiency

Figure 5: Forest plot for random effects meta-analysis of studies investigating relationships between childhood obesity and iron deficiency

Chapter 7

Figure 1: Differences between the original and adapted ToyBox interventions

Figure 2: Participant timeline for the ToyBox-Scotland feasibility study

Chapter 8

Figure 1: Consort flow diagram for the ToyBox-Scotland study

Summary of publications and presentations from thesis

Published manuscripts

Chapter 3

Malden, S., Gillespie, J., Hughes, A., Gibson, AM., Martin, A., Farooq, A., Summerbell, C., Reilly, JJ. (2020). Obesity in young children and its relationship with diagnosis of asthma, Vitamin D deficiency, Iron deficiency, specific allergies and flat footedness: a systematic review and meta-analysis. *Obesity Reviews:* IN PRESS.

Chapter 5

Malden, S., Reilly, JJ., Gibson, AM., Bardid, F., Hughes, A. (2020). Procedures and Challenges of Adapting an Existing Public Health Intervention for use in Another Setting: The ToyBox-Scotland Preschool Obesity Prevention Programme. *Sage Research Methods Cases*. doi:10.4135/9781529724547.

Chapter 7

Malden, S., Hughes, A., Gibson, A.M., Bardid, F., Androutsos, O., De Craemer, M., Manios, Y., Summerbell, C., Cardon, G. and Reilly, J. (2018). Adapting the ToyBox obesity prevention intervention for use in Scottish pre-schools: protocol for a feasibility cluster randomised controlled trial. *BMJ open.* **8:**e023707.

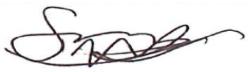
Chapter 8

Malden, S., Reilly, J., Gibson, A.M., Bardid, F., Androutsos, O., De Craemer, M., Manios, Y., Summerbell, C., Cardon, G. and Hughes, A. (2019). A feasibility cluster randomised controlled trial of a preschool obesity prevention intervention: ToyBox-Scotland. *BMC Pilot and Feasibility Studies*. 5(1), p.128.

Chapter 9

Malden, S., Reilly, JJ., Hughes, A., Bardid, F., Summerbell, C., De Craemer, M., Cardon, G., Androutsos, O., Manios, Y., Gibson, AM. (2020). Assessing the acceptability of an adapted preschool obesity prevention programme: ToyBox-Scotland. *Child: Care, Health and Development*.1– 10.

The author declares that all the manuscripts presented in this thesis were prepared as part of this thesis by the author, who led on all aspects of the studies presented, and was responsible for drafting each manuscript.

Signed: 

Conference presentations from thesis

S. Malden, J.J. Reilly, AM. Gibson, F. Bardid, A. Hughes. (S. Malden, 2018). Adaptation of the ToyBox pre-school obesity prevention programme for use in Scotland: Intervention adaptation processes and baseline results of a feasibility cluster randomised controlled trial. *25th European Congress on Obesity. Poster session 3; Childhood and Adolescent Obesity. Day 3. Vienna, Austria.*

S. Malden, A. Hughes, AM. Gibson, F. Bardid, O. Androutsos, M. De Craemer, Y. Manios, C. Summerbell, G. Cardon, JJ. Reilly. (S. Malden 2019). Feasibility of the ToyBox-Scotland obesity prevention intervention in preschools: Results of a cluster randomised controlled trial. *26th European Congress on Obesity 2019. Glasgow, UK.*

S. Malden, J. Gillespie, JJ. Reilly, A. Martin, AM. Gibson, C. Summerbell, A. Hughes. (S. Malden, 2019). The relationship between obesity in early childhood and physical morbidity in childhood and adolescence: a systematic review and meta-analysis. *26th European Congress on Obesity 2019. Glasgow, UK.*

O. Androutsos, L. Gibson, B. P. Koon, W. L. Cheah, **S. Malden,** J.J. Reilly. (S. Malden, 2019). *Accepted Symposium:* The ToyBox kindergarten/nursery Intervention to Prevent Obesity in Pre-school Children: Impact, Experiences & Outcomes, and Translation across Europe, Malaysia and Scotland. *26th European Congress on Obesity 2019. Glasgow, UK.*

S. Malden, A. Hughes, AM. Gibson, F. Bardid, O. Androutsos, M. De Craemer, Y. Manios, C. Summerbell, G. Cardon, JJ. Reilly. (S. Malden 2019). The ToyBox Pre-School Obesity Prevention Intervention for use in Scotland: Results of a Feasibility Cluster Randomised Controlled Trial (cRCT). *ISBNPA conference 2019. Prague, Czech Republic.*

Relevant publications not from thesis

Reilly, J. J., Hughes, A. R., Gillespie, J., **Malden, S**. Martin, A. (2019). Physical activity interventions in early life aimed at reducing later risk of obesity and related non-communicable diseases: A rapid review of systematic reviews. *Obesity Reviews*. **20** (S1): 61– 73.

Malden, S., Jepson, R., Laird, Y., McAteer, J. (2019). A theory based evaluation of an intervention to promote positive health behaviors and reduce social isolation in people experiencing homelessness. *Journal of Social Distress and the Homeless,* DOI: 10.1080/10530789.2019.1623365.

Malden, S & Doi, L. (2019). The Daily Mile: Teachers' perspectives of the barriers and facilitators to the delivery of a school-based physical activity intervention. *BMJ Open.***9:**e027169.

Inglis, G., Archibald, D., Doi, L., Laird, Y., **Malden, S**., Marryat, L., McAteer, J., Pringle, J. and Frank, J. (2018). Credibility of subgroup analyses by socioeconomic status in public health intervention evaluations: An underappreciated problem? *SSM-Population Health*. Volume **6**, Pages 245-251.

Doi, L., Wason, D., **Malden, S.**, Jepson, R. (2018). Supporting the health and well-being of school-aged children through a school nurse programme: a realist evaluation. *BMC Health Services Research*. **18**:664.

Table of Contents

Declaration of authenticity and author's rights……………………………………….1

Abstract………………………………………………………………………….2

Acknowledgements……………………………………………………………...4

List of abbreviations…………………………………………………………….5

List of tables……………………………………………………………………..7

List of figures……………………………………………………………………9

Summary of publications and presentations from thesis……………………………10

Relevant publications not from thesis………………………………………………13

Chapter 1: Thesis preface and introduction…………………………………...21

1. References…………………………………………………………………...24

Chapter 2: Methodology of Systematic Review…………………………………25

1. Preface……………………………………………………………………….25
2. Introduction and context……………………………………………………….26
3. Planning phase………………………………………………………………27

3.1.Literature search and inclusion………………………………………………..27

4. Study screening, data extraction and quality assessment……………………31
5. Data analysis…………………………………………………………………...33
6. References…………………………………………………………………...34

Chapter 3: Obesity in young children and its relationship with diagnosis of asthma, Vitamin D deficiency, Iron deficiency, specific allergies and flat footedness: a systematic review and meta-analysis ……………………………...36

1. Preface……………………………………………………………………….36
2. Abstract……………………………………………………………………...36
3. Introduction…………………………………………………………………..37

4. Methods……………………………………………………………………...40
4.1.Inclusion and exclusion criteria……………………………………………..40
4.2.Search strategy……………………………………………………………...42
4.3.Quality assessment…………………………………………………………43
4.4.Data extraction………………………………………………………...……44
4.5.Data synthesis and meta-analysis………………………………….……….45
5. Results…………………………………………………………………………46
5.1.Description of included studies…………………………………..………46
5.2.Study characteristics………………...…………………………………………48
5.3.Study quality……...…………………………...…………………………48
5.4.Association between childhood obesity and asthma…………..……………49
5.5.Association between childhood obesity and vitamin D deficiency………..…..51
5.6.Association between childhood obesity and iron deficiency…….……..…..52
5.7.Association between childhood obesity and flat-footedness (pes planus)…..53
5.8.Association between childhood obesity and allergies…………..…………..54
6. Discussion……………………………………………………………………...55
7. References……………………………………………………………………...73

Chapter 4: Obesity prevention interventions in childhood………………...……79

1. Introduction……………………………………………………………………79
2. Multi-component interventions: The need to address multiple obesogenic behaviours……………………………………………………………………...80
3. The importance of targeting the populations most at need…………………81
4. The importance of intervention setting……………………………………...83
5. Translating interventions to other settings…………………………………..85
6. Why test feasibility before a full-scale trial?...88
7. Why The ToyBox Study was chosen as a good fit for Scottish Preschools...89
8. References……………………………………………………………………...92

Chapter 5: Procedures and challenges of adapting an existing public health intervention for use in another setting: The ToyBox-Scotland preschool obesity prevention programme…………………………………………………………98

1. Preface…………………………………………………………………………98

2. Abstract……………………………………………………………………..98
3. Project overview and context……………………………………………..99
4. Research design……………………………………..…………………....101
4.1.Step 1: Identifying the problem and potential solutions……………….….102
4.2.Step 2: Stakeholder involvement and consultation……………….…..…..104
4.3.Step 3: Demonstrating the need for ToyBox in Scottish preschools…....….105
4.4.Step 4: Co-creation of The adapted ToyBox Scotland intervention…….….106
4.5.Step 5: Development of additional interactive parent-child activities…….106
4.6.Step 6: Testing the feasibility and acceptability of the adapted intervention in Scottish preschools…………………………………………….…………..107
5. Method in Action………………………………………………………..109
6. Practical lessons learned………………………………………………...112
6.1.Lesson 1: Collaboration is key……………………………………………112
6.2.Lesson 2: Co-creation is a useful tool for intervention development and adaptation when used appropriately……………………………………112
6.3.Lesson 3: Engaging parents in the co-creation processes can be difficult...113
6.4.Lesson 4: There remains a need for further guidance on adapting interventions………..……………………………………………………114
7. Conclusion………………………………………………………………115
8. References……………………………………………………………….117

Chapter 6: Rationale for the Methodology of the feasibility cluster RCT and accompanying process evaluation………………………………………………119

1. Preface…………………………………………………………………..119
1.1.Author contributions………………...…………………………………119
2. Introduction………………………………………………………….……..120
3. Selecting the appropriate study design……………………………...……..121
3.1.Study design during feasibility testing……………….……………………122
4. Measuring physical activity and sedentary behaviour……………………..123
4.1.Measuring physical activity and sedentary behaviour with accelerometers………………………………………………..…………124
5. Measuring weight status…………………………………….…………..125
5.1.Body mass index (BMI)……………..……………………….…………….125

5.2.Bioelectric Impedance analysis (BIA)……….……………………………126
6. Using questionnaires to measure demographics and health behaviours in the home environment…………………………………………………...…….127
7. Feasibility and process evaluation measures……………………...…….129
7.1.Assessing acceptability of the intervention and trial………………...…….130
8. References…………………………………………………...……..132

Chapter 7: Adapting the ToyBox obesity prevention intervention for use in Scottish pre-schools: Protocol for a feasibility cluster randomised controlled trial…………………………………………………………..………136

1. Preface……………………………………………………………...136
2. Abstract…………………………………………...……………..136
2.1.Strengths and limitations of this study…………....…………………….138
3. Introduction……………………………………..…………………138
4. Methods…………………………………………...………………..141
4.1.Patient and Public Involvement………………….…..………………141
4.2.Study setting and participants…………………..……..………………141
4.3.Recruitment and consent………..…………………………..……………..142
4.4.Intervention…………………………………………………..…….143
4.5.Adaptation of ToyBox for use in Scotland…………….……..……………145
4.6.Practitioner training……..……………………………..………………149
4.7.Outcomes…………...……………………………...………………150
4.8.Process evaluation…….…………………………...……………….153
4.9.Ethics and dissemination……..…………………...………………….155
4.10. Sample size……………………….……………..………………156
4.11. Randomisation……..…………………………..………………156
5. Data management……………………………………...……………....157
6. Analysis…………………………………………...………………..157
7. Discussion…………………………………………...………………..158
7.1.Trial governance……………………..………………...………………..159
7.2.*Safety procedures*……..……………………………………………159
8. References………………………………………………………….160

Chapter 8: A feasibility cluster randomised controlled trial of a preschool obesity prevention intervention: ToyBox-Scotland…………………..………..165

1. Preface…………………………………………….………………..……165
2. Abstract…………………………………………………………….….165
3. Background………………………………………………………...167
4. Methods……………………………………………………………….168

4.1.*Study design*….……………………………………………………….168
4.2.Setting, sampling and participants…………….……………………..169
4.3.Intervention…………………………………………………….…..169
4.4.Procedures and outcomes……………………..……………………….171
4.5.Implementation fidelity……………………...……………………….171
4.6.Secondary outcome measures………………….…………………….…….172
4.7.Analysis……....……………………………………………………….174

5. Results………………………………………………………………..177

5.1.Feasibility of Trial Recruitment and Retention……………………………177
5.2.Intervention fidelity…………………………..………………………177
5.3.Participation in outcome measures………………………………………..179
5.4.Behavioural and health outcomes…………….……………………………180

6. Discussion…………………………………………………………….181
7. Conclusions……………………………………………………………...187
8. Declarations……………………………………………………………..187

8.1.Ethics approval and consent to participate……………..………………...187

9. References…………………………………………………………….188

Chapter 9: Assessing the acceptability of an adapted preschool obesity prevention programme: ToyBox-Scotland…………………...………………193

1. Preface……………………………..………………………………193
2. Abstract…………………………...……………………………………..193

2.1.*Key messages*…………..………… ………………………………………195

3. Introduction…………………………………………………………...195
4. Methods……………………………………………………………….196

4.1.Setting and participants…………………..………………………………..197

4.2.Recruitment……………………..……………………………………………197
4.3.Measures and data collection…………………………….……………………..198
4.4.Data analysis……………………………………………………………………198
5. Results…………………………………………………………………………...200
5.1.Preschool acceptability……………..……………………………………..200
5.2.Trial procedures…….……………………………………………………..207
5.3.Home acceptability……….………………………………………………..209
5.4.Trial procedures…………………………...……………………………213
6. Discussion……………………………………………………………….………214
7. References……………………………………………………………………….219

Chapter 10: thesis discussion and conclusions………………………………….222

1. Preface……………………………………………………………...………222
2. Background…………………………………………...……………………222
3. Summary of findings…………….…………………………………………224
4. Thesis limitations………………….………………………………………226
5. Future research and recommendations……………………………………..227
6. Policy implications……………………...…………………………………228
7. Conclusions………………...………………………………………………230
8. References………………………………………………………………….231

Appendix glossary………………………………...………………………….233

Appendix A……………………………………………………...……………235

Appendix B……………………………………………………..…………..248

Appendix C……………………...…………………………………………252

Appendix D…………………………...……………………………………260

Appendix E…………………………...……………………………………263

Appendix F………………………………………………………………….284

Appendix G……………………..………………………………………….286

Appendix H…………………………..……………………………………287

Appendix I……………………………………………………………………………289

Appendix J…………………...………………………………………………………290

Appendix K………………...…………………………………………………………291

Appendix L……………………..……………………………………………………293

Appendix M……………………..……………………………………………………294

Appendix N……………………………..……………………………………………295

Appendix O……………….…………………………………………………………..297

Appendix P……………………………...……………………………………………299

Chapter 1: Thesis preface and introduction

Childhood obesity rates have significantly increased worldwide within the last three decades [1]. In the UK, where childhood obesity is estimated to be approximately 10-20% in England [2], there has been no sign of improvement in recent years [3]. Scotland in particular has one of the highest rates of childhood obesity in Europe [4]. The increase in childhood obesity observed in recent decades, has also been accompanied by an increase in numerous co-morbid conditions among children, indicating that obesity in childhood may have significant health impacts if not addressed early [1].

A growing body of research has demonstrated the impact that behavioural factors such as diet, sedentary behaviour (SB) and low physical activity (PA) levels have on the development of childhood obesity [5, 6]. The rise in childhood obesity has coincided with an increased availability of, and growing tendency to, eat foods high in saturated fats and sugar [7], in addition to the popularisation of sedentary activities over active hobbies and active play [8, 9]. Naturally, child health researchers have attempted to prevent the onset of childhood obesity through the development and implementation of behavioural interventions which target these energy-balance related behaviours [10-14].

This thesis details work that first aimed to demonstrate the harmful effects childhood obesity can have on children's health by investigating co-morbidities of childhood obesity (defined as children younger than ten years of age) in a systematic review and meta-analysis of observational studies (chapter 3). The thesis then presents a summary of the existing evidence base for behavioural childhood obesity prevention interventions in the literature (chapter 4), and introduces the reader to the concept of adapting existing, successful interventions for use in other settings. This chapter also discusses the importance of feasibility studies during the development of an intervention, and how guidelines recommend to undertake such studies.

The thesis then presents the methods used to adapt the ToyBox obesity prevention programme [13] for use in the Scottish preschool context. Chapter 5 details the steps that were taken to adapt the original intervention for use in Scottish preschools, and discusses the challenges that were encountered during this process. This chapter introduces the reader to the concept of co-production [15] which was used to actively engage stakeholders in the intervention adaptation process. Chapter 6 provides a detailed rationale for the evaluation methods adopted to test the feasibility of the adapted intervention, while Chapter 7 then presents the protocol for the feasibility cRCT. This chapter details the procedures used and the rationale for the specific methods adopted to test the feasibility of the intervention in the new setting. The results of the subsequent trial are presented across two distinct chapters, both dealing with separate aspects of feasibility. Chapter 8 primarily presents results relating to the feasibility of the cRCT as an appropriate evaluation method of the ToyBox Scotland intervention. The chapter presents results regarding trial recruitment rates, retention/adherence rates and intervention fidelity. Chapter 9 focuses on the acceptability of the intervention components, and methods of evaluation from the perspectives of both preschool practitioners, and participating parents, by using a mixed-methods approach.

Collectively, the manuscripts presented in this thesis attempt to bring together two of the major fields within public health; epidemiology and complex intervention development/evaluation. A large systematic review and meta-analysis of epidemiological research aims to demonstrate the harmful effects of obesity in childhood, and make a case for early intervention. The adaptation of a pre-existing intervention for use in Scottish preschools then aims to show how best to adapt behavioural interventions which have shown promise in one setting, and apply these to another. Finally, chapter 10 discusses the findings of the body of work presented in the thesis, and presents conclusions and recommendations for future research.

1. References

1 GBD Obesity Collaborators. Health effects of overweight and obesity in 195 countries over 25 years. *New England Journal of Medicine*. 2017; 377: 13-27.

2 Rudolf M, Perera R, Swanston D, Burberry J, Roberts K, Jebb S. Observational analysis of disparities in obesity in children in the UK: Has Leeds bucked the trend? *Pediatric obesity*. 2019; 14: e12529.

3 Viner RM, Hargreaves DS. Trajectories of change in childhood obesity prevalence across local authorities 2007/08–2015/16: a latent trajectory analysis. *Journal of Public Health*. 2019; 41: 724-31.

4 Scottish Government. A healthier future: Scotland's diet and healthy weight delivery plan. 2018.

5 Anderson PM, Butcher KF. Childhood obesity: trends and potential causes. *The Future of children*. 2006: 19-45.

6 Ebbeling CB, Pawlak DB, Ludwig DS. Childhood obesity: public-health crisis, common sense cure. *The lancet*. 2002; 360: 473-82.

7 Barnard ND. Trends in food availability, 1909–2007. *The American journal of clinical nutrition*. 2010; 91: 1530S-36S.

8 Atkin AJ, Corder K, van Sluijs EM. Bedroom media, sedentary time and screen-time in children: a longitudinal analysis. *International Journal of Behavioral Nutrition and Physical Activity*. 2013; 10: 137.

9 Lee ST, Wong JE, Shanita SN, Ismail MN, Deurenberg P, Poh BK. Daily physical activity and screen time, but not other sedentary activities, are associated with measures of obesity during childhood. *International journal of environmental research and public health*. 2015; 12: 146-61.

10 Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, Dyer A. Two-year follow-up results for Hip-Hop to Health Jr.: a randomized controlled trial for overweight prevention in preschool minority children. *The Journal of pediatrics*. 2005; 146: 618-25.

11 Kipping R, Jago R, Metcalfe C, White J, Papadaki A, Campbell R*, et al.* NAP SACC UK: protocol for a feasibility cluster randomised controlled trial in nurseries and at home to increase physical activity and healthy eating in children aged 2–4 years. *BMJ open*. 2016; 6: e010622.

12 Langford R, Jago R, White J, Moore L, Papadaki A, Hollingworth W*, et al.* A physical activity, nutrition and oral health intervention in nursery settings: process evaluation of the NAP SACC UK feasibility cluster RCT. *BMC public health*. 2019; 19: 865.

13 Manios Y. The ‘ToyBox-study’obesity prevention programme in early childhood: an introduction. *obesity reviews*. 2012; 13: 1.

14 Reilly JJ, Kelly L, Montgomery C, Williamson A, Fisher A, McColl JH*, et al.* Physical activity to prevent obesity in young children: cluster randomised controlled trial. *Bmj*. 2006; 333: 1041.

15 Greenhalgh T, Jackson C, Shaw S, Janamian T. Achieving research impact through co-creation in community-based health services: literature review and case study. *The Milbank Quarterly*. 2016; 94: 392-429.

Chapter 2: Methodology of Systematic Review

1. Preface

The systematic review “Obesity in young children and its relationship with diagnosis of asthma, Vitamin D deficiency, Iron deficiency, specific allergies and flat footedness: a systematic review and meta-analysis” was accepted for publication in the journal ‘Obesity Reviews’. Due to word restrictions imposed by the journal’s author guidelines, it was not possible to provide a comprehensive description of the methods used during the review process within the manuscript. Therefore, this chapter aims to provide additional detail regarding the methods used to conduct the systematic review.

Stephen Malden (SM) designed the study, formulated the research questions, executed the searches and conducted all screening, quality assessment and analysis. Two experienced Cochrane reviewers, Dr Anne Martin (AM) and Professor Carolyn Summerbell (CS) guided the methods used throughout the process. SM was the lead author and led all aspects of the study. Search strategies were devised with assistance from Professor John Reilly (JJR), AM, Dr Adrienne Hughes (AH) and Dr Ann-Marie Gibson (AMG). Study screening was conducted independently by SM and Jenny Gillespie (JG), with cross checking of data extraction and quality appraisal undertaken by AMG, AH and JJR. Meta-analysis was performed by SM and Aziz Farooq (AF), and data synthesis undertaken by SM with advice provided by AM. All authors contributed to and approved the final submitted manuscript.

2. Introduction and context

When discussing the approach to take with this systematic review, the topic of co-morbid conditions and their association with obesity in childhood was considered a viable topic for the review for a number of reasons. Firstly, this is an area of research for which research activity is high, with new publications demonstrating associations between health outcomes and obesity in children published regularly [1-4]. Additionally, new, emerging associations are continuously being identified by the research in this field [5], highlighting the need for a comprehensive systematic review of this literature.

Members of this research team were involved in a similar systematic review which was published in 2003 [6], which identified conditions such as asthma, chronic inflammation, cardiovascular disease markers and musculoskeletal disorders to be associated with overweight and/or obesity in childhood. Given the rate at which new publications emerge in this field, it was deemed appropriate to reinvestigate this topic. A number of systematic reviews have been conducted with a similar approach and aim to the present study [7-10], identifying associations between childhood weight status and a multitude of health conditions. However, the tendency for these reviews to include studies which do not consider obesity as a distinctly different outcome from overweight (i.e. overweight status equating to ≥85th to <95th percentile, and obesity ≥95th percentile) means that our understanding of the impact of true obesity on childhood comorbidity is not as well investigated as the abundance of reviews in this area would suggest, especially considering childhood is often loosely defined using a wide age range including young children and adolescents collectively. Therefore, the aim of this current systematic review and meta-analysis was to investigate the relationship between obesity (as defined by internationally recognised standards) in young children < 10 years old (World Health Organization, 2014) and co-morbid conditions (physical health only). The review protocol was published on PROSPERO (CRD42018079387) on 08/01/2018.

3. Planning phase

3.1 Literature search and inclusion

As mentioned previously, a large number of systematic reviews have been published in this area to date. We therefore first assessed these reviews to determine whether they were of sufficient quality, and whether they had accounted for stratification of weight status in their inclusion criteria and analysis. Additionally, we referred to current best practice clinical guidelines in childhood obesity treatment (National Institute for Health and Care Excellence, 2015), and the quality of evidence presented for a number of conditions which have shown to be associated with childhood obesity in the past. The reasons for doing this were twofold; firstly, by determining which conditions had already been well-established as co-morbidities of childhood obesity, we could avoid producing results which do not add a significant contribution to the field. Secondly, doing this allowed us to have a more manageable workload, as this research area is particularly vast. We determined that outcomes such as diabetes, metabolic syndrome, markers of cardiovascular disease, dental carries and musculoskeletal pain had either been recently reviewed, or had already been extensively shown to be associated with childhood obesity. Therefore, these outcomes were considered as out-with the scope of this current review.

Once we had established the specific outcomes which were not of interest in this review, we then further developed our inclusion and exclusion criteria (detailed in chapter 3), and devised a search strategy following the PECO framework (Population, Exposure, Comparison and Outcomes).

Searches were conducted across five databases for this review (MEDLINE, Embase, CINAHL, AMED and SPORTDiscus). These databases were selected to reflect the likelihood that the research of interest was likely to cross multiple disciplines (e.g., medicine, public health/epidemiology, nursing, sport science, physiotherapy) and to ensure that we would identify all the relevant literature whilst also keeping the volume of identified records manageable. In the interests of keeping the workload manageable, we also limited our searches to 2001-present, considering that a comprehensive, high quality systematic review had previously been published in 2003, having conducted searches up to 2001 [6]. The full search terms used in the search strategy are detailed in table 1.

In addition to database searches, we also conducted both forward and backward citation searches on all eligible studies that were included in the review after screening. This involved both reviewing studies' reference lists for any relevant titles, and reviewing all literature up to the present date that had cited the included studies to account for any potentially relevant literature that had been published in the time between the initial searches, and completion of screening.

Table 1. Systematic review database search strategy using PECO framework

Population (combine terms with OR)		**Exposure (combine terms with OR)**		**Comparison (no necessary comparison required)**		**Outcome (Combine terms with OR)**

Child* Youth* Pediatr* Paediatr* School-age* Pre-school* Teen* Adolesc* High school Secondary school Elementary school Primary school Pre-pubert* Pre-adolesc* Kindergarten Nursery Infan* Young pe* Youngster* Boy* Girl* Toddler* baby or babies r newborn* or neonat* or preschool* or pre school* or playschool* or playgroup* or kindergarten* or kindergarden*)	AND	Obes* Overweight Over-weight or over weight or overeat* or over eat* or overfeed* or over feed*). Obesity Unhealthy weight Weight* Adipos* BMI Body mass index Body Fat* Hip to waist ratio Skinfold* ((High or increase*) adj2 (Waist circumference)	AND	/	AND	neoplasms Asthma Health Health conditions Health outcome* Comorbidit* Slipped capital femoral epiphysis NAFLD Non alcoholic fatty liver disease Endocrine disorder* Muscoloskeletal diseases Intraocular pressure IOP Flat foot Fat feet Blounts disease Tibia vara Pes planus

4. Study screening, data extraction and quality assessment

Title and abstracts were first screened by SM, before 20% of the articles were independently screened by a second reviewer (JG) and any discrepancies in inclusion/exclusion were discussed and agreed upon. While best practice in systematic reviewing indicates that double screening should be conducted on all titles and abstracts [11], we were significantly limited by the sheer volume of identified studies, and a restrictive timeline. We therefore had to take a pragmatic approach to the initial screening process, allowing more time to be allocated to full text screening, which was conducted independently by two reviewers (SM and JG). Any studies which were excluded at this stage were assigned a code delineating the reason for exclusion, which could then be added to the PRISMA flow diagram (chapter 3).

Data extraction was also conducted independently by two reviewers (SM extracted all studies, with each study also independently extracted by either AMG, AH or JJR). Prior to extraction, the team developed a data extraction template which contained the following headings: Author, country, population description, setting, recruitment methods, aim of study, study design, sampling technique, study start date, study end date, total participants, age group, outcome names, outcome definitions, outcome identification, time points measured, type of measurement, exposure names, exposure definitions, exposure identification, time points measured, type of measurement, imputation of missing data, power calculation, statistical test used, statistic value, statistic effect size, p value, p value significance, covariates, comments.

Quality assessment is detailed in chapter 3. Briefly, the quality of each included study was assessed using the Newcastle Ottawa Scale (NOS) for case control and cohort studies, and an adapted version of the scale was used for cross sectional studies [12]. The NOS was selected as it uses a rating system instead of a checklist, wherein a study is judged on three broad perspectives (selection of the study groups; the comparability of the groups; and the ascertainment of either the exposure or outcome of interest) [13] and is designed specifically for reviews which are intending to use meta-analysis. The scale has also shown to be valid and reliable in comparison to more comprehensive but time-consuming quality assessment tools [14]. Quality assessment was undertaken independently by two reviewers (SM and either AMG, AH, or JJR) before any discrepancies were discussed and agreed upon.

We originally planned to conduct an overall quality of evidence assessment as recommended by the Cochrane handbook [11]. Grading of Recommendations, Assessment, Development and Evaluations (GRADE) [15], is commonly used to award a rating of very low, low, moderate and high to each outcome included in a systematic review. However, due to the possible effects of residual confounding, all observational studies are required to start with a grading of low. The grade can then be further reduced based on the assessment of additional criteria including risk of bias, imprecision, inconsistency, indirectness and publication bias. Given that our review only included observational studies, it was agreed that conducting GRADE assessment would not be pragmatic given the short timescale, coupled with the current lack of consideration the tool offers to good quality observational research. At present, GRADE considers all observational research to be of low-very low quality of evidence. However, well-designed observational studies may be the best available evidence in the absence of good quality RCT depending on the field of study.

5. Data analysis

Due to varying levels of heterogeneity in our included studies, we were required to conduct both meta-analyses, and a narrative synthesis on those studies which did not meet the criteria for a pooled analysis. There is currently no consensus on the appropriate methods or reporting styles for conducting narrative syntheses in systematic reviews, and conditions for establishing trustworthiness are often absent from such studies, highlighting the importance of following the recommendations available from Cochrane [11, 16]. SM reviewed the results (both the primary outcome, effect sizes, and levels of significance) of the eligible studies and described them objectively in relation to the other included studies for each outcome. Another reviewer also checked the narration to confirm the reported findings accurately reflected the results presented by the individual studies.

Under the guidance of a statistician, we conducted a random effects meta-analysis on the three eligible outcomes (asthma, vitamin D deficiency, iron deficiency). Random-effects was selected over a fixed-effects model to account for the likely heterogeneity that including studies of different designs, population groups, and study settings would likely introduce to the analysis. Full details of the methodological procedures of the analysis are described in chapter 3.

6. References

1 Chen Z, Salam MT, Alderete TL, Habre R, Bastain TM, Berhane K*, et al.* Effects of childhood asthma on the development of obesity among school-aged children. *American journal of respiratory and critical care medicine*. 2017; 195: 1181-88.

2 Crivelli M, Wyss K, Grize L, Matthys B, Aebi T, Zemp E. Are overweight and obesity in children risk factors for anemia in early childhood? Results from a national nutrition survey in Tajikistan. *International journal of public health*. 2018; 63: 491-99.

3 Senaprom S, Yamborisut U, Rojroongwasinkul N, Wimonpeerapattana W, Purttiponthanee S, Khouw I*, et al.* FACTORS ASSOCIATED WITH VITAMIN D STATUS AMONG THAI CHILDREN AGED 3-13 YEARS. *Southeast Asian Journal of Tropical Medicine and Public Health*. 2016; 47: 277.

4 Weinmayr G, Forastiere F, Büchele G, Jaensch A, Strachan DP, Nagel G*, et al.* Overweight/obesity and respiratory and allergic disease in children: international study of asthma and allergies in childhood (ISAAC) phase two. *PloS one*. 2014; 9: e113996.

5 Akinci A, Cetinkaya E, Aycan Z, Oner O. Relationship between intraocular pressure and obesity in children. *Journal of glaucoma*. 2007; 16: 627-30.

6 Reilly JJ, Methven E, McDowell ZC, Hacking B, Alexander D, Stewart L*, et al.* Health consequences of obesity. *Archives of disease in childhood*. 2003; 88: 748-52.

7 Papoutsakis C, Priftis KN, Drakouli M, Prifti S, Konstantaki E, Chondronikola M*, et al.* Childhood overweight/obesity and asthma: is there a link? A systematic review of recent epidemiologic evidence. *Journal of the Academy of Nutrition and Dietetics*. 2013; 113: 77-105.

8 Paulis W, Silva S, Koes B, van Middelkoop M. Overweight and obesity are associated with musculoskeletal complaints as early as childhood: a systematic review. *Obesity Reviews*. 2014; 15: 52-67.

9 Pereira-Santos M, Costa PRdF, Assis A, Santos CAdST, Santos DBd. Obesity and vitamin D deficiency: a systematic review and meta-analysis. *Obesity reviews*. 2015; 16: 341-49.

10 Pulgaron ER. Childhood obesity: a review of increased risk for physical and psychological comorbidities. *Clinical therapeutics*. 2013; 35: A18-A32.

11 Higgins JP, Green S. Cochrane handbook for systematic reviews of interventions: John Wiley & Sons 2011.

12 Herzog R, Álvarez-Pasquin MJ, Díaz C, Del Barrio JL, Estrada JM, Gil Á. Are healthcare workers' intentions to vaccinate related to their knowledge, beliefs and attitudes? A systematic review. *BMC public health*. 2013; 13: 154.

13 Peterson J, Welch V, Losos M, Tugwell P. The Newcastle-Ottawa scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. *Ottawa: Ottawa Hospital Research Institute*. 2011.

14 Voss PH, Rehfuess EA. Quality appraisal in systematic reviews of public health interventions: an empirical study on the impact of choice of tool on meta-analysis. *J Epidemiol Community Health*. 2013; 67: 98-104.

15 Balshem H, Helfand M, Schünemann HJ, Oxman AD, Kunz R, Brozek J*, et al.* GRADE guidelines: 3. Rating the quality of evidence. *Journal of clinical epidemiology*. 2011; 64: 401-06.
16 Popay J, Roberts H, Sowden A, Petticrew M, Arai L, Rodgers M*, et al.* Guidance on the conduct of narrative synthesis in systematic reviews. *A product from the ESRC methods programme Version*. 2006; 1: b92.

Chapter 3: Obesity in young children and its relationship with diagnosis of asthma, Vitamin D deficiency, Iron deficiency, specific allergies and flat footedness: a systematic review and meta-analysis

1. Preface

This manuscript was accepted for publication in the journal *Obesity Reviews*. The design, search execution, and interpretation of results was primarily undertaken by SM who was guided by two experienced Cochrane systematic reviewers in AM, and CS. SM formulated the initial search strategy, conducted the searches, and screened the titles, abstracts and full text results. JG screened a proportion of titles/abstracts and independently screened all full text results. SM extracted all the studies, and either JJR, AMG or AH independently extracted all studies. Quality assessment was conducted by SM, JJR, AMG and AH. Data analysis and interpretation was conducted by SM, with guidance on the Meta analysis from AF. All authors approved the final manuscript before submission.

2. Abstract

There is evidence that a number of medical conditions and co-morbidities are associated with obesity in young children. This review explored whether there is evidence of associations with other conditions or co-morbidities. Observational studies of young children (mean age < 10 years) were identified using electronic searches of five databases (MEDLINE, Embase, CINAHL, AMED and SPORTDiscus). Of 27,028 studies screened, 41 (comprising 44 comparisons) met the inclusion criteria. These studies provided data on five distinct disease/conditions;

asthma (n=16), Vitamin D deficiency (n=10), Iron deficiency (n=10), allergies (n=4), and flat-footedness (n=4). Thirty-two studies were appropriate for meta-analysis using random-effects models and revealed obesity was significantly associated with having asthma (OR 1.5, 95% CI 1.3-1.7), vitamin D deficiency (OR 1.9, 95% CI 1.4-2.5) and iron deficiency (OR 2.1, 95% CI 1.4-3.2). Heterogeneity (I^2) ranged from 57-61%. Narrative synthesis was conducted for all studies. There was no evidence of a consistent association between obesity in young children and eczema, dermatitis or rhinitis due to the low number of studies. However, there was an association with flat-footedness. These results have implications for health policy and practice, and families. Further research leading to a greater understanding of the associations identified in this review is suggested.

3. Introduction

While having obesity in childhood is a known predictor of numerous health conditions in adulthood [1, 2], a growing evidence base has demonstrated the adverse health effects obesity has during childhood and adolescence. Specifically, an abundance of research has demonstrated the link between having childhood obesity and cardio-metabolic disease markers such as high cholesterol, hypertension and abnormal glucose tolerance, with children with obesity at a three-fold increased risk of hypertension than children without obesity for example [3-5]. A recent systematic review of observational studies and randomised trials demonstrated that 5-15 year old children with obesity had 7.49 mmHg higher systolic blood pressure, 0.15 mmol/L higher total cholesterol, 0.26 mmol/L higher triglycerides and significantly higher fasting insulin and insulin resistance than children without obesity [6]. The latter finding further supports recent research demonstrating the association between having childhood obesity and the development of type 2 diabetes in youth [7].

While the relationship between having childhood obesity and cardio-metabolic risk factors has been well established by published research, including several systematic reviews, the potential relationship between having obesity in childhood and other co-morbid conditions is not as clearly understood. Furthermore, a focus on these co-morbidities in younger children with obesity is limited to date. Epidemiological research has demonstrated associations between childhood obesity and increased risk of asthma, sleep apnoea, vitamin D deficiency, non-alcoholic fatty liver disease, dental caries, eye disorders, atopic disease and musculoskeletal complaints among other conditions [8-16]. However, recent systematic reviews investigating the health impacts of having childhood obesity have not been definitive regarding these conditions. Specifically, asthma has increasingly been linked to having childhood obesity, however a review by Pulgaron (2013) identified a number of studies in which no association between childhood obesity and asthma was reported [17]. Another systematic review and meta-analysis of 48 epidemiological studies demonstrated a weak but significant link between asthma and overweight/obesity in children [18]. However, a systematic review of 10 longitudinal studies demonstrated that children who had obesity as a child were more likely to suffer from asthma either in childhood or in adolescence [19], a finding supported by an umbrella review of risk factors for childhood obesity [20]. ·

There are a number of plausible explanations for the equivocal findings observed for the relationship between having some co morbidities and childhood obesity.

However, one issue that is rarely discussed sufficiently in the literature is the methodological issues that may arise from the practice of combining children with overweight and obesity during participant recruitment and subsequent analyses. Many observational studies grouped children with obesity and overweight as a combined exposure variable, instead of considering both conditions as two distinct groups. Participants with overweight and obesity would rarely be combined in adult studies of co-morbidities but are routinely combined in paediatric studies. Possible reasons for this may be that there is relatively low prevalence of children with obesity in some populations historically, in comparison to overweight, therefore recruiting an adequately powered sample to measure the outcomes of interest may be more difficult if the inclusion criteria are limited to individuals with obesity. While overweight without obesity in childhood is associated with numerous health conditions [21], the grouping of participants with overweight and obesity together without appropriate stratification or subgroup analysis may dilute the real relationship between true obesity and the outcome of interest, which in some cases is considerably more pronounced than the effects of having overweight alone [6, 22]. Such issues are evident from studies that have stratified by BMI percentile, where the risk of co-morbidity rises as BMI increases, or prevalence is higher in groups with obesity compared to groups with overweight as defined by standardised cut-offs [11, 22].

Another potential source of inconsistent findings in research on the co-morbidities of child and adolescent obesity may be the numerous different age ranges used to define 'childhood' amongst the published literature. Whilst some studies will distinguish childhood from adolescence using either internationally recognised categories, or researcher-defined cut-offs, others will take an all-encompassing approach and group all participants together from early childhood up to late adolescence. An issue with this approach is that the physiological, behavioural and metabolic differences between a young child and an older adolescent may have a significant influence on the outcome of interest [23].

The aim of this current systematic review was therefore to update and synthesise the evidence base on the physical co-morbidities of childhood obesity, focusing specifically on the impact of obesity (rather than overweight) in children under 10 years old, and excluding co-morbidities of childhood obesity which have been well-established by previous systematic reviews and meta-analyses.

4. Methods

This systematic review was prospectively registered with PROSPERO-registration number: CRD42018079387. Preferred Reporting Items for Systematic reviews and Meta-analyses (PRISMA) checklist was used to inform the conduct and reporting of this review. The methods used were guided by two expert Cochrane reviewers (AM and CS).

4.1 Inclusion and exclusion criteria

Observational studies of a cross-sectional, longitudinal or case-control design were included if they reported one measure of adiposity (e.g. Body Mass Index) in childhood (WHO definition; ≤9.9 years) and measured at least one physical health outcome in either childhood or adolescence (age 0-19 years). Studies which included children older than 10 years of age were included if the mean age of the overall sample was ≤9.9 years. Therefore, the overall age range of children within the included studies was 2-19 years (a number of studies stratified by age groups).

Included studies were required to contain both groups with obesity and groups without obesity as a comparison within the sample, and be published in English. Studies were also required to include both children with and without the respective co-morbid conditions. Studies that only recruited children with co-morbidities were excluded.

A number of co-morbid conditions including cardiovascular disease markers, diabetes, dental carries, sleep apnoea and metabolic syndrome were not incorporated into the search strategy for this review as the relationship is either well established, or a recent good-quality systematic review has been published relating to these conditions [24-26]. Therefore, any studies reporting exclusively on these outcomes concerning childhood obesity were excluded. However, all other potential co-morbidities of childhood obesity were deemed eligible for inclusion in the review providing they met the inclusion criteria. Studies were excluded if:

- The study population had a prior health condition that would limit generalizability of the study findings (such as children born pre-term, or who had a disability).
- Studies that exclusively recruited children who had the outcome of interest (co-morbidity) without an unaffected comparison group (as this would not allow for the assessment of weight status on the incidence of the condition)
- All participants in the study population had the exposure (obesity) without a comparison group that did not have obesity.
- Reported exclusively non-physical conditions (i.e. mental health conditions).

- Recognised definitions of obesity were not used or reported in the study (e.g. $\geq 95^{th}$ percentile for age and gender using national or international growth charts).
- Children with Obesity and overweight were combined without stratification during analysis.
- The mean age of the sample was over 9.9 years at the time of obesity exposure.
- Anthropometry or presence of morbidities were obtained through parental or self-report (parental reporting of doctor diagnosis of condition was included).

4.2 Search strategy

A computerized search of five electronic bibliographic databases (MEDLINE, Embase, CINAHL, AMED within Ovid and SPORTDiscus within Ebsco database platforms) was undertaken from January 2001 to December 2016. A forward citation search was also conducted on all eligible studies up to December 2018. This allowed for the identification of relevant studies that had been published during the time that had elapsed between the original search and completion of full-text screening. A comprehensive systematic review was published in 2003 in this subject area [5] limiting the need to search databases from their inception. The search strategy used was checked and approved by a specialist librarian in addition to an experienced systematic reviewer (AM) before being executed in two database platforms (Ovid and EBSCOhost). The search strategy consisted of three categories, namely (i) population group, incorporating truncated terms such as ‘child*’, ‘infan*’, and ‘adolesc*’. (ii) Exposure, using adiposity-related terms (e.g., ‘body mass index’, ‘obes*’ and ‘adipos*). (iii) Outcomes, where broad headings were initially used (e.g., ‘health’, ‘comorbid*, or co-morbid*’) before becoming more focused on specific health conditions that were identified as potential co-morbidities of obesity from the published literature (e.g., ‘pes planus’, ‘asthma’, ‘musculoskeletal diseases’). Where possible, MESH-headings were used in addition to free-text words to account for databases without the MESH function and specific conditions not covered under MESH-headings. The search was restricted to children, human subjects, and primary research studies.

Identified studies were independently screened for eligibility by two reviewers (SM and JG), initially by title and abstract (a random 20% of identified papers were double-screened), before double full-text screening was conducted for all papers which were deemed eligible after title and abstract screening. In addition to the two reviewers discussing any inconsistencies in identification, where consensus could not be reached a 3rd reviewer (JRR) was included in the discussion to support resolution of the decision. Following full text screening, eligible studies had their reference lists searched for potentially relevant studies, as did relevant published systematic reviews. Relevant titles were exported to an excel spreadsheet and screened using the same methods as initially applied to the articles identified through database searches.

4.3 Quality assessment

The quality of eligible studies was assessed using an adapted version of the Newcastle Ottawa scale (NOS) previously used in a review by Herzog et al. (2013) [27]. The tool has been adapted to assess the quality of cross-sectional studies in addition to cohort and case-control studies. The scale assesses studies against the following criteria; (i) selection of the sample; (ii) comparability of the sample/participants; (iii) Assessment of exposure and outcomes. Stars are awarded for high quality aspects of each study against the three aforementioned criteria, with a total of 9 stars available for case-control and cohort studies, and 8 stars available for cross-sectional designs. Studies awarded less than 5 stars were classed as having a high risk of bias, while an award of ≥5 stars indicated low risk of bias. The scale has been specifically designed for non-randomised studies, and does not report summary scores, which have been shown to be unreliable [28]. Two researchers independently appraised each study before discussing any disagreements. No formal overall assessment of the quality of evidence was undertaken, as this review only included observational studies, which are deemed by GRADE [29] to be of either low to very low quality of evidence.

4.4 Data extraction

The following data were extracted from each study; authors, publication year, study design, study population characteristics (sample size, geographic location, age ranges, % female), method of recruitment, exposure (exposure assessment method, the definition of obesity), outcomes (outcome assessment method, the definition of outcome, number of outcomes), method of analysis, reported effect estimates (odds ratios, relative risk, proportions, prevalence and relevant confidence intervals), level of significance reported and confounders controlled for in the analysis. We also planned to collect any data on the socioeconomic status (SES) of children under study, given the known association between some medical conditions and SES in adults, and this field was included in our data extraction form. Data were extracted by two researchers independently using the pre-designed form, which was piloted on a random sample of studies prior to full data extraction commencing.

4.5 Data synthesis and meta-analysis

Both meta-analysis and narrative synthesis were performed for this review. Due to the inconsistent nature of information reported in a number of included studies, coupled with considerable study heterogeneity, it was not possible to include all the studies in the meta-analyses. Where narrative synthesis was adopted, recommendations outlined in the Cochrane handbook of systematic reviews were followed [30], whereby the characteristics of each study were summarised in terms of the study design, risk of bias, and study context for each outcome. This was then followed by an exploration of the similarities and differences between each studies' findings.

Random-effects meta-analysis was conducted on three outcomes in this review; asthma, vitamin D deficiency, and iron deficiency. Odds ratios and corresponding 95% confidence intervals were collated from studies reporting these results. For studies that did not report odds ratios, information was collected on the number of children with obesity versus children without obesity, in addition to the number who presented with the outcome of interest within these two exposure groups. Pooled odds ratios and 95% confidence intervals were generated using random-effects method on MetaXL meta-analysis software (Version 5.3; EpiGear International Pty Ltd). Forest plots were generated for each outcome, and funnel plots were used to visually assess publication bias. Heterogeneity and inconsistency was assessed using

Cochran's Q statistical test, with the inconsistency test (I^2 >50%) used to indicate moderate heterogeneity.

Where a significant proportion of the studies were of high risk of bias, a sensitivity analysis was conducted to assess whether their removal from the model significantly affected the overall result. For all analyses, the level of significance was set at ≤0.05.

5. Results

5.1 Description of included studies

Of the 27028 studies identified following database searches and de-duplication, 41 met the inclusion criteria (Figure 1). These studies presented results investigating relationships between childhood obesity and five distinct health outcomes; asthma (n=16) [31-45], vitamin D deficiency (n=10) [46-55], iron deficiency (n=10) [34, 56-64], flat footedness/pes planus (n=4)[65-68] and allergies (n=4) [34, 39, 69, 70]. Two of the studies identified reported results for more than one of the outcomes.

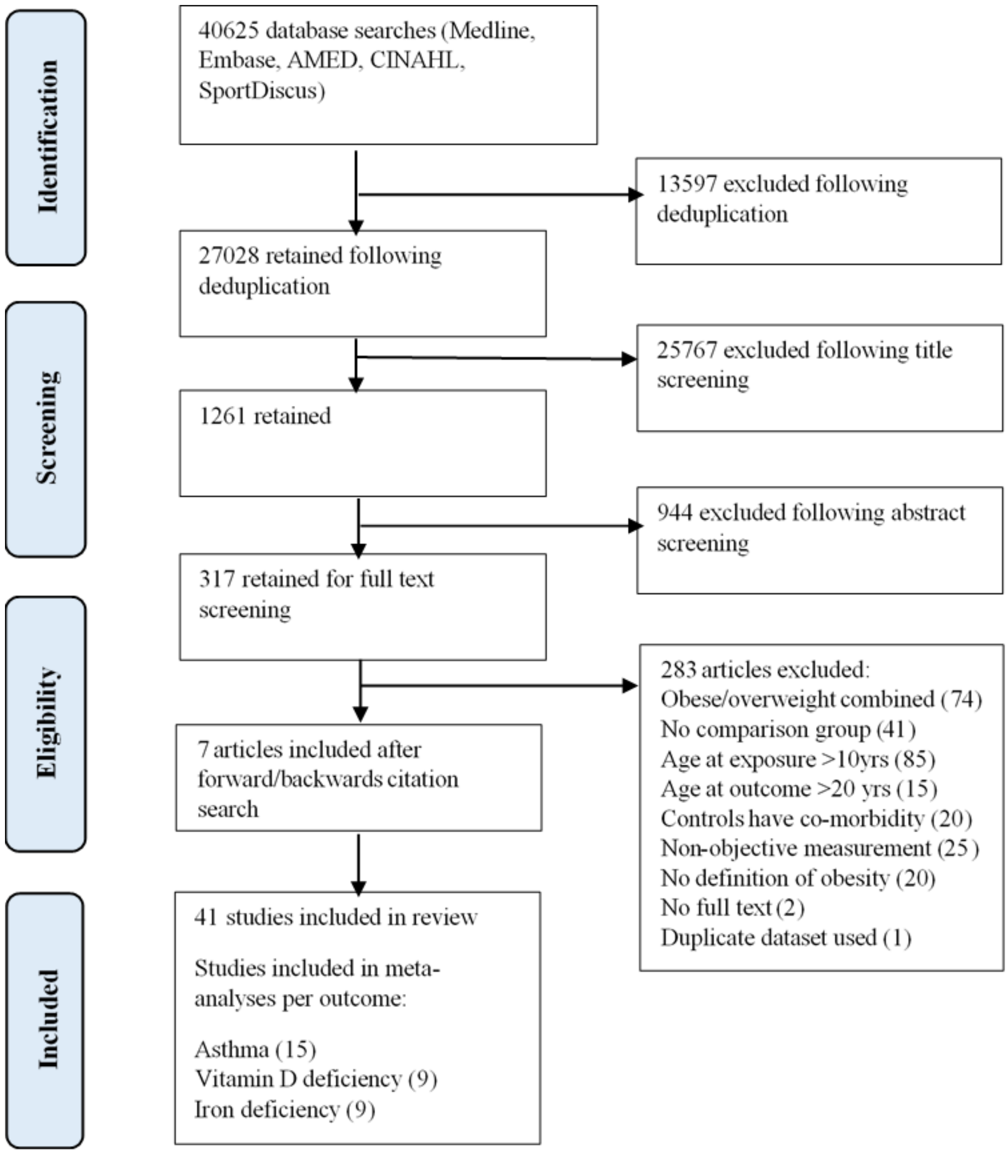


Figure 1. PRISMA flow diagram

Although one of the original aims of the review was to investigate obesity in children under <10 years and co-morbidity in later childhood or adolescence, we did not identify any longitudinal studies that followed young children into adolescence. Therefore, all analyses investigated the associations between having obesity and co-morbid conditions during childhood defined as under 10 years of age.

5.2 Study characteristics

Study characteristics are summarised in tables 1-5. The majority of included studies were cross-sectional studies (n=30), followed by case-control studies (n=8). Four studies were longitudinal, three being prospective cohort studies, and one a mendelian randomization study. Studies varied considerably by sample size, from a case-control study with 100 participants, to a repeat cross-sectional study totalling 36,152 participants. All studies involved the objective measurement of anthropometry by trained practitioners. All outcomes were objectively measured using established protocols, with the exception of asthma and allergies, for which the majority of studies employed valid diagnostic survey methods to obtain confirmation via parental report of diagnosis by a health professional.

5.3 Study quality

Overall, cohort studies were rated as having a lower risk of bias than the case-control studies, with mean NOS scores of 7.4/9 and 6.3/9, respectively (a higher score equates to a lower risk of bias). Cross-sectional studies had a mean score of 6.3 out of a possible 8 stars. In general, studies of all designs did not adequately describe or justify sample sizes, or demonstrate the representativeness of the sample to the general population. Due to the stringent inclusion criteria adopted for this review, the included studies all scored highly on the NOS items pertaining to 'assessment of exposures and outcomes'. Six studies received a rating of below 5 stars (4 cross-sectional and 2 case-control), and were deemed to have a high risk of bias. The NOS score and corresponding risk of bias for each study are summarised in Tables 1-5.

5.4 Association between childhood obesity and asthma

Fifteen studies were grouped comparing the odds of asthma diagnosis between children with and without obesity [31-45, 71]. Six studies presented results separately for different subgroups within the study sample (i.e. by age group and ethnicity) [32, 34, 38, 39, 42, 44], and these results are presented separately in the forest plot output (figure 2). Additionally, subgroup analysis of four studies that presented results separately for boys and girls is also included in the forest plot. The meta-analysis demonstrated that having childhood obesity significantly increased the odds of asthma diagnosis by over 50% in comparison to children without obesity (OR 1.5; 95% CI 1.3-1.7). Inconsistency was moderate ($I^2 = 57\%$). In subgroup analysis by sex, boys showed higher odds than girls for having asthma and obesity (OR 2.0; 95% CI 1.4-2.9 and OR 1.6; 95% CI 1.2-2.2, respectively). However, this finding was not statistically significant ($p>0.05$). Two of the studies were assessed as having a high risk of bias [31, 33]. However, removal of these studies from the model in a sensitivity analysis did not lead to a statistically significant change in the pooled result (OR 1.5; 95% CI 1.3-1.7). No publication bias was indicated by the funnel plot (figure 3).

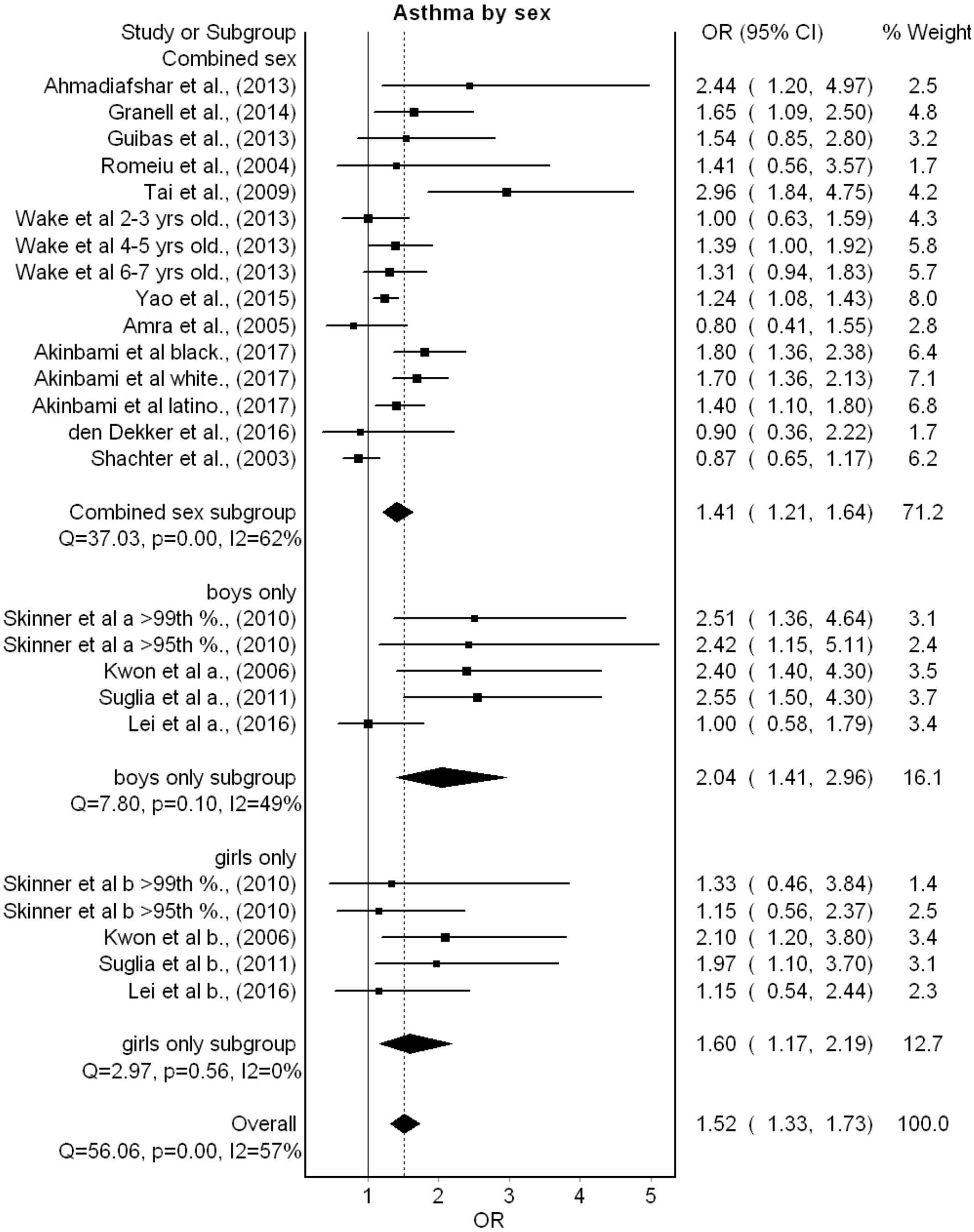


Figure 2. Forest plot for random effects meta-analysis of studies investigating relationships between childhood obesity and asthma.

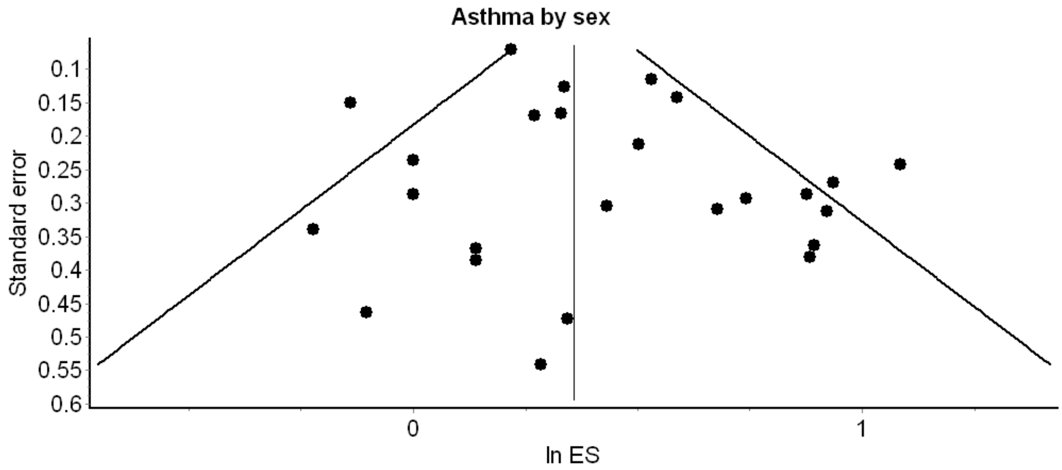


Figure 3. Funnel plot for studies reporting on the relationship between obesity and asthma

One additional study met the inclusion criteria for the review, but was not appropriate for inclusion in the meta-analysis, as it was a large prospective cohort study [71] which presented time-to-event analysis that would be poorly interpreted by conversion to odds., as The study was evaluated as having a low risk of bias, and reported that having moderate obesity (≥95th centile) and extreme obesity (≥99th centile) both significantly increased the risk of asthma diagnosis [71], .

5.5 Association between childhood obesity and Vitamin D deficiency

Nine separate studies were included in the meta-analysis of vitamin D deficiency and obesity [46-48, 50-55], resulting in a pooled odds ratio of 1.9 (95% CI 1.4-2.5) (figure 4) . The studies showed moderate heterogeneity (I^2 58%)).The majority of studies defined deficiency as <20 ng/ml, and one study reported separate odds ratios for deficiency and severe deficiency which have been added to the forest plot separately[50]. Studies that reported serum levels in nmol/L were less uniform, with deficiency cut-offs ranging from <17.5 nmol/L to <30 nmol/L[51, 55] (see table 2). Two of the studies included in the meta-analysis had a high risk of bias [46, 48]. When these studies were removed during sensitivity analysis, the pooled effect size was reduced to OR 1.7 (95% CI 1.3-2.3).

One additional study [49] reported insufficient data to allow for pooling within the meta-analysis, and was judged as having a high risk of bias [49]. This study reported significantly lower vitamin D levels in children with obesity, due to its small sample size, this study would not have significantly influenced the overall effect size in pooled analysis had it been included.

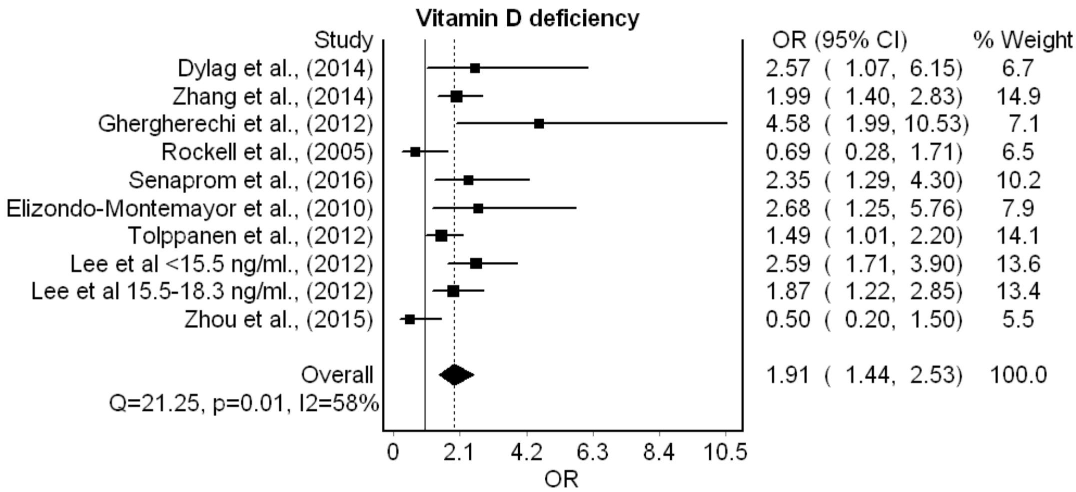


Figure 4. Forest plot for random effects meta-analysis of studies investigating relationships between childhood obesity and vitamin D deficiency.

5.6 Association between childhood obesity and iron deficiency

Ten studies investigated the relationship between childhood obesity and iron deficiency [34, 56-64], of which nine were appropriate for meta-analysis (Figure 5). Two of these studies conducted separate analyses by gender [34, 59], with both subgroups included in the model individually. Meta-analysis revealed that having obesity doubled the odds of iron deficiency diagnosis (OR 2.1; 95% CI 1.4-3.2). However, the removal of one study [56] with a large effect size during sensitivity analysis reduced the association (OR 1.8; 95% CI 1.3-2.6).

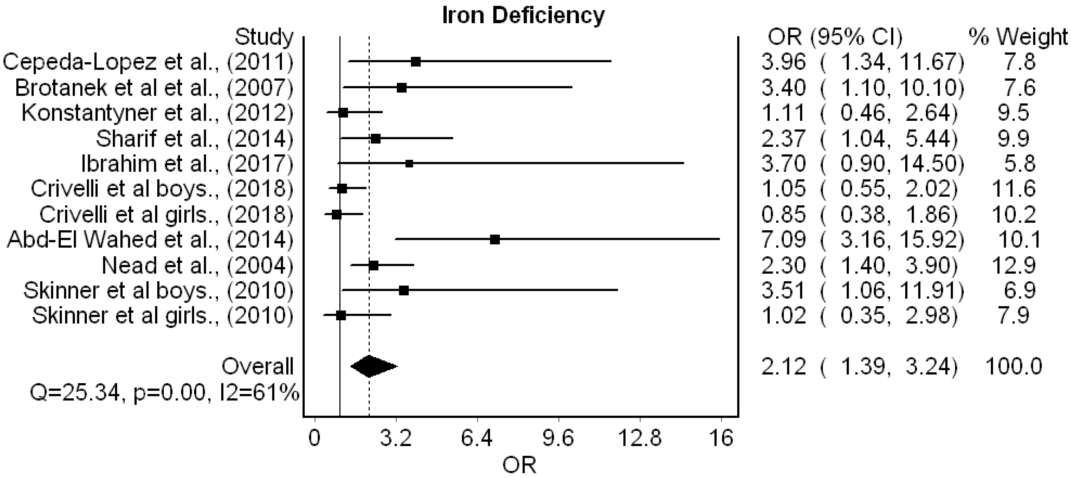


Figure 5. Forest plot for random effects meta-analysis of studies investigating relationships between childhood obesity and iron deficiency.

One case-control study [60] assessed as having a low risk of bias was not appropriate for meta-analysis due to insufficient reporting of data necessary for calculation of odds, and found children with obesity to have significantly different markers of iron deficiency than the control group. Specifically, Children with obesity had significantly lower iron, Transferrin saturation, and total-iron binding capacity along with higher ferritin, soluble transferrin receptors, and hepcidin-25 than children of normal weight.

5.7 Association between childhood obesity and pes planus (flat-footedness)

Four studies investigated the relationship between childhood obesity and having flat-footedness [65-68]. Of these, one was a longitudinal study [65], two were of a cross-sectional design [66, 67] and one was a case control study [68]. All four studies were of low risk of bias and reported a statistically significant association between having flat-footedness and obesity. One study [66] investigated both bilateral and unilateral flat-footedness, but only found having obesity to significantly increase the odds of the bilateral condition (OR 1.9; 95% CI 1.2-2.9), while the remaining three studies investigated bilateral flat-footedness only.. All four studies were assessed as having a low risk of bias following quality assessment (table 4).

5.8 Association between childhood obesity and allergies

Four studies assessed the relationship between childhood obesity and allergic conditions [34, 39, 69, 70]. Two distinct conditions were investigated within the studies; all four studies assessed eczema/dermatitis and one study also included rhinitis as an outcome [39]. Additionally, one study reported results from the skin prick test [70]. Three of these studies had a cross-sectional design and one was a case-control study [69]. All four studies had a low risk of bias (table 5). Three of the four studies found having obesity to increase the odds of eczema/dermatitis diagnosis, however these effects were small to moderate [39, 69, 70]. One study reported no association between eczema and obesity/severe obesity[34]. Having obesity was found to slightly increase the odds of rhinitis diagnosis in one study (OR 1.3 95% CI 1.0-1.7) when the sample was analysed collectively. However, a differential effect by gender was reported, as the association was only evident in girls and not boys [39]. Obesity was not found to significantly increase the odds of a positive skin prick test (OR 1.1 95% CI 0.9-1.4).

6. Discussion

This systematic review and meta-analysis investigated associations between obesity in young children and multiple co-morbid conditions. Though this topic has been studied through both primary research and recent systematic reviews [17, 18, 72-78], we investigated obesity as a distinct condition from overweight. This is in contrast to similar systematic reviews in the subject area, which have included studies that combine individuals with overweight or obesity, or do not stratify by weight status in the analysis [17-19, 73, 78]. We also used more stringent inclusion criteria to define childhood as children under 10 years, potentially offsetting the physiological, cultural and behavioural effects that later childhood/adolescence can have on obesity co-morbidities [79, 80].

The results of our review offer a number of important findings. Firstly, the meta-analysis of childhood obesity and asthma diagnosis appears to support previous results from systematic reviews in this area [18, 77, 78], while also further distinguishing the effects of having obesity considered explicitly from overweight. Chen et al. (2013)[77] reported a significantly higher risk of incident asthma among children and adolescents with obesity compared to children without obesity (relative risk 2.02; 95% CI 1.16-3.50), while a narrative synthesis by Papoutsakis et al. (2013)[18] concluded that there was a clear relationship between childhood obesity and asthma incidence. Our finding that having obesity at a young age increased the odds of asthma by over 50%, indicates that there is a possible relationship between the two conditions. However, we did not identify any longitudinal studies that were appropriate for meta-analysis based on our inclusion criteria, meaning the cross-sectional data that our findings are based on cannot offer any indication of a causal link between obesity and asthma. One cohort study included in our narrative synthesis found that not only did having a higher BMI predispose children to subsequent asthma development, but children with both asthma and obesity or overweight were also more likely to develop a severe asthma phenotype than healthy weight children with asthma [71]. A meta-analysis of six longitudinal studies also found that asthma risk increased by 35% among children with obesity/overweight [78]. Conversely, Chen et al. (2017) reported that asthma in fact preceded the onset of obesity even after controlling for glucocorticosteroid usage, with children with asthma having 51% higher risk of developing obesity at follow-up than children without asthma [81] .

There may be legitimate physiological and behavioural explanations for both directions of the relationship. Firstly, physiological consequences of obesity such as reduced lung and tidal volume, low-grade systemic inflammation and changes in adipose-derived hormones likely promote the onset of asthma [82]. Conversely, children with normal weight and asthma may be at a higher risk of developing overweight and obesity due to the observed tendency for children with asthma to avoid moderate-vigorous physical activity [83, 84], an important protective factor against excess weight gain[85]. Additionally, asthma medications such as glucocorticosteroids are theorised to promote weight gain through increased lipid metabolism and storage [81].

Of the four identified studies relating to musculoskeletal disorders included in our review, all related to flat-footedness, and all found having obesity to significantly increase risk. Other musculoskeletal disorders have been studied in relation to childhood obesity, however these did not meet our inclusion criteria. A recent review by Paulis and colleagues (2014) found musculoskeletal pain to be related to childhood overweight and obesity [73], supporting the findings of our review that obesity may have structural/biomechanical consequences. Potential physiological explanations for this are expressed in the literature, with excess fat deposits on feet, or excess load-bearing due to excess weight causing arches to collapse in children with obesity [68].

This review identified vitamin D deficiency as a condition that is associated with obesity in young children, a finding that has only previously been investigated in a small number of systematic reviews [17, 74, 75]. Periera-Santos and colleagues found that obesity in children and adolescents increased the prevalence of vitamin D deficiency by 37% in a meta-analysis of eight studies [74]. Another meta-analysis reported a pooled odds ratio of 3.43 (95% CI 2.33-5.06) [75]. Our finding from the present review that having obesity increases the odds of vitamin D deficiency further supports these findings. However, as with asthma, the studies which met the inclusion criteria for this review were all cross-sectional in nature, and therefore a causal relationship could not be confirmed. Physiological mechanisms of vitamin D deficiency as a consequence of obesity have been discussed in the literature [86], however the nature of the relationship is still poorly understood. A longitudinal study of Colombian 5-12 year olds found vitamin D deficient participants had a 0.1/year greater change in BMI than vitamin D sufficient children [9], indicating that the physiological effects of obesity such as impaired hydroxylation may contribute to lower vitamin D levels in children with obesity [87] .. It is also important to consider that vitamin D deficiency has been shown to increase asthma severity, which may indicate each condition may mediate any relationship with obesity [88]. Despite this, few studies included in this review controlled for this potential confounding (tables 1 and 2). Furthermore, it is theorized that having obesity may impair the bioavailability of vitamin D for bloodstream absorption, as it is fat-soluble, and instead stored in adipose tissue reservoirs [89], further highlighting the complexity of the relationship between the two conditions.

This review also found that childhood obesity increased the odds of having iron deficiency, which to our knowledge is only the second such meta-analysis to demonstrate this relationship, and the first to do so exclusively in children aged <10 years [76]. An important observation that applies to both vitamin D and iron deficiency, is that they are both nutritional deficiencies. It could therefore be that causation may be related to diet quality, as children with obesity have been shown to have poorer nutritional intake (lower nutrient density, consuming less iron-rich foods) than children with normal weight in epidemiological studies [90]. A small number of studies included in our review controlled for diet in their analysis [47, 49, 58], still finding the conditions to be associated with obesity. However, the majority of studies concerning vitamin D and iron status did not include diet/nutrient intake as a covariate, which may have confounded the results obtained for these studies. In the case of vitamin D, this can be extended to include time spent outdoors (or physical activity as a proxy measure of ultraviolet light exposure), as it has been demonstrated that children with obesity spend less time in outdoor play and longer periods sedentary indoors [91]. With vitamin D levels mediated by sunlight exposure [47], this could potentially explain the differences observed in children with obesity from a behavioural perspective. Therefore, the results of a number of included studies that did not control for these covariates should be interpreted with caution [46, 48, 50-53, 55]. In the case of iron deficiency, while mechanisms explaining effects of obesity on iron deficiency are not fully understood, individuals with obesity have both increased iron requirements (secondary to increased blood volume) and reduced iron absorption (secondary to increased inflammation) [92].. Interventions to reduce weight status in children with vitamin D and iron deficiency would therefore enhance understanding of the causal effects of having obesity in these conditions.

While the inclusion criteria adopted for this review is a strength of this study study there are a number of limitations that should be considered when interpreting the findings. We decided against conducting an overall assessment of the quality of evidence for each outcome by using Grade assessment criteria [29]. Despite this, an alternative assessment of some key quality indicators adds further context to the strength of the evidence presented in this review. Specifically, the majority of studies were cross-sectional or case-control studies, which are more susceptible to bias than longitudinal studies of the same methodological rigour. Secondly, inconsistency was evident as the moderate-high heterogeneity observed within the meta-analyses in this review reflect the fact that a number of included studies did not adequately control for confounding factors in their analyses. It is therefore possible that the results of this review may have been affected by residual confounding, and should be interpreted with caution. Definitive causal effects of childhood obesity on the co-morbid conditions identified in this review have still to be established, but plausible mechanisms have been identified as discussed above. It would therefore be beneficial for behavioural and environmental obesity treatment interventions to include measurement of morbidity as an outcome in evaluations, to determine if reductions in weight status are also accompanied by improvements in disease symptoms/presentation.

This systematic review and meta-analysis identified a number of co-morbidities of childhood obesity that were not well-established previously. Evidence of an association between childhood obesity and diagnosis of asthma, vitamin D deficiency, flat footedness and allergies is reported, in addition to the novel finding that iron deficiency is a potential co-morbidity of childhood obesity. Additionally, it appears that a better understanding of any important inequalities (by SES) in the relationship between obesity and health conditions in young children is needed to help support policy and practice with regards to obesity prevention in children [93]. Healthcare professionals may find our results helpful when treating pediatric patients with obesity, in terms of additional assessment and consideration for the co-morbid conditions identified and investigated in this review. The potential for obesity to cause harm as early as childhood is apparent, and efforts to prevent obesity in the early years could in turn alleviate the health burden of conditions associated with having excess weight in childhood.

Acknowledgements: This research was funded by the Cunningham Trust. AM was supported by the UK Medical Research Council (grant number MC_UU_12017/14) and the Scottish Government Chief Scientist Office (grant number SPHSU14) We are grateful to the reviewers who provided useful and insightful comments during peer review.

Conflicts of interest: The Authors declare that they have no conflicts of interest.

Table 1. Studies reporting on the relationship between obesity and asthma

Author and publication year	Study design	Country	Sample size (n)	age range or mean age	Obesity definition	Outcome definition	Outcome identification	Covariates	Results	Study quality (based on NOS score)
Ahmadiafshar et al. (2013)	case control	Iran	400	6-15 years	CDC growth charts	Report of Doctor diagnosis	asthma- history, clinical findings and pulmonary function test	-	Obesity increased odds of asthma: (OR = 2.44; 95% CI = 1.2-4.97)	High risk of bias (4/9)
Black et al. (2013)	prospective Cohort	USA	14,987	6-10 years	CDC growth charts: moderately obese (>95th percentile OR BMI >=30), and extremely obese (≥99th percentile OR BMI >=35)	Asthma Index ICD-9 code 493	Parental questionnaire	Sex, race/ethnicity, insurance payer	Obesity increased the risk of asthma: Moderate obese: overall (HR 1.32 95% CI = 1.26- 1.39) girls HR 1.36 95% CI = 1.27-1.46) boys (HR 1.28 95% CI = 1.21-1.36) Extreme obese: overall (HR 1.49 95% CI = 1.41-1.5) girls (HR 1.56 95% CI = 1.43-1.71) boys (HR 1.43 95% CI = 1.33-1.5)	Low risk of bias (9/9)
Skinner et al. (2010)	cross sectional	USA	2792	3-5 years	≥95th percentile obese; ≥99th percentile very obese	Report of Doctor diagnosis of asthma	Parental questionnaire/interview	age, race/ethnicity, income, insurance status	Obese or very obese status increased odds of asthma in boys but not in girls: very obese: boys (OR 2.51 95% CI 1.36-4.64; girls OR 1.33 95% CI 0.46-3.84). obese: boys (OR 2.42 95% CI 1.15-5.11; girls OR 1.15 95% CI 0.56-2.37)	Low risk of bias (8/8)
Granell et al. (2014)	mendillian randomization	UK	4835 (2376 girls)	7 and 9 years	≥95th percentile	Report of Doctor diagnosis of asthma	Parental questionnaire	-	Obesity increased the risk of asthma at 7 years old (RR 0.21; 95% CI 0.14-0.31)	Low risk of bias (9/9)
Guibas et al. (2013)	cross sectional	Greece	1622 (789 girls)	2-5 years	≥95th percentile	Report of Doctor diagnosis of asthma	Parental questionnaire	prenatal smoking, gestational age, birthweight, gender, parity, breastfeeding, passive smoking at	Obese status did not significantly increase odds of asthma (OR 1.54; 95% CI 0.85-280)	Low risk of bias (6/8)

								home, nationality, parental educational level		
Kwon et al. (2006)	cross sectional	USA	853 (431 girls)	7.5 years	UK 1990 growth charts	Report of Doctor or nurse diagnosis of asthma and evidence of asthma-like symptoms or asthma related emergency care use during the past year	Parental questionnaire	age, race/ethnicity, nativity, household smoking exposure	Obese status increased odd of asthma in boys and girls: (boys OR 2.4; 95% CI 1.4-4.3. Girls OR 2.1; 95% CI 1.2-3.8)	Low risk of bias (7/8)
Romeiu et al. (2004)	cross sectional	USA	3337	2-5 years	IOTF cuttoffs	Report of Doctor diagnosis of asthma and report of current asthma symptoms	Parental questionnaire	wheezing, atopy, physical activity, vitamin C consumption, dietary intake, race, poverty income ratio, passive smoking, parental asthma, hay fever ever	Obese status did not significantly increase the odds of asthma (OR 1.41; 95% CI .56-3.57)	Low risk of bias (7/8)
Suglia et al. (2011)	cross sectional	USA	1815	3 years	CDC growth charts	report of doctor diagnosis of asthma which had been active within the last year	Parental questionnaire	sex, race/ethnicity, low birth weight, maternal education, parent marital status, maternal age, public assistance, daycare attendance, maternal	Obese status increased odds of asthma in boys and girls (whole sample OR 2.26; 95% CI 1.5-3.3. Boys OR 2.55; 95% CI 1.5-4.3. Girls OR 1.97; 95% CI 1.1 - 3.7)	Low risk of bias (7/8)

								depression, intimate partner violence, child neglect, housing quality, tobacco exposure		
Tai et al. (2009)	cross sectional	Australia	1509 (737 girls)	4-5 years	CDC growth charts	Report of doctor diagnosis of asthma	Parental questionnaire	sex	Obese status increased odds of asthma (OR 2.96; 95% CI 1.84-4.75)	Low risk of Bias (5/8)
Wake et al. (2013)	cross sectional	Australia	13879	2-7 years	CDC growth charts	Report of doctor diagnosis of asthma with medication use in last 12 months	Parental questionnaire	-	Asthma prevalence: 2-3 yrs= normal weight- 10.1 (0.5); obese- 13.5 (2.4). 4-5 yrs= normal weight- 14.5 (0.6); obese- 19.1 (2.5). 6-7 yrs= normal weight- 15.4 (0.6); obese- 19.4 (2.6)	Low risk of bias (7/8)
Yao et al. (2015)	cross sectional	China	12 092 (5761 girls)	8.2 years	IOTF cuttoffs	Report of doctor diagnosis of asthma	Parental questionnaire	age, sex	Obese status increased the odds of asthma (OR 1.242; 95% CI .080, 1.429)	Low risk of bias (5/8)
Amra et al. (2005)	cross sectional	Iran	2413	7-12 years	IOTF cuttoffs	Report of doctor diagnosis of asthma	parental questionnaire	sex, age, parental smoking, family history	Obese status was significantly associated with asthma	High risk of bias (4/8)
Akinbami et al. (2017)	repeat cross sectional	USA	36,152	2-19 years	Cole et al 2000	CDC asthma surveillance definition	Parental questionnaire	age, sex, income status	Obese status significantly increased odds of asthma in white, black and Mexican American children (white OR 1.7; 95% CI 1.4- 2.2. black OR 1.8; 95% CI 1.6- 2.1. Mexican American OR 1.4; 95% CI 1.1- 1.8)	Low risk of bias (7/8)
den Dekker et al. (2016)	cross sectional	Netherlands	6178	6.2 years	≥95th percentile	Global Initiative for Asthma definition	Parental Questionnaire	maternal age, pre-pregnancy BMI, educational level, history of asthma and atopy, psychological distress	Obese status did not increase the odds of asthma (OR 0.90; 95% CI 0.36 - 2.22)	Low risk of bias (7/8)

								during pregnancy, parity, smoking during pregnancy, child's sex, gestational age at birth, birth weight, ethnicity, breast-feeding, pet keeping, physical activity, lower respiratory tract infections, current height		
Lei et al. (2016)	cross sectional	China	3327 (1,663 girls)	2-14 years	CDC growth charts	Report of doctor diagnosis of asthma	parental questionnaire	-	Obese status did not increase the odds of asthma (overall OR 1.09; 95% CI 0.68-1.72. boys OR 1.0; 95% CI 0.58-1.79. girls OR 1.15; 95% CI 0.54-2.44)	Low risk of bias (6/8)
Shachter et al. (2003)	cross sectional	Australia	5993 (2976 girls)	9.8 years	IOTF cuttoffs	Report of Doctor diagnosis of asthma, with present symptoms	Parental Questionnaire	family history of asthma, sex, atopy status, exposure to cigarette smoke	Obese status did not increase the odds of asthma (OR 0.87; 95% CI 0.65-1.17)	Low risk of bias (7/8)

Table 2. Studies reporting on the relationship between obesity and vitamin D deficiency

Author and publication year	Study design	Country	Sample size (n)	age range or mean age	Obesity definition	Outcome definition	Outcome identification	Covariates	Results	Study quality (based on NOS score)
Dylag et al. (2014)	Cross sectional	Poland	100 (55 girls)	1-5 years	WHO growth reference charts	Optimal vitamin D levels: >30≤50 ng/ml; suboptimal vitamin D levels: ≤30≥20 ng/ml; vitamin D Deficiency: <20 ng/ml	Blood test/assay	Age	Significantly lower mean difference in vitamin D concentrations: 23.6±10.8 obese, 26.6±9.8 non-obese.	High risk of bias (4/8)
Elizondo-Montemayor et al. (2010)	Cross sectional	Mexico	198 (98 girls)	9 years	WHO growth reference charts	Optimal vitamin D levels: ≥30 ng/ml; vitamin D insufficiency: 21-29 ng/ml; vitamin D deficiency: <20 ng/ml	overnight fasting blood sample assessed using competitive immunoluminometric direct assay	skin phototype, physical activity, screen time, vitamin use, diet	Obese status increased the odds of vitamin D deficiency (OR 2.679; 95% CI 1.245-5.765)	Low risk of bias (6/8)
Ghergherechi et al. (2012)	Case control	Iran	109	8.9 years	>95% centile for age and gender	<20ng DL vitamin D deficiency; <10 ng DL severe vitamin D deficiency	Blood test/assay	Age, sex, height	Vitamin D deficiency obese group = 76.9%; non-obese= 42.1%. Severe vitamin D deficiency obese group = 44.2%; non-obese= 17.5%	High risk of bias (4/9)
Jazar et al. (2011)	Cross sectional	Jordan	200 (100 girls)	3.3 years	CDC growth charts	vitamin D insufficiency, from 15 to 20 ng/mL; vitamin D deficiency, ≤ 15 ng/mL; severe vitamin D deficiency ≤ 5 ng/mL	Blood test/assay	duration of breastfeeding, duration of formula feeding, duration of outdoor physical activity, calcium intake, and dietary	Significantly lower mean serum vitamin D levels in obese participants compared to controls (obese serum vit D levels = 13.0 ± 2.5 v normal weight 25.4 ± 0.6)	High risk of bias (4/8)

								vitamin D intake		
Lee et al. (2013)	Cross sectional	South Korea	1660 (756 girls)	9 years	BMI ≥95th percentile for age and sex	< 20 ng/ml vitamin D deficient	blood collected after overnight fasting and 25(OH)D concentrations measured by chemiluminescent immunoassay	-	Obese status increased odds of having lower mean serum vitamin D levels	Low risk of bias (5/8)
Rockell et al. (2005)	Cross sectional	New Zealand	1585 (784 girls)	5-14 years	IOTF cuttoffs	Vitamin D deficient <17.5 nmol/L; vitamin D insufficient: <37.5 nmol/L	Blood sample/assay	age, ethnicity, latitude (North vs. South Island), season ("summer" vs winter" months)	Both vitamin D deficiency and insufficiency was significantly associated with obese status	Low risk of bias (7/8)
Senaprom et al. (2016)	Cross sectional	Thailand	477 (239 girls)	7.8 years	BMI-for-age Z-score (BAZ) >3 SD above the median for children aged 3-5.9 years (WHO, 2006) and as a BAZ >2 SD above the median for children aged 6-13 years	Vitamin D deficiency <50 nmol/l	fasting blood sample analysed by chemiluminescence immunoassay	-	Obese status was significantly associated with vitamin D deficiency	Low risk of bias (5/8)
Tolppanen et al. (2012)	Prospective cohort	United Kingdom	7555 (3744 girls)	9.8 years	Cole et al international BMI cuttoff values	Vitamin D deficiency < 20 ng/ml	non-fasting blood samples assayed using HPLC tandem mass spectrometry	-	Odds of vitamin D deficiency in obese participants was 1.49 (95% CI 1.01-2.20)	Low risk of bias (7/9)
Zhang et al. (2014)	Cross sectional	China	1488 (656 girls)	8.8 years	Chinese obesity task force cuttoff values	Vitamin D deficiency= <20 ng/mL; vitamin D insufficiency= 20-30 ng/mL; vitamin D sufficiency = >30 ng/mL	Blood sample and liquid chromatography	age, gender, dietary energy intake, energy expenditure	Significantly higher prevalence of vitamin D deficiency among obese participants compared to normal weight	Low risk of bias (7/8)
Zhou et al. (2014)	Cross sectional	Australia	221 (105 girls)	1-5 years	WHO growth reference charts	Deficiency =vit D<30 nmol/L; insufficiency = Vit D ≥30 and<50 nmol/L	Non-fasting blood sample and assay	-	No significant difference between mean serum vitamin D levels in obese and normal weight individuals	Low risk of bias (6/8)

Table 3. Studies reporting on the relationship between obesity and iron deficiency

Author and publication year	**Study design**	**Country**	**Sample size (n)**	**age range or mean age**	**Obesity definition**	**Outcome definition**	**Outcome identification**	**Covariates**	**Results**	**Study quality (based on NOS score)**
Abd-El Wahed et al. (2014)	Case control	Egypt	120 (62 girls)	9.25 years	CDC growth charts	the presence of two or more of the following abnormal parameters: Mean corpuscular volume (MCV) is 76 fl or less; Serum TS 15% or less; Serum ferritin less than 10 mg/ml	Blood sample/assay	Age, sex	Obese status increased odds of iron deficiency (OR 7.09; 95% CI 3.16–15.92)	Low risk of bias (8/8)
Brotanek et al. (2007)	Cross sectional	United States	960 (434 girls)	1-3 years	weight-for-length status of ≥95th percentile	Ages 1 to 2 years, iron deficiency <10% transferrin saturation < 10 g/L of serum ferritin, and >1.42 mol/L of red blood cells erythrocyte protoporphyrin. For 3-year-old children, < 12% < 10 g/L, and >1.24 mol/L of red blood cells	Blood sample/assay	race/ethnicity, interview language, preschool/day care attendance	Obese status increased odds of iron deficiency (OR 3.34; 95% CI 1.10-10.12)	Low risk of bias (8/8)
Cepeda-Lopez et al. (2011)	Cross sectional	Mexico	1174 (49% girls)	8.17 years	WHO growth reference charts	either 1) low serum iron (<60 ug/dL) or 2) elevated TIBC (>360 ug/dL) and low %TS (<20%) values	Blood sample/assay	Age, sex, region, area, caregiver eduation	Obese status increased the odds of iron deficiency (OR 3.96; 95% CI 1.34-11.67)	Low risk of bias (7/8)
Skinner et al. (2010)	Cross sectional	United States	2792	3-5 years	CDC growth charts	Taking medication for anemia and laboratory values of hemoglobin <11 g/dL.16	Blood sample/assay	Age, ethnicity, income, insurance status	Obese status increased the odds of anaemia in boys but not in girls (Boys OR 3.51; 95% CI 1.06-11.91. Girls OR 1.02; 95% CI 0.35-2.98)	Low risk of bias (8/8)
Crivelli et al. (2018)	Cross sectional	Tajikistan	1320 (653 girls)	2-5 years	WHO growth reference charts	WHO cut-off value for iron deficiency in children (Hb <11 g/dl)	finger prick test using Drabkin's reagent for Hb analysis	age, sex, location, parental education, region	Obese status did not increase odds of iron deficiency in boys or girls (Boys: OR 1.05 95% CI 0.55–2.0; girls: OR 0.85 95% CI 0.38–1.86)	Low risk of bias (7/8)
Hamza et al. (2013)	Case control	Egypt	100 (42 girls)	9.8 years	Cole et al	Fe deficient when 2 or more Fe profile values were abnormal for age and gender: serum	Blood sample/assay	age	Fe, TS and TIBC were significantly lower, while ferritin, sTfR and hepcidin-25 were	Low risk of bias (8/9)

						Fe <20 µg/dl, TICB >494 µg/dl, ferritin <12 µg/dl, TS <16% [2] , and sTfR >8.3 mg/l			significantly higher in obese children versus controls	
Ibrahim et al. (2017)	Case control	Jordan	150 (61 girls)	2.1 years	WHO growth reference charts	Internationally accepted cut-off values for biochemical iron markers: Hb (g/l)= 9.5-14.5; SF (ng/ml) =29-160; and SI (µg/dl)= 25- 115.	Blood sample/assay	Age	Odds of iron deficiency in obese group compared to normal weight was 3.7 (95% CI 0.9-14.5)	Low risk of bias (6/8)
Konstantyner et al. (2012)	Cross sectional	Brazil	1325	1-2 years	WHO growth reference charts	mild iron deficiency anemia: Hb < 11.0 g/dL; moderate iron deficiency anemia: Hb < 9.5 g/dL	high performance liquid chromatography (HPLC) of dried blood spot samples	-	Obese status did not increase the odds of mild or moderate anemia. mild anemia: OR 1.11 (0.46; 2.64); moderate anemia: 2.41 (0.80; 7.30)	Low risk of bias (7/8)
Nead et al. (2004)	Cross sectional	United States	9698	2-16 years	CDC growth charts	iron-deficient if 2 of 3 values were abnormal for age and gender. Anemia =Hemoglobin cutoff points used to define anemia were based on the 5th percentiles for the reference groups	Blood sample/assay	Age, gender, race/ethnicity, poverty status, caretaker education	Obese status increased the odds of iron deficiency (OR 2.3; 95% CI 1.4-3.9)	Low risk of bias (6/8)
Sharif et al. (2014)	Case control	Iran	100 children (49 girls)	9.5 years	CDC growth charts	Serum iron levels less than 50microg/dL and TIBC higher than 450 microg/dL were defined as iron deficiency	blood sample biochemistry method and plasma ferritin by ELISA method	-	Prevalence of iron deficiency significantly higher in obese versus normal weight children (48% versus 28%)	Low risk of bias (5/9)

Table 4. Studies reporting on the relationship between obesity and musculoskeletal disorders

Author and publication year	**Study design**	**Country**	**Sample size (n)**	**age range or mean age**	**Obesity definition**	**Outcome definition**	**Outcome identification**	**Covariates**	**Results**	**Study quality (based on NOS score)**
Chen 1 et al. (2013)	prospective Cohort	Taiwan	580 (283 girls)	3-5 years	Taiwanese FDA definitions of obesity for children and adolescents	Flatfoot= AB distance by CSI > 62.70 %. CSI is defined as the ratio of the minimum width of the midfoot arch region (B) to the maximum width of the metatarsus region (A)	Clinician measurement using digital footprint mat	Age	Prevalence of flatfoot was significantly higher in obese children	Low risk of bias (6/9)
Chen 2 et al. (2011)	cross sectional	Taiwan	1598 (765 girls)	3-6 years	Taiwanese FDA definitions of obesity for children and adolescents	clinical presentations of malformation of the medial longitudinal arch in a weight bearing position	Clinician examination of foot	age, sex, joint laxity, W sitting	Obese status increased the odds of bilateral flatfoot, but di not increase odds of unilateral flatfoot (Bilateral OR 1.90; 95% CI 1.22-2.95. unilateral OR 1.39; 95% CI 0.80-2.41)	Low risk of bias (6/8)
Ezema et al. (2014)	cross-sectional	Nigeria	474 (253 girls)	6-10 years	CDC growth charts	Plantar arch index value >1.15	Ink footprint test	-	Prevalence of flatfoot was significantly higher in obese children	Low risk of bias (7/8)
Riddiford-Harland et al. (2011)	case control	Australia	150 (98 girls)	8.3 years	Cole et al. (2000)	Clinical presentation of reduced foot arch on ultrasound	Ultrasound	Age, sex	Prevalence of flatfoot was significantly higher in obese children	Low risk of bias (8/9)

Table 5. Studies reporting on the relationship between obesity and allergies

Author and publication year	Study design	Country	Sample size (n)	age range or mean age	Obesity definition	Outcome definition	Outcome identification	Covariates	Results	Study quality (based on NOS score)
Lei et al. (2016)	Cross sectional	China	3327 (1,663 girls)	2-14 years	Chinese growth charts	Allergic Rhinitis and its Impact on Asthma criteria and atopic dermatitis using the Hanifin and Rajka criteria	Clinical examination by doctor	-	Rhinitis overall: 1.33 (1.04–1.72); girls: 1.48 (1.00–2.18); boys: 1.20 (0.86–1.67). Dermatitis overall: 1.33 (1.02–1.74); girls: 1.42 (0.93–2.16); boys: 1.24 (0.87–1.75)	Low risk of bias (6/8)
Silverberg et al. (2011)	Case control	United States	1242 (592 girls)	7 years	WHO growth reference charts for <2 year olds; CDC growth charts for > 2 year olds	International Classification of Diseases–ninth revision diagnostic code 691.8 for atopic dermatitis	Clinical examination by doctor	Sex; season of birth; comorbid asthma, allergic rhinoconjunctivitis, and food allergy; race/ethnicity; and immunization up-to-date, Age at the time of the study and at first diagnosis of atopic dermatitis, height, height for age, weight, weight for age, head circumference, head circumference for age	Obese status increased odds of atopic dermatitis (OR 2.00 95% CI 1.22-3.26)	Low risk of bias (8/9)
Skinner et al. (2010)	Cross sectional	United States	2792	3-5 years	CDC growth charts	Clinical guidelines for eczema diagnosis	Parental report of doctor diagnosis of eczema	Age, race/ethnicity,	Obese or very obese status did not increase odds of	Low risk of bias (8/8)

								income, insurance status	eczema diagnosis in boys or girls	
Weinmayr et al. (2014)	cross sectional	Multi-centre: Brazil, Estonia, Georgia, Germany, Ghana, Greece, India, Italy, Latvia, Netherlands, New Zealand, Norway, Palestine, Spain, Sweden, Turkey	10652	9.4 years	Cole et al 2000	Clinical guidelines for allergic presentations	Clinical examination by trained fieldworker, skin prick test	Sex	skin prick test= OR 1.13 (0.91;1.42), examined eczema without wheeze = 2.07 (1.03;4.17)	Low risk of bias (7/8)

7. References

1 Kelsey MM, Zaepfel A, Bjornstad P, Nadeau KJ. Age-related consequences of childhood obesity. *Gerontology*. 2014; 60: 222-28.

2 Reilly JJ, Kelly J. Long-term impact of overweight and obesity in childhood and adolescence on morbidity and premature mortality in adulthood: systematic review. *International journal of obesity*. 2011; 35: 891.

3 Sorof J, Daniels S. Obesity hypertension in children: a problem of epidemic proportions. *Hypertension*. 2002; 40: 441-47.

4 Meyer AA, Kundt G, Steiner M, Schuff-Werner P, Kienast W. Impaired flow-mediated vasodilation, carotid artery intima-media thickening, and elevated endothelial plasma markers in obese children: the impact of cardiovascular risk factors. *Pediatrics*. 2006; 117: 1560-67.

5 Reilly JJ, Methven E, McDowell ZC, *et al.* Health consequences of obesity. *Archives of disease in childhood*. 2003; 88: 748-52.

6 Friedemann C, Heneghan C, Mahtani K, Thompson M, Perera R, Ward AM. Cardiovascular disease risk in healthy children and its association with body mass index: systematic review and meta-analysis. *Bmj*. 2012; 345: e4759.

7 Goran MI, Ball GD, Cruz ML. Obesity and risk of type 2 diabetes and cardiovascular disease in children and adolescents. *The Journal of Clinical Endocrinology & Metabolism*. 2003; 88: 1417-27.

8 Schwimmer JB, Deutsch R, Kahen T, Lavine JE, Stanley C, Behling C. Prevalence of fatty liver in children and adolescents. *Pediatrics*. 2006; 118: 1388-93.

9 Gilbert-Diamond D, Baylin A, Mora-Plazas M*, et al.* Vitamin D deficiency and anthropometric indicators of adiposity in school-age children: a prospective study. *The American journal of clinical nutrition*. 2010; 92: 1446-51.

10 Riddiford-Harland D, Steele J, Storlien L. Does obesity influence foot structure in prepubescent children? *International journal of obesity*. 2000; 24: 541.

11 Von Kries R, Hermann M, Grunert V, Von Mutius E. Is obesity a risk factor for childhood asthma? *Allergy*. 2001; 56: 318-22.

12 Bonuck K, Chervin RD, Howe LD. Sleep-disordered breathing, sleep duration, and childhood overweight: a longitudinal cohort study. *The Journal of pediatrics*. 2015; 166: 632-39.

13 Vázquez-Nava F, Vázquez-Rodríguez EM, Saldívar-González AH, Lin-Ochoa D, Martínez-Perales GM, Joffre-Velázquez VM. Association between obesity and dental caries in a group of preschool children in Mexico. *Journal of public health dentistry*. 2010; 70: 124-30.

14 Akinci A, Cetinkaya E, Aycan Z, Oner O. Relationship between intraocular pressure and obesity in children. *Journal of glaucoma*. 2007; 16: 627-30.

15 Ahmadizar F, Vijverberg SJ, Arets HG*, et al.* Childhood obesity in relation to poor asthma control and exacerbation: a meta-analysis. *European Respiratory Journal*. 2016; 48: 1063-73.

16 Figueroa-Munoz J, Chinn S, Rona R. Association between obesity and asthma in 4–11 year old children in the UK. *Thorax*. 2001; 56: 133-37.

17 Pulgaron ER. Childhood obesity: a review of increased risk for physical and psychological comorbidities. *Clinical therapeutics*. 2013; 35: A18-A32.

18 Papoutsakis C, Priftis KN, Drakouli M*, et al.* Childhood overweight/obesity and asthma: is there a link? A systematic review of recent epidemiologic evidence. *Journal of the Academy of Nutrition and Dietetics*. 2013; 113: 77-105.

19 Noal R, Menezes A, Macedo S, Dumith S. Childhood body mass index and risk of asthma in adolescence: a systematic review. *Obesity reviews*. 2011; 12: 93-104.
20 Castro-Rodriguez JA, Forno E, Rodriguez-Martinez CE, Celedón JC. Risk and protective factors for childhood asthma: what is the evidence? *The Journal of Allergy and Clinical Immunology: In Practice*. 2016; 4: 1111-22.
21 Bell LM, Byrne S, Thompson A*, et al.* Increasing body mass index z-score is continuously associated with complications of overweight in children, even in the healthy weight range. *The Journal of Clinical Endocrinology & Metabolism*. 2006; 92: 517-22.
22 Chang J-H, Wang S-H, Kuo C-L, Shen HC, Hong Y-W, Lin L-C. Prevalence of flexible flatfoot in Taiwanese school-aged children in relation to obesity, gender, and age. *European journal of pediatrics*. 2010; 169: 447-52.
23 Trost SG, Pate RR, Sallis JF*, et al.* Age and gender differences in objectively measured physical activity in youth. *Medicine and science in sports and exercise*. 2002; 34: 350-55.
24 Manohar N, Hayen A, Fahey P, Arora A. Obesity and dental caries in early childhood: A systematic review and meta-analyses. *Obesity Reviews*. 2019.
25 McCurley JL, Crawford MA, Gallo LC. Prevention of type 2 diabetes in US hispanic youth: a systematic review of lifestyle interventions. *American journal of preventive medicine*. 2017; 53: 519-32.
26 Andersen IG, Holm J-C, Homøe P. Obstructive sleep apnea in obese children and adolescents, treatment methods and outcome of treatment–a systematic review. *International journal of pediatric otorhinolaryngology*. 2016; 87: 190-97.
27 Herzog R, Álvarez-Pasquin MJ, Díaz C, Del Barrio JL, Estrada JM, Gil Á. Are healthcare workers' intentions to vaccinate related to their knowledge, beliefs and attitudes? A systematic review. *BMC public health*. 2013; 13: 154.
28 Voss PH, Rehfuess EA. Quality appraisal in systematic reviews of public health interventions: an empirical study on the impact of choice of tool on meta-analysis. *J Epidemiol Community Health*. 2013; 67: 98-104.
29 Balshem H, Helfand M, Schünemann HJ*, et al.* GRADE guidelines: 3. Rating the quality of evidence. *Journal of clinical epidemiology*. 2011; 64: 401-06.
30 Rodgers M, Sowden A, Petticrew M*, et al.* Testing methodological guidance on the conduct of narrative synthesis in systematic reviews: effectiveness of interventions to promote smoke alarm ownership and function. *Evaluation*. 2009; 15: 49-73.
31 Ahmadiafshar A, Tabbekhha S, Mousavinasab N, Khoshnevis P. Relation between asthma and body mass index in 6-15 years old children. *Acta Medica Iranica*. 2013: 615-19.
32 Akinbami LJ, Rossen LM, Fakhouri TH, Simon AE, Kit BK. Contribution of weight status to asthma prevalence racial disparities, 2–19 year olds, 1988–2014. *Annals of epidemiology*. 2017; 27: 472-78. e3.
33 Amra B, Rahmani A, Salimi S, Mohammadzadeh Z, Golshan M. Association between asthma and body mass index in children. *Iranian Journal of Allergy, Asthma and Immunology*. 2005: 33-38.
34 Cockrell Skinner A, Perrin EM, Steiner MJ. Healthy for now? A cross-sectional study of the comorbidities in obese preschool children in the United States. *Clinical pediatrics*. 2010; 49: 648-55.

35 Granell R, Henderson AJ, Evans DM, *et al.* Effects of BMI, fat mass, and lean mass on asthma in childhood: a Mendelian randomization study. *PLoS medicine*. 2014; 11: e1001669.
36 Guibas G, Manios Y, Xepapadaki P, *et al.* The obesity–asthma link in different ages and the role of Body Mass Index in its investigation: findings from the G enesis and H ealthy G rowth S tudies. *Allergy*. 2013; 68: 1298-305.
37 Herman T, Ros KP, de Jongste JC, Reiss IK, Jaddoe VW, Duijts L. Body fat mass distribution and interrupter resistance, fractional exhaled nitric oxide, and asthma at school-age. *Journal of Allergy and Clinical Immunology*. 2017; 139: 810-18. e6.
38 Kwon HL, Ortiz B, Swaner R, *et al.* Childhood asthma and extreme values of body mass index: the Harlem Children's Zone Asthma Initiative. *Journal of Urban Health*. 2006; 83: 421-33.
39 Lei Y, Yang H, Zhen L. Obesity is a risk factor for allergic rhinitis in children of Wuhan (China). *Asia Pacific Allergy*. 2016; 6: 101-04.
40 Romieu I, Mannino DM, Redd SC, McGeehin MA. Dietary intake, physical activity, body mass index, and childhood asthma in the Third National Health And Nutrition Survey (NHANES III). *Pediatric pulmonology*. 2004; 38: 31-42.
41 Schachter L, Peat J, Salome C. Asthma and atopy in overweight children. *Thorax*. 2003; 58: 1031-35.
42 Suglia SF, Chambers EC, Rosario A, Duarte CS. Asthma and obesity in three-year-old urban children: role of sex and home environment. *The Journal of pediatrics*. 2011; 159: 14-20. e1.
43 Tai A, Volkmer R, Burton A. Association between asthma symptoms and obesity in preschool (4-5 year old) children. *Journal of Asthma*. 2009; 46: 362-65.
44 Wake M, Clifford S, Patton G, *et al.* Morbidity patterns among the underweight, overweight and obese between 2 and 18 years: population-based cross-sectional analyses. *International journal of obesity*. 2013; 37: 86.
45 Yao J, Zhou Y, Wang J, *et al.* Relationship between obesity and sex, and prevalence of asthma-like disease and current wheeze in Han children in Nanjing, China. *Journal of International Medical Research*. 2015; 43: 139-46.
46 Dylag H, Rowicka G, Strucinska M, Riahi A. Assessment of vitamin D status in children aged 1-5 with simple obesity. *Roczniki Państwowego Zakładu Higieny*. 2014; 65.
47 Elizondo-Montemayor L, Ugalde-Casas PA, Serrano-González M, Cuello-García CA, Borbolla-Escoboza JR. Serum 25-hydroxyvitamin d concentration, life factors and obesity in Mexican children. *Obesity*. 2010; 18: 1805-11.
48 Ghergherehchi R, Tabrizi A. Vitamin D deficiency and secondary hyperparathyroidism in pediatrics obesity. *Caspian Journal of Internal Medicine*. 2010; 1: 119-27.
49 Jazar AS, Takruri HR, Bulos NAK. Vitamin D status in a sample of preschool children aged from 1 to 6 years visiting the pediatrics clinic at Jordan University hospital. *Jordan Medical Journal*. 2011; 171: 1-18.
50 Lee S, Kim SM, Park H, *et al.* Serum 25-hydroxyvitamin D levels, obesity and the metabolic syndrome among Korean children. *Nutrition, Metabolism and Cardiovascular Diseases*. 2013; 23: 785-91.

51 Rockell JE, Green TJ, Skeaff CM*, et al.* Season and ethnicity are determinants of serum 25-hydroxyvitamin D concentrations in New Zealand children aged 5–14 y. *The Journal of nutrition*. 2005; 135: 2602-08.
52 Senaprom S, Yamborisut U, Rojroongwasinkul N*, et al.* Factors associated with vitamin D statud among Thai children aged 3-13 years. *Southeast Asian Journal of Tropical Medicine and Public Health*. 2016; 47: 277.
53 Tolppanen A-M, Fraser A, Fraser WD, Lawlor DA. Risk factors for variation in 25-hydroxyvitamin D3 and D2 concentrations and vitamin D deficiency in children. *The Journal of Clinical Endocrinology & Metabolism*. 2012; 97: 1202-10.
54 Zhang H-q, Teng J-h, Li Y*, et al.* Vitamin D status and its association with adiposity and oxidative stress in schoolchildren. *Nutrition*. 2014; 30: 1040-44.
55 Zhou SJ, Skeaff M, Makrides M, Gibson R. Vitamin D status and its predictors among pre-school children in A delaide. *Journal of paediatrics and child health*. 2015; 51: 614-19.
56 Abd-El Wahed MA, Mohamed MH, Ibrahim SS, El-Naggar WA. Iron profile and dietary pattern of primary school obese Egyptian children. *The Journal Of The Egyptian Public Health Association*. 2014; 89: 53-59.
57 Brotanek JM, Gosz J, Weitzman M, Flores G. Iron deficiency in early childhood in the United States: risk factors and racial/ethnic disparities. *Pediatrics*. 2007; 120: 568-75.
58 Cepeda-Lopez AC, Osendarp SJ, Melse-Boonstra A*, et al.* Sharply higher rates of iron deficiency in obese Mexican women and children are predicted by obesity-related inflammation rather than by differences in dietary iron intake. *The American journal of clinical nutrition*. 2011; 93: 975-83.
59 Crivelli M, Wyss K, Grize L, Matthys B, Aebi T, Zemp E. Are overweight and obesity in children risk factors for anemia in early childhood? Results from a national nutrition survey in Tajikistan. *International journal of public health*. 2018; 63: 491-99.
60 Hamza RT, Hamed AI, Kharshoum RR. Iron homeostasis and serum hepcidin-25 levels in obese children and adolescents: relation to body mass index. *Hormone research in paediatrics*. 2013; 80: 11-17.
61 Ibrahim LS, Tayyem RF. Evaluation of Iron Deficiency and the Intake of Macro-and Micronutrients among Normal, Overweight, and Obese Children Under 5 Years in Amman. *Iranian Journal of Pediatric Hematology & Oncology*. 2018; 8.
62 Konstantyner T, Roma Oliveira TC, de Aguiar Carrazedo Taddei JA. Risk factors for anemia among Brazilian infants from the 2006 National Demographic Health Survey. *Anemia*. 2012; 2012.
63 Nead KG, Halterman JS, Kaczorowski JM, Auinger P, Weitzman M. Overweight children and adolescents: a risk group for iron deficiency. *Pediatrics*. 2004; 114: 104-08.
64 Sharif M, Madani M, Tabatabaie F. Comparative evaluation of iron deficiency among obese and non-obese children. *Iranian journal of pediatric hematology and oncology*. 2014; 4: 160.
65 Chen K-C, Tung L-C, Yeh C-J, Yang J-F, Kuo J-F, Wang C-H. Change in flatfoot of preschool-aged children: a 1-year follow-up study. *European journal of pediatrics*. 2013; 172: 255-60.

66 Chen K-C, Yeh C-J, Tung L-C, Yang J-F, Yang S-F, Wang C-H. Relevant factors influencing flatfoot in preschool-aged children. *European journal of pediatrics*. 2011; 170: 931-36.
67 Ezema C, Abaraogu U, Okafor G. Flat foot and associated factors among primary school children: A cross-sectional study. *Hong Kong Physiotherapy Journal*. 2014; 32: 13-20.
68 Riddiford-Harland D, Steele J, Baur L. Are the feet of obese children fat or flat? Revisiting the debate. *International Journal of Obesity*. 2011; 35: 115.
69 Silverberg JI, Kleiman E, Lev-Tov H*, et al.* Association between obesity and atopic dermatitis in childhood: a case-control study. *Journal of Allergy and Clinical Immunology*. 2011; 127: 1180-86. e1.
70 Weinmayr G, Forastiere F, Büchele G*, et al.* Overweight/obesity and respiratory and allergic disease in children: international study of asthma and allergies in childhood (ISAAC) phase two. *PloS one*. 2014; 9: e113996.
71 Black MH, Zhou H, Takayanagi M, Jacobsen SJ, Koebnick C. Increased asthma risk and asthma-related health care complications associated with childhood obesity. *American journal of epidemiology*. 2013; 178: 1120-28.
72 Cepeda-Lopez AC, Aeberli I, Zimmermann MB. Does obesity increase risk for iron deficiency? A review of the literature and the potential mechanisms. *International journal for vitamin and nutrition research*. 2010; 80: 263.
73 Paulis W, Silva S, Koes B, van Middelkoop M. Overweight and obesity are associated with musculoskeletal complaints as early as childhood: a systematic review. *Obesity Reviews*. 2014; 15: 52-67.
74 Pereira-Santos M, Costa PRdF, Assis A, Santos CAdST, Santos DBd. Obesity and vitamin D deficiency: a systematic review and meta-analysis. *Obesity reviews*. 2015; 16: 341-49.
75 Yao Y, Zhu L, He L*, et al.* A meta-analysis of the relationship between vitamin D deficiency and obesity. *International journal of clinical and experimental medicine*. 2015; 8: 14977.
76 Zhao L, Zhang X, Shen Y, Fang X, Wang Y, Wang F. Obesity and iron deficiency: a quantitative meta-analysis. *Obesity reviews*. 2015; 16: 1081-93.
77 Chen Y, Dong G, Lin K, Lee Y. Gender difference of childhood overweight and obesity in predicting the risk of incident asthma: a systematic review and meta-analysis. *Obesity Reviews*. 2013; 14: 222-31.
78 Egan KB, Ettinger AS, Bracken MB. Childhood body mass index and subsequent physician-diagnosed asthma: a systematic review and meta-analysis of prospective cohort studies. *BMC pediatrics*. 2013; 13: 121.
79 Stice E, Presnell K, Shaw H, Rohde P. Psychological and behavioral risk factors for obesity onset in adolescent girls: a prospective study. *Journal of consulting and clinical psychology*. 2005; 73: 195.
80 Stice E, Presnell K, Spangler D. Risk factors for binge eating onset in adolescent girls: a 2-year prospective investigation. *Health psychology*. 2002; 21: 131.
81 Chen Z, Salam MT, Alderete TL*, et al.* Effects of childhood asthma on the development of obesity among school-aged children. *American journal of respiratory and critical care medicine*. 2017; 195: 1181-88.
82 Shore SA. Obesity and asthma: possible mechanisms. *Journal of Allergy and Clinical Immunology*. 2008; 121: 1087-93.

83 Holderness H, Chin N, Ossip DJ, Fagnano M, Reznik M, Halterman JS. Physical activity, restrictions in activity, and body mass index among urban children with persistent asthma. *Annals of Allergy, Asthma & Immunology*. 2017; 118: 433-38.
84 Lam K-M, Yang Y-H, Wang L-C, Chen S-Y, Gau B-S, Chiang B-L. Physical activity in school-aged children with asthma in an urban city of Taiwan. *Pediatrics & Neonatology*. 2016; 57: 333-37.
85 Steinbeck KS. The importance of physical activity in the prevention of overweight and obesity in childhood: a review and an opinion. *Obesity reviews*. 2001; 2: 117-30.
86 Vimaleswaran KS, Berry DJ, Lu C, *et al.* Causal relationship between obesity and vitamin D status: bi-directional Mendelian randomization analysis of multiple cohorts. *PLoS medicine*. 2013; 10: e1001383.
87 Wamberg L, Christiansen T, Paulsen SK, *et al.* Expression of vitamin D-metabolizing enzymes in human adipose tissue—the effect of obesity and diet-induced weight loss. *International journal of obesity*. 2013; 37: 651-57.
88 Jolliffe DA, Greenberg L, Hooper RL, *et al.* Vitamin D supplementation to prevent asthma exacerbations: a systematic review and meta-analysis of individual participant data. *The lancet Respiratory medicine*. 2017; 5: 881-90.
89 Carrelli A, Bucovsky M, Horst R, *et al.* Vitamin D storage in adipose tissue of obese and normal weight women. *Journal of Bone and Mineral Research*. 2017; 32: 237-42.
90 Jennings A, Welch A, van Sluijs EM, Griffin SJ, Cassidy A. Diet quality is independently associated with weight status in children aged 9–10 years. *The Journal of nutrition*. 2011; 141: 453-59.
91 Cleland V, Crawford D, Baur LA, Hume C, Timperio A, Salmon J. A prospective examination of children's time spent outdoors, objectively measured physical activity and overweight. *International journal of obesity*. 2008; 32: 1685.
92 Cepeda-Lopez AC, Zimmermann MB, Wussler S, *et al.* Greater blood volume and Hb mass in obese women quantified by the carbon monoxide-rebreathing method affects interpretation of iron biomarkers and iron requirements. *International Journal of Obesity*. 2019; 43: 999-1008.
93 Brown T, Moore TH, Hooper L, *et al.* Interventions for preventing obesity in children. *Cochrane Database of Systematic Reviews*. 2019.

Chapter 4: Obesity prevention interventions in childhood

1. Introduction

With persistently high childhood obesity rates observed worldwide [1], and a growing evidence base linking childhood obesity to numerous co-morbidities [2, 3], efforts to prevent the onset of obesity in the early years and later childhood have increased in recent years [4, 5].

Typically, interventions have focused on individual behaviour change, targeting the energy-balance related behaviours that are believed to contribute to changes in adiposity [6-8]. Specifically, interventions will target physical activity, diet, and more recently, sedentary behaviour, with the aim of increasing healthy levels of these behaviours and in turn preventing the onset of overweight and obesity [8-12]. Another important factor in determining the success of an intervention is the setting in which it is implemented. Obesity prevention interventions in the early years range considerably by setting. However, the majority are community based rather than hospital based, with hospitals used more frequently in secondary prevention programmes [13]. Schools, community centres and childcare settings are increasingly used [9, 10, 14, 15], with an increasing importance being applied to the home environment in recent literature [5, 16].

While new interventions which aim to prevent obesity in young children have increased in numbers in recent years, so too has the practice of adapting successful programmes for use in other countries/settings [17]. For this practice to be effective, sufficient context-specific adaptation and refinement of the intervention components must first be undertaken [18], however at present, no formal best practice guidelines on adapting interventions exists. Additionally, feasibility testing of interventions prior to full-scale evaluation is being increasingly advocated as a means to ensure the intervention and the proposed evaluation methods are fit for purpose prior to implementation [19]. Despite this, there remains a poor grasp among the research community regarding the definition, scope and ramifications of feasibility studies [20].

This chapter will summarise the current research landscape concerning obesity prevention interventions in the early years by discussing important aspects such as the effectiveness of different intervention components, intervention settings, and the advantages of adapting existing interventions to other settings and testing feasibility prior to effectiveness trials.

2. Multi-component interventions: The need to address multiple obesogenic behaviours

Given the complexity of the numerous causal and associated factors of childhood obesity [21], it has become apparent that a multi-faceted approach is needed in any intervention aimed at preventing obesity in the early years [22]. Despite this, a number of interventions have employed a single component approach to obesity prevention, with a focus primarily being given to either physical activity, or diet/nutrition. While single-component interventions have been shown to reduce weight in secondary prevention trials [23], the evidence on the effectiveness of single component interventions for primary prevention is more equivocal. Reilly and colleagues [8] delivered a physical activity intervention to 4 and 5 year old children in Glasgow primary schools. The findings showed significant increases in motor competence, however no significant reductions in BMI were observed between the intervention and control schools. Similarly, another intervention in Thailand focusing exclusively on physical activity during school breaks observed no overall significant reduction in BMI between intervention and control groups [24]. Such observations are not limited to physical activity interventions. Null results have also been reported for diet-based, single-component trials [25].

Increasingly, interventions which use multicomponent approaches (i.e. targeting multiple behaviours such as physical activity, sedentary behaviour, and diet through a variety of methods) are showing more promise than single component interventions. Recent systematic reviews conclude that interventions should be multicomponent [7, 22, 26], as does recommendations by both the National Institute for Clinical Excellence and the World Health Organization [27, 28]. However, there still remains a considerable number of multicomponent interventions that find no significant reduction in weight related outcomes [7, 29], indicating that the success of an intervention is related to other complex factors, in addition to the behaviours targeted. For example, the US Hip Hop to Health study initially reported significant improvements in weight-related outcomes following a multicomponent intervention (targeting physical activity and diet) delivered to African-American pre-schoolers [15]. However, when the same intervention was delivered to a Latino-American population group, no significant effects on weight outcomes were observed [6]. This highlights the importance of considering the wider social, cultural and economic factors which exist within and between different population groups, and how these can impact upon the effectiveness of obesity prevention efforts [29].

3. The importance of targeting the populations most at need

There is a strong social gradient observed in the prevalence of childhood obesity in high-income countries, with those of low socioeconomic status (SES) accounting for a significant proportion of the disease burden [30]. For instance, the recent Scottish Health Survey identified an approximately 10% higher prevalence of obesity among 2-15 year olds within the lowest two SES quintiles, in comparison to the highest quintile [31]. This relationship is also evident throughout the UK [32, 33], and is also observed in other developed regions such as the United States [30] and Australia [34]. It is therefore critical that any childhood obesity intervention that aims to prevent obesity at the population level, adequately recruit and target these high risk groups. However, a systematic review conducted by McGill and colleagues [35] identified a number of interventions relating to dietary habits that significantly increased health inequalities within the study samples. Specifically, one study which aimed to reduce overweight prevalence in children only observed significant reductions in weight for children from high SES families, and positive effects on prevention of obesity among children with normal-weight mothers [36]. While any significant effects on weight outcomes are positive with regard to obesity prevention, interventions which widen the already stark social inequalities in obesity prevalence do not offer long term solutions to the problem, and should be further adapted to ensure they are also reaching the population groups most at need [37].

Well-designed childhood obesity prevention studies will take steps such as stratified sampling, or oversampling of low SES groups to ensure they can test the effect of the intervention across the social landscape [38]. However, a number of challenges exist when seeking to engage low SES groups in research studies, with studies reporting considerable challenges regarding recruiting low SES participants into health interventions [37]. Such barriers are both logistical and attitudinal in nature, and include poor transportation access, perceived neighbourhood safety, childcare, culture/linguistic differences and a distrust of healthcare and related research [39-41]. Recruitment is not the only challenge related to research with low SES groups; trials consistently report higher attrition rates or incomplete data collection for participants of lower SES, when compared to high SES groups [42]. A systematic review of recruitment and retention in childhood obesity prevention trials found that interventions which exclusively targeted minorities had lower retention than those that targeted a mixed sample or exclusively white populations [43]. Similarly, Jelalian et al. [44] found ethnic minority status (a commonly used proxy measure of SES in USA) to be a significant predictor of attrition in an adolescent weight management programme.

Considering these observations, it appears that any efforts to prevent obesity in children must ensure the intervention adequately recruits and retains low SES groups, and also ensures that they adequately engage with the programme in order to gain any benefits.

4. The importance of intervention setting

Where an intervention is delivered is another factor that appears to have considerable impact on the outcomes observed in childhood obesity prevention trials. What has become apparent in recent years, is that interventions which are delivered across multiple settings and environments, have greater potential to reduce obesogenic behaviours, and in turn improve weight-related outcomes. However, a systematic review of childhood obesity trials by Wang and Colleagues [45], found that intervention effectiveness differed by setting, and the school environment was the most effective place to deliver an intervention.

The community setting is also commonly used to implement obesity prevention programmes [46, 47], but the effectiveness of such interventions remains equivocal [45]. While a number of community interventions have reported positive effects on weight related outcomes, a number have also reported no effects [22, 45, 48]. A review by Bleich et al. [48] supported the current view that interventions delivered across multiple settings (specifically in combination with the school environment) are more likely to be effective than those that are implemented within the community alone.

The home environment is often advocated as an important setting to implement obesity prevention programmes [22], despite relatively poor outcomes in comparison to trials delivered in other settings, based on results of systematic reviews [49]. However targeting home behaviours is the most challenging setting to change behaviour, yet has arguably the most potential to reduce children's exposure to obesogenic factors [5, 50]. Process evaluations of studies conducted in the home setting often identify barriers to delivery such as a lack of time or complicated resources which negatively impact on the fidelity of the intervention [51, 52]. Additionally, combined setting interventions with a home component often do not adequately develop the intervention content with parents/caregivers, instead focusing more on the school or community, with the home environment appended to the intervention [50]. This often involves passive parental involvement, such as the provision of educational leaflets, which have been shown to be largely ineffective within health promotion research [53].

Interventions which have used more active parental engagement in combination with either a community or school based intervention, have shown potential to improve weight related outcomes, or energy-balance related behaviours [5]. Furthermore, experts argue that it is critical to actively involve parents during childhood obesity prevention trials, especially during the early years when they have the most influence over a child's behaviour [54]. Three recent systematic reviews of parental involvement in early years obesity prevention trials have demonstrated that there is a relationship between the level of parental involvement in an intervention, and favourable weight related outcomes in children [5, 54, 55]. Effective interventions tended to share similar parental components, namely parental responsibility for participation/implementation, restructuring the home environment, prompt self-monitoring (monitoring child's behaviour), and goal-setting related behaviour change techniques.

It therefore appears to be important for any intervention to address obesogenic behaviours across multiple settings, while actively engaging parents to deliver home-based components. The benefit of implementing an intervention within the pre-school/school environment as opposed to the general community, is that the compulsory nature of pre-school/school attendance may increase intervention fidelity when compared to community based groups which are reliant on voluntary attendance.

5. Translating interventions to other settings

In recent years, the growing urgency to address the high levels of childhood obesity observed globally has led to the implementation of numerous prevention programmes internationally [22]. Yet there remains a tendency for researchers to develop new interventions, despite the existence of established programmes which have been shown to have positive effects on weight related outcomes and/or energy balance-related behaviours. There are a number of legitimate reasons to develop new interventions, particularly if the target group is within a different demographic or geographic population, as contextual factors can greatly influence the mechanisms of an intervention's function [56, 57]. However, there is a growing body of research which is now adapting previously promising or successful interventions for use in new, distinct settings/countries to prevent childhood obesity [17, 58, 59].

One such example is the US Nutrition and Physical Activity Self-Assessment for Child Care (NAP SACC) study, which was originally developed and implemented within preschool settings in North Carolina, USA [60, 61]. The intervention consisted of environmental and policy changes within preschools to encourage healthy eating and healthy levels of physical activity/sedentary behaviour amongst children, informed by self-assessments by preschool staff. A pilot study of the intervention revealed that a number of improvements were observed for the variety of available healthy foods, active play/outdoor time, and decreased fried foods on preschool menus in addition to overall staff knowledge [61]. Following the promising findings of the NAP SACC study, it was adapted for use in English preschools and homes [17]. A number of steps were taken to adapt the intervention to the UK preschool context, including aligning the intervention actions with UK guidance on nutrition, physical activity, and oral health. Additionally, extensive development activities were undertaken with stakeholders which involved interviews and focus groups with preschool managers, health visitors, public health professionals, local authority staff and parents [17]. Process evaluation of the feasibility cluster RCT found that the intervention was acceptable to preschool staff, local authority staff and parents, indicating that the undertaken adaptations had appropriately considered the contextual differences between the USA and UK preschool environment [59].

Similar to the NAP SACC study, the Healthy Habits Happy Homes (4H) intervention was implemented in children's homes across low-income neighbourhoods in the Greater Boston area, USA [16, 62], before being adapted for use in Scotland, UK [58]. The original intervention used a combination of motivational interviewing, mailed educational materials, and text messaging to influence health behaviours relating to diet/nutrition, physical activity and sedentary behaviour in the home. Following a randomised trial within the Greater Boston area, intervention children had significantly reduced television viewing times on weekend days, decreased BMI, and increased sleep duration. Various activities were employed to engage relevant stakeholders in the adaptation process of the 4H intervention in Scotland, and included co-production of the study website, and workshops with key members of the community [58].

One commonality between the adapted NAP SACC and 4H interventions, is the emphasis that was placed on working with key stakeholders during adaptation to ensure the interventions were contextually appropriate for the new setting. As previously discussed, the fact that an intervention has been effective with one population, does not mean it will necessarily transfer to another and have the same effect. As noted above, the Hip Hop to Health study was efficacious with African-American children in Chicago, but was ineffective with a Latino-American population in the same city [6]. It therefore appears to be important to consider the different cultural and socio-demographic factors between populations when adapting an intervention [29].

One issue with adapting interventions to other settings/countries, is that at present, there is no published guidance regarding how to adapt an intervention, however guidelines are currently being developed by the UK Medical Research Council [63]. On the contrary, numerous guidelines and frameworks exist with regards to developing new interventions [64-66], which may encourage researchers to develop a new intervention, rather than adapt an existing one. Specifically, there remains uncertainty regarding how to adapt an intervention, and how much adaptation can be undertaken without significantly altering the core components of the intervention and mechanisms of the underlying theory. Overall, the practice of adapting existing interventions to new settings is a newly emerging research area, which would benefit from the publication of evidence-based guidelines.

6. Why test feasibility before a full-scale trial?

The practice of both developing and/or adapting an intervention carries with it the need to evaluate the intervention in order to determine its potential to combat the health condition. In the case of childhood obesity, feasibility and pilot trials are increasingly being used to first test the acceptability and fidelity of an intervention and the proposed evaluation methods prior to effectiveness testing [17, 58, 67-69]. Indeed, feasibility and pilot testing is now recommended as an integral aspect of intervention development and evaluation by the UK Medical Research Council [56, 64]. Despite this, it is common for interventions to be developed and then tested at full scale, potentially missing important issues which could otherwise have been rectified following a feasibility or pilot study [70]. This issue is further compounded by a relatively poor grasp among the research community with regards to the difference between a feasibility and pilot study. Specifically, feasibility studies allow for the assessment of recruitment and retention rates, in addition to other important feasibility parameters such as willingness of participants to be randomised, acceptability of proposed outcome measurement methods, and overall acceptability of intervention components [71]. Pilot studies, while similar to feasibility studies, place a greater focus on the direction of the intervention effect, and are undertaken to determine if an intervention has the potential to elicit the desired benefits in a full-scale trial [70]. Both feasibility and pilot studies are not adequately powered to justify the use of inferential statistics, yet it is common for studies to use such methods, against the recommendations of experts on the subject [71].

The main advantage of conducting a feasibility trial prior to full-scale effectiveness testing, is the potential to identify detrimental limitations with study design, intervention delivery, and intervention components which would negate the benefits of the intervention within the target population[70, 71]. This also has economic advantages, at a time when funding for public health research is not plentiful, ensuring the feasibility of an intervention prior to full scale-up can ensure cost-effectiveness and that the intervention is functioning as intended; potentially avoiding the delivery of an expensive, but ineffective randomised trial [72].

7. Why The ToyBox Study was chosen as a good fit for Scottish Preschools

Considering the issues discussed previously in this chapter, the ToyBox study was selected as the appropriate intervention to be adapted for use in Scottish preschools for a number of reasons. Firstly, when selecting a potential intervention to be adapted, it was deemed important that it had been appropriately developed using underlying theory and evaluated using robust methods as recommended by intervention development guidelines [64]. The development of ToyBox was underpinned by numerous behavioural theories; namely social cognitive theory [73], the socio-ecological model , the theory of planned behaviour [74], goalsetting theory [75] and the Health belief model [76]. Collectively, the use of these theories can be used to explain how the planned activities and environmental changes employed by ToyBox, are assumed to lead to the desired behavioural change. For example, the utilisation of planned, teacher-led physical activity sessions are an example of active learning within social cognitive theory, while the use of tip cards and newsletters which challenge parents to progressively change behaviours in the home employ aspects of goalsetting theory [77].

In addition to being theory-driven, the chosen intervention should also, ideally, demonstrate favourable effects on the outcomes of interest-namely energy-balance related behaviours such as physical activity, sedentary behaviour and diet. The original ToyBox study (http://www.toybox-study.eu/) has been extensively evaluated across Europe [10, 78] showing that it can lead to improvements in the key energy-balance related behaviours which contribute to obesity development when implemented effectively [10].

Secondly, the relatively low cost and simplistic structure of the ToyBox programme, and its ability to reach both the preschool and the home environment make it a promising choice for implementation in Scotland. Simple active games, environmental changes to the classroom, and parental materials can all easily be adapted to suit a new preschool context. This is evident from the extensive implementation of ToyBox across six European countries that all have different policies and practices, but who were able to feasibly implement ToyBox. This further supports the decision to adapt ToyBox for use in Scotland, as it has already proven feasible to adapt the programme for use in other countries from the original Greek/Belgian interventions [78]. Furthermore, the original intervention developers were supportive of the programme being adapted and applied to other settings, and were willing to collaborate by providing the relevant intervention materials and evaluation tools such as classroom activity guides, practitioner logbooks, and questionnaires. This was encouraging as often researchers can be resistant or protective of the integrity of the intervention, and be resistant to assisting outside research centres in altering the content of the intervention.

Finally, the core components and aims of the ToyBox programme were well-aligned with current health and wellbeing policies aimed at reducing obesity in the early years. Specifically, the Scottish government's diet and healthy weight delivery plan, which calls for regular physical activity, reduced sedentary behaviour, and increased fruit and vegetable consumption in the early years [79], and Education Scotland's Health and Wellbeing Outcomes for early years' education [80]. This would make convincing local authorities to allow the intervention to be introduced into Scottish Preschools more straightforward, and to get the necessary approvals to evaluate.

8. References

1 Blüher M. Obesity: global epidemiology and pathogenesis. *Nature Reviews Endocrinology*. 2019: 1.
2 Reilly JJ, Methven E, McDowell ZC, Hacking B, Alexander D, Stewart L*, et al.* Health consequences of obesity. *Archives of disease in childhood*. 2003; 88: 748-52.
3 Skinner AC, Perrin EM, Moss LA, Skelton JA. Cardiometabolic risks and severity of obesity in children and young adults. *New England Journal of Medicine*. 2015; 373: 1307-17.
4 Ling J, Robbins LB, Wen F. Interventions to prevent and manage overweight or obesity in preschool children: A systematic review. *International journal of nursing studies*. 2016; 53: 270-89.
5 Ward DS, Welker E, Choate A, Henderson KE, Lott M, Tovar A*, et al.* Strength of obesity prevention interventions in early care and education settings: A systematic review. *Preventive medicine*. 2017; 95: S37-S52.
6 Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, Dyer A. Hip-hop to health Jr. for Latino preschool children. *Obesity*. 2006; 14: 1616-25.
7 Reilly JJ, Hughes AR, Gillespie J, Malden S, Martin A. Physical activity interventions in early life aimed at reducing later risk of obesity and related non-communicable diseases: A rapid review of systematic reviews. *Obesity Reviews*. 2019; 20: 61-73.
8 Reilly JJ, Kelly L, Montgomery C, Williamson A, Fisher A, McColl JH*, et al.* Physical activity to prevent obesity in young children: cluster randomised controlled trial. *Bmj*. 2006; 333: 1041.
9 Cruz TH, Davis SM, Myers OB, O'Donald ER, Sanders SG, Sheche JN. Effects of an obesity prevention intervention on physical activity among preschool children: The CHILE Study. *Health promotion practice*. 2016; 17: 693-701.
10 De Craemer M, De Decker E, Verloigne M, De Bourdeaudhuij I, Manios Y, Cardon G. The effect of a kindergarten-based, family-involved intervention on objectively measured physical activity in Belgian preschool boys and girls of high and low SES: the ToyBox-study. *International Journal of Behavioral Nutrition and Physical Activity*. 2014; 11: 38.
11 Ahrens W, Bammann K, Siani A, Buchecker K, De Henauw S, Iacoviello L*, et al.* The IDEFICS cohort: design, characteristics and participation in the baseline survey. *International Journal of Obesity*. 2011; 35: S3.
12 Ward DS, Benjamin SE, Ammerman AS, Ball SC, Neelon BH, Bangdiwala SI. Nutrition and physical activity in child care: results from an environmental intervention. *American journal of preventive medicine*. 2008; 35: 352-56.
13 Banks J, Sharp DJ, Hunt LP, Shield JP. Evaluating the transferability of a hospital-based childhood obesity clinic to primary care: a randomised controlled trial. *Br J Gen Pract*. 2012; 62: e6-e12.
14 Davis SM, Sanders SG, FitzGerald CA, Keane PC, Canaca GF, Volker-Rector R. CHILE: an evidence-based preschool intervention for obesity prevention in Head Start. *Journal of School Health*. 2013; 83: 223-29.

15 Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, Dyer A. Two-year follow-up results for Hip-Hop to Health Jr.: a randomized controlled trial for overweight prevention in preschool minority children. *The Journal of pediatrics*. 2005; 146: 618-25.
16 Haines J, McDonald J, O'Brien A, Sherry B, Bottino CJ, Schmidt ME*, et al.* Healthy habits, happy homes: randomized trial to improve household routines for obesity prevention among preschool-aged children. *JAMA pediatrics*. 2013; 167: 1072-79.
17 Kipping R, Jago R, Metcalfe C, White J, Papadaki A, Campbell R*, et al.* NAP SACC UK: protocol for a feasibility cluster randomised controlled trial in nurseries and at home to increase physical activity and healthy eating in children aged 2–4 years. *BMJ open*. 2016; 6: e010622.
18 Castro FG, Barrera M, Martinez CR. The cultural adaptation of prevention interventions: Resolving tensions between fidelity and fit. *Prevention Science*. 2004; 5: 41-45.
19 Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D*, et al.* How we design feasibility studies. *American journal of preventive medicine*. 2009; 36: 452-57.
20 Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC medical research methodology*. 2010; 10: 67.
21 Finegood DT, Merth TD, Rutter H. Implications of the foresight obesity system map for solutions to childhood obesity. *Obesity*. 2010; 18: S13-S16.
22 Brown T, Moore TH, Hooper L, Gao Y, Zayegh A, Ijaz S*, et al.* Interventions for preventing obesity in children. *Cochrane Database of Systematic Reviews*. 2019.
23 Ho M, Garnett SP, Baur LA, Burrows T, Stewart L, Neve M*, et al.* Impact of dietary and exercise interventions on weight change and metabolic outcomes in obese children and adolescents: a systematic review and meta-analysis of randomized trials. *JAMA pediatrics*. 2013; 167: 759-68.
24 Mo-suwan L, Pongprapai S, Junjana C, Puetpaiboon A. Effects of a controlled trial of a school-based exercise program on the obesity indexes of preschool children. *The American journal of clinical nutrition*. 1998; 68: 1006-11.
25 Kramer M, Chalmers B, Hodnett E, Sevkovskaya Z, Dzikovich I, Shapiro S*, et al.* Promotion of Breastfeeding Intervention Trial (Probot): A Cluster-Randomized Trial in the Republic of Belarus. *Short and Long Term Effects of Breast Feeding on Child Health*. Springer 2002; 327-45.
26 Kipping RR, Jago R, Lawlor DA. Obesity in children. Part 2: Prevention and management. *Bmj*. 2008; 337: a1848.
27 Kumaran A, Sakka S, Dias RP. Obesity in children: recent NICE guidance. *Archives of Disease in Childhood-Education and Practice*. 2017; 102: 84-88.
28 World Health Organization. Childhood overweight and obesity. *Global Strategy on Diet, Physical Activity and Health*. WHO: Geneva 2016.
29 Monasta L, Batty G, Macaluso A, Ronfani L, Lutje V, Bavcar A*, et al.* Interventions for the prevention of overweight and obesity in preschool children: a systematic review of randomized controlled trials. *Obesity Reviews*. 2011; 12: e107-e18.

30 Wang Y. Cross-national comparison of childhood obesity: the epidemic and the relationship between obesity and socioeconomic status. *International journal of epidemiology*. 2001; 30: 1129-36.
31 Tod E, Bromley C, Millard AD, Boyd A, Mackie P, McCartney G. Obesity in Scotland: a persistent inequality. *International journal for equity in health*. 2017; 16: 135.
32 Massion S, Wickham S, Pearce A, Barr B, Law C, Taylor-Robinson D. Exploring the impact of early life factors on inequalities in risk of overweight in UK children: findings from the UK Millennium Cohort Study. *Archives of disease in childhood*. 2016; 101: 724-30.
33 Ness AR, Leary S, Reilly J, Wells J, Tobias J, Clark E*, et al.* The social patterning of fat and lean mass in a contemporary cohort of children. *International Journal of Pediatric Obesity*. 2006; 1: 59-61.
34 O'Dea JA. Gender, ethnicity, culture and social class influences on childhood obesity among Australian schoolchildren: implications for treatment, prevention and community education. *Health & social care in the community*. 2008; 16: 282-90.
35 McGill R, Anwar E, Orton L, Bromley H, Lloyd-Williams F, O'Flaherty M*, et al.* Are interventions to promote healthy eating equally effective for all? Systematic review of socioeconomic inequalities in impact. *BMC public health*. 2015; 15: 457.
36 Plachta-Danielzik S, Pust S, Asbeck I, Czerwinski-Mast M, Langnäse K, Fischer C*, et al.* Four-year follow-up of school-based intervention on overweight children: the KOPS study. *Obesity*. 2007; 15: 3159-69.
37 Bonevski B, Randell M, Paul C, Chapman K, Twyman L, Bryant J*, et al.* Reaching the hard-to-reach: a systematic review of strategies for improving health and medical research with socially disadvantaged groups. *BMC medical research methodology*. 2014; 14: 42.
38 Vaughan R. Oversampling in health surveys: Why, when, and how? American Public Health Association: 2017.
39 Brannon EE, Kuhl ES, Boles RE, Aylward BS, Benoit Ratcliff M, Valenzuela JM*, et al.* Strategies for recruitment and retention of families from low-income, ethnic minority backgrounds in a longitudinal study of caregiver feeding and child weight. *Children's Health Care*. 2013; 42: 198-213.
40 Levkoff S, Sanchez H. Lessons learned about minority recruitment and retention from the Centers on Minority Aging and Health Promotion. *The Gerontologist*. 2003; 43: 18-26.
41 Pyatak EA, Blanche EI, Garber SL, Diaz J, Blanchard J, Florindez L*, et al.* Conducting intervention research among underserved populations: lessons learned and recommendations for researchers. *Archives of physical medicine and rehabilitation*. 2013; 94: 1190-98.
42 Jensen CD, Aylward BS, Steele RG. Predictors of attendance in a practical clinical trial of two pediatric weight management interventions. *Obesity*. 2012; 20: 2250-56.
43 Cui Z, Seburg EM, Sherwood NE, Faith MS, Ward DS. Recruitment and retention in obesity prevention and treatment trials targeting minority or low-income children: a review of the clinical trials registration database. *Trials*. 2015; 16: 564.

44 Jelalian E, Hart CN, Mehlenbeck RS, Lloyd-Richardson EE, Kaplan JD, Flynn-O'Brien KT*, et al.* Predictors of attrition and weight loss in an adolescent weight control program. *Obesity*. 2008; 16: 1318-23.
45 Wang Y, Cai L, Wu Y, Wilson R, Weston C, Fawole O*, et al.* What childhood obesity prevention programmes work? A systematic review and meta-analysis. *Obesity reviews*. 2015; 16: 547-65.
46 DeMattia L, Lee Denney S. Childhood obesity prevention: successful community-based efforts. *The ANNALS of the American Academy of Political and Social Science*. 2008; 615: 83-99.
47 Economos CD, Hyatt RR, Goldberg JP, Must A, Naumova EN, Collins JJ*, et al.* A community intervention reduces BMI z-score in children: Shape Up Somerville first year results. *Obesity*. 2007; 15: 1325-36.
48 Bleich SN, Segal J, Wu Y, Wilson R, Wang Y. Systematic review of community-based childhood obesity prevention studies. *Pediatrics*. 2013; 132: e201-e10.
49 Showell NN, Fawole O, Segal J, Wilson RF, Cheskin LJ, Bleich SN*, et al.* A systematic review of home-based childhood obesity prevention studies. *Pediatrics*. 2013; 132: e193-e200.
50 Knowlden A, Sharma M. Systematic review of family and home-based interventions targeting paediatric overweight and obesity. *Obesity Reviews*. 2012; 13: 499-508.
51 Langford R, Bonell C, Jones H, Campbell R. Obesity prevention and the Health promoting Schools framework: essential components and barriers to success. *International Journal of Behavioral Nutrition and Physical Activity*. 2015; 12: 15.
52 Kipping R, Jago R, Lawlor D. Developing parent involvement in a school-based child obesity prevention intervention: a qualitative study and process evaluation. *Journal of Public Health*. 2012; 34: 236-44.
53 Rune KT, Mulgrew K, Sharman R, Lovell GP. Effect of an obesity pamphlet on parental perception and knowledge of excess weight in their children: results of a randomised controlled trial. *Health Promotion Journal of Australia*. 2015; 26: 129-32.
54 Skouteris H, McCabe M, Swinburn B, Newgreen V, Sacher P, Chadwick P. Parental influence and obesity prevention in pre-schoolers: a systematic review of interventions. *Obesity reviews*. 2011; 12: 315-28.
55 Golley RK, Hendrie G, Slater A, Corsini N. Interventions that involve parents to improve children's weight-related nutrition intake and activity patterns–what nutrition and activity targets and behaviour change techniques are associated with intervention effectiveness? *Obesity reviews*. 2011; 12: 114-30.
56 Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W*, et al.* Process evaluation of complex interventions: Medical Research Council guidance. *bmj*. 2015; 350: h1258.
57 Pallan M, Parry J, Adab P. Contextual influences on the development of obesity in children: a case study of UK South Asian communities. *Preventive medicine*. 2012; 54: 205-11.
58 Gillespie J, Hughes A, Gibson A-M, Haines J, Taveras E, Reilly JJ. Protocol for Healthy Habits Happy Homes (4H) Scotland: feasibility of a participatory approach to adaptation and implementation of a study aimed at early prevention of obesity. *BMJ open*. 2019; 9: e028038.

59 Langford R, Jago R, White J, Moore L, Papadaki A, Hollingworth W, *et al.* A physical activity, nutrition and oral health intervention in nursery settings: process evaluation of the NAP SACC UK feasibility cluster RCT. *BMC public health*. 2019; 19: 865.
60 Ammerman AS, Ward DS, Benjamin SE, Ball SC, Sommers JK, Molloy M, *et al.* An intervention to promote healthy weight: Nutrition and Physical Activity Self-Assessment for Child Care (NAP SACC) theory and design. *Preventing chronic disease*. 2007; 4: A67-A67.
61 Benjamin SE, Ammerman A, Sommers J, Dodds J, Neelon B, Ward DS. Nutrition and physical activity self-assessment for child care (NAP SACC): results from a pilot intervention. *Journal of nutrition education and behavior*. 2007; 39: 142-49.
62 Taveras EM, McDonald J, O'Brien A, Haines J, Sherry B, Bottino CJ, *et al.* Healthy Habits, Happy Homes: methods and baseline data of a randomized controlled trial to improve household routines for obesity prevention. *Preventive medicine*. 2012; 55: 418-26.
63 Evans RE, Craig P, Hoddinott P, Littlecott H, Moore L, Murphy S, *et al.* When and how do ‘effective’interventions need to be adapted and/or re-evaluated in new contexts? The need for guidance. BMJ Publishing Group Ltd: 2019.
64 Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *Bmj*. 2008; 337: a1655.
65 Wight D, Wimbush E, Jepson R, Doi L. Six steps in quality intervention development (6SQuID). *J Epidemiol Community Health*. 2016; 70: 520-25.
66 Kok G, Schaalma H, Ruiter RA, Van Empelen P, Brug J. Intervention mapping: protocol for applying health psychology theory to prevention programmes. *Journal of health psychology*. 2004; 9: 85-98.
67 Schwartz RP, Hamre R, Dietz WH, Wasserman RC, Slora EJ, Myers EF, *et al.* Office-based motivational interviewing to prevent childhood obesity: a feasibility study. *Archives of pediatrics & adolescent medicine*. 2007; 161: 495-501.
68 Adab P, Pallan MJ, Cade J, Ekelund U, Barrett T, Daley A, *et al.* Preventing childhood obesity, phase II feasibility study focusing on South Asians: BEACHeS. *BMJ open*. 2014; 4: e004579.
69 Foster GD, Sundal D, McDermott C, Jelalian E, Lent MR, Vojta D. Feasibility and preliminary outcomes of a scalable, community-based treatment of childhood obesity. *Pediatrics*. 2012; 130: 652-59.
70 Whitehead AL, Sully BG, Campbell MJ. Pilot and feasibility studies: is there a difference from each other and from a randomised controlled trial? *Contemporary clinical trials*. 2014; 38: 130-33.
71 Abbott JH. The distinction between randomized clinical trials (RCTs) and preliminary feasibility and pilot studies: what they are and are not. JOSPT, Inc. JOSPT, 1033 North Fairfax Street, Suite 304, Alexandria, VA …: 2014.
72 Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, *et al.* A tutorial on pilot studies: the what, why and how. *BMC medical research methodology*. 2010; 10: 1.
73 Bandura A. Social cognitive theory: An agentic perspective. *Annual review of psychology*. 2001; 52: 1-26.

74 Ajzen I. From intentions to actions: A theory of planned behavior. *Action control*. Springer 1985; 11-39.
75 Locke EA, Latham GP. Goal setting theory. *Motivation: Theory and research*. 1994; 13: 29.
76 Rosenstock IM, Strecher VJ, Becker MH. Social learning theory and the health belief model. *Health education quarterly*. 1988; 15: 175-83.
77 De Decker E, De Craemer M, De Bourdeaudhuij I, Verbestel V, Duvinage K, Iotova V*, et al.* Using the intervention mapping protocol to reduce European preschoolers' sedentary behavior, an application to the ToyBox-Study. *International Journal of Behavioral Nutrition and Physical Activity*. 2014; 11: 19.
78 Manios Y. The 'ToyBox-study'obesity prevention programme in early childhood: an introduction. *obesity reviews*. 2012; 13: 1.
79 Scottish Government. A healthier future: Scotland's diet and healthy weight delivery plan. 2018.
80 Education Scotland. Curriculum for excellence: Health and wellbeing. Retrieved from: 2004.

Chapter 5: Procedures and challenges of adapting an existing public health intervention for use in another setting: The ToyBox-Scotland preschool obesity prevention programme

This peer-reviewed manuscript was published in Sage Research Methods Cases in January 2020 and is included in the thesis in its published form here.

1. Preface

This manuscript details the steps taken to adapt the original ToyBox intervention for use in Scottish preschools. Stephen Malden conducted the intervention development work with stakeholders, under the guidance of JJR, AH and AMG, and Farid Bardid (FB). Stephen Malden prepared the first draft of the manuscript. All aforementioned authors contributed to the second draft of the manuscript.

2. Abstract

Childhood obesity is a major public health issue, which is reflected in the high number of interventions, which have been developed to target the behaviors that cause obesity in childhood such as a lack of physical activity, poor diet, and sedentary behavior. The ToyBox programme was originally developed and tested in mainland Europe, and has now been adapted for use in Scottish preschools. This case describes the systematic approach that was taken to adapt the ToyBox programme. The intervention mapping protocol was used to guide the adaptation process in the absence of guidelines for adapting existing interventions. A Co-creation approach was used to involve stakeholders in intervention adaptation procedures. Preschool

practitioners participated in workshops, where proposed intervention components were discussed and agreed upon. Proposed intervention activities were trialed out in a volunteer preschool, and an experienced preschool practitioner assisted in the adaptation of classroom materials, intervention content, and methods of delivery in order to align the intervention with Scottish preschool practice. The adaptations resulted in the ToyBox-Scotland intervention being significantly different from the original European programme, whereby two major components of the original intervention were removed, and substantial adaptations were made to the delivery and content of the remaining components. Involving stakeholders in the adaptation of an existing intervention is important to ensure the programme is suitable for those who will be delivering and receiving it. However, it is currently unclear as to how much adaptation should be undertaken, highlighting the need for the creation of evidence-based guidelines for intervention adaptation.

3. Project Overview and Context

Public health intervention research focuses on the development of programmes that target a specific health issue within a specific population group. Typically, when a similar issue is identified within another population group, or within a different geographical location, a new intervention is usually developed to address these issues. Examples of this are abundant within the intervention development literature, where multiple interventions that address the same outcomes, often using markedly similar components, exist for a number of health conditions. This is particularly apparent within childhood obesity prevention research. A recent systematic review identified multiple distinct interventions aimed at preventing obesity in childhood [1]. This likely reflects the need for such interventions at present, with childhood obesity rates remaining high internationally, after rising drastically within the last three decades [2]. However, another reason may be the lack of guidance regarding how to transfer or adapt an intervention between different population groups or settings. At present, there is no published guidance that details how to achieve this, although guidelines are under development [3].

Despite the tendency for researchers to develop new interventions, there have been some recent examples where existing interventions have been transferred to other settings within childhood obesity research. Two such examples are the 'NAP SACC' trial [4] and the 'Healthy Habits, Happy Homes' study [5], which target obesogenic behaviors and environments at preschools and in children's homes, respectively. Both interventions were originally developed in the United States, following specific guidelines and frameworks for the development of complex public health interventions [6]. Prior to implementation of the interventions within the UK, considerable adaptation was undertaken of the intervention components, in collaboration with both the original research teams and relevant stakeholders within the communities where the interventions were set to be delivered. However, these adaptations were not guided by specific recommendations.

We were faced with a similar issue when we adapted the ToyBox preschool obesity prevention programme for use in Sottish preschools [7]. ToyBox was chosen as a viable intervention to develop as it has proven effective at improving health behaviors associated with childhood obesity in multiple European countries, indicating that the intervention could be transferred to other settings and still achieve its desired aims. However, significant differences exist between preschools in these countries and Scotland (age, ethos, level of teacher training etc.). Therefore we had to carefully plan our approach to intervention adaptation in order to ensure the programme was suitably tailored to the Scottish preschool context.

This paper will describe how, in the absence of specific guidelines, we adapted the ToyBox intervention for use in Scotland. The tendency to develop new interventions rather than adapting existing ones may be due to there being extensive guidance documents available for intervention development in comparison to intervention adaptation. Therefore, we will also discuss challenges we encountered during adaptation, and how we overcame these. We will also highlight areas where additional guidelines would have been beneficial to the adaptation process.

Section summary

- *Adapting existing interventions for use in other settings is becoming more common.*
- *There are no published recommendations or guidelines regarding how to adapt an intervention to another setting.*

4. Research Design

We employed a systematic approach to the adaptation of the intervention, by loosely following guidelines for the development of complex public health interventions [6, 8]. However, as these guidelines do not address the adaptation of interventions, we were required to seek alternative approaches in addition to intervention development guidelines. We opted to use a co-creation approach [9] as an integral aspect of the intervention adaptation, as such methods have been shown to enhance the acceptability of interventions in the literature [9]. This involved collaboration with the original ToyBox research team, preschool practitioners, and Glasgow City council representatives throughout the study. Following intervention adaptation, we conducted a feasibility cluster randomized controlled trial of the intervention in six local authority preschools in Glasgow (three intervention versus 3 usual curriculum control). Testing feasibility and acceptability is an integral aspect of intervention development and evaluation [6], and assists researchers in determining whether the intervention is functioning as intended, and whether the proposed evaluation methods are feasible before progressing to a full-scale trial. This case study will primarily focus on the steps taken to adapt the intervention, with details of the feasibility study published elsewhere [7]. The following sections detail the steps we took to adapt the intervention:

4.1.Step 1: Identifying the problem and potential solutions

Our first step involved the identification of the problem that is to be addressed. In this case, childhood obesity rates in Scotland are at 16%, with little sign of this number decreasing. It was also identified that at present, there is no preschool curriculum component, which specifically focuses on physical activity and sedentary behavior in Scotland, although aspects of this are covered under health and wellbeing outcomes. We also conducted literature reviews, both of the consequences of obesity in early childhood, and of the effectiveness of existing interventions at preventing obesity [10, 11]. From these literature searches, we identified key components of obesity prevention in the early years that would need to be incorporated into any adapted intervention we developed. Specifically, interventions that focused on multiple health behaviors, (i.e. physical activity, sedentary behavior, and diet) and were implemented in more than one setting (i.e. schools and homes), were generally most effective and preventing obesity. The ToyBox study [12], was identified as a viable intervention to be adapted for use in Scotland considering it is delivered in both preschools and homes, and addressed multiple health behaviors. Additionally, the fact that the intervention had been adapted for use in six culturally different European countries (Greece, Belgium, Spain, Germany, Bulgaria and Poland), demonstrated that it had the potential to be adapted for use in Scotland.

Following the identification of an appropriate intervention for adaptation, it was also important to identify the differences that exist between the original population group, and Scottish preschool population. These differences are highlighted in Table 1. Careful consideration of these differences would be required during the intervention adaptation process.

Table 1. Differences between Scotland and the original population group targeted by ToyBox

Differing factors	**Mainland Europe (original ToyBox programme)**	**Scotland (adapted ToyBox programme)**
Children's age	4-6 years old	3-5 years old
Weather	Central and southern European countries with low rainfall and warm temperatures	Glasgow wettest city in western Europe
Sociodemographic factors	Majority of participating regions have narrower inequalities than Scotland (with exception of Bulgaria and Poland).	Wider health and social inequalities evident in Scotland. Glasgow most deprived city in Western Europe
Preschool policies	Policies range from teacher led to child led	Focus on child-led learning

Language	Original materials translated to American English	Specific Scotland-specific language used in education documents in Scotland.

4.2.Step 2: Stakeholder involvement and consultation

The first step in commencing the adaptation process was to begin collaboration with key researchers from the original ToyBox study research team. This allowed us to obtain all the materials needed to implement and evaluate the intervention such as the classroom activity guides, general practitioner guide (appendix A), teacher logbooks, and parental materials. Another benefit of creating close links with the original intervention developers, was that we could learn from their knowledge and experiences regarding challenges with intervention implementation. Specifically, the research teams suggested that we should have a stronger focus actively involving parents in the delivery of the intervention at home, as opposed to the passive approach that was adopted by the original intervention.

We also established strong links with Glasgow City Council from the outset, holding a number of meetings with the Education Services team. These meetings allowed us to identify where within the preschool curriculum any adapted ToyBox intervention would fit. It also allowed us to coordinate recruitment efforts so that the intervention was not implemented in preschools that were already running programmes that would compromise the delivery of the intervention. The classroom manuals were shared with members of the Education Services team, who then analysed them to identify any components that would need to be adapted or removed from the programme prior to implementation.

4.3.Step 3: Demonstrating the need for ToyBox in Scottish preschools

Once we had established our target population (3-5 year old children who attend a local authority preschool in Glasgow, Scotland) we set out to investigate the extent to which the ToyBox programme would be needed in Glasgow's preschools. Firstly, through our contacts with Glasgow City Council, we arranged hour-long observations of four preschool settings in the city. During these observations, we recorded the number of children who engaged in active play and prolonged periods of sitting (>15 minutes). Secondly, we conducted a small needs assessment study involving 15 children, who wore an activPAL accelerometer on their leg for three full days at preschool and at home. The activPAL measures posture and movement to determine the amount of time an individual spends in active, upright or sedentary activities [13]. The results of this needs assessment study revealed that children were physically active for an average of 144 minutes per day (almost 40 minutes below the recommended amount for children younger than 5 years), and had multiple bouts of sedentary time lasting more than 30 minutes.

Following the needs assessment study, we conducted a half-day workshop with 11 preschool teachers, where we discussed topics such as current health and wellbeing practices in preschools, areas for improvement with regards to PA and the classroom environment, and health behaviors in children's homes. We also had an interactive discussion involving the ToyBox classroom materials, where teachers viewed the documents and provided feedback. Finally, we presented evidence that supported the need for ToyBox in Scottish preschools, both national surveys [14] and the results of our observations and needs assessment study, and discussed a number of important aspects such as time constraints, curriculum targets, and space/resources that we would need to consider while adapting the intervention.

4.4. Step 4: Co-creation of The adapted ToyBox Scotland intervention

In order to ensure that the adaptations made to the original ToyBox materials were acceptable to Scottish preschool teachers, we adopted a co-creation approach during the adaptation process. Co-creation is becoming a more common tool within intervention development research, which involves stakeholders who will participate in the delivery and receipt of an intervention in its development [9]. We therefore recruited an early years practitioner who worked in a managerial role within a local authority preschool in Glasgow. This practitioner was provided with all the classroom materials, and asked to deliver the activities within the programme over a 4-week period within her preschool, and record how each session was received by the children and other staff. We also worked closely with the co-creating practitioner to identify aspects of the language within the manuals that would need to be adapted before implementation.

4.5. Step 5: Development of additional interactive parent-child activities

In order to develop more interactive home materials, we consulted previous literature on successful home materials for childhood obesity [15], and followed advice gathered from teachers workshops on how to engage parents. We recruited a graphic designer to assist us in the development of interactive games and sticker incentives for parents to deliver to their children.

4.6.Step 6: Testing the feasibility and acceptability of the adapted intervention in Scottish preschools

Once all adaptation processes had taken place, we implemented the intervention in three preschools in Glasgow. A further three preschools that continued to deliver the usual curriculum were recruited as control schools. We employed a feasibility cluster randomized controlled design, and measured participating children at baseline, and 15-17 weeks later. Feasibility testing is an integral aspect of intervention development and evaluation, and is recommended by the UK Medical Research Council [6]. The primary outcome of interest was the feasibility and acceptability of both the intervention, and our methods of evaluation. The specific methods of evaluation were:

1. BMI z score (height and weight measured by a trained researcher)
2. Objectively measured physical activity and sedentary time (measured by wearing the activPAL accelerometer
3. Sociodemographic information and home snacking, water consumption and screen time (measured by parental questionnaire)
4. Intervention fidelity (measured by teacher logbooks and parental questionnaire)

Throughout the intervention adaptation process, we followed the steps presented in the intervention mapping protocol where applicable (Table 2), which was used to develop the original toybox intervention. Additionally, as intervention adaptation requires different approaches to intervention development, we were required to diverge from the guidelines.

Table 2. Intervention mapping protocol [8].

Step 1: Needs assessment	• High childhood obesity rates in Scotland • Objective measurement of physical activity in sample of pre-schoolers
Step 2: Matrices	• Defining expected changes to behaviour and environment • Defining objectives
Step 3: Selection of methods and strategy	• Consultation with potential participants • Selecting strategies • Matching strategies to objectives
Step 4: Development of programme components and design	• Consultation with stakeholders (co-creation) • Identifying resources needed for programme • Developing materials of the programme • Pre-test developed materials with all relevant stakeholders
Step 5: Programme adoption and implementation plan	• Identifying adopters and users (Preschool children and their parents in Glasgow, via preschool practitioners) • Defining objectives relating to adoption, implementation and sustainability
Step 6: Evaluation plan	• Feasibility cluster randomised controlled trial • Process evaluation

Section summary

- *A systematic approach was employed to adapt the ToyBox preschool obesity prevention intervention to Scottish preschools.*
- *Co-creation was used to engage and involve stakeholders throughout the adaptation process.*

5. Method in Action

The approach we took to adapt the intervention was systematic, building on existing theory and literature before actively involving stakeholders in the adaptation process. The co-creation approach taken allowed us to identify any potential issues, which may have arisen early on in the adaptation process, and work to find solutions to rectify these together with those who would be responsible for delivering the intervention. A surprising example of this was that both Glasgow City Council and preschool staff felt strongly that the eating/snacking components of the intervention were not needed within the preschool environment, mainly due to most Glasgow preschools having strict policies in place regarding junk food and sugar-sweetened beverages. This is not something that we would have foreseen had we not consulted with stakeholders early during adaptation. The result of this was that these components were ultimately removed from the preschool aspect of the intervention, but were retained for the home component, where all agreed that these behaviors still needed targeting in the home.

Co-creation also had a major influence on the nature of the physical activity and sedentary behavior components of the intervention, in addition to the language used in the preschool activity manuals. One issue identified during the initial trial run of the activities, was that the majority were more practitioner-led. In contrast, the Scottish preschool curriculum encourages the use of child-led activities (where children are given autonomy to guide the activities themselves) wherever possible [16]. Therefore, a significant proportion of PA and SB games were removed as they required major practitioner guidance, while some were adapted to make them more child-led. A major asset of the adapted intervention, was that we were able to work with a preschool practitioner to align the intervention activities with existing health and wellbeing objectives set out by the national education policies in Scotland. This meant that by participating in the intervention, practitioners were contributing towards their remit as preschool educators, as opposed to being burdened with additional workload. Considering extra workload is a major barrier to intervention fidelity in school-based programmes, this was an important aspect of the adaptation process.

The end result was considerably different to the original Toybox programme. We made extensive adaptations, detailed in Table 3. This was considerably more than we had initially anticipated, and had we not involved stakeholders and practitioners from the outset, we likely would not have made a number of the adaptations mentioned in Table 3, meaning the intervention would have looked substantially different, and may not have been as acceptable to practitioners. These components were adapted solely based on the feedback received during co-creation sessions. However, this raises another important issue: At which point does adaptation change an intervention to the point where it is no longer reflective of the original intervention? The fact that we removed the eating/snacking and water consumption components from the preschool setting, and reduced the number of PA activities, means that we essentially delivered half of the original intervention in Scottish preschools. Similarly, the development of an additional home component in the form of parent-child interactive activities and sticker incentives added an additional behavioral change component to the intervention that was previously not part of the ToyBox programme. This raises the question of whether the adapted intervention is in fact now a distinctly different intervention from ToyBox, and reinforces the need for robust, evidence-based guidance on intervention adaptation.

Table 3. Resulting adaptations to the ToyBox-Scotland programme with reasons

Original ToyBox intervention components	**ToyBox Scotland adaptations**	**Reasons for adaptations**
26 physical activity sessions	11 physical activity sessions retained, 15 removed	• Teacher-led style of delivery • Younger age of children made some activities too complex
Health behaviours targeted at preschool: physical activity, sedentary behaviour, eating/snacking, water consumption	Physical activity and sedentary behaviour retained; eating/snacking and water consumption removed from preschool component	• Stakeholders believed that Scottish preschools already have good policies in place which prevent unhealthy eating and drinking within preschools
Classroom materials written in seven languages, including American English	English version of classroom materials adapted so language was reflective of wording used in Scottish preschool documents	• Stakeholders felt materials would be more user friendly if the language used was more familiar
Passive parental involvement using tip cards, newsletters and posters	Active parental component added in form of parent-child homework activities, and sticker incentives	• Original ToyBox research team recommended actively involving parents more in the intervention. • Stakeholders agreed and that home materials needed to be interactive

Section summary

- *The adapted intervention was considerably different from the original ToyBox programme in a number of ways.*
- *Stakeholders may have considerably different views than the research team, which highlights the importance of consultation and co-creation in intervention programmes.*

6. Practical Lessons Learned

6.1. Lesson 1: Collaboration is key

Collaborating with the original research team is not necessarily required when adapting an intervention, but in this case, it benefitted the adaptation process. The inside knowledge regarding the barriers and facilitators to getting an intervention up and running often go unpublished, so by creating good working links with the original intervention developers, we were able to discuss these points, which helped inform decisions made during adaptation. We were also given access to all the relevant materials, such as classroom activity guides, logbooks, and questionnaires along with support and guidance from the original researchers.

6.2. Lesson 2: Co-creation is a useful tool for intervention development and adaptation when used appropriately

Taking the time to do the relevant groundwork with practitioners who will be responsible for delivering the intervention can be very beneficial to ensuring an intervention is appropriate for the setting. The considerable changes to the intervention's content that were made due to the consultations with the City council, practitioner workshops, and trialing of activities within preschools demonstrates how influential the stakeholders were in adapting the intervention. Additionally, having access to relevant "gatekeepers" was essential for recruitment and buy-in. For example, having Council representatives on board from the outset meant that we had direct access to relevant head teachers, all preschools in Glasgow, and a viable recruitment pathway for the RCT. A caveat to this is that co-creation activities must be adequately planned in advance of any workshops or meetings taking place. It became clear that both council workers and preschool staff had limited time to dedicate to co-creation activities. Therefore all the meetings needed to be well structured with clear objectives in order to maximize benefit from the process.

6.3.Lesson 3: Engaging parents in the co-creation processes can be difficult

Whilst we had positive experiences working with practitioners during intervention development, we struggled to engage parents in the process to the same degree. Research has shown that specific barriers exist for parents, which can prevent them from engaging in research activities, e.g., time constraints. Socially disadvantaged groups are particularly difficult to engage with, which may have influenced our lack of success with regards to involving parents in the co-creation process. Incentives and school presentations are two methods that have proven successful in engaging parents in other interventions, which we should consider employing in any further adaptation work with parents in the future.

6.4. Lesson 4: There remains a need for further guidance on adapting interventions

Co-creation has potential in intervention development/adaptation research, but it should be used cautiously. The stakeholders may want to change an intervention significantly, as we observed here, to the point that a number of key components of the original programme are either removed or considerably adapted. At present, there is no formal guidance for adapting existing interventions to other settings, and it is therefore unclear as to how much adaptation is acceptable, and how much constitutes the creation of a distinctly new intervention. Intervention development guidelines and models such as the intervention mapping protocol used here, can offer a systematic blueprint for adaptation to an extent. However, there remains considerable gaps within these current guidelines. The strong views of both the practitioners and council staff that preschool policies have made the eating/snacking component of the intervention in preschools unnecessary, conflicts with the existing research on this area, which indicates that there may still be a need to improve preschool dietary habits in the UK [17]. However, we respected the views of the stakeholders and removed these components from the intervention. Had we been able to demonstrate that diet was still in fact an issue in preschools, as we did with our needs assessment study for physical activity, then we may have been able to include the eating/snacking components without undermining the stakeholder's observations.

Section summary

- *Parental engagement in the co-creation process is difficult and requires more attention in future intervention work.*
- *More guidance is needed with regards to intervention adaptation guidelines.*

7. Conclusion

This case study describes the approach taken to adapt the ToyBox preschool obesity prevention intervention for use in the Scottish preschool context. We used a systematic approach and involved stakeholders throughout using co-creation, which resulted in significant adaptations to the content and delivery of the ToyBox programme in Scotland. The difference between an adapted intervention and a newly developed intervention is currently a grey area within public health research. Major components were omitted from the Scottish version of ToyBox based on the views and recommendations of stakeholders who had experience of the preschool education system. The development of guidelines on the adaptation of existing interventions would help to determine the extent to which an intervention can be adapted, and what approaches to take to achieve optimal results.

Section summary

- *Preschool staff were extensively involved in the adaptation of the intervention.*
- *ToyBox Scotland is significantly different to the original ToyBox intervention.*
- *It is unclear whether the level of adaptation was optimal. The development of guidelines would help to clarify this.*

8. References

1 Brown T, Moore TH, Hooper L, Gao Y, Zayegh A, Ijaz S*, et al.* Interventions for preventing obesity in children. *Cochrane Database of Systematic Reviews*. 2019.

2 Ebbeling CB, Pawlak DB, Ludwig DS. Childhood obesity: public-health crisis, common sense cure. *The lancet*. 2002; 360: 473-82.

3 Evans RE, Craig P, Hoddinott P, Littlecott H, Moore L, Murphy S*, et al.* When and how do 'effective'interventions need to be adapted and/or re-evaluated in new contexts? The need for guidance. BMJ Publishing Group Ltd: 2019.

4 Langford R, Jago R, White J, Moore L, Papadaki A, Hollingworth W*, et al.* A physical activity, nutrition and oral health intervention in nursery settings: process evaluation of the NAP SACC UK feasibility cluster RCT. *BMC public health*. 2019; 19: 865.

5 Gillespie J, Hughes A, Gibson A-M, Haines J, Taveras E, Reilly JJ. Protocol for Healthy Habits Happy Homes (4H) Scotland: feasibility of a participatory approach to adaptation and implementation of a study aimed at early prevention of obesity. *BMJ open*. 2019; 9: e028038.

6 Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *Bmj*. 2008; 337: a1655.

7 Malden S, Hughes AR, Gibson A-M, Bardid F, Androutsos O, De Craemer M*, et al.* Adapting the ToyBox obesity prevention intervention for use in Scottish preschools: protocol for a feasibility cluster randomised controlled trial. *BMJ open*. 2018; 8: e023707.

8 Eldredge LKB, Markham CM, Ruiter RA, Fernández ME, Kok G, Parcel GS. Planning health promotion programs: an intervention mapping approach: John Wiley & Sons 2016.

9 Greenhalgh T, Jackson C, Shaw S, Janamian T. Achieving research impact through co-creation in community-based health services: literature review and case study. *The Milbank Quarterly*. 2016; 94: 392-429.

10 Malden S, Hughes A, Gibson A-M, Martin A, Summerbell C, Reilly J. The relationship between obesity in early childhood and physical morbidity in childhood and adolescence: a systematic review and meta-analysis. *26th European Congress on Obesity*: 2019.

11 Reilly JJ, Hughes AR, Gillespie J, Malden S, Martin A. Physical activity interventions in early life aimed at reducing later risk of obesity and related non-communicable diseases: A rapid review of systematic reviews. *Obesity Reviews*. 2019; 20: 61-73.

12 Manios Y, Grammatikaki E, Androutsos O, Chinapaw M, Gibson E, Buijs G*, et al.* A systematic approach for the development of a kindergarten-based intervention for the prevention of obesity in preschool age children: the ToyBox-study. *obesity reviews*. 2012; 13: 3-12.

13 Ridgers ND, Salmon J, Ridley K, O'Connell E, Arundell L, Timperio A. Agreement between activPAL and ActiGraph for assessing children's sedentary time. *International Journal of Behavioral Nutrition and Physical Activity*. 2012; 9: 15.

14 Reilly JJ, Johnstone A, McNeill G, Hughes AR. Results from Scotland's 2016 report card on physical activity for children and youth. *Journal of physical activity and health*. 2016; 13: S251-S55.

15 Epstein LH, Gordy CC, Raynor HA, Beddome M, Kilanowski CK, Paluch R. Increasing fruit and vegetable intake and decreasing fat and sugar intake in families at risk for childhood obesity. *Obesity research*. 2001; 9: 171-78.
16 Priestley M, Humes W. The development of Scotland's Curriculum for Excellence: amnesia and déjà vu. *Oxford Review of Education*. 2010; 36: 345-61.
17 Lucas P, Patterson E, Sacks G, Billich N, Evans C. Preschool and school meal policies: an overview of what we know about regulation, implementation, and impact on diet in the UK, Sweden, and Australia. *Nutrients*. 2017; 9: 736.

Chapter 6: Rationale for the Methodology of the feasibility cluster RCT and accompanying process evaluation

1. Preface

The aim of this chapter is to provide additional background and justification for the methods presented in the published protocol paper for the ToyBox-Scotland evaluation which was published in *BMJ Open* in 2018 (chapter 7). The methods described here were used to test the feasibility of the ToyBox-Scotland intervention, the results of which have been published in *BMC Pilot and Feasibility Studies* (chapter 8), and *Child: care, health and development* (chapter 9) in 2019 and 2020, respectively.

1.1. *Author Contribution*

The cRCT and process evaluation were designed and conducted by SM, who was lead author. JJR, AH, and AMG directly assisted with study design and selection of appropriate outcome measures. Odysseas Androutsos (OA) , Yannis Manios (YM) , FB, Marieke De Craemer (MDC) , Greet Cardon (GC), and CS offered general support and guidance from the perspectives of the original ToyBox evaluation team. All authors read and approved the published manuscripts.

During data collection, SM was assisted by an undergraduate student during fieldwork. Specifically, the student assisted with set-up of equipment to measure participants, and recorded field notes. During data analysis, Xanne Jansen (XJ) advised on procedures and methods for analysis of accelerometer data, and AMG offered advice and independent assessment of the qualitative coding framework and thematic analysis.

2. Introduction

The ToyBox-Scotland intervention was delivered over an 18 week period within preschools in the Glasgow City Council area from February to May 2018. This time period also coincided with the cluster RCT that was implemented to evaluate the feasibility of the intervention in Scottish preschools. An additional study was also conducted at the end of the RCT, to evaluate aspects of acceptability using both quantitative and qualitative methods. Consent was sought from parents/caregivers for their child to participate in the study, and consent was also obtained from early years' practitioners and parents/caregivers for participation in interviews and focus groups. Study information sheets and consent forms for both the RCT and the process evaluation can be viewed in appendices B and C, respectively. The CONSORT baseline characteristics of participants in the cRCT are presented in table 1. Full results are presented in chapters 8 and 9.

Table 1. CONSORT baseline characteristics table for ToyBox Scotland study sample

Characteristics	***Intervention (n=26)***	***Control (n=16)***
Age y (mean SD)	4.5 (0.5)	4.3 (0.7)
***N* (%) girls**	10 (38)	7 (44)
Height cm (mean SD)	106.5 (5.4)	104.5 (5.1)
Weight kg (mean SD)	18.3 (2.5)	17.7 (2.6)
BMI category *n* (%)		
Obese	2 (7.7)	2 (12.5)
Overweight	6 (23.1)	3 (18.7)
Normal/under weight	18 (69.2)	11 (68.8)

A variety of methods were employed to measure the various aspects of feasibility and acceptability presented in these papers, and this methods chapter will describe these methods, justify their usage, and discuss potential advantages and disadvantages of alternative methods that have been used in similar studies.

3. Selecting the appropriate study design

Traditionally, randomised controlled trials (RCTs) have been regarded as the "gold standard" for evaluating and providing evidence of effectiveness for healthcare-related interventions, from the medical sciences to social research [1]. There are a number of design characteristics which give RCTs an advantage over other study designs, particularly with regards to minimising bias, and inferring a casual effect of a drug treatment or complex intervention [2]. Newer, observational study designs such as natural experiments and longitudinal analyses of large datasets have recently emerged that challenge the idea of the RCT being the most robust research method [3, 4]. However, it is generally accepted that the RCT is still the best option when seeking to assess whether a preventative social intervention has the intended impact on the target population [1, 2].

A variation of the RCT design is the cluster RCT, where the unit of randomisation is not the individual, but rather a site or "cluster" containing multiple individuals within itself. Such study designs are often the preferred choice when testing an intervention where recruitment will take place across multiple similar sites such as schools, hospitals, or community centres, where participants within each cluster will share similar characteristics [5]. The advantage of the cluster RCT is that it avoids the potential for contamination bias to affect outcomes [6], whereby participants in the control group may inadvertently receive parts of the intervention. Cluster RCTs carry their own set of disadvantages when compared to traditional RCTs. One of the major challenges with cluster RCTs is the need to account for the clustered nature of the data during analysis. As variation will exist between individuals contained within each cluster, multilevel modelling is often employed, whereby the analysis can account for the hierarchical structure of the data [7]. However, for such an analysis to be adequately powered, more resources may be needed to increase recruitment [7]. Additionally, cluster RCTs are considered to be more susceptible to recruitment bias and selection bias than traditional RCTs. For example, while random allocation negates selection bias, it can be reintroduced if loss to follow-up occurs at a higher rate within one cluster than in others [8]. Despite this, cluster RCTs are still argued to be the best option to take when investigating the impact of an intervention that is delivered across multiple sites of the same setting [9]. Cluster RCTs are consistently used by good quality research in education and child health, as allocation by class/school is more practical than creating new groups based on individually assigned treatment and control groups [10-13].

3.1. *Study design during feasibility testing*

When conducting a feasibility study, there is still no clear consensus upon whether the chosen study design needs to reflect the design that will ultimately be used during effectiveness testing, or whether the design can be more indistinct, before being finalised during a pilot testing phase [14]. However, the case for employing a well-defined study design during feasibility is strong, as important feasibility parameters relating to the acceptability of design components can be investigated (such as participant/cluster willingness to be randomised), which are more difficult to alter during pilot or effectiveness testing [14].

A feasibility cluster RCT design was therefore selected as the most appropriate approach to take with this present study. However, due to the anticipated low numbers of clusters, conducting hierarchical modelling of outcome data would most likely not be possible.

4. Measuring physical activity and sedentary behaviour

Interventions aimed at preventing childhood obesity that involve activities designed to improve energy-balance related behaviours, will often utilise some form of physical activity measurement [12]. As one of the main contributors to weight regulation, changes in physical activity levels from baseline to follow-up can be an important indicator of the potential for an intervention to improve obesity prevalence, even in cases where a significant effect on weight status is not identified in the trial [10, 13]. This is especially true considering changes in weight status at a population level can take significantly longer to manifest than the typical follow-up period of an RCT [15].

When selecting a method to measure children's physical activity levels, there exists multiple options that all carry their own set of limitations and advantages. Subjective methods are the most cost-effective approach, and involve the use of validated questionnaires, surveys or activity diaries to gather parental or self-report data [16]. Such approaches are primarily used for population-based studies, or routine data collection for national surveys [17], and are considered to carry a significant risk of reporting biases; specifically recall bias and social desirability bias [18, 19].

In recent years, technological advances have made objective measurement of physical activity more affordable, however cost is still a major barrier for some research institutions. Devices that objectively measure children's physical activity include pedometers, accelerometers and heart rate monitors [20, 21]. Such devices considerably reduce the bias associated with subjective methods, and accelerometers in particular can provide a particularly nuanced understanding of physical activity by differentiating between physical activity intensities, and sedentary behaviour [22].

4.1. *Measuring physical activity and sedentary behaviour with accelerometers*

Accelerometers are widely used to measure habitual free-living physical activity in children [23]. While an increasing variety of manufacturers and devices are available, two devices are consistently featured in high quality research; the Actigraph and the activPAL. Actigraphs are worn in an elastic band around the waist or wrist in some models, and have been shown to be one of the most effective devices for accurately measuring overall physical activity, and differing intensities of physical activity (low intensity PA, and moderate-vigorous intensity PA) [24]. However, a limitation of the Actigraph is that it requires removal for bathing, some contact sports, and during sleep [25]. This can lead to measurement bias, as younger children and their parents often forget to re-attach the monitor once they resume free-living daily activities. Additionally, while the ActiGraph performs highly at identifying different PA intensities, it is less adept at differentiating between sedentary behaviour and non-sedentary upright activities such as standing [26, 27].

While its ability to measure moderate-vigorous physical activity (MVPA) is not as robust as the ActiGraph [28], to assess PA and SB in the ToyBox-Scotland study, the activPAL was selected for a number of reasons. Firstly, the activPAL is attached to the wearer via medical adhesive tape directly to the mid-thigh, where it can remain for up to one week [26]. This method of attachment allows the wearer to continue wearing the device during bathing activities and sleep, significantly reducing the risk of measurement bias as a result of repeated removals. As the activPAL measures axis of movement [26], it is also able to differentiate between stationary standing, and sedentary behaviours involving sitting/lying down. As one of the components of the ToyBox intervention involved the removal of chairs from classrooms [10], this feature would allow for the capture of non-sedentary play such as painting, reading and drawing while standing, that would not be accurately captured by the ActiGraph. Additionally, the activPAL has also been demonstrated to effectively estimate sleep time [29]

5. Measuring weight status

5.1. *Body mass index (BMI)*

Body mass index is a commonly used method of estimating adiposity in children [30]. BMI z scores are used to classify a child's weight status adjusted for age and sex, presented as a standard deviation from the mean in a given reference population [31]. While other variations of BMI classification exist such as total BMI value and BMI percentile/prevalence (85th percentile =overweight; ≥95th percentile = obese), the mean BMI z score is generally considered to be the most appropriate method to use when studying intervention effects on weight status in children [32]. While percentile scores/prevalence are often used to categorically describe a study population, the advantage of using mean z scores is that they provide a more accurate estimate of poor anthropometric status than observed prevalence, thus reducing the required sample size needed to detect significant changes in weight status [31, 33]. This is due to the fact that from a statistical perspective, differences in means have greater statistical power when discriminating across target groups, than differences in prevalence/percentile categories [33].

The present study used mean BMI z score, using two distinct reference populations. UK90 is the most widely used anthropometric reference population dataset for children aged 4 years and over in the UK [34]. As the preschool sample would also likely include three year old children, we were also used the World Health Organisation (WHO) reference population data to calculate z scores for three year olds [35]. Data were entered into LMS; an anthropometric analysis software add-in for Microsoft excel. The programme allows for the calculation of BMI z scores based on preselected reference populations, and the latest version accounts for the transition between two different datasets which would occur when a child was three years old at baseline, but four years old at follow-up [36]. The data collection procedures followed to obtain anthropometric data are detailed in chapter 7.

5.2. *Bioelectric Impedance analysis (BIA)*

In addition to measuring BMI, it was also deemed useful to test the feasibility of a second measure of weight status. Since BMI is considered a crude measure of adiposity [31], researchers will often employ another anthropometric measure such as hip to waist ratio, skinfold thickness tests, or waist circumference to further validate BMI measures [37-39]. It is also evident from clinical interventions that measuring change in fat mass is more sensitive than measuring changes in anthropometry [40], making this an important aspect to investigate in obesity prevention research, Another method that is increasingly being used in child health research is bioelectrical impedance analysis (BIA). BIA involves the placement of electrodes on the hand and foot of an individual in the supine position, often after following a strict protocol of fasting and limited physical activity [41]. A harmless electrical current is then passed through the body between the electrodes, and the resistance (i.e. impedance) met by this current gives an indication of the type of organic tissue that the body is composed of. BIA can therefore estimate the body composition of an individual, giving a percentage of muscle mass/fat-free mass, fat mass, body water, and a corresponding impedance value [41, 42].

While BIA protocols have been developed and validated, the majority of this research is related to studies of adult populations [42]. However, an increasing number of studies are using BIA with child populations [43]. Despite the absence of a validated protocol with this population group, BIA with children has been shown to be feasible in a number of previous studies, though not in pre-school children. Results indicate that the intra-day and between-day variation in BIA measurement in children is low, indicating that results of a similar accuracy to adult populations is achievable, if the necessary physiological and methodological parameters are controlled for such as fasting and prior activity [42]. However, there is still a dearth of research involving BIA and pre-school aged children, with the various protocols such as fasting, voiding, and avoiding strenuous exercise cited as major challenges in implementing accurate BIA with this population group [44]. Therefore, BIA was selected as a secondary outcome measure in this study, to test whether it was feasible to collect accurate BIA readings from preschool children to compliment anthropometric data. Full details of data collection procedures are reported in chapter 7.

6. Using questionnaires to measure demographics and health behaviours in the home environment

In order to collect demographic information, screen time, and dietary habits in the home environment, two validated questionnaires from the original ToyBox study were adapted and used. The food frequency questionnaire (FFQ) is a 37 item questionnaire which primarily aims to assess energy intake, consumption of fruits/vegetables, and high-energy density foods such as sugar-sweetened beverages and confectionary [45]. The primary caregiver questionnaire (PCQ) is a demographic and health lifestyle questionnaire which parents/caregivers complete regarding their child. The original ToyBox study PCQ consisted of 229 items pertaining to demographics (family structure, parental age/profession, ethnic background etc), snacking behaviours, sedentary behaviours (screen time, reading etc), physical activity (team sports/sports club attendance etc), and sleep patterns [46]. Both questionnaires use a combination of Likert scales, multiple choice questions, and open ended questions to gather the required information from parents/caregivers.

Both questionnaires have been extensively used in the ToyBox study across Europe, with site-specific adaptations taking place as required [46]. The FFQ was found to be valid and reliable [47]. However, limitations of the questionnaire have been identified in the literature. Specifically, the length of the FFQ and the complexity of some questions related to daily energy intake have been criticised by some researchers, and this issue can lead to both reporting bias and a poor response rate in some studies [48]. The PCQ has been less extensively used, however its validity and reliability have been demonstrated [46]. As with the FFQ, adaptations have been made to the questionnaire to reflect the contextual differences across the different ToyBox sites.

The FFQ and PCQ used in the present study were both adapted to suit the Scottish context. Specifically, the PCQ length was reduced by omitting questions pertaining to prenatal/postnatal health, maternal health and breastfeeding/weaning. During workshops with preschool practitioners, these items were deemed to be overly intrusive, and were also deemed to be beyond the scope of the ToyBox-Scotland study. Additionally, questions that required parents to calculate daily/weekly energy (kcal) consumption were deemed by preschool practitioners to be overly complicated, who stated we could anticipate low response rates to these items. The adapted version of the FFQ that was used for the ToyBox-Scotland study consisted of ten items, and the language used in some questions was altered to reflect the form of English used in the United Kingdom. The questionnaire can be viewed in appendix D.

The PCQ used in the ToyBox Scotland study was altered to include additional demographic questions relating to postcode, UK-specific ethnic classification groups and to reflect English language usage in the UK. The resulting questionnaire was shortened to 129 items and can be viewed in appendix E.

7. Feasibility and process evaluation measures

The primary outcome of this study was feasibility of the intervention and evaluation methods. In order to assess whether the study was feasible, a number of parameters were assessed which are detailed in chapter 7. Briefly, feasibility of trial procedures was assessed by collating recruitment rates (preschool level and individual level), attrition rates, and outcome compliance/response rates. Intervention fidelity and acceptability was assessed with the practitioner logbook (chapter 8, table 1) and post intervention feedback surveys (appendix F). The criterion for progressing to further effectiveness testing of the intervention, was the intervention being assessed as having been implemented with high fidelity overall within both preschool environments and the home (≥60% mean fidelity score), as this is what was considered high fidelity for process evaluation in the original ToyBox programme [49].

7.1. *Assessing acceptability of the intervention and trial*

In addition to the use of quantitative methods to assess acceptability, we also employed qualitative methods to gain additional contextual information regarding how the intervention would be received by those who were delivering it, and receiving it, as recommended by the MRC [50]. Preschool practitioners from the intervention preschools participated in focus groups post intervention. Focus groups were chosen as the appropriate data collection method over individual interviews for a number of reasons. Firstly, time constraints and staffing schedules made it more feasible for staff to meet for a group discussion during quiet periods in the preschool, rather than coordinating multiple interviews that would require additional classroom cover and disruption. Secondly, focus groups would allow for the practitioners to openly discuss how the intervention affected their practices collectively. In contrast, individual interviews were selected as the appropriate method to use for data collection with parents/caregivers. As with practitioners, the reasons for this were both logistical and methodological; organising a convenient time to hold a focus group with multiple parents was identified as a challenge by preschool staff, therefore arranging individual interviews at the convenience of the participant was the approach taken. Secondly, unlike preschool staff, parents/caregivers do not have a working relationship with each other, and may withhold information during focus groups when discussing potentially sensitive issues such as their child's health behaviours [51].

Data collection procedures and analysis are described in detail elsewhere [52, 53]. Briefly, one researcher (SM) with extensive experience in conducting qualitative research conducted the focus groups and interviews with participants.

Interview/focus group topic guides were developed by the research team, which aimed to collect information regarding how the intervention affected practice/health behaviours (in preschool and the home), perceived quality of intervention materials, and any barriers and facilitators to implementation. Interview and focus group topic guides can be viewed in appendices G and H, respectively.

During data collection, the researcher followed principles of reflexivity in order to account for the risk of bias that is presented during qualitative research [54]. Specifically, field notes were taken during interviews, which detailed instances where it was suspected that the researcher's interests, assumptions and research motives may bias participant's responses, or bias the interpretation of the data during analysis.

Focus groups/interviews were audio recorded and transcribed verbatim, before a thematic analysis [55] was conducted. The analysis is described in detail in chapter 9. Thematic analysis was used as it is considered to be a flexible research method, which would allow for the exploration of the range of potential interview topics that typically present during intervention evaluation research [55].

8. References

1 Ritter GW. Using the proper tool for the task: RCTs are the gold standard for estimating programme effects–a response to Stewart-Brown et al. *Journal of Children's Services*. 2012.

2 Hariton E, Locascio JJ. Randomised controlled trials—The gold standard for effectiveness research. *BJOG: an international journal of obstetrics and gynaecology*. 2018; 125: 1716.

3 Chemla G, Hennessy CA. The paradox of policy-relevant RCTs and natural experiments: Centre for Economic Policy Research 2016.

4 Henry D, Tolan P, Gorman-Smith D, Schoeny M. Alternatives to randomized control trial designs for community-based prevention evaluation. *Prevention Science*. 2017; 18: 671-80.

5 Kotz D, Spigt M, Arts IC, Crutzen R, Viechtbauer W. Use of the stepped wedge design cannot be recommended: a critical appraisal and comparison with the classic cluster randomized controlled trial design. *Journal of clinical epidemiology*. 2012; 65: 1249-52.

6 Magill N, Knight R, McCrone P, Ismail K, Landau S. A scoping review of the problems and solutions associated with contamination in trials of complex interventions in mental health. *BMC medical research methodology*. 2019; 19: 4.

7 Christie J, O'Halloran P, Stevenson M. Planning a cluster randomized controlled trial: methodological issues. *Nursing research*. 2009; 58: 128-34.

8 Bolzern J, Mnyama N, Bosanquet K, Torgerson DJ. A review of cluster randomized trials found statistical evidence of selection bias. *Journal of clinical epidemiology*. 2018; 99: 106-12.

9 Brown AW, Li P, Bohan Brown MM, Kaiser KA, Keith SW, Oakes JM*, et al.* Best (but oft-forgotten) practices: designing, analyzing, and reporting cluster randomized controlled trials. *The American journal of clinical nutrition*. 2015; 102: 241-48.

10 De Craemer M, De Decker E, Verloigne M, De Bourdeaudhuij I, Manios Y, Cardon G. The effect of a kindergarten-based, family-involved intervention on objectively measured physical activity in Belgian preschool boys and girls of high and low SES: the ToyBox-study. *International Journal of Behavioral Nutrition and Physical Activity*. 2014; 11: 38.

11 Kipping R, Jago R, Metcalfe C, White J, Papadaki A, Campbell R*, et al.* NAP SACC UK: protocol for a feasibility cluster randomised controlled trial in nurseries and at home to increase physical activity and healthy eating in children aged 2–4 years. *BMJ open*. 2016; 6: e010622.

12 Reilly JJ, Hughes AR, Gillespie J, Malden S, Martin A. Physical activity interventions in early life aimed at reducing later risk of obesity and related non-communicable diseases: A rapid review of systematic reviews. *Obesity Reviews*. 2019; 20: 61-73.

13 Reilly JJ, Kelly L, Montgomery C, Williamson A, Fisher A, McColl JH*, et al.* Physical activity to prevent obesity in young children: cluster randomised controlled trial. *Bmj*. 2006; 333: 1041.

14 Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D*, et al.* How we design feasibility studies. *American journal of preventive medicine*. 2009; 36: 452-57.

15 Livingstone MBE, McCaffrey T, Rennie KL. Childhood obesity prevention studies: lessons learned and to be learned. *Public health nutrition*. 2006; 9: 1121-29.
16 Hart TL, Ainsworth BE, Tudor-Locke C. Objective and subjective measures of sedentary behavior and physical activity. *Medicine & Science in Sports & Exercise*. 2011; 43: 449-56.
17 Hamer M, Stamatakis E, Steptoe A. Dose-response relationship between physical activity and mental health: the Scottish Health Survey. *British journal of sports medicine*. 2009; 43: 1111-14.
18 Adams SA, Matthews CE, Ebbeling CB, Moore CG, Cunningham JE, Fulton J*, et al.* The effect of social desirability and social approval on self-reports of physical activity. *American journal of epidemiology*. 2005; 161: 389-98.
19 Cerin E, Cain KL, Oyeyemi AL, Owen N, Conway TL, Cochrane T*, et al.* Correlates of agreement between accelerometry and self-reported physical activity. *Medicine and science in sports and exercise*. 2016; 48: 1075.
20 Hensen SJ. Measuring physical activity with heart rate monitors. *American journal of public health*. 2017; 107: e24.
21 Le Masurier GC, Tudor-Locke C. Comparison of pedometer and accelerometer accuracy under controlled conditions. *Medicine & Science in Sports & Exercise*. 2003; 35: 867-71.
22 Reilly JJ, Penpraze V, Hislop J, Davies G, Grant S, Paton JY. Objective measurement of physical activity and sedentary behaviour: review with new data. *Archives of disease in childhood*. 2008; 93: 614-19.
23 Verloigne M, Van Lippevelde W, Maes L, Yıldırım M, Chinapaw M, Manios Y*, et al.* Levels of physical activity and sedentary time among 10-to 12-year-old boys and girls across 5 European countries using accelerometers: an observational study within the ENERGY-project. *International journal of behavioral nutrition and physical activity*. 2012; 9: 34.
24 Gomersall SR, Ng N, Burton NW, Pavey TG, Gilson ND, Brown WJ. Estimating physical activity and sedentary behavior in a free-living context: a pragmatic comparison of consumer-based activity trackers and ActiGraph accelerometry. *Journal of medical Internet research*. 2016; 18: e239.
25 Choi L, Liu Z, Matthews CE, Buchowski MS. Validation of accelerometer wear and nonwear time classification algorithm. *Medicine and science in sports and exercise*. 2011; 43: 357.
26 Ridgers ND, Salmon J, Ridley K, O'Connell E, Arundell L, Timperio A. Agreement between activPAL and ActiGraph for assessing children's sedentary time. *International Journal of Behavioral Nutrition and Physical Activity*. 2012; 9: 15.
27 Rosenberger ME, Buman MP, Haskell WL, McConnell MV, Carstensen LL. 24 hours of sleep, sedentary behavior, and physical activity with nine wearable devices. *Medicine and science in sports and exercise*. 2016; 48: 457.
28 Janssen X, Cliff DP, Reilly JJ, Hinkley T, Jones RA, Batterham M*, et al.* Validation and calibration of the activPAL™ for estimating METs and physical activity in 4–6 year olds. *Journal of science and medicine in sport*. 2014; 17: 602-06.
29 Alghaeed Z, Reilly JJ, Chastin SF, Martin A, Davies G, Paton JY. The influence of minimum sitting period of the ActivPAL™ on the measurement of breaks in sitting in young children. *PloS one*. 2013; 8.
30 Abarca-Gómez L, Abdeen ZA, Hamid ZA, Abu-Rmeileh NM, Acosta-Cazares B, Acuin C*, et al.* Worldwide trends in body-mass index, underweight,

overweight, and obesity from 1975 to 2016: a pooled analysis of 2416 population-based measurement studies in 128· 9 million children, adolescents, and adults. *The Lancet*. 2017; 390: 2627-42.
31 Cole TJ, Faith MS, Pietrobelli A, Heo M. What is the best measure of adiposity change in growing children: BMI, BMI%, BMI z-score or BMI centile? *European journal of clinical nutrition*. 2005; 59: 419-25.
32 Inokuchi M, Matsuo N, Takayama JI, Hasegawa T. BMI z-score is the optimal measure of annual adiposity change in elementary school children. *Annals of human biology*. 2011; 38: 747-51.
33 World Health Organization. Physical status: The use of and interpretation of anthropometry, Report of a WHO Expert Committee. 1995.
34 Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: international survey. *Bmj*. 2000; 320: 1240.
35 WHO Multicentre Growth Reference Study Group. WHO Child Growth Standards based on length/height, weight and age. *Acta paediatrica (Oslo, Norway: 1992) Supplement*. 2006; 450: 76.
36 Pan H, Cole T. LMSgrowth, a Microsoft Excel add-in to access growth references based on the LMS method. Version 2.77. 2012. 2017.
37 Ahrens W, Bammann K, Siani A, Buchecker K, De Henauw S, Iacoviello L*, et al.* The IDEFICS cohort: design, characteristics and participation in the baseline survey. *International Journal of Obesity*. 2011; 35: S3.
38 Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, Dyer A. Two-year follow-up results for Hip-Hop to Health Jr.: a randomized controlled trial for overweight prevention in preschool minority children. *The Journal of pediatrics*. 2005; 146: 618-25.
39 Haines J, McDonald J, O'Brien A, Sherry B, Bottino CJ, Schmidt ME*, et al.* Healthy habits, happy homes: randomized trial to improve household routines for obesity prevention among preschool-aged children. *JAMA pediatrics*. 2013; 167: 1072-79.
40 Reilly JJ, Martin A, Hughes AR. Early-life obesity prevention: Critique of intervention trials during the first one thousand days. *Current obesity reports*. 2017; 6: 127-33.
41 De Beer M, Timmers T, Weijs PJ, Gemke RJ. Validation of total body water analysis by bioelectrical impedance analysis with deuterium dilution in (pre) school children. *e-SPEN, the European e-Journal of Clinical Nutrition and Metabolism*. 2011; 6: e223-e26.
42 Brantlov S, Ward LC, Jødal L, Rittig S, Lange A. Critical factors and their impact on bioelectrical impedance analysis in children: a review. *Journal of medical engineering & technology*. 2017; 41: 22-35.
43 Talma H, Chinapaw M, Bakker B, HiraSing R, Terwee C, Altenburg T. Bioelectrical impedance analysis to estimate body composition in children and adolescents: a systematic review and evidence appraisal of validity, responsiveness, reliability and measurement error. *Obesity reviews*. 2013; 14: 895-905.
44 Kyle U, Earthman CP, Pichard C, Coss-Bu J. Body composition during growth in children: limitations and perspectives of bioelectrical impedance analysis. *European journal of clinical nutrition*. 2015; 69: 1298-305.

45 Mouratidou T, Graffe MIM, Huybrechts I, De Decker E, De Craemer M, Androutsos O*, et al.* Reproducibility and relative validity of a semiquantitative food frequency questionnaire in European preschoolers: The ToyBox study. *Nutrition*. 2019; 65: 60-67.
46 González-Gil E, Mouratidou T, Cardon G, Androutsos O, De Bourdeaudhuij I, Góźdź M*, et al.* Reliability of primary caregivers reports on lifestyle behaviours of E uropean pre-school children: the T oy B ox-study. *Obesity reviews*. 2014; 15: 61-66.
47 Huybrechts I, De Backer G, De Bacquer D, Maes L, De Henauw S. Relative validity and reproducibility of a food-frequency questionnaire for estimating food intakes among Flemish preschoolers. *International journal of environmental research and public health*. 2009; 6: 382-99.
48 Saloheimo T, González SA, Erkkola M, Milauskas DM, Meisel JD, Champagne CM*, et al.* The reliability and validity of a short food frequency questionnaire among 9–11-year olds: a multinational study on three middle-income and high-income countries. *International journal of obesity supplements*. 2015; 5: S22-S28.
49 Pinket A-S, Van Lippevelde W, De Bourdeaudhuij I, Deforche B, Cardon G, Androutsos O*, et al.* Effect and process evaluation of a cluster randomized control trial on water intake and beverage consumption in preschoolers from six European countries: the ToyBox-study. *PloS one*. 2016; 11.
50 Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *Bmj*. 2008; 337: a1655.
51 Stenhammar C, Wells M, Åhman A, Wettergren B, Edlund B, Sarkadi A. 'Children are exposed to temptation all the time'–parents' lifestyle-related discussions in focus groups. *Acta paediatrica*. 2012; 101: 208-15.
52 Malden S, Hughes AR, Gibson A-M, Bardid F, Androutsos O, De Craemer M*, et al.* Adapting the ToyBox obesity prevention intervention for use in Scottish preschools: protocol for a feasibility cluster randomised controlled trial. *BMJ open*. 2018; 8: e023707.
53 Malden S, Reilly JJ, Hughes A, Bardid F, Summerbell C, De Craemer M*, et al.* Assessing the acceptability of an adapted preschool obesity prevention programme: ToyBox-Scotland. *Child: Care, Health and Development*. 2020; 46: 213-22.
54 Berger R. Now I see it, now I don't: researcher's position and reflexivity in qualitative research. *Qualitative Research*. 2015; 15: 219-34.
55 Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology*. 2006; 3: 77-101.

Chapter 7: Adapting the ToyBox obesity prevention intervention for use in Scottish pre-schools: Protocol for a feasibility cluster randomised controlled trial

This peer-reviewed manuscript was published in BMJ Open in September 2018 and is included in the thesis exactly in its published form

1. Preface

This manuscript details the methodology for the feasibility cluster randomised controlled trial of the adapted ToyBox-Scotland intervention. The chapter describes the design of the study, outcomes of interest, methods of outcome measurement, the rationale for the study design employed, and a brief overview of the steps taken to adapt the intervention (described in detail in the previous chapter). The study was designed by SM under the supervision of JJR, AMG and AH. The original ToyBox research team collaborators supported study design and contributed to the preparation of the manuscript. We thank Jacqui Glover for assisting with adaptation of intervention materials, Charlotte Mackenzie for assisting with data collection, and Diana Mateescu for designing the home activity packs and wallchart.

2. Abstract

Introduction: There is an increasing need for the adoption of effective pre-school obesity prevention interventions to combat the high levels of early-childhood obesity in the UK. This study will examine the feasibility and acceptability of the adapted version of the ToyBox intervention –a pre-school obesity prevention programme– for use in Scotland (ToyBox-Scotland). This will inform the design of a full-scale cluster randomised controlled trial (RCT).

Methods and analysis: The ToyBox-Scotland intervention will be evaluated using a feasibility cluster RCT, which involves 3-5 year old children at six pre-schools in Glasgow, three randomly assigned to the intervention group and three to the usual-care control group. The original ToyBox intervention was adapted for the Scottish context using a co-production approach. Within the 18-week intervention, physical activity and sedentary behaviour will be targeted in the pre-school through environmental changes to the classroom, physical activity sessions, and movement breaks. Parents will receive home activity packs every three weeks containing sticker incentives and interactive parent-child games that target sedentary behaviour, physical activity, eating/snacking and water consumption. As this is a feasibility study, parameters such as recruitment rates, attrition rates, and standard deviations of outcome measures will be obtained which will inform a power calculation for a future RCT. Additional variables to be assessed include accelerometer-measured physical activity, sedentary behaviour and sleep, body mass index, home screen-time, eating/snacking and water consumption. Outcomes will be assessed at baseline and 14-17 weeks later. Intervention fidelity will be assessed using questionnaires and interviews with parents and practitioners, observation and session delivery records.

Ethics and dissemination: This study was granted ethical approval by the University of Strathclyde's School of Psychological Sciences and Health Ethics Committee. Results will be disseminated through publication in peer-reviewed journals, presentation at conferences, and in a lay summaries provided to participants.

Trial registration number: ISRCTN12831555

2.1. *Strengths and limitations of this study*

- Site-specific adaptation of a previously successful intervention (ToyBox, which targets key obesogenic behaviours in early childhood) for use in another country (ToyBox Scotland).
- Culturally relevant, multicomponent intervention targeting the pre-school and home setting.
- Co-production approach used to involve stakeholders (i.e. early years practitioners) in the intervention development and adaptation process.
- Use of both quantitative (e.g., objective measures, observation and self-report) and qualitative (e.g., logbook, interviews) methods to test feasibility.
- The study is limited by a short duration and a small number of clusters.
- Direct parental input is needed to further develop the home component of the intervention.

3. Introduction

Childhood obesity is a global public health problem, particularly in developed countries [1 2]. Overweight and obesity rates for children under ten years of age in Europe were reported to be approximately 20%, with the United Kingdom (UK) having one of the highest levels of childhood obesity within this region[3-5]. The rates reported for Scotland are particularly high, with at least 22.9% of 4-5 year olds being overweight or obese in 2016/2017[6, 7].

The causal factors contributing to childhood obesity are complex [8, 9]. However, a substantial evidence base has demonstrated that energy balance-related behaviours such as physical activity (PA), sedentary behaviour (SB) and the consumption of unhealthy drinks and snacks have a major influence on the development of childhood obesity [10-19]. While efforts to address these energy-balance related behaviours are often focused around school-aged children [20], intervening at an earlier age is merited. Recent research has demonstrated that physical inactivity and sedentary behaviour in the early years tracks into later childhood and adolescence[21]. Specifically, children who engage in healthy behaviours from an early age are more likely to maintain such behaviours throughout childhood [22, 23], potentially preventing the onset of obesity when it is perhaps more difficult to reverse [24].

Results of obesity prevention interventions targeting pre-school children (3-5 year olds) are equivocal [25]. Some reported encouraging findings regarding weight-related outcomes [26-32], while others were ineffective[33-36]. Interestingly, successful interventions tend to have similar characteristics in that they target multiple behaviours (e.g. physical activity and diet) and/or multiple environments (e.g., pre-school and home). Two examples are the 14 week US Hip Hop to Health study[28] and the year-long Spanish Ballabeina Study[29] in which the pre-school and home-based interventions led to significantly improved weight-related outcomes in comparison to control groups. A novel strength of the Hip Hop to Health study was that it improved weight-related outcomes in a hard-to-reach minority group. Such findings highlight the importance of focusing on obesity prevention efforts both at pre-school and at home, and the benefit of adapting interventions in order to successfully engage specific population groups.

In Scotland, children between the ages of three and five years are entitled to 600 hours of free childcare per year, which the majority of children spend in a pre-school setting [37]. As these children still spend a substantial amount of time at home, it is important that interventions contain a home-based component in order to target obesity-related health behaviours across both environments.

ToyBox is one such intervention which was developed to prevent obesity in young children from varying backgrounds through the use of a multicomponent, evidence- and theory-based, family-involved intervention implemented in pre-schools and homes across six European countries from 2012-2013 [38]. Extensive intervention development and site-specific adaptation was undertaken, detailed elsewhere [39-43]. ToyBox aimed to improve energy balance-related behaviours through the delivery of teacher-led physical activity and sedentary behaviour sessions, promotion of water and healthy snacking/eating, environmental changes to the classroom, and parental education materials and parent-child activities. Evaluations of ToyBox have demonstrated that the intervention was feasible, while significant improvements in physical activity and sedentary behaviours were observed [43, 44]. In the Belgian cohort, children at intervention pre-schools significantly increased their vigorous PA ($ß = 1.47$, $p = 0.03$) and moderate-to-vigorous PA ($ß = 1.27$, $p = 0.03$) from baseline to follow-up, while control participant's activity levels remained constant or decreased[45]. Furthermore, while there were no significant interaction effects on sedentary behaviour for the total sample, among children who spent the most time in sedentary activities at baseline, a significant reduction in objectively measured sedentary time of -4.17% was observed for the intervention group in comparison to the control group (-0.41%)[45]. Process evaluation of the intervention has also identified important areas for consideration in any future expansion or adaptation of the intervention, such as the need for more active parental involvement [44]. Due to the differences between pre-schools in Scotland/the UK and other European countries, the feasibility and efficacy of the programme cannot be assumed and must therefore be tested following appropriate adaptation. Interventions which are not appropriately adapted to the specific environment, often fail to have the desired impact. Therefore, extensive adaptation of intervention components and stakeholder involvement is becoming an increasingly common practice in intervention development and adaptation[46], in addition to feasibility testing prior to full scale evaluation[47]. The present feasibility cluster RCT aims to test the feasibility of the culturally adapted ToyBox intervention for use in Scotland (ToyBox-Scotland), a country with high childhood obesity rates [5]. As this is a feasibility study, the primary aim will be to assess whether progression to a full-scale cluster RCT is merited through the evaluation of important aspects such as intervention fidelity and acceptability.

4. Methods

This protocol has been prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement [48, 49].

4.1.Patient and Public Involvement

This intervention was adapted with the assistance of an early years' practitioner and staff at a local authority pre-school. Results of the study will be disseminated to participants through a presentation to early years' practitioners and a lay summary of results will be provided to parents.

4.2.Study setting and participants

Participants will be recruited from six local authority pre-school settings in Glasgow. The city is one of the most socioeconomically deprived areas in western Europe, with 34-41% of the child population living in poverty [50]. In 2015, at least 5.9% of 4-5 year olds in Glasgow were severely obese (BMI $\geqslant$ 98th centile) [50], with rates considerably higher amongst more deprived population groups[7].

The intervention will be delivered to all 3-5 year old children in the participating pre-schools.

Inclusion criteria:

- *Pre-school level inclusion criteria:* Glasgow City Council pre-school settings (nurseries, early years centres, or family learning centres) that are delivering the Scottish Curriculum for Excellence (for 3-18 year olds) in accordance with Education Scotland's early learning and childcare frameworks and guidance [51].
- *Individual level inclusion criteria:* 3-5 year old pre-school year children and their parents/caregivers who consent to both themselves and the child participating in data collection.

Exclusion criteria:

- Children for whom parental/caregiver consent is not provided and children with health conditions which would affect their participation in the intervention.

4.3.Recruitment and consent

All local authority pre-schools in Glasgow (n=112) were contacted via email by a City Council representative on behalf of the research team to provide information on the study, and request expressions of interest to participate. Eleven pre-schools expressed an interest. The majority of these pre-schools were located within the 20%

most deprived areas in Scotland as defined by the Scottish Index of Multiple Deprivation (SIMD). The SIMD compiles data on a number of domains including education, crime, health, income and housing to develop an area-based indicator of deprivation for all neighbourhoods in Scotland. Six pre-schools with similar SIMD scores (all with low-medium deprivation scores), demographics and class size were invited to participate. A seventh pre-school with similar characteristics to the study preschools agreed to assist with adaptation and co-production of the intervention, which is discussed in more detail later. Pre-school head teachers were provided with information sheets when approached to participate. All parents/caregivers of 3-5 year old preschool-year children at participating pre-schools received an information sheet detailing the intervention and data collection procedures via preschool staff, along with a consent form for their child's participation in data collection. All participating nurseries will receive £200 to offset the additional costs of taking part. Children will receive a colouring book for participation in data collection.

4.4.Intervention

The original ToyBox-study utilised various theories of health behaviour change including social cognitive theory, theory of planned behaviour and health belief model to influence energy balance-related behaviours both in pre-school settings and with families in the home [39]. The programme was developed using the PRECEDE-PROCEED model[52] and the intervention mapping protocol[53]. The overall aim of the intervention was to improve children's health behaviours in relation to obesity and it has subsequently been implemented in > 300 pre-schools across Europe (Greece, Spain, Germany, Poland, Bulgaria and Belgium). The ToyBox-study had four main areas of focus (i.e., physical activity, sedentary behaviour, healthy snacking, and water consumption) as detailed in Table 1. Classroom activities focused on each targeted behaviour for four consecutive weeks, before the cycle was repeated for a further two weeks for each behaviour. Classroom guides were designed for each targeted health behaviour containing instructions for the set up and delivery of activities and workshops, in addition to interactive stories involving cartoon animal role models. Practitioners were given autonomy in choosing activities from the provided classroom guides to deliver throughout the day and week. However, they were encouraged to deliver sessions totalling one hour per week, and to gradually introduce more advanced activities from the classroom guides as the intervention progressed. Teachers were provided with training on the programme delivery before starting the intervention.

Table 1. Original ToyBox-study intervention structure for classroom and home behaviour focus [54].

First Focus				**Repetition**			
4 weeks	4 weeks	4 weeks	4 weeks	2 weeks	2 weeks	2 weeks	2 weeks
Water drinking	Physical activity	Eating and snacking	Sedentary behaviour	Water drinking	Physical activity	Eating and snacking	Sedentary behaviour

The family-based component of the intervention involved the provision of tip cards, posters and newsletters to parents/caregivers. Distribution of these materials coincided with the particular behaviour being focused on at the pre-school. Tip cards offered suggestions of ways to improve each health behaviour in the home, posters featured cartoon characters from the classroom guides performing behaviours, while newsletters reinforced health messages.

4.5. Adaptation of ToyBox for use in Scotland

ToyBox-Scotland follows the same principles and procedures as the original ToyBox-study. However, adaptations have been made to reflect the cultural, legislative and infrastructural differences between pre-schools in Scotland and the other European countries included in the original ToyBox-study, a practice supported by intervention development literature[39]. During initial planning of ToyBox-Scotland, regular meetings were held with Glasgow City Council's education services team where the content and relevance of the original intervention materials were discussed, and the components of the intervention were assessed to ensure they aligned with key healthy weight policies for Scotland[55, 56]. A major outcome of these meetings was that the council strongly felt that the diet component of the intervention would be rendered obsolete in the Scottish pre-school setting due to nearly all local authority pre-schools prohibiting children consuming 'junk food' or sugar-sweetened beverages on the premises. This was discussed in a workshop with early years' practitioners, who confirmed that only healthy snacks, water and milk were permitted in their pre-schools. However, the practitioners believed that eating, snacking and water consumption needed to be addressed in the home environment. Practitioners were less certain about the levels of physical activity and sedentary behaviour in pre-schools. Some believed that children were 'always on the move', and that physical activity was not an issue in Scottish pre-schools, while others thought more could be done to keep children active. Again, there was a consensus that both behaviours were major issues at home. In order to gain more insight into this, a small needs assessment study was conducted (results unpublished) which involved a sample of 15 pre-schoolers wearing an activPAL accelerometer for three consecutive days while at pre-school and at home to measure physical activity and sedentary behaviour. The findings suggest considerable periods of inactivity exist both at pre-school and at home, which is in line with recent research on sedentary behaviour and physical activity levels in pre-schoolers[10, 21]. This highlights the need to address these behaviours in early childhood as noted by the 2016 WHO commission report on ending childhood obesity[57] and the newly-published 24 hour movement guidelines[58] . Nursery visits were also conducted in four pre-schools across Glasgow to observe children's physical activity and sedentary behaviour. While outdoors, children were generally active, however in the classroom, activity levels varied. A number of opportunities to reduce sedentary behaviour by making changes to the classroom environment were identified [39].

Involving stakeholders in the development and adaptation of interventions is a crucial step in ensuring a programme is acceptable and practical for those who will be responsible for delivering it [59]. It was therefore deemed necessary to involve pre-school staff in the development and adaptation of ToyBox-Scotland, and a seventh pre-school was recruited to assist with intervention adaptation following the principles of co-production[60], before the cluster RCT was undertaken in the other six preschools. An experienced early years practitioner from this pre-school assisted by reviewing all of the classroom guides from the original ToyBox intervention, trialling out each activity with the children, and matching the ToyBox-Scotland programme with the Scottish pre-school education curriculum. A number of meetings were held with the early years practitioner during this period, and together with the research team, a number of changes to the classroom guides and materials were agreed upon. One of the main changes was to ensure the included activities were child-led, rather than practitioner-led, which is in keeping with the curriculum of pre-school education in Scotland. Child-led learning in the context of the Scottish curriculum ensures that children are given the freedom to interact with learning tasks and materials with minimal adult direction[37]. Therefore, activities which did not allow for this were either removed or adapted. Out of 26 physical activity sessions from the original ToyBox-study, eleven were selected as they offered the most opportunities for child-led learning while still engaging with the physical activity elements. These were also the activities that the children found easiest to engage with, reflecting the younger age of Scottish pre-school children compared to children from other European countries[61]. The selected activities were also included as they were the most likely to encourage MVPA as opposed to lower intensity PA throughout the session. The sedentary behaviour activities (consisting of "movement breaks", "movement corners" and classroom activities) were also trialled out. A number of the more cognitively/physically complex movement breaks and classroom activities were removed following recommendations from early years practitioners as the activities tended to break down or children would lose focus during delivery. The objective of the movement breaks is to interrupt prolonged periods of sitting, but these are shorter than the physical activity sessions. Finally, extensive revisions to the classroom guides and materials were undertaken to ensure the language used is relevant to the Scottish context. The structure of the adapted ToyBox-Scotland intervention is summarised in Table 2.

Table 2. Adapted ToyBox-Scotland intervention structure. WC= water consumption; PA= physical activity; ES= eating and snacking; SB= sedentary behaviour.

<table>
<tr><th></th><th colspan="8">First focus</th><th colspan="8">Repetition</th></tr>
<tr><td></td><td colspan="2">3 weeks</td><td colspan="2">3 weeks</td><td colspan="2">3 weeks</td><td colspan="2">3 weeks</td><td colspan="2">2 weeks</td><td colspan="2">2 weeks</td><td colspan="2">1 weeks</td><td colspan="2">1 weeks</td></tr>
<tr><td>Pre-school</td><td colspan="2">Physical activity</td><td colspan="2">Sedentary behaviour</td><td colspan="2">Physical activity</td><td colspan="2">Sedentary behaviour</td><td colspan="2">Physical activity</td><td colspan="2">Sedentary behaviour</td><td colspan="2">Physical activity</td><td colspan="2">Sedentary behaviour</td></tr>
<tr><td>Home</td><td>WC</td><td>PA</td><td>ES</td><td>SB</td><td>WC</td><td>PA</td><td>ES</td><td>SB</td><td>WC</td><td>PA</td><td>ES</td><td>SB</td><td>WC</td><td>PA</td><td>ES</td><td>SB</td></tr>
</table>

Although the original ToyBox intervention included a home component, subsequent evaluations of the programme concluded that more active parental involvement was needed [44, 45]. ToyBox-Scotland will adopt the original home materials, but will also provide parent-child homework tasks (appendices I-O), designed to increase physical activity, reduce sedentary behaviour, and encourage healthy snacking and water consumption over junk food and sugar-sweetened beverage consumption. A Scottish-themed sticker chart (appendix P) was developed along with animal stickers, which parents award to the children for completion of the homework activities. The use of sticker incentives is cost-effective and has been used in successful interventions to change health behaviours with this age group [62-64]. While the original ToyBox study utilised passive parental education techniques such as tip cards and newsletters, ToyBox –Scotland will use interactive games and activities which require active involvement from parents and children, a recommendation of the original study. The ToyBox-Scotland intervention will run for a total of 18 weeks from March to June 2018. Control pre-schools will continue to follow the standard curriculum during this period. Figure 1 outlines the differences between the original and adapted intervention and intervention development processes.

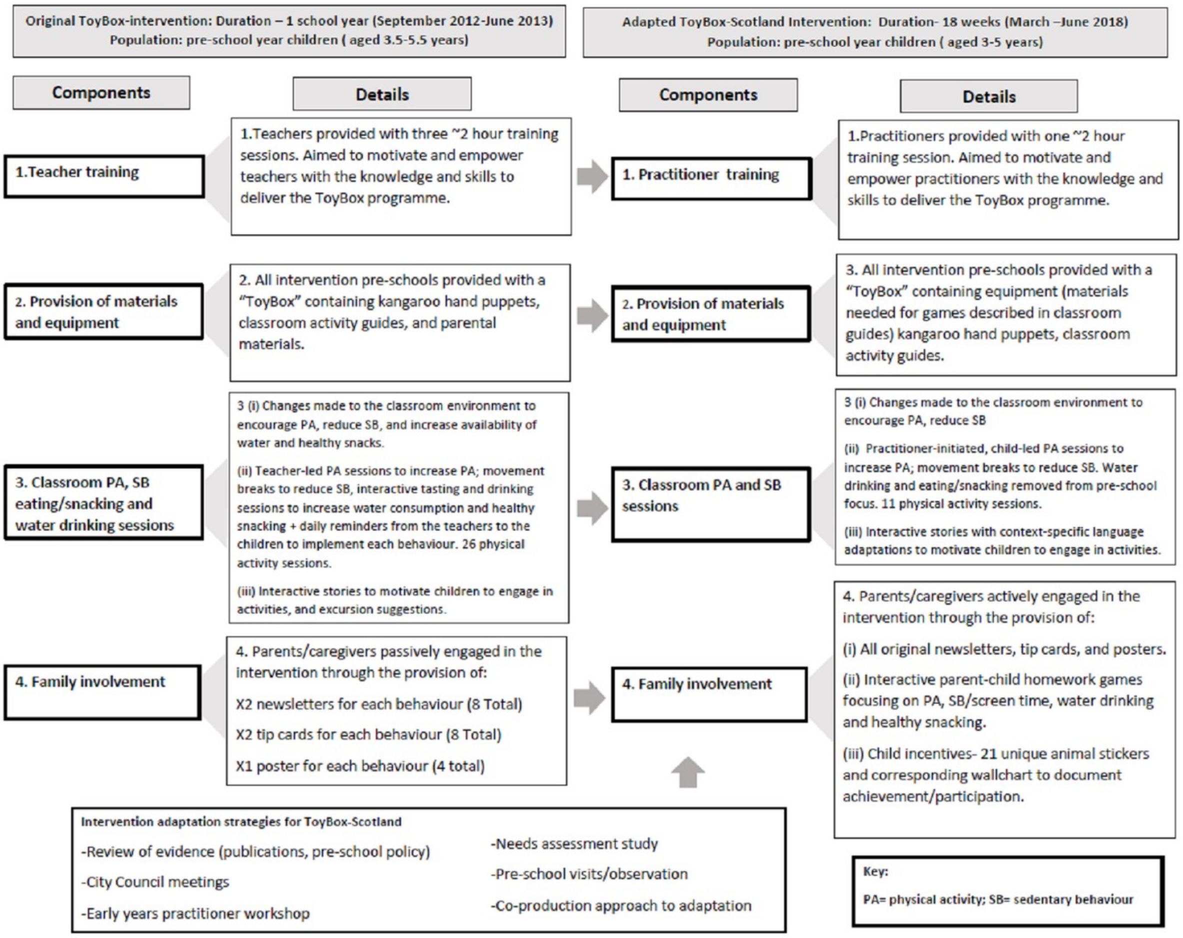


Figure 1. Differences between the original and adapted ToyBox interventions

4.6. Practitioner training

Early years practitioners in the intervention group will receive a 2 hour 30 minute training session prior to intervention commencement, delivered by the lead researcher and the early years practitioner involved in co-producing ToyBox-Scotland. The session will cover guidelines for designing a movement-friendly classroom environment, delivery of the physical activity /sedentary behaviour components, use of the practitioner logbook, and a briefing on the content and timing of the parental component of the intervention. During the first three weeks of intervention delivery, the lead researcher and co-producing early years practitioner will visit the pre-schools to assist with any issues, and observe delivery of the programme to ensure it is being delivered as intended.

Parents will be provided with an introductory pack at the start of the intervention detailing what ToyBox-Scotland is and how it relates to them. They will be given instructions on how to use the wallchart and stickers to incentivise their child's behaviour, and short instructions for each homework game will be provided to parents via the early years practitioners.

4.7.Outcomes

Data collection will take place at baseline and 14-17 weeks later. The main outcome of the study is to determine the feasibility and acceptability of the ToyBox-Scotland intervention within Scottish pre-schools, which will involve the assessment of the following:

1. Recruitment rates (pre-school and individual-level)

2. Intervention fidelity (measured by assessing the practitioner's logbook of the number of sessions conducted per week, and structure followed in relation to classroom guides. Observation of delivery will also be undertaken, as will qualitative interviews with practitioners and parents upon completion of the intervention).

3. Pre-School and Participant attrition rates

4. Acceptability of the methods used for measuring the intervention effect (assessment of whether children wear the ActivPAL for the desired time-period, and through questionnaire response rates).

Additional variables will be measured to assess the direction of intervention effect, and to calculate standard deviations and intracluster correlation coefficients to inform sample size calculations for a full scale cluster RCT. Other outcomes, measured at baseline and follow-up, are as follows:

1. *Pre-school and home physical activity* - Children will be fitted with the activPAL accelerometer (PAL technologies, Glasgow UK for seven consecutive days, including one weekend. Mean minutes spent in physical activity will be recorded, both moderate-to-vigorous physical activity and total physical activity.
2. *Pre-school and home sedentary time* -Total time spent sitting/lying and interruption of time spent sitting/lying will be assessed using the activPAL. Previous studies have demonstrated the activPAL's suitability for measuring sedentary time and physical activity with this age group [65, 66] in addition to its high performance at measuring stepping when compared to other accelerometers [67].
3. *Total night-time sleep* - activPALs will be used to assess night-time sleep, with sleep time defined as the time-point (to the second) where no movement from the sitting/lying axis plane of movement is detected by the device for a minimum of 120 minutes. The devices have been successfully used to

accurately estimate total sleep time and interruption of sleep in previous research [68].

4. *Body mass index*- Children's height and weight will be measured by a trained researcher (SM) using a stadiometer (Marsden, UK) and electronic scales (Tanita, Amsterdam, Netherlands) respectively. Measurements will be taken to the nearest 0.1cm for height and 01.kg for weight, with shoes removed. Height and weight measures will be taken twice and the average will be calculated. zBMI will be calculated from the height and weight measures, with obesity and overweight defined as 95th and 85th percentiles respectively, in accordance with the UK 1990 growth reference data [69].
5. *Body composition* - Fat mass and fat-free mass will be estimated via supine arm-to-leg bioelectrical impedance analysis using the Bodystat 1500. Measures will be taken by a trained researcher (SM) in the presence of a practitioner. Detailed descriptions of the methodological procedures and validation of this measure in children are available elsewhere [70]. Measures will be taken twice and averaged.
6. *Home eating/snacking, water consumption and screen-time*- Questionnaires will be completed by parents/caregivers of participating children and will include questions relating to eating/snacking behaviour (such as fruit/vegetable consumption, refined sugar consumption), daily water intake, daily physical activity and time spent using screen devices. During baseline data collection, these questionnaires will also contain relevant questions relating to demographics. The questionnaires were developed for use in the original ToyBox-study and have been adapted for ToyBox-Scotland.

Specifically, both questionnaires were shortened and the language altered following recommendations from early years practitioners (for example “kindergarten” was changed to “nursery”). No previously un-validated items were added. Details regarding the original questionnaire development, test-retest reliability and validity are published elsewhere [71].

4.8.Process evaluation

A process evaluation will be conducted to assess intervention fidelity and acceptability as follows:

Intervention fidelity- pre-school component: A researcher will observe the delivery of two sessions of physical activity and sedentary behaviour at each pre-school. The researcher will assess if the delivered sessions match the instructions provided in the classroom guides. Specifically, details on the duration of the sessions, proportion of children who participate, intensity of physical activity sessions, and practitioner instruction/engagement will be recorded. Practitioners will complete logbooks which will detail which specific sessions/activities were delivered each week, and note any issues.

Intervention acceptability- pre-school component: Semi-structured interviews will be conducted at the preschools with a sample of early years’ practitioners who deliver the intervention. Interviews will primarily focus on the barriers and facilitators to delivery and identify any areas for improvement in the event that a full-scale trial is implemented. Practitioners will also be asked to complete a pre and post-intervention questionnaire, which along with interview and logbook data will be used for data triangulation.

Intervention fidelity- home component: Practitioners will document the proportion of eligible children who are given home material packs and who take them home from the pre-school. End of intervention feedback questionnaires will be provided to parents in the final homework packs. The questionnaires will seek to determine the level of engagement with each block of materials, parental perceptions of the homework tasks/materials, and perceived changes to behaviour or enhanced knowledge as a result of the homework tasks/intervention materials.

Intervention acceptability- home component: In addition to the end of study questionnaire, a sample of parents will also participate in a semi-structured interview to gain an in-depth understanding of their views and experiences of engaging with the intervention materials. Interview topics will mainly focus on parent/child perceptions, barriers/facilitators to participation and ways in which the content or delivery of the materials can be improved upon. Interviews will be conducted either at the pre-school or by telephone. This information will be used to inform further adaptations of the home component of the intervention. A timeline of participants' involvement in the study is detailed in figure 2.

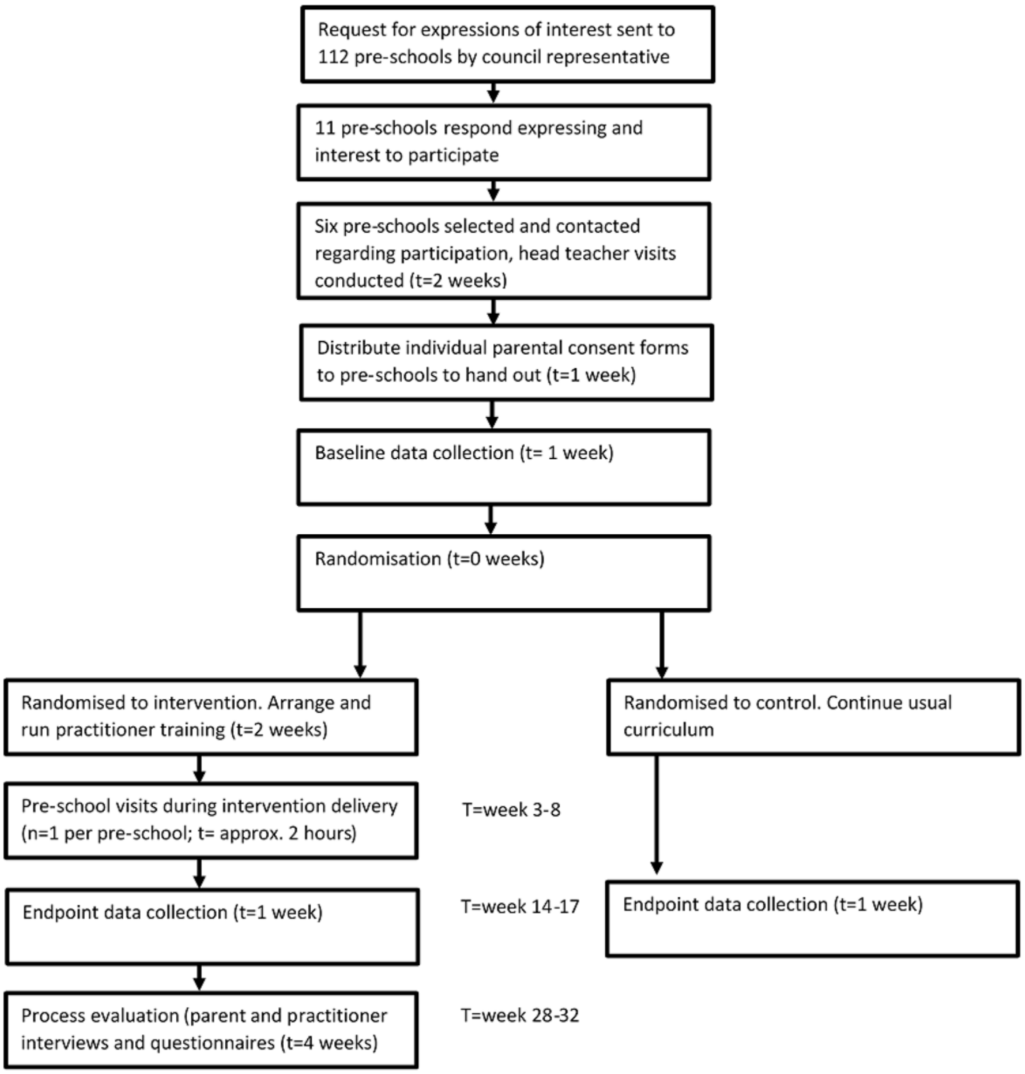


Figure 2. Participant timeline for the ToyBox-Scotland feasibility study.

4.9. Ethics and dissemination

This study was granted ethical approval by the University of Strathclyde's School of Psychological Sciences and Health Ethics Committee. Any amendments to the study protocol will be submitted for ethical approval prior to implementation. Informed consent will be obtained from all participants via parental consent forms. Verbal assent will be sought from children prior to their enrolment in the study. Findings of the study will be disseminated via publications in peer-reviewed journals, conference presentations and lay summary reports/presentations which will be given to parents/caregivers and preschool staff who participate in the study.

4.10. Sample size

As this is a feasibility study, one of the main objectives is to collect appropriate data to inform a power calculation for a future full-scale cluster RCT. Therefore, no sample size calculation was undertaken for this study, and the inclusion of six pre-schools is unlikely to be sufficient for any definitive conclusions to be drawn regarding the intervention's effect on health and behaviour outcomes. Rather, the sample will be sufficient to measure important feasibility parameters in a sample of pre-schools that are representative of the Glasgow City pre-school environment. Furthermore, feasibility testing is recommended as one of the key elements of the intervention development and evaluation process outlined by the UK Medical Research Council [47].

4.11. Randomisation

Randomisation will occur following completion of baseline data collection, and will be conducted by a blinded independent researcher. Simple randomisation will be undertaken at the pre-school level, with three pre-schools randomised to intervention (ToyBox-Scotland) arm and three to the control (usual curriculum) arm. As all recruited pre-schools are of a similar socioeconomic status and size, no pairing will be undertaken prior to randomisation.

5. Data management

Data will be stored on the University of Strathclyde's centralised secure data storage system. Only the immediate research team will have access to raw data. Parental questionnaires will be kept by head-teachers after completion and returned to the researcher. Consent forms will be stored separately from participant data, and a unique identifier code will be assigned to each participant. Data will be stored for a maximum of 5 years before being securely destroyed. Data from interviews will be deleted immediately from voice recorders after the transcription, with pseudonyms used in all reports in place of participant's names. Data will be available in anonymised format from the University of Strathclyde institutional repository. All data collection and storage procedures will be GDPR compliant.

6. Analysis

A descriptive analysis will summarise the findings in relation to the feasibility and acceptability parameters of interest such as the proportion of children measured at baseline and follow-up to calculate recruitment and attrition rates. Data collected will be used to calculate the standard deviation of the outcome measures and the sample sizes needed to detect a significant difference in a full-scale trial. Summary statistics will be applied to the outcome measures, with results presented as means (± standard deviation), and where appropriate odds ratios (95% confidence interval). Level of significance will be set at 0.05. Subgroup analysis will be performed to determine differences in recruitment and retention rates by socioeconomic status and direction of intervention effects by socioeconomic status, sex and weight status. However, due to the small sample size anticipated, these analyses will be exploratory in nature, and will be used to inform a future trial rather than to draw definitive conclusions regarding the effectiveness of the intervention. Participants who drop out will also be compared to those who complete the study, to determine if any significant differences exist. Data analysis will be conducted using IBM SPSS statistical analysis software.

Interview data will be transcribed verbatim prior to thematic analysis. Data will be coded by two researchers independently, and themes will be formed from the identified codes that summarise the participant's responses. Data will be entered into NVivo 10 qualitative data analysis software to assist with coding and development of themes.

7. Discussion

This paper provides a description of the protocol for the ToyBox-Scotland pre-school obesity prevention intervention trial. The original ToyBox-study successfully improved key energy balance-related behaviours amongst European pre-school children [44], and has now been adapted for use in the Scottish pre-school setting. By using a co-production approach to adapt the programme, it is hoped that the intervention will be more culturally relevant and user-friendly for the practitioners who will be responsible for its delivery. Considerable adaptation has also been applied to the home component of the intervention in an effort to increase parental engagement. Adapting successful interventions for use in other settings is becoming an increasingly common practice in child health research [72]. However, for success to translate from one setting to the other, adequate context-specific adaptations must be made to ensure the intervention can function as intended and still meets its desired aims [73]. The study outlined in this protocol aims to test whether the ToyBox-Scotland obesity prevention intervention is feasible and acceptable in the Scottish pre-school and home setting, and to determine whether progression to a full scale cluster RCT is recommended.

7.1.Trial governance

The principal investigators (AH and JJR) are responsible for overseeing the study. The study manager (SM) is responsible for liaising with study participants, co-ordinating data collection, and data management/storage. AH, AMG and FB will advise on specific aspects of the study including recruitment, practitioner training, data analysis and process evaluation procedures. Any changes to the study protocol will be discussed before the trial registry is updated.

7.2.Safety procedures

All pre-school staff are first aid-trained, and pre-schools have their own health and safety policies, which ToyBox-Scotland does not breach. In the event of an accident occurring as a direct consequence of participation in the study, (no high-risk activities were identified by risk assessment during ethics application), pre-school staff will report this to the research team and appropriate measures will be taken according existing policies.

8. References

1 Abarca-Gómez L, Abdeen ZA, Hamid ZA, Abu-Rmeileh NM, Acosta-Cazares B, Acuin C*, et al.* Worldwide trends in body-mass index, underweight, overweight, and obesity from 1975 to 2016: a pooled analysis of 2416 population-based measurement studies in 128· 9 million children, adolescents, and adults. *The Lancet*. 2017; 390: 2627-42.

2 Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. *Jama*. 2014; 311: 806-14.

3 Ahrens W, Pigeot I, Pohlabeln H, De Henauw S, Lissner L, Molnár D*, et al.* Prevalence of overweight and obesity in European children below the age of 10. *International Journal of Obesity*. 2014; 38: S99-S107.

4 Wijnhoven T, Raaij J, Spinelli A, Rito AI, Hovengen R, Kunesova M*, et al.* WHO European Childhood Obesity Surveillance Initiative 2008: weight, height and body mass index in 6–9-year-old children. *Pediatric obesity*. 2013; 8: 79-97.

5 Ng M, Fleming T, Robinson M, Thomson B, Graetz N, Margono C*, et al.* Global, regional, and national prevalence of overweight and obesity in children and adults during 1980–2013: a systematic analysis for the Global Burden of Disease Study 2013. *The lancet*. 2014; 384: 766-81.

6 Scottish Government. Health of Scotland's Population- Obesity. The Scotttish Government: Edinburgh 2017.

7 National Health Service Scotland. Body Mass Index of Primary 1 Children in Scotland School Year 2016/17 2017.

8 McGlashan J, Johnstone M, Creighton D, de la Haye K, Allender S. Quantifying a Systems Map: Network Analysis of a Childhood Obesity Causal Loop Diagram. *PloS one*. 2016; 11: e0165459.

9 Orr MG, Kaplan GA, Galea S. Neighbourhood food, physical activity, and educational environments and black/white disparities in obesity: a complex systems simulation analysis. *J Epidemiol Community Health*. 2016: jech-2015-205621.

10 Saldanha-Gomes C, Heude B, Charles M, de Lauzon-Guillain B, Botton J, Carles S*, et al.* Prospective associations between energy balance-related behaviors at 2 years of age and subsequent adiposity: the EDEN mother–child cohort. *International Journal of Obesity*. 2017; 41: 38.

11 Janssen I, LeBlanc AG. Systematic review of the health benefits of physical activity and fitness in school-aged children and youth. *International journal of behavioral nutrition and physical activity*. 2010; 7: 40.

12 Jiménez-Pavón D, Kelly J, Reilly JJ. Associations between objectively measured habitual physical activity and adiposity in children and adolescents: Systematic review. *Pediatric Obesity*. 2010; 5: 3-18.

13 Te Morenga L, Mallard S, Mann J. Dietary sugars and body weight: systematic review and meta-analyses of randomised controlled trials and cohort studies. *Bmj*. 2013; 346: e7492.

14 Basterfield L, Pearce MS, Adamson AJ, Frary JK, Parkinson KN, Wright CM*, et al.* Physical activity, sedentary behavior, and adiposity in English children. *American journal of preventive medicine*. 2012; 42: 445-51.

15 Cardon G, De Bourdeaudhuij I, Iotova V, Latomme J, Socha P, Koletzko B*, et al.* Health Related Behaviours in Normal Weight and Overweight Preschoolers of a Large Pan-European Sample: The ToyBox-Study. *PloS one*. 2016; 11: e0150580.

16 Ekelund U, Luan Ja, Sherar LB, Esliger DW, Griew P, Cooper A*, et al.* Moderate to vigorous physical activity and sedentary time and cardiometabolic risk factors in children and adolescents. *Jama*. 2012; 307: 704-12.
17 Frantsve-Hawley J, Bader JD, Welsh JA, Wright JT. A systematic review of the association between consumption of sugar-containing beverages and excess weight gain among children under age 12. *Journal of Public Health Dentistry*. 2017.
18 Hooper L, Abdelhamid A, Moore HJ, Douthwaite W, Skeaff CM, Summerbell CD. Effect of reducing total fat intake on body weight: systematic review and meta-analysis of randomised controlled trials and cohort studies. *Bmj*. 2012; 345: e7666.
19 Tremblay MS, LeBlanc AG, Kho ME, Saunders TJ, Larouche R, Colley RC*, et al.* Systematic review of sedentary behaviour and health indicators in school-aged children and youth. *International Journal of Behavioral Nutrition and Physical Activity*. 2011; 8: 98.
20 Wang Y, Wu Y, Wilson RF, Bleich S, Cheskin L, Weston C*, et al.* Childhood obesity prevention programs: comparative effectiveness review and meta-analysis. 2013.
21 Jones RA, Hinkley T, Okely AD, Salmon J. Tracking physical activity and sedentary behavior in childhood: a systematic review. *American journal of preventive medicine*. 2013; 44: 651-58.
22 Skinner JD, Carruth BR, Bounds W, Ziegler PJ. Children's food preferences: a longitudinal analysis. *Journal of the American Dietetic Association*. 2002; 102: 1638-47.
23 Moore LL, Gao D, Bradlee ML, Cupples LA, Sundarajan-Ramamurti A, Proctor MH*, et al.* Does early physical activity predict body fat change throughout childhood? *Preventive medicine*. 2003; 37: 10-17.
24 Nader PR, Huang TT-K, Gahagan S, Kumanyika S, Hammond RA, Christoffel KK. Next steps in obesity prevention: altering early life systems to support healthy parents, infants, and toddlers. *Childhood Obesity (Formerly Obesity and Weight Management)*. 2012; 8: 195-204.
25 Waters E, de Silva-Sanigorski A, Hall BJ, Brown T, Campbell KJ, Gao Y*, et al.* Interventions for preventing obesity in children. *The Cochrane database of systematic reviews*. 2011: Cd001871.
26 Annesi JJ, Smith AE, Tennant GA. Reducing high BMI in African American preschoolers: effects of a behavior-based physical activity intervention on caloric expenditure. *Southern medical journal*. 2013; 106: 456-59.
27 de Silva-Sanigorski AM, Bell AC, Kremer P, Nichols M, Crellin M, Smith M*, et al.* Reducing obesity in early childhood: results from Romp & Chomp, an Australian community-wide intervention program. *The American journal of clinical nutrition*. 2010; 91: 831-40.
28 Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, Dyer A. Two-year follow-up results for Hip-Hop to Health Jr.: A randomized controlled trial for overweight prevention in preschool minority children. *The Journal of Pediatrics*. 2005; 146: 618-25.
29 Niederer I, Bürgi F, Ebenegger V, Marques-Vidal P, Schindler C, Nydegger A*, et al.* Effects of a lifestyle intervention on adiposity and fitness in overweight or low fit preschoolers (Ballabeina). *Obesity*. 2013; 21.

30 Yin Z, Parra-Medina D, Cordova A, He M, Trummer V, Sosa E*, et al.* Miranos! Look at us, we are healthy! An environmental approach to early childhood obesity prevention. *Childhood Obesity (Formerly Obesity and Weight Management)*. 2012; 8: 429-39.
31 Eliakim A, Nemet D, Balakirski Y, Epstein Y. The effects of nutritional-physical activity school-based intervention on fatness and fitness in preschool children. *Journal of Pediatric Endocrinology and Metabolism*. 2007; 20: 711-18.
32 Alkon A, Crowley AA, Neelon SEB, Hill S, Pan Y, Nguyen V*, et al.* Nutrition and physical activity randomized control trial in child care centers improves knowledge, policies, and children's body mass index. *BMC Public Health*. 2014; 14: 215.
33 Birken CS, Maguire J, Mekky M, Manlhiot C, Beck CE, DeGroot J*, et al.* Office-based randomized controlled trial to reduce screen time in preschool children. *Pediatrics*. 2012; 130: 1110-15.
34 Dennison BA, Russo TJ, Burdick PA, Jenkins PL. An intervention to reduce television viewing by preschool children. *Archives of pediatrics & adolescent medicine*. 2004; 158: 170-76.
35 Mo-suwan L, Pongprapai S, Junjana C, Puetpaiboon A. Effects of a controlled trial of a school-based exercise program on the obesity indexes of preschool children. *The American journal of clinical nutrition*. 1998; 68: 1006-11.
36 Winter SM, Sass DA. Healthy & ready to learn: examining the efficacy of an early approach to obesity prevention and school readiness. *Journal of Research in Childhood Education*. 2011; 25: 304-25.
37 Scottish Government. Early learning and childcare. Scottish Government: Edinburgh 2017.
38 Manios Y. The 'ToyBox-study'obesity prevention programme in early childhood: an introduction. *obesity reviews*. 2012; 13: 1.
39 Manios Y. Methodological procedures followed in a kindergarten-based, family-involved intervention implemented in six European countries to prevent obesity in early childhood: the ToyBox-study. *Obesity Reviews*. 2014; 15: 1-4.
40 Payr A, Birnbaum J, Wildgruber A, Kreichauf S, Androutsos O, Lateva M*, et al.* Concepts and strategies on how to train and motivate teachers to implement a kindergarten-based, family-involved intervention to prevent obesity in early childhood. The ToyBox-study. *obesity reviews*. 2014; 15: 40-47.
41 Duvinage K, Ibrügger S, Kreichauf S, Wildgruber A, De Craemer M, De Decker E*, et al.* Developing the intervention material to increase physical activity levels of European preschool children: the ToyBox-study. *obesity reviews*. 2014; 15: 27-39.
42 Nixon C, Moore H, Douthwaite W, Gibson E, Vogele C, Kreichauf S*, et al.* Identifying effective behavioural models and behaviour change strategies underpinning preschool-and school-based obesity prevention interventions aimed at 4–6-year-olds: a systematic review. *Obesity Reviews*. 2012; 13: 106-17.
43 Androutsos O, Katsarou C, Payr A, Birnbaum J, Geyer C, Wildgruber A*, et al.* Designing and implementing teachers' training sessions in a kindergarten-based, family-involved intervention to prevent obesity in early childhood. The ToyBox-study. *obesity reviews*. 2014; 15: 48-52.
44 Latomme J, Cardon G, De Bourdeaudhuij I, Iotova V, Koletzko B, Socha P*, et al.* Effect and process evaluation of a kindergarten-based, family-involved

intervention with a randomized cluster design on sedentary behaviour in 4-to 6-year old European preschool children: The ToyBox-study. *PloS one*. 2017; 12: e0172730.
45 De Craemer M, De Decker E, Verloigne M, De Bourdeaudhuij I, Manios Y, Cardon G. The effect of a cluster randomised control trial on objectively measured sedentary time and parental reports of time spent in sedentary activities in Belgian preschoolers: the ToyBox-study. *International Journal of Behavioral Nutrition and Physical Activity*. 2016; 13: 1.
46 Sutherland RL, Nathan NK, Lubans DR, Cohen K, Davies LJ, Desmet C*, et al.* An RCT to Facilitate Implementation of School Practices Known to Increase Physical Activity. *American journal of preventive medicine*. 2017; 53: 818-28.
47 Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *Bmj*. 2008; 337: a1655.
48 Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K*, et al.* SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Annals of internal medicine*. 2013; 158: 200-07.
49 Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA*, et al.* SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *Bmj*. 2013; 346: e7586.
50 Understanding Glasgow: The Glasgow Indicators Project. Scottish Cities. Glasgow Centre for Population Health: Glasgow 2015.
51 Education Scotland. Early learning and childcare (ELC). Education Scotland: Glasgow 2016.
52 Green LW, Kreuter MW. Health program planning: An educational and ecological approach: McGraw-Hill New York 2005.
53 Kok G, Schaalma H, Ruiter RA, Van Empelen P, Brug J. Intervention mapping: protocol for applying health psychology theory to prevention programmes. *Journal of health psychology*. 2004; 9: 85-98.
54 ToyBox-Study. ToyBox – a European multi-country study to develop an obesity prevention programme specifically for pre-school children. Harokopio University Athens 2012.
55 Scottish Government. A Healthier Future –Scotland's Diet & Healthy Weight Delivery Plan. Edinburgh 2018.
56 scottish Government. A More Active Scotland: Scotland's Physical Activity Delivery Plan. Edinburgh 2018.
57 WHO. Report of the commission on ending childhood obesity. WHO Geneva: 2016.
58 Tremblay MS, Chaput J-P, Adamo KB, Aubert S, Barnes JD, Choquette L*, et al.* Canadian 24-hour movement guidelines for the early years (0–4 years): an integration of physical activity, sedentary behaviour, and sleep. *BMC Public Health*. 2017; 17: 874.
59 Wight D, Wimbush E, Jepson R, Doi L. Six steps in quality intervention development (6SQuID). *J Epidemiol Community Health*. 2015: jech-2015-205952.
60 Hawkins J, Madden K, Fletcher A, Midgley L, Grant A, Cox G*, et al.* Development of a framework for the co-production and prototyping of public health interventions. *BMC public health*. 2017; 17: 689.

61 European Commission/EACEA/Eurydice. Early Childhood Education and Care Systems in Europe. National Information Sheets. Luxembourg: Publications Office of the European Union 2015.
62 Horne PJ, Tapper K, Lowe C, Hardman C, Jackson M, Woolner J. Increasing children's fruit and vegetable consumption: a peer-modelling and rewards-based intervention. *European journal of clinical nutrition*. 2004; 58: 1649-60.
63 Corsini N, Slater A, Harrison A, Cooke L, Cox DN. Rewards can be used effectively with repeated exposure to increase liking of vegetables in 4–6-year-old children. *Public health nutrition*. 2013; 16: 942-51.
64 Wardle J, Cooke LJ, Gibson EL, Sapochnik M, Sheiham A, Lawson M. Increasing children's acceptance of vegetables; a randomized trial of parent-led exposure. *Appetite*. 2003; 40: 155-62.
65 Davies G, Reilly J, McGowan A, Dall P, Granat M, Paton J. Validity, practical utility, and reliability of the activPAL in preschool children. *Medicine and science in sports and exercise*. 2012; 44: 761-68.
66 Martin A, McNeill M, Penpraze V, Dall P, Granat M, Paton JY*, et al.* Objective measurement of habitual sedentary behavior in pre-school children: comparison of activPAL With Actigraph monitors. *Pediatric exercise science*. 2011; 23: 468-76.
67 Harrington DM, Welk GJ, Donnelly AE. Validation of MET estimates and step measurement using the ActivPAL physical activity logger. *Journal of sports sciences*. 2011; 29: 627-33.
68 Alghaeed Z, Reilly JJ, Chastin SF, Martin A, Davies G, Paton JY. The influence of minimum sitting period of the activPAL™ on the measurement of breaks in sitting in young children. *PLoS One*. 2013; 8: e71854.
69 Cole TJ, Freeman JV, Preece MA. Body mass index reference curves for the UK, 1990. *Archives of disease in childhood*. 1995; 73: 25-29.
70 De Beer M, Timmers T, Weijs PJ, Gemke RJ. Validation of total body water analysis by bioelectrical impedance analysis with deuterium dilution in (pre) school children. *e-SPEN, the European e-Journal of Clinical Nutrition and Metabolism*. 2011; 6: e223-e26.
71 Mouratidou T, Miguel M, Androutsos O, Manios Y, De Bourdeaudhuij I, Cardon G*, et al.* Tools, harmonization and standardization procedures of the impact and outcome evaluation indices obtained during a kindergarten-based, family-involved intervention to prevent obesity in early childhood: the ToyBox-study. *obesity reviews*. 2014; 15: 53-60.
72 Kipping R, Jago R, Metcalfe C, White J, Papadaki A, Campbell R*, et al.* NAP SACC UK: protocol for a feasibility cluster randomised controlled trial in nurseries and at home to increase physical activity and healthy eating in children aged 2–4 years. *BMJ open*. 2016; 6: e010622.
73 Castro FG, Barrera M, Martinez CR. The cultural adaptation of prevention interventions: Resolving tensions between fidelity and fit. *Prevention Science*. 2004; 5: 41-45.

Chapter 8: A feasibility cluster randomised controlled trial of a preschool obesity prevention intervention: ToyBox-Scotland.

This peer –reviewed manuscript was published in BMC Pilot and Feasibility Studies in November 2019 and is included in this thesis exactly in its published from

1. Preface

This manuscript details the results of a feasibility cluster randomised controlled trial of the ToyBox-Scotland intervention. The paper primarily deals with evaluation-related elements of feasibility such as recruitment/retention rates, feasibility of outcome measurements, and intervention fidelity. SM conducted data collection and data analysis under the supervision of JJR AH and AMG. XJ assisted with analysis of accelerometer data. FB offered guidance on methods. The original ToyBox collaborators from Belgium, Greece and Durham contributed to preparation of the manuscript. We thank all parents, children and preschool staff who participated in the study.

2. Abstract

Background: High levels of childhood obesity have been observed globally over the last three decades. Preschools are promising settings to implement obesity prevention interventions in the early years. The aim of this study was to test the feasibility of a cluster randomised controlled trial of the ToyBox-Scotland preschool obesity prevention intervention.

Methods: Six preschools in predominantly deprived areas of Glasgow, UK, were randomised to either the ToyBox intervention (n=3), or usual curriculum control group (n=3). The intervention ran for 18 weeks from March-June 2018, and consisted of practitioner-led physical activity and sedentary behaviour sessions in preschools, with an additional interactive home component. Primary outcome measures were intervention fidelity, recruitment rates, attrition rates, and compliance with trial procedures. Secondary outcomes were body mass index (BMI) z-score, bioelectrical impedance analysis (BIA), objectively-measured physical activity and sedentary time via activPAL accelerometer, and parent-reported home eating, snacking and water consumption.

Results: The preschool component of the intervention was implemented with high fidelity (64%), while the home component was implemented with low fidelity (41%). A cluster level recruitment rate of 10% was achieved, and the individual-level recruitment rate was 18% (42/233 children, mean age 4.4 years; 17 girls). The attrition rate was 14%, and compliance rates varied considerably by outcome. Compliance was highest for BMI (86%), while 19% of the sample returned valid accelerometer data for both baseline and follow-up and the parental questionnaire response rate was 23%. Both intervention and control groups showed small increases in BMI z-scores at follow-up of 0.02 and 0.06, respectively. Both groups had small decreases in physical activity and increases in sedentary time at follow-up.

Conclusions: Before progression to an effectiveness trial, additional procedures should be considered to improve recruitment rates, compliance with outcome measures and implementation of the home-based component of the ToyBox-Scotland intervention.

Trial registration: ISRCTN12831555 https://doi.org/10.1186/ISRCTN12831555

Keywords: Childhood obesity, feasibility, physical activity, sedentary behaviour, prevention

3. Background

High levels of childhood obesity are evident globally [1], with obesity in the early years being linked to elevated total and low-density lipoprotein (LDL) cholesterol in children as young as three years [2]. While the causes of childhood obesity are multifactorial, research has demonstrated causal links between excess weight and energy balance-related behaviours such as physical activity (PA), sedentary behaviour (SB), and diets high in fat and refined sugars [3, 4].

Preschools offer a potentially effective setting to address obesity prevention, and a number of interventions have targeted such settings with varying levels of success [5-7]. Specifically, multicomponent interventions which target PA, SB and diet both in the preschool and home environment tend to show the most promise with regards to improving energy-balance related behaviours and preventing obesity in young children [8, 9].

One such intervention is called ToyBox, which employs teacher-led sessions to target energy-balance related behaviours at preschool, while behaviours in the home environment are targeted using informative materials for parents [10]. The intervention, when tested in 6 countries across Europe, led to significant improvements in water consumption [11], PA, SB [6] and family-related determinants of unhealthy snacking [12]. The intervention has subsequently been adapted for use in other European countries, Malaysia [13], and most recently in Scotland [14], where context-specific adaptations were made to the intervention content and delivery to suit the social and cultural needs of Scottish preschools. However, prior to testing an intervention in an effectiveness trial, the UK Medical Research Council recommends that a feasibility study should be conducted first as it is considered an integral aspect of intervention development and evaluation [15]. Therefore, the aim of this study was to test the feasibility of a cluster randomised controlled trial (RCT) of the ToyBox-Scotland preschool obesity prevention programme, to inform the design of a future full scale RCT.

4. Methods

4.1. Study design

This study was designed in accordance with the CONSORT statement's extension to randomised pilot and feasibility trials [16]. This study had a cluster RCT design consisting of an intervention group (three preschools) and a control group (three preschools). As this was a feasibility study, no sample size calculation was undertaken. As all participating preschools were similar in size and demographics, no matching was undertaken prior to randomisation. An independent researcher was presented with six identical envelopes by a member of the research team not involved in data collection or analysis. Each envelope contained the name of the participating preschools. They were then instructed to select three envelopes at random to be control preschools. The remaining envelopes were assigned to the intervention group. Data were collected between January and June 2018. This study was approved by the University of Strathclyde's School of Psychological Sciences and Health Ethics Committee.

4.2. Setting, sampling and participants

Glasgow is the largest urban area in Scotland, and is one of the most socioeconomically deprived areas in Western Europe, with over a third of the cities' children estimated to be living in poverty [17]. A Glasgow City Council representative contacted a convenience sample of all local authority preschools in the Glasgow City area via email to seek expressions of interest to participate (n=112). Eleven preschools expressed an interest to participate in the study, of which six were selected based on similarities in demographics, size and socio-economic status (SES). Head teachers at participating preschools were visited by the study manager and provided with information sheets and consent forms, which they distributed to parents/caregivers of all 3-5 year old children at their preschools. Children were excluded from the study if they had a health condition that would significantly limit their ability to participate in the intervention, or if parental consent was not provided. The intervention was delivered to all 3-5 year old children in the intervention preschools. All six preschools received £200 after the completion of the study to offset any participation costs.

4.3. Intervention

Prior to commencement of the present study, the original ToyBox intervention [10] was adapted to suit the Scottish preschool setting. The process of adaptation is described in detail elsewhere [14]. Briefly, alterations to the number of PA and SB sessions were made to reflect the focus on child-led learning in Scottish preschool practice and classroom manuals were re-written to reflect the language used in the Scottish education system. Additional adaptations included the removal of the preschool-based eating/snacking and water consumption components and the addition of more interactive parent/child activities to address energy-balance behaviours (i.e. eating/snacking, water consumption, PA and SB) in the home environment. All adaptations were undertaken using a co-creation approach [18], whereby relevant stakeholders and an experienced early years' practitioner assisted the research team with the adaptation process.

Preschools receiving the ToyBox-Scotland intervention were provided with a ~2.5 hour practitioner training session prior to the intervention. Preschools received a box with additional classroom materials such as kangaroo hand puppets and classroom activity guides. Classroom activity guides offered detailed instructions on the delivery of PA and SB sessions, and the setup of the classroom environment to encourage PA and active play and to reduce SB. Practitioners were given autonomy to deliver the intervention throughout the day when time allowed, but were encouraged to deliver activities for a total of one hour per week, and gradually increase this as the intervention progressed. Parents received a sticker wallchart and bi-weekly activity packs containing tip cards, newsletters, interactive games and sticker incentives to award to their child after they completed each of the home-based activities. The intervention was delivered for 18 weeks, where PA and SB were targeted in both preschool and home environment, and eating and water consumption was targeted in the home environment, as detailed in Table 1.

Table 1. Intervention structure for ToyBox-Scotland

	First focus								**Repetition**							
	3 weeks		3weeks		3 weeks		3 weeks		2 weeks		2 weeks		1 week		1 week	
Preschool	PA		SB		PA		SB		PA		SB		PA		SB	
Home	WC	PA	ES	SB	WC	PA	ES	SB	WC	PA	ES	SB	WC	PA	ES	SB

ES=eating & snacking, PA= physical activity, SB= sedentary behaviour, WC= water consumption

4.4. Procedures and outcomes

Participants were measured at two time-points by one researcher (SM) and a fieldwork assistant, who were both trained in the measures. Baseline assessment was undertaken in late January/early February 2018, with follow-up measurement taking place 15-17 weeks later. An early years' practitioner at each preschool was present for all data collection procedures to prepare and accompany children through data collection and assist with any issues. Although parental consent was collected for all participating children, child assent was obtained from each child on the measurement day, and children who did not want to participate in any of the data collection procedures were not obliged to do so. The primary outcome measure for this study was the feasibility of the intervention and trial. Therefore, the primary outcomes of interest were recruitment rates, attrition rates, implementation fidelity and compliance rates with data collection procedures. A number of secondary outcomes were also assessed, detailed below.

4.5. Implementation fidelity

Implementation fidelity refers to the extent to which an intervention is implemented as intended by those who developed it [19]. Fidelity was assessed in both the preschool and home environments using the following methods:

Preschool component: In order to assess implementation fidelity at preschools, practitioners were supplied with a monthly logbook for the duration of the programme, which was adapted from the original ToyBox study logbook [20]. For each month that the intervention was delivered (n=4), practitioners completed five-point Likert scales, which assessed the extent to which the components of the intervention were delivered. Namely, changes to the classroom environment, children performing health behaviours, and classroom experiences.

Home component: Practitioners recorded how many eligible children were supplied with home activity packs each month, while parents/caregivers received a post-intervention questionnaire (supplementary file 1). This questionnaire comprised yes/no questions and 5-point Likert scales, with questions designed to identify to what extent the parents/caregivers received and engaged with the intervention materials at home.

4.6.Secondary outcome measures

Body mass index (BMI): Height and weight were measured by the same researcher with children wearing light clothing and with shoes removed. Height was measured using a stadiometer (Marsden, UK) to the nearest 0.1cm, and weight was measured using an electronic scale (Tanita, Amsterdam, Netherlands) to the nearest 0.1kg. Measurements were conducted in a private meeting room, with children measured in small groups of 3-4 at a time. Only the researcher was able to see the readings. Both height and weight measurements were taken twice and the average calculated. BMI z-scores were calculated from the height and weight data using standardised methods [21]. Children aged ≥4 years were categorised using UK90 growth reference charts [22], while the WHO growth reference was used to calculate z-scores for 3 year olds [23]. Children <85th percentile were classified as normal weight, ≥85th percentile as overweight and ≥95th percentile as obese.

Objectively measured PA: PA was measured objectively using the activPAL accelerometer (model ActivPAL3; PAL Technologies Ltd., Glasgow, UK). The activPAL is a small wearable device that is attached to the front of the mid-thigh, and measures postural information, which can be categorised into sitting/lying, standing and moving/stepping activity [24]. Once attached, the device can be worn continuously for 7-10 days. Participants were fitted with the activPAL by the assisting early-years practitioners under the instruction of the researchers. Parents were instructed to leave the activPAL on for seven consecutive days, with three days wear time [25] considered valid for this study.

Body composition: Supine arm-to-leg bioelectrical impedance analysis (BIA) was used to measure fat mass and fat-free mass with the Bodystat 1500 (Bodystat Ltd, Douglas, Isle of Man). Measures were taken twice and the average was calculated. A full description of the procedures and formulae to use with this age group is available elsewhere [26].

Objectively measured SB: The activPAL was used to assess sedentary time during waking hours using the same procedure as PA described above [27]. Periods of night time sleep were differentiated from waking sedentary time by studying the raw data files to determine when no significant changes in axis of movement (from sitting/lying to standing) were detected from one 24-hour period to the next, as such observations indicate the participant is asleep during these times.

Home eating, snacking, water consumption and screen time: The Primary Caregiver Questionnaire (PCQ) and the Food Frequency Questionnaire (FFQ) used in the original ToyBox study were adapted for use in the present study. Specifically, the number of questions in each were reduced as recommended by stakeholders during development meetings (questions related to maternal/post-natal nutrition were removed from the FFQ and family history questions removed from the PCQ). The questionnaires required parents to provide information on their children's fruit/vegetables, confectionary, water and sugar-sweetened beverage consumption in addition to the use of screen devices and sleep patterns. Questionnaires were supplied to preschools by the research team in paper format, and were then distributed to participating parents when they collected their children by preschool staff. Full details regarding the development, validity and test-retest reliability of the questionnaires are reported elsewhere [28-30].

4.7. Analysis

In order to assess fidelity of implementation in this study, scoring systems used by Verloigne et al [31] and Pinket et al [32] were adapted and used to assign codes to participant's logbook and questionnaire responses that indicated the level of implementation. For dichotomous items, a positive response (yes) was coded as 1, while a negative response (no) received a 0. For Likert-scale items, a response of either 4 (agree/often) or 5 (strongly agree/always) was coded as 1, while all other responses (1-3; strongly disagree/never; disagree/not often; neither agree nor disagree/sometimes) were coded as 0. Total implementation fidelity scores of 72 and 11 were available for practitioners and parents, respectively. Accelerometer data were entered into PAL analysis software and mean daily time spent in PA, step count, sedentary time, and sleep were computed for all devices which met the 3 day valid wear-time cut-off. To calculate and categorise participant's weight status from the height and weight measurements, data was entered into the LMS Growth add-in for Microsoft Excel to generate z-scores and percentile scores. As this is a feasibility study, the use of inferential statistics and effectiveness testing is not recommended due to the small sample size and the preliminary nature of the outcomes measured [33]. Instead, descriptive statistics were used to assess feasibility parameters such as fidelity of implementation, recruitment, retention and attrition rates from baseline to follow-up, presented as proportions. High, medium and low fidelity was classified as an overall implementation score of ≥60%, ≥50 <60% and <50% respectively, following recommendations from similar studies [19]. For the secondary outcomes, means ± standard deviations are presented, with the mean change from baseline to follow-up for each outcome calculated along with 95% confidence intervals where appropriate. Process evaluation data (e.g. teacher logbooks and parental feedback surveys) were analysed prior to outcome data, as recommended by current guidelines on process evaluation [34].

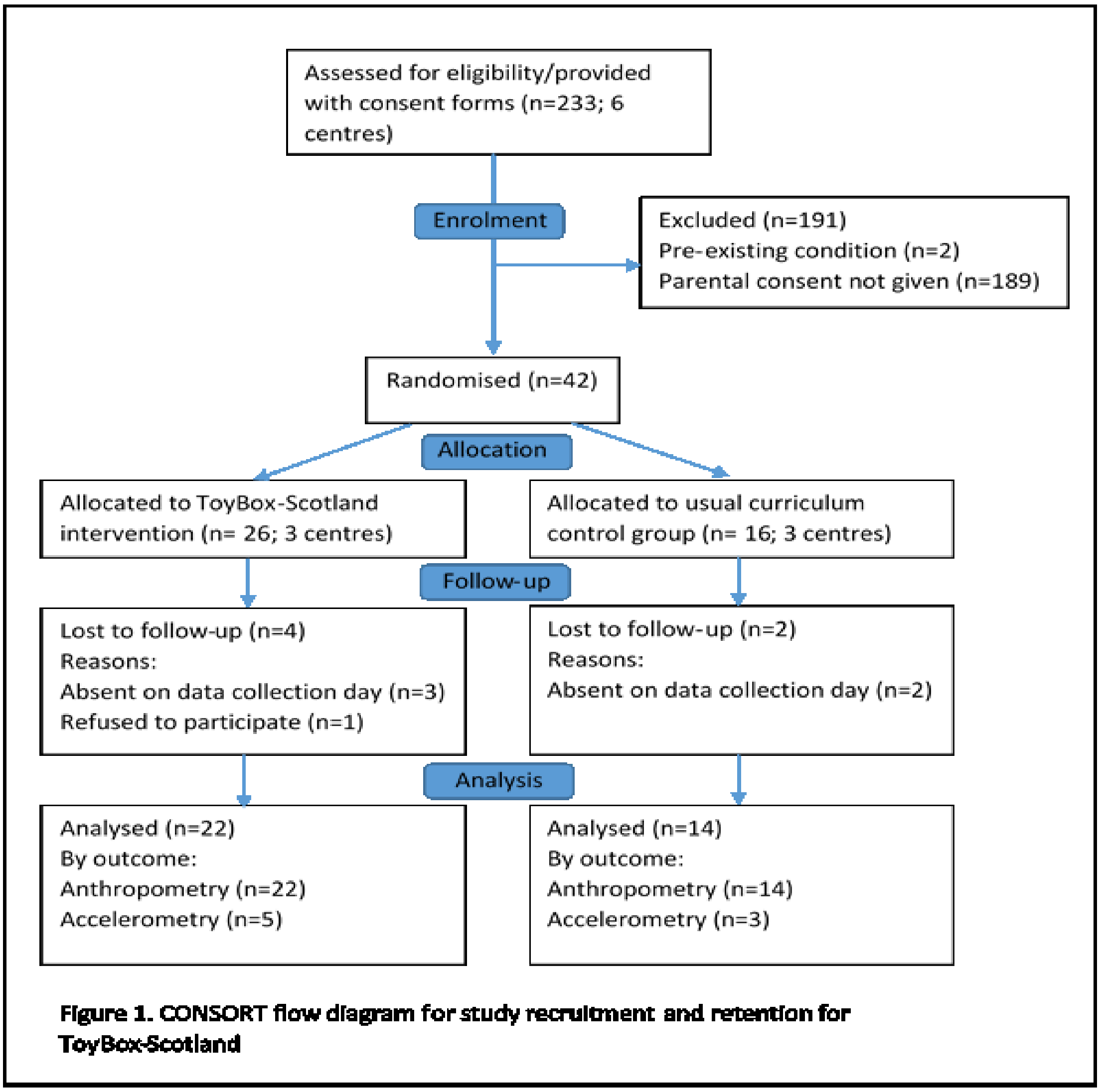


Figure 1. Consort flow diagram for the ToyBox-Scotland study

5. Results

5.1. Feasibility of Trial Recruitment and Retention

Eleven out of 112 preschools responded positively to an invitation to take part in the study (Cluster-level response rate = 10%). A total of 233 consent forms were distributed, of which 42 children (mean age 4.4±0.46 years; 17 girls) provided parental consent and completed baseline assessment (individual-level recruitment rate = 18%) before preschools were randomised to the ToyBox-Scotland intervention arm (3 centres; n=26; 10 girls) or the usual curriculum control arm (3 centres; n= 16; 7 girls). See Figure 1 for CONSORT flow diagram.

5.2. Intervention fidelity

All intervention preschools returned complete logbooks for the 4 month study period. Overall, the intervention was implemented with high fidelity across the three intervention preschools (64%), with one preschool implementing with medium fidelity (52%), and two with high fidelity (79% and 61%). Intervention components relating to PA were generally implemented with higher fidelity than SB components (table 2). Twenty-six parents returned post intervention feedback surveys, of which seven were incomplete and excluded (19/125; 15% response rate). The overall implementation score for the home component of the intervention was low (41%) based on post intervention survey responses. Specific preschool implementation scores from practitioners' logbook data are detailed in table 2.

Table 2. Implementation fidelity score logbook items and responses.

		Scoring and results (% coded as 1 over the 4 months)			
Component	**Logbook question**	**PS A**	**PS B**	**PS C**	**Overall (fidelity score)**
Preschool environment	Were the number of chairs in the classroom reduced to encourage standing play?*	0%	0%	0%	0% (LOW)
	Was equipment and space appropriately arranged for physical activity sessions every day of the week?*	100%	50%	100%	83% (HIGH)
	Was the classroom appropriately arranged for movement breaks every day of the week?*	100%	75%	0%	58% (MED)
	Were any movement corners set up and made available to the children?*	75%	0%	0%	25% (LOW)
Children performing the health behaviours	Did you regularly remind children to drink water?*	100%	100%	100%	100% (HIGH)
	Did you remind children to drink water after they have been active?*	100%	100%	100%	100% (HIGH)
	Did you remind children to bring healthy snacks from home (or remind the catering service/canteen to provide healthy snacks to children?)*	100%	100%	100%	100% (HIGH)
	How much time did you devote to physical activity sessions on an average weekly basis this month? +	100%	75%	100%	92% (HIGH)
Classroom experiences	Did you implement the classroom experiences for physical activity as described in the manual?*	100%	50%	100%	83% (HIGH)
	Did you devote on average at least one hour per week to the classroom activities for physical activity as described in the manual?*	100%	50%	100%	92% (HIGH)
	Did you devote on average at least one hour per week to the classroom activities for sedentary behaviour as described in the manual?*	50%	0%	0%	17% (LOW)
	Which classroom activity(ies) regarding physical activity did you implement this month? +	100%	50%	50%	67% (HIGH)
	How many of the little kangaroo stories for physical activity did you use this month? +	19%	0%	25%	11% (LOW)
	How many of the little kangaroo stories for sedentary behaviour did you use this month? +	8%	0%	0%	3% (LOW)
	Which classroom activity(ies) regarding sedentary behaviour did you implement this month? +	100%	25%	0%	42% (LOW)
Delivery of home materials and engagement with parents	Did you provide parents with the pre-prepared home activity packs when these were delivered to the nursery?*	100%	75%	100%	92% (HIGH)
	Estimate the number of parents to whom you directly delivered programme materials. If you did + (total 125 children)	100%	85%	100%	95% (HIGH)
	Estimate the number of parents for whom you spent time to explain the purpose of the material and encourage them to follow the	11%	7%	15%	12% (LOW)

	recommendations of the material + (total 125 children)				
	Total aggregate scores (% responses coded as 1. Total available points = 72	79%	52%	61%	OVERALL SCORE= 64%

This form was repeated four times, once for each month the intervention was delivered. * indicates scoring determined by 5 point scale, "1= Never, 2= not often, 3= sometimes, 4= often, 5= always" ≥4 = 1; ≤3 = 0. + indicates scoring determined by a "yes/no" response, or a numerical response. Yes= 1; no= 0. Numerical responses equate to ≥60% = 1; <60% = 0. PS= preschool.

5.3.Participation in outcome measures

Anthropometry: Eighty-six percent (36/42) of participants provided valid height and weight measurements at baseline and follow-up. Five children were absent on the follow-up data collection day, and one did not want to participate.

Body composition: Six children out of 42 (14%) adequately complied with the BIA protocol at baseline. However, the readings from these were not valid as children did not adhere to the protocol and the use of BIA was not carried forward to follow-up.

Accelerometery: Fifty-two percent of the participants provided valid accelerometer data at baseline (n=22). Reasons for invalid measurement were as follows: device malfunction (n= 8); removed before valid wear-time due to skin irritation (n=7); device loss (n= 5). Only participants who supplied valid data at baseline were fitted with an accelerometer at follow-up. Nineteen percent of the original sample returned valid accelerometer data at follow-up. Reasons for loss of data at follow-up were: removed before valid wear time cut-off (no specific reason provided; n= 5); device lost (n= 4); child absent on data collection day (n=5).

Parental questionnaires (demographics/family history, dietary habits, screen time): Early years practitioners distributed the PCQ and FFQ to the parents/caregivers of all participating children at baseline (n=42). Twenty-three percent of parents returned completed questionnaires for both baseline and follow-up (n=10).

5.4.Behavioural and health outcomes

For the 22 participants that provided valid accelerometer data at baseline, mean daily minutes spent in PA was 163 (30) and 151 (40) for the intervention and control groups respectively (mean daily steps of 11437 (2351) for the intervention group, and 10827 (2895) for the control group). The intervention group spent an average of 420 (72) minutes/day sedentary, and the control group spent 396 (72) minutes sedentary. Table 3 summarises the results for participants that completed measurement at baseline and follow-up. Small increases in BMI-z score were observed for both groups, however the increase was larger in the control group. Both groups showed reductions in mean daily minutes spent in PA and daily steps from baseline to follow-up, with the larger decreases observed in the intervention group. Sedentary time per day increased by almost 30 minutes and 10 minutes in the intervention and control groups, respectively.

Table 3. Behavioural and health outcomes at baseline and follow-up

	Intervention			Control		
Pre and post-results	**Baseline**	**Follow-up**		**Baseline**	**Follow-up**	
Measurement	**Mean (SD)**	**Mean (SD)**	**Mean Change (95% CI)**	**Mean (SD)**	**Mean (SD)**	**Mean Change (95% CI)**
BMI z-score	0.41 (1.16)	0.43 (1.09)	0.02 (-0.11, 0.15)	0.35 (1.17)	0.41(1.07)	0.06 (-0.04, 1.05)
Total daily PA (min)	165 (58)	151 (27)	-14 (-87, 115)	144 (41)	143 (42.1)	-1 (-117, 121)
Total daily ST (min)	428 (62)	456 (100)	28 (-174, 120)	407 (81)	417 (52)	10 (-216, 192)
Total daily steps (count)	12035 (4084)	10718 (2020)	-1316 (-5818, 8451)	10221 (3004)	10017 (3240)	-204 (-8235, 8644)

6. Discussion

This study investigated the feasibility of a cluster randomised controlled trial of the adapted ToyBox-Scotland childhood obesity prevention intervention. Participating preschools were willing to be randomised, and trial procedures and pre-school based intervention components were deemed feasible by preschool staff. The intervention was implemented with high fidelity within the preschool. However, implementation of the home component was lower, a finding that is commonly reported in other school-based interventions with home components [32 35]. The cluster level recruitment rate of 10% in this study is lower than that achieved in similar feasibility studies targeting young children [36-38], as was the observed individual-level recruitment rate of 18% [36, 37, 39, 40]. Conversely, the overall trial retention rate of 86% (14% attrition rate) is similar to-or higher than other trials [6, 36]. However, within those participants that were retained from baseline to follow-up, the collection of valid measures varied considerably by outcome.

At 41%, the level of implementation observed in the home environment was low. Additionally, the low post intervention survey response rate of 15% indicates that implementation was even lower, as it is unlikely that non-respondents engaged highly with the intervention. These findings are unsurprising, considering the home environment has previously been identified as one of the more challenging settings to implement obesity prevention interventions in [41], particularly in low SES groups. While overall preschool intervention fidelity was high, it was apparent from logbook responses that PA components of the intervention were implemented at a higher level than SB components (table 2). This finding was also observed in the original ToyBox study, where SB implementation scores were relatively low across multiple intervention sites within the six participating regions [35]. Considering these findings, we adapted the programme accordingly, reducing the number of more time-consuming activities in the intervention [14]. Despite this, the relatively poor implementation scores observed for SB activities highlights that further adaptation may be needed for the SB component, and for the home-based components as a whole.

In the Belgian ToyBox study cohort, recruitment involved a personal visit by a member of research staff to all eligible preschools (n=97), which resulted in a cluster-level recruitment rate of 28% [6]. Additionally, the study achieved an individual-level recruitment rate of 39%, utilising the same procedures of staff-administered information sheets and consent forms to parents as our study. However, it is important to consider the differences in demographics recruited between the two studies. The Belgian study recruited participants from 27 preschools, for which 55% were classed as either medium or high SES. In our study, all but one of the 6 recruited preschools were within the 20% most deprived areas in Scotland. An abundance of research has demonstrated that more deprived population groups are more difficult to recruit into trials, and are also more likely to drop out than participants in higher SES groups [42-44]. Therefore, the lack of medium-high SES preschools recruited to this present trial may have negatively impacted on the recruitment rates achieved. Considering these observations, in any future trial, it may be of benefit to conduct personal visits to eligible preschools to improve the school recruitment rates, and also target preschools in areas of high, medium and low SES, using different strategies to recruit participants from deprived populations to account for the lower recruitment rates observed within these areas.

Eighty six percent of the original sample completed height and weight measures in this study, which is comparable to anthropometric measurement rates of similar studies [7, 39, 45, 46], indicating that these procedures are feasible with this population group. However, we encountered significant issues with the collection of valid BIA data at baseline, and measurement of this outcome was not carried forward to follow-up. Obtaining accurate BIA readings requires participants to follow a strict protocol consisting of a period of fasting and restricted PA prior to and during collection of the readings, which was not possible with this sample. Furthermore, there are conflicting arguments in the literature regarding the validity of such methods with children [47]. Our intended use of BIA was to further validate BMI z-scores with another measure, as BMI is a crude proxy measure for adiposity [48, 49]. Therefore, in any future trial it may be beneficial to use other anthropometric measures alongside BMI such as waist circumference, skinfold thickness or hip-waist ratio which have proved feasible in other trials [6, 45], and show high agreement with BMI estimates.

With regards to accelerometry, a number of factors prevented the collection of valid wear-time data at both baseline and follow-up. Studies that use objective measures of free-living PA and SB in children offer conflicting findings with regards to compliance with measurement procedures. A recent review of attrition rates and non-compliance with accelerometers in childhood PA trials, found that non-compliance at follow-up ranged from 3-70% across 23 studies [50]. Conversely, Jones et al. (2011) used Actigraph accelerometers worn for two consecutive days in a pilot RCT of a fundamental movement skills and PA intervention in preschool children, reporting high adherence rates of 96% and 97% for baseline and 6 month follow-up, respectively [51], indicating that reduced wear-time may increase compliance. However, a similar study used the Actigraph for seven days in pre-schoolers and achieved an 86% adherence rate, indicating additional factors likely influence accelerometer compliance [52].

While some unavoidable reasons for loss of data such as device malfunction/loss and child absence in our study reflect issues commonly encountered in accelerometer studies mentioned previously, a number of reasons for the early removal of the device are specific to the activPAL accelerometer that we used. Specifically, a small number of parents reported that their child developed a rash due to wearing the waterproof medical adhesive which attached the device to the leg. While this was likely a harmless sweat rash, a recent study also found that adolescents who were asked to record their reasons for removing the activPAL in a compliance study cited skin irritation as the primary reason for early removal [53], a finding which is supported by another study on pre-schoolers [24]. These issues could be addressed by reducing required wear time, and improving communication with parents so that they are aware of how to reattach the device, or how to distinguish a sweat rash from an allergic reaction. Alternatively, the activPAL showed to be comparable with other wearable devices that are perhaps less invasive and more participant-friendly in their attachment methods [24, 27] which may be valid alternatives in further trials. Regardless of the device used, creating better links with parents from recruitment through to follow-up will likely facilitate the collection of a higher proportion of valid accelerometer data, and should be a priority in any future trial. A number of trials have reported favourable results from the use of reminder texts/phone calls to parents or the provision of small monetary incentives for the safe return of accelerometers [39].

Parental response rates to the FFQ and PCQ questionnaires were also considerably lower than rates observed in the original ToyBox study and in other trials [54]. Although efforts to reduce the length of these questionnaires were taken prior to the trial commencing, additional adaptation may be needed to increase the response rates. Due to the need to calculate portion sizes and recall dietary patterns, the FFQ can be time-consuming to complete [55, 56], and parents may not know what their child has eaten while at preschool. This, coupled with the relatively low levels of adult literacy observed in the areas which we sampled [57], may have negatively impacted our questionnaire response rates. Therefore, other more time-efficient alternatives to the FFQ and PCQ should be explored [56].

This study had a number of limitations. Firstly, due to the low preschool-level response rate, it was only possible to sample preschools located in areas of lower SES, which limits the generalisability of our findings to the wider Scottish preschool population. However, this issue is somewhat unavoidable when conducting research within Glasgow, which has a significantly higher concentration of deprived localities than the rest of Scotland's local authority areas [58]. This issue could be addressed in future through the use of stratified sampling, which would allow for the assessment of differences in intervention effectiveness between SES groups. Despite this, due to the marked social patterning observed in obesity risk, there is a need to target interventions at low SES groups [59], therefore the lessons learned from this study will be of value during the design of future trial procedures.

Secondly, while the aim of this study was to test feasibility, and not to test effectiveness, the low response rates to questionnaires and non-compliance with accelerometer measures makes it difficult to determine any direction of intervention effect, which would have indicated whether the intensity of the intervention was likely to be sufficient. Despite these limitations, the data gathered during this trial is sufficient to assess the feasibility of the study design and the fidelity of the intervention, which will assist with the development of effectiveness and efficacy trials. Another important aspect of feasibility testing not addressed in this present paper is acceptability of the intervention and trial procedures. Items pertaining to acceptability were included in both teacher and parent post-intervention questionnaires, and qualitative interviews and focus groups were conducted with both parents and practitioners, respectively. A separate paper will present these data and explore acceptability by identifying important barriers and facilitators to implementation.

7. Conclusions

The findings of this study indicate that although aspects of this cluster RCT of the ToyBox Scotland intervention were feasible, more efforts to increase recruitment rates, accelerometer compliance and questionnaire response rates should be further investigated before progression to any future trial. Specifically, more development activities should be undertaken with preschools, parents and children to ensure that both the intervention components, and the methods of evaluation are appropriate and acceptable before progressing to further effectiveness testing.

Testing feasibility before progressing to a fully powered trial is an effective way to identify issues with sampling/recruitment, implementation fidelity, trial design and methods of outcome measurement. This study, coupled with the results of an ongoing investigation of the barriers and facilitators to implementation of the intervention, will further highlight priorities for further adaptation prior to any future trial of the ToyBox Scotland intervention.

8. Declarations

8.1.Ethics approval and consent to participate

This study was granted approval by the University of Strathclyde's School of Psychological Sciences and Health ethics committee. All parents/caregivers of participating children provided written informed consent for their child to participate in the study.

9. References

1 Broyles S, Denstel K, Church T, Chaput J, Fogelholm M, Hu G*, et al.* The epidemiological transition and the global childhood obesity epidemic. *International journal of obesity supplements*. 2015; 5: S3.

2 Skinner AC, Perrin EM, Moss LA, Skelton JA. Cardiometabolic risks and severity of obesity in children and young adults. *New England Journal of Medicine*. 2015; 373: 1307-17.

3 Saldanha-Gomes C, Heude B, Charles M, de Lauzon-Guillain B, Botton J, Carles S*, et al.* Prospective associations between energy balance-related behaviors at 2 years of age and subsequent adiposity: the EDEN mother–child cohort. *International Journal of Obesity*. 2017; 41: 38.

4 Jackson SL, Cunningham SA. The stability of children's weight status over time, and the role of television, physical activity, and diet. *Preventive medicine*. 2017; 100: 229-34.

5 Jouret B, Ahluwalia N, Dupuy M, Cristini C, Negre-Pages L, Grandjean H*, et al.* Prevention of overweight in preschool children: results of kindergarten-based interventions. *International journal of obesity*. 2009; 33: 1075.

6 De Craemer M, De Decker E, Verloigne M, De Bourdeaudhuij I, Manios Y, Cardon G. The effect of a kindergarten-based, family-involved intervention on objectively measured physical activity in Belgian preschool boys and girls of high and low SES: the ToyBox-study. *International Journal of Behavioral Nutrition and Physical Activity*. 2014; 11: 38.

7 Reilly JJ, Kelly L, Montgomery C, Williamson A, Fisher A, McColl JH*, et al.* Physical activity to prevent obesity in young children: cluster randomised controlled trial. *Bmj*. 2006; 333: 1041.

8 Bluford DA, Sherry B, Scanlon KS. Interventions to prevent or treat obesity in preschool children: a review of evaluated programs. *Obesity*. 2007; 15: 1356-72.

9 Brown T, Moore THM, Hooper L, Gao Y, Zayegh A, Ijaz S*, et al.* Interventions for preventing obesity in children. *Cochrane Database of Systematic Reviews*. 2019.

10 Manios Y. The 'ToyBox-study'obesity prevention programme in early childhood: an introduction. *obesity reviews*. 2012; 13: 1.

11 Lambrinou CP, van Stralen MM, Androutsos O, Moreno LA, Iotova V, Socha P*, et al.* Mediators of the effectiveness of an intervention promoting water consumption in preschool children: the ToyBox study. *Journal of School Health*. 2018; 88: 877-85.

12 Lambrinou C-P, van Stralen MM, Androutsos O, Cardon G, De Craemer M, Iotova V*, et al.* Mediators of the effectiveness of a kindergarten-based, family-involved intervention on pre-schoolers' snacking behaviour: the ToyBox-study. *Public health nutrition*. 2019; 22: 157-63.

13 Reeves S, Poh B, Essau C, Summerbell C, Cheah W, Koh D*, et al.* ToyBox Study Malaysia: Improving healthy energy balance and obesity-related behaviours among pre-schoolers in Malaysia. *Nutrition bulletin*. 2018; 43: 290-95.

14 Malden S, Hughes AR, Gibson A-M, Bardid F, Androutsos O, De Craemer M*, et al.* Adapting the ToyBox obesity prevention intervention for use in Scottish preschools: protocol for a feasibility cluster randomised controlled trial. *BMJ open*. 2018; 8: e023707.

15 Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *Bmj*. 2008; 337: a1655.
16 Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L*, et al.* CONSORT 2010 statement: extension to randomised pilot and feasibility trials. 2016; 2: 64.
17 Child Poverty. *Understanding Glasgow: The Glasgow Indicators Project*. Glasgow Centre for Population Health: 2017.
18 Jackson CL, Greenhalgh T. Co-creation: a new approach to optimising research impact. *Med J Aust*. 2015; 203: 283-4.
19 Durlak JA, DuPre EP. Implementation matters: A review of research on the influence of implementation on program outcomes and the factors affecting implementation. *American journal of community psychology*. 2008; 41: 327-50.
20 Androutsos O, Apostolidou E, Iotova V, Socha P, Birnbaum J, Moreno L*, et al.* Process evaluation design and tools used in a kindergarten-based, family-involved intervention to prevent obesity in early childhood. The T oy B ox-study. *Obesity reviews*. 2014; 15: 74-80.
21 Cole TJ. The LMS method for constructing normalized growth standards. *European journal of clinical nutrition*. 1990; 44: 45-60.
22 Cole T. Growth monitoring with the British 1990 growth reference. *Archives of Disease in Childhood*. 1997; 76: 47-49.
23 Group WMGRS. WHO Child Growth Standards based on length/height, weight and age. *Acta paediatrica (Oslo, Norway: 1992) Supplement*. 2006; 450: 76.
24 De ED, De MC, Santos-Lozano A, Van EC, Cardon G. Validity of the ActivPAL™ and the ActiGraph monitors in preschoolers. *Medicine and science in sports and exercise*. 2013; 45: 2002-11.
25 Addy CL, Trilk JL, Dowda M, Byun W, Pate RR. Assessing preschool children's physical activity: how many days of accelerometry measurement. *Pediatric exercise science*. 2014; 26: 103-09.
26 De Beer M, Timmers T, Weijs PJ, Gemke RJ. Validation of total body water analysis by bioelectrical impedance analysis with deuterium dilution in (pre) school children. *e-SPEN, the European e-Journal of Clinical Nutrition and Metabolism*. 2011; 6: e223-e26.
27 Martin A, McNeill M, Penpraze V, Dall P, Granat M, Paton JY*, et al.* Objective measurement of habitual sedentary behavior in pre-school children: comparison of activPAL With Actigraph monitors. *Pediatric exercise science*. 2011; 23: 468-76.
28 Mouratidou T, Miguel M, Androutsos O, Manios Y, De Bourdeaudhuij I, Cardon G*, et al.* Tools, harmonization and standardization procedures of the impact and outcome evaluation indices obtained during a kindergarten-based, family-involved intervention to prevent obesity in early childhood: the ToyBox-study. *obesity reviews*. 2014; 15: 53-60.
29 Mouratidou T, Graffe MIM, Huybrechts I, De Decker E, De Craemer M, Androutsos O*, et al.* Reproducibility and relative validity of a semiquantitative food frequency questionnaire in European preschoolers: The ToyBox study. *Nutrition*. 2019; 65: 60-67.
30 González-Gil E, Mouratidou T, Cardon G, Androutsos O, De Bourdeaudhuij I, Góźdź M*, et al.* Reliability of primary caregivers reports on lifestyle behaviours of

E uropean pre-school children: the T oy B ox-study. *Obesity reviews*. 2014; 15: 61-66.
31 Verloigne M, Ahrens W, De Henauw S, Verbestel V, Mårild S, Pigeot I, *et al.* Process evaluation of the IDEFICS school intervention: putting the evaluation of the effect on children's objectively measured physical activity and sedentary time in context. *obesity reviews*. 2015; 16: 89-102.
32 Pinket A-S, Van Lippevelde W, De Bourdeaudhuij I, Deforche B, Cardon G, Androutsos O, *et al.* Effect and process evaluation of a cluster randomized control trial on water intake and beverage consumption in preschoolers from six European countries: the ToyBox-study. *PloS one*. 2016; 11: e0152928.
33 Abbott JH. The distinction between randomized clinical trials (RCTs) and preliminary feasibility and pilot studies: what they are and are not. JOSPT, Inc. JOSPT, 1033 North Fairfax Street, Suite 304, Alexandria, VA …: 2014.
34 Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, *et al.* Process evaluation of complex interventions: Medical Research Council guidance. *bmj*. 2015; 350: h1258.
35 Latomme J, Cardon G, De Bourdeaudhuij I, Iotova V, Koletzko B, Socha P, *et al.* Effect and process evaluation of a kindergarten-based, family-involved intervention with a randomized cluster design on sedentary behaviour in 4-to 6-year old European preschool children: The ToyBox-study. *PloS one*. 2017; 12: e0172730.
36 Barber SE, Jackson C, Hewitt C, Ainsworth HR, Buckley H, Akhtar S, *et al.* Assessing the feasibility of evaluating and delivering a physical activity intervention for pre-school children: a pilot randomised controlled trial. *Pilot and feasibility studies*. 2016; 2: 12.
37 Ginja S, Arnott B, Araujo-Soares V, Namdeo A, McColl E. Feasibility of an incentive scheme to promote active travel to school: a pilot cluster randomised trial. *Pilot and Feasibility Studies*. 2017; 3: 57.
38 Lloyd JJ, Wyatt KM, Creanor S. Behavioural and weight status outcomes from an exploratory trial of the Healthy Lifestyles Programme (HeLP): a novel school-based obesity prevention programme. *BMJ open*. 2012; 2: e000390.
39 Brown B, Harris KJ, Heil D, Tryon M, Cooksley A, Semmens E, *et al.* Feasibility and outcomes of an out-of-school and home-based obesity prevention pilot study for rural children on an American Indian reservation. *Pilot and feasibility studies*. 2018; 4: 129.
40 Kipping R, Langford R, White J, Metcalfe C, Papadaki A, Hollingworth W, *et al.* P25 Feasibility cluster randomised controlled trial and process evaluation of an environmental intervention in nurseries and a web-based home intervention to increase physical activity, oral health and healthy eating in children aged 2–4 years: nap sacc uk. BMJ Publishing Group Ltd: 2017.
41 Knowlden A, Sharma M. Systematic review of family and home-based interventions targeting paediatric overweight and obesity. *Obesity Reviews*. 2012; 13: 499-508.
42 Heinrichs N, Bertram H, Kuschel A, Hahlweg K. Parent recruitment and retention in a universal prevention program for child behavior and emotional problems: Barriers to research and program participation. *Prevention Science*. 2005; 6: 275-86.
43 Plueck J, Freund-Braier I, Hautmann C, Beckers G, Wieczorrek E, Doepfner M. Recruitment in an indicated prevention program for externalizing behavior-

parental participation decisions. *Child and adolescent psychiatry and mental health*. 2010; 4: 15.
44 McDonald L, FitzRoy S, Fuchs I, Fooken I, Klasen H. Strategies for high retention rates of low-income families in FAST (Families and Schools Together): An evidence-based parenting programme in the USA, UK, Holland and Germany. *European Journal of Developmental Psychology*. 2012; 9: 75-88.
45 Sacher PM, Kolotourou M, Chadwick PM, Cole TJ, Lawson MS, Lucas A*, et al.* Randomized controlled trial of the MEND program: a family-based community intervention for childhood obesity. *Obesity*. 2010; 18: S62-S68.
46 Hughes AR, Stewart L, Chapple J, McColl JH, Donaldson M, Kelnar C*, et al.* Randomized, controlled trial of a best-practice individualized behavioral program for treatment of childhood overweight: Scottish Childhood Overweight Treatment Trial (SCOTT). *Pediatrics*. 2008; 121: e539-e46.
47 Talma H, Chinapaw M, Bakker B, HiraSing R, Terwee C, Altenburg T. Bioelectrical impedance analysis to estimate body composition in children and adolescents: a systematic review and evidence appraisal of validity, responsiveness, reliability and measurement error. *Obesity reviews*. 2013; 14: 895-905.
48 Kakinami L, Henderson M, Chiolero A, Cole TJ, Paradis G. Identifying the best body mass index metric to assess adiposity change in children. *Archives of disease in childhood*. 2014; 99: 1020-24.
49 Reilly J, Dorosty A, Emmett P. Identification of the obese child: adequacy of the body mass index for clinical practice and epidemiology. *International journal of obesity*. 2000; 24: 1623.
50 Howie EK, Straker LM. Rates of attrition, non-compliance and missingness in randomized controlled trials of child physical activity interventions using accelerometers: A brief methodological review. *Journal of Science and Medicine in Sport*. 2016; 19: 830-36.
51 Jones RA, Riethmuller A, Hesketh K, Trezise J, Batterham M, Okely AD. Promoting fundamental movement skill development and physical activity in early childhood settings: a cluster randomized controlled trial. *Pediatric exercise science*. 2011; 23: 600-15.
52 Stark LJ, Spear S, Boles R, Kuhl E, Ratcliff M, Scharf C*, et al.* A pilot randomized controlled trial of a clinic and home-based behavioral intervention to decrease obesity in preschoolers. *Obesity*. 2011; 19: 134-41.
53 Shi Y, Huang WY, Yu JJ, Sheridan S, Sit CH-P, Wong SH-S. Compliance and Practical Utility of Continuous Wearing of activPAL™ in Adolescents. *Pediatric exercise science*. 2019: 1-7.
54 De Craemer M, Lateva M, Iotova V, De Decker E, Verloigne M, De Bourdeaudhuij I*, et al.* Differences in energy balance-related behaviours in European preschool children: the ToyBox-study. *PLoS One*. 2015; 10: e0118303.
55 Buzzard IM, Stanton CA, Figueiredo M, Fries EA, Nicholson R, Hogan CJ*, et al.* Development and reproducibility of a brief food frequency questionnaire for assessing the fat, fiber, and fruit and vegetable intakes of rural adolescents. *Journal of the American Dietetic Association*. 2001; 101: 1438-46.
56 Koleilat M, Whaley SE. Reliability and validity of food frequency questions to assess beverage and food group intakes among low-income 2-to 4-year-old children. *Journal of the Academy of Nutrition and Dietetics*. 2016; 116: 931-39.

57 Dani K, Stobo D, Capell H, Madhok R. Audit of literacy of medical patients in north Glasgow. *Scottish medical journal*. 2007; 52: 21-24.
58 Macintyre S, Macdonald L, Ellaway A. Do poorer people have poorer access to local resources and facilities? The distribution of local resources by area deprivation in Glasgow, Scotland. *Social science & medicine*. 2008; 67: 900-14.
59 Knai C, Lobstein T, Darmon N, Rutter H, McKee M. Socioeconomic patterning of childhood overweight status in Europe. *International journal of environmental research and public health*. 2012; 9: 1472-89.

Chapter 9: Assessing the acceptability of an adapted preschool obesity prevention programme: ToyBox-Scotland

This peer-reviewed manuscript was published in Child: care, health & development in December 2019 and is included in its published form.

1. Preface

This manuscript details a mixed-methods study to assess the acceptability of the ToyBox-Scotland intervention to preschool practitioners and parents who were delivering it. The study primarily investigated participant's experiences interacting with the intervention materials and seeked to identify barriers and facilitators to delivery and participation in ToyBox-Scotland. SM designed the Study under the supervision of JJR AH and AMG. SM conducted data collection and data analysis assisted by AMG. The original ToyBox collaborators contributed to preparation of the manuscript. We thank all parents and preschool staff who participated in the study.

2. Abstract

Background: Childhood obesity is a global public health issue. Interventions to prevent the onset of obesity in the early years are often implemented in preschool settings. The ToyBox intervention was originally delivered across Europe and targeted energy-balance related behaviours in preschools and children's homes through teacher-led activities and parental education materials, and has now been adapted for use in Scotland. This study assessed the acceptability of the 18-week adapted intervention to both parents and teachers.

Methods: Mixed methods were employed to collect both qualitative and quantitative data. Preschool staff and children's parents/caregivers completed post-intervention feedback surveys, from which acceptability scores were calculated and presented as proportions. Focus groups were conducted with preschool staff, while parents/caregivers participated in semi-structured interviews. A thematic analysis was applied to qualitative data following the development of a coding framework. Quantitative and qualitative data were analysed using SPSS and NVivo 10, respectively.

Results: Preschool staff rated the intervention as highly acceptable based on post-intervention feedback surveys (80%; mean score 8.8/11). Lower acceptability scores were observed for parents/caregivers (49%; 3.9/8). Nine practitioners participated in focus groups (n=3). User-friendliness of the intervention materials, integration of the intervention with the curriculum and flexibility of the intervention were identified as facilitators to delivery. Barriers to delivery were time, insufficient space and conflicting policies within preschools with regard to changing classroom layouts. Parental interviews (n=4) revealed a lack of time to be a major barrier which prevented parents from participating in home-based activities. Parents perceived the materials to be simple to understand and visually appealing.

Conclusions: This study identified a number of barriers and facilitators to the delivery and evaluation of the ToyBox-Scotland preschool obesity prevention programme, which should be considered before any further scale-up of the intervention.

2.1. Key Messages

- Preschools offer a promising environment for obesity prevention interventions to be implemented

- Preschool staff perceived the provision of concise materials to facilitate the delivery of classroom-based physical activity sessions

- Lack of time was identified as a major barrier to delivery of the home component of the intervention by parents

3. Introduction

Addressing the high levels of childhood obesity is a major priority in public health research and practice internationally [1]. Preventative efforts in the early years is of particular importance [2, 3]. However, interventions to prevent obesity in preschool-aged children have produced mixed results to date [4-7]. One such intervention, Toybox, has recently been tested in six countries in Europe [8], and involved classroom and home-based activities, which targeted physical activity (PA), sedentary behaviour (SB), eating/snacking, and water consumption. The results show that Toybox has a positive impact on some energy balance related behaviours and, importantly, does not lead to intervention-generated inequalities [9-12]. The authors of the present paper, some of whom were also involved with the original Toybox study, have adapted the intervention for Scotland [13], and have conducted a feasibility cluster Randomised Controlled Trial (cRCT) of Toybox-Scotland in Glasgow.

Traditionally, evaluations of complex interventions such as Toybox-Scotland have focussed on effectiveness outcomes (e.g., difference in change in weight-related outcomes between intervention and control group), with the assessment of feasibility and acceptability typically limited or lacking in such studies [5, 14, 15]. This is despite the fact that the importance of assessing feasibility and acceptability within a rigorous process of development and evaluation of a complex intervention is recommended by the UK's Medical Research Council (MRC) [16]. Additionally, although more recent studies have assessed components of feasibility and acceptability [17, 18], such studies rarely use multiple data collection methods to achieve data triangulation, instead opting to exclusively use questionnaires or interviews/focus groups [12, 19].

The aim of this study was to assess the acceptability of the Toybox-Scotland intervention, and a number of outcome measures, within a feasibility cRCT conducted in pre-school settings in Glasgow. Aspects of acceptability considered here include the experience of delivering the intervention (by preschool practitioners) and receiving and implementing the intervention (reported by parents), and specific experiences of outcome measurement during the cRCT. In contrast, the results relating to the feasibility of the intervention and the trial have been published elsewhere (Malden et al., 2019), and include measures of intervention fidelity, attrition rates, and compliance with outcomes measures.

4. Methods

A Mixed methods design was employed consisting of questionnaires and logbooks, in addition to focus groups and semi-structured interviews with practitioners and parents/caregivers. Ethics approval was granted by the University of Strathclyde's School of Psychological Sciences and Health Ethics Committee.

4.1. Setting and participants

This study was embedded within a feasibility cRCT, which was conducted in six preschools in Glasgow, UK from January-June 2018. Preschools were predominantly located within the 20% most deprived localities in Scotland. In brief, forty-two 3-5 year old children were recruited to the trial, which tested the ToyBox-Scotland intervention in three preschools compared with three control (usual curriculum) preschools. The intervention was delivered by preschool practitioners in sessions within the normal preschool day. The intervention targeted PA and SB through classroom activities, changes to the classroom environment to reduce SB, and home-based parent-child activities targeting PA, SB, eating/snacking and water consumption [13]. Practitioners received a 2-hour training session prior to implementation. Details on the content and delivery of the training sessions are reported elsewhere [13].

4.2. Recruitment

Practitioners within the three intervention preschools were invited to participate in focus groups through preschool head teachers, who provided their staff with information sheets and consent forms. A purposive sampling strategy was used to recruit parents from the intervention preschools via practitioners who provided information sheets and consent forms for parents.

4.3.Measures and data collection

Data collection was undertaken by one researcher (SM) who has extensive training and experience in conducting interviews with participants in public health intervention research.

Intervention acceptability-preschool component: Preschool practitioners took part in focus groups conducted within staff rooms at intervention preschools. Focus groups were facilitated by a topic guide with questions exploring barriers and facilitators to delivery of the intervention and conduct of the RCT, and aspects which could be improved for future implementation. Practitioners also completed post-intervention feedback forms containing a mixture of Likert scales and open-ended questions that investigated staff perceptions of the intervention, and areas for improvement.

Intervention acceptability-home component: One to one, semi-structured interviews were conducted with parents within a private room at the preschools. The interview topic guide explored parents' views and experiences of the home component of ToyBox-Scotland, and barriers and facilitators to participation. All interviews were audio recorded and transcribed verbatim. Parents/caregivers were given a £25 shopping voucher as an incentive for participation. All parents within intervention preschools were provided with a post-intervention feedback survey by practitioners.

4.4.Data analysis

Participants' responses to post-intervention feedback surveys were coded using a similar approach to that employed by Verloigne et al. [20] and Pinket et al. [12]. Specifically, positive likert scale responses (responses of either "agree" or "strongly agree") were coded as 1, while non-responses or negative responses ("neither agree nor disagree", "disagree" or "strongly disagree") were coded as 0. Dichotomous responses of "yes" or "no" were coded as 1 or 0, respectively. A total acceptability score of 11 was available for practitioner surveys, and 8 for parental surveys. Proportions were calculated to give the total acceptability score as a percentage for each sample. At present, there are no specific guidelines on quantifying the level of acceptability in intervention research. Therefore, recommendations proposed by Durlak et al. (2008) for categorising fidelity scoring were adopted whereby a threshold of $\geq$60% was classified as high acceptability [21].

Interview and focus group data were analysed using an inductive thematic analysis [22]. A coding framework was developed by one researcher (SM) using the framework approach [23], before the coding was independently checked by another researcher (AMG). Any discrepancies in the assignment of codes to text, or the definition of codes were discussed and agreed upon, before codes were grouped into themes and sub-themes. Additional data from open-ended questions in practitioner logbooks and parental surveys were also added to the dataset during coding. Data analysis was conducted using NVivo 10 software. Method triangulation was employed by considering the findings of both the quantitative surveys and qualitative focus groups/interviews collectively. The collection of both quantitative and qualitative data from two distinct groups (teachers and parents) regarding a specific phenomenon (acceptability of intervention components and delivery) increases reliability and validity of the findings [24]. All survey data were analysed prior to the analysis of outcome data as recommended by current process evaluation guidelines [16].

5. Results

Post intervention feedback surveys were distributed to all participants of eligible children (n=125) for which twenty-six were returned. Seven of these were incomplete and were excluded, leaving 19 for analysis. Nine preschool practitioners completed post intervention feedback surveys, and participated in focus groups, while four parents took part in a semi-structured interview. All participants were women and all parental interviewees identified themselves as the child's mother.

5.1. Preschool acceptability

The total acceptability score from post intervention practitioner questionnaire responses was 80% (mean score 8.8/11), indicating that acceptability of the intervention was high. Based on the focus group findings, four themes and twenty sub-themes were identified relating to intervention acceptability, barriers, and facilitators to implementation, which are detailed below:

The need for obesity prevention interventions in Scottish preschools:

Increasing opportunities:

There was a consensus that interventions such as ToyBox-Scotland were needed in Scottish preschools. Practitioners cited high levels of childhood obesity, increasing use of screen devices and a lack of access to opportunities to engage in healthy behaviours as a rationale for the programme:

> My initial thoughts were it would be good for the children because a lot of our children live in high rise flats and they don't have much time to go out and play. Also, in society today, parents are afraid to let their children out to play. So, there's less physical activity again and a lot of children are hooked

to their phones and their iPads and things. So, I thought it was good for the children.

Aligning with preschool and government health objectives:

A major asset of the ToyBox programme was that it enabled preschool staff to meet health and wellbeing curriculum targets in the Scottish education system. Practitioners stated that they could easily match ToyBox activities to the Scottish Curriculum for Excellence's Experiences and Outcomes (Education Scotland, 2017).

Practitioner perceptions of intervention content and materials:

In general, practitioners found the intervention to be acceptable and feasible to deliver. A number of barriers and facilitators to implementation were identified and discussed. Specifically, the classroom materials and activity guides were perceived to be a useful resource, which made the delivery of physical activity sessions easier by reducing the need for prior planning:

> I think because it gave me something to do and something to plan for, that it was all organised, and then I was not stressed. I was like that's it; this is what I'm doing and this is it, you know, it's all planned out for you.

All participants agreed that the classroom materials were visually appealing, used appropriate language, and provided clear, concise instructions, which aided the delivery of the programme:

> I think they're quite easy to use [classroom activity guides] because they're step-by-step and obviously, you've got a picture to represent as well. Some

> of us need that. Like, what is this we're doing? But also, it tells you everything you need.

Practitioners also felt that the classroom activity guides allowed flexibility in delivery, and PA sessions could be easily adapted to suit the context of the specific preschool:

> I like it because it gives you a base for stuff as well. So, we can do the wee chiffon cloth game but we can also make it a bit different and we can try different things with it. So, we can adapt it as well and make it harder, give more of a challenge or we can scaffold it. We can do different things with them all.

There were mixed feelings about making changes to the preschool environment. Some participants were against the idea to begin with, but accepted it once changes were made:

> I mean, initially, when we were talking about losing chairs and that kind of thing, I was a bit apprehensive about it because you get used to what you're used to. But, you know, since making the changes, it's been good.

Parent and child perceptions:

A number of practitioners reported receiving feedback from parents regarding both the changes implemented in the preschool, and the parent-child activities provided as part of the intervention. However, others stated that they received no feedback from parents. In general, parental feedback was positive and focused on how the home component of the intervention had benefited them:

> A lot of parents have been coming back and saying it gave them ideas and useful things to do when they were going out and at the weekend. It was things that they could do that didn't cost any money.

Practitioners at one preschool stated that although they did not receive any direct feedback from parents, children told the practitioners that they were engaging with the home materials with their parents:

> Some of them were saying they were doing it and if we were talking to the children, they were saying they were doing it, but getting any kind of evidence, we didn't get a lot of evidence. But verbally, children would say they were doing the games with mum or dad

Practitioners believed that the children enjoyed the preschool-based component of the intervention, based on children's reactions and asking to do specific activities again.

Practitioner training:

Participants found the pre-intervention training session to be informative and sufficient to allow them to implement the intervention in the preschool:

> I think it was fine. It was all explained and the handbooks are really quite self-explanatory and I think the staff found them easy to use as well.

Level of implementation:

The intervention was implemented with high fidelity across the three preschools (Malden et al., 2019). However, practitioners highlighted a number of barriers and facilitators to implementation of specific intervention components.

Environmental changes to the classroom:

The level of environmental change varied between each preschool. One preschool did not remove any chairs from the classroom, and cited a lack of space and conflicting preschool policy as the reason:

> We didn't [remove chairs] purely because we've got a new head teacher in place and he was trying to set up the environment in different ways before he introduced any of these programmes. What's happened is, we've actually got less space to move around. I think the new head teacher is looking at ways to reduce the children running around the playroom.

The remaining two preschools did remove chairs, which offered was perceived to offer more space for children to be active. One preschool also adopted an open door policy, giving children the freedom to go outside:

> There was taking away the chairs and giving them more space, and then we changed that making it an open door policy out here…There's more floorspace for them to extend their playing as well.
>
> At the art area as well, there's less sitting down painting.

Mode of delivery:

The way in which practitioners delivered the intervention differed slightly between preschools. All practitioners stated that they delivered the programme indoors and outdoors, weather permitting. However, one preschool only delivered PA sessions in the gym hall, and did not utilise the classroom. Most practitioners stated that they did not deliver sessions from start to finish, instead they split sessions up throughout the day:

> See the warm up games? They were kind of most popular. The kids, kind of enjoyed them quite a lot like fire, water, storm. They really enjoyed that, and you don't need any resources for that. So we would start with those and do the rest later.

Practitioners generally agreed that children were able to participate in the sessions with minimal instruction. This was seen as a benefit, as child-led learning is encouraged as part of the Scottish preschool curriculum:

> We didn't need a member of staff there; the kids were just wanting to do it themselves. They sometimes take it their own way as well, with their own wee bits and pieces which was nice to see.

Sedentary behaviour:

Movement games that aimed to break up sedentary time were implemented with less fidelity across all three preschools than the PA sessions. However, movement corners were set up within the preschools, with a number of practitioners stating that they created their own movement corners, which were not in the manuals:

> We have made more cosy areas for children to just go and chill out. The book corner's a little bit bigger, so they can jump around or chill out

Practitioners were more conscious about when children were sitting down and used the SB activities to break up sitting time:

> Yes, rather than sitting the kids down we've got them to stand stretching and things.

Conversely, some practitioners felt a number of the SB activities did not work so well, as children would lose interest, or instructions and props were insufficient, however they were able to adapt these and make them more engaging:

> But I think she had written the difficulty in following the story without pictures or props. I think it was just the story and the book but there were no kind of pictures to go with it. So, she said once she introduced the props and it was kind of simplified, the children engaged and they enjoyed the role play with the puppets and searching around the garden.

Physical activity sessions:

Practitioners generally enjoyed delivering the PA sessions, and this was reflected in the level of implementation in comparison to the SB activities:

> The cardboard rolls one we did. Barefoot land, she's done that twice. Because she spoke about that one in the staff room and she said that the

> children really enjoyed that. It was a bit different. We've never really done anything like that, and I think that was fab.

Barriers to delivery:

In general, the intervention was perceived to be simple to deliver, this was facilitated by easy-to-use resources, and the programme offering flexibility for delivery. Barriers to delivery were preschool-specific, and were mainly related to logistical issues such as lack of time and space in one preschool:

> Probably just not having the physical space all the time. We've only got the gym hall, the use of the gym hall and weather permitting. We're outdoors every day no matter what the weather but depending on the weather, it's sometimes hard to carry out the physical activities because we've only got one playroom.

5.2. Trial procedures

Acceptability of trial procedures:

Overall, practitioners felt that the trial procedures to measure the feasibility of the ToyBox study were acceptable, and the time taken to conduct data collection was manageable. However, a major issue highlighted by all participants was the acceptability of the activPAL accelerometers. While it was felt that children enjoyed wearing the devices, practitioners agreed that they were overly invasive, and that parents did not find them acceptable for a number of reasons, including skin irritation.

However, all practitioners stated that alternative devices (e.g., wrist or ankle-worn accelerometers) would be more practical for this group, and would be more acceptable to parents.

> I think it's still good though if you still use a tracker of some sort, but maybe... Or like these wee watches. They're great.

> Yes, I'm thinking more like a wristband-y thing might be better. Or put them on their ankle or something and it can stay on there.

Parental response rates to questionnaires were low in the trial, and practitioners attributed this to parents being too busy, or lacking the reading ability to complete the questionnaires:

> Some parents actually physically can't read. And things that are coming home from school on bits of paper is linked to actual primary school, and parents will just put it to the side and you have to keep chasing them up and chasing them up which we've found for your questionnaires.

All practitioners found the monthly activity logbook, which was used to measure fidelity, to be acceptable and time efficient to use.

Trial recruitment:

Practitioners at two of the preschools stated that they actively engaged with parents during study recruitment, which they felt aided recruitment:

> I stood at the door and I was like, so this is what we're doing and…just sign here. And I did explain fully what it was about and the impact that it would have. I was really keen.

Practitioners offered a number of suggestions to increase recruitment rates. Specifically, having more face-to-face interactions between the research team and parents, and the use of social media:

> I think if you can meet them [parents] and explain the benefits that it will have in front of the parents, and then if they see an actual outcome, an impact for their child and their family, then they tend to go with that.

5.3.Home acceptability

Acceptability scores from parental post-intervention feedback surveys totalled 49% (mean score 3.9/8), indicating low acceptability. Table 1 summarises the parental responses to each acceptability item on the survey. Items relating to acceptability of materials and activities (items 1, 2, 3 and 8) were higher than items relating to the perceived effect of the intervention on health behaviours (items 4-7). Results of semi-structured interviews are presented below.

Table 1. Acceptability scores per item for parental feedback surveys

Item number	Survey Question	% coded as 1 (agree/strongly agree)
1	Overall, did your child enjoy the activities in the programme?	84%
2	Overall, did your child like the stickers and wallchart provided?	79%
3	Did you enjoy doing the activities with your child?	58%
4	Do you think the activities helped your child be more physically active?	37%
5	Do you think the activities helped your child spend less time sitting/being inactive?	21%
6	Do you think the activities helped your child eat healthier snacks?	21%
7	Do you think the activities helped your child drink more water instead of sugary juices?	16%
8	Were the instructions provided for the games and activities easy to read and clear	79%

Parental perceptions of materials and activities:

Parents generally found the materials to be visually appealing. The length of the activity packs was deemed appropriate, and the language was easy to understand and instructions were easy to follow:

> I quite like them visually [the materials], like for me; like I'm not quick, so I need to read things over, like just to make sure it goes in again. But no, I think it's quite visually…nice, and easy to make sense of what was being said.

Two of the parents stated that they enjoyed engaging in the activities with their child, while the remaining two stated that they did not use the activities enough to form strong opinions:

> I can't remember in detail like each one, but to me they looked fine and the stickers and poster were really nice, he did really like them like I said good visuals and that. Can't think of anything right now to be honest, like I said it's more just the time that was a problem, think as a single parent it's not that easy to do everything, you know.

Parental recognition of obesogenic behaviours:

Parents stated that while they may not have utilised the suggested activities fully, the materials stimulated their thinking about obesogenic behaviours and to what extent their child is engaging in PA, screen time, and healthy snacking. With regards to knowledge, parents generally did not feel that they learned anything new through receiving the materials:

> It kind of got me thinking a bit more about what he's doing like for keeping active and that. And I'd say I'm pretty good with watching what he eats and drinks and stuff, so not really on that side, but I did think a bit more about keeping him active.

Child perceptions:

All parents stated that their children enjoyed the activities, and the stickers and accompanying materials were well received by the children according to the parents:

> They had nice wee sketches on them, my kids really liked the stickers as I said. She's at that age where stickers are really good.

Level of implementation:

As highlighted in the parental survey results, parents stated that they did not implement the programme fully. All stated that they implemented some of the activities, but were mainly limited by time constraints and other commitments:

> I would just say, when the packs came out, we would try the odd activity. I never got a chance to do all of them, as I say, due to personal circumstances. I…would just go through them with him and let him choose what one he wants to do.

An important facilitator identified by two parents was that children would prompt them to implement the activities, sometimes due to reinforcement from preschools:

> As any busy mum working full time, you get to a point at night and go, oh, and try and get the activities done; but he was actually really good at prompting, because in the background the nursery must have been highly speaking about it; so he'd go, Mu-um, activities; and I'm like, oh, again.

Use of sticker incentives and wallchart:

Parent's implementation of the sticker incentives and accompanying wallchart varied. One parent used the wallchart as intended, awarding a sticker to their child once an activity was complete. The remaining participants used the stickers more loosely; one participant did not use the wallchart, but still gave the stickers to her child. Two parents stated that their children stuck the stickers to their clothes instead of the chart. All participants felt that the stickers were an effective incentive for influencing their children's behaviour to an extent:

> I think it was really good and really engaging, because the way it's laid out, like for me it wasn't difficult, it really wasn't difficult to understand;

[child's name] got it; and as and when you're putting your stickers on, obviously because it matches and colour coordinated he knew, he could do it; he says, like, we've done that one, we did this. It was really good.

Use of activities:

In general, parents perceived their overall use of the materials to be low. The main barrier identified to participation was time constraints:

> Mainly just time. I work shifts and my partner does too, so we have the three of them and between getting them fed and bathed and that, school, nursery, and all that. There would be times I'd get the packs and have a look at them and go like "ok I'll give that a try" but then never get around to it.

Parents recalled specific activities which they did implement, and their children's reactions to these:

> Now he's more into water as well; so, it was just trying to… He was measuring himself [measuring water consumption] just to make sure, like he'd get up in the morning and go like, oh, like straightaway. Which was really good. It was more it made him more aware.

5.4. Trial procedures

Acceptability of accelerometers:

Three of the four parents were involved in the cRCT, and their children wore the accelerometer during the study. They offered insights regarding the device's acceptability. Specifically, while the children liked wearing the device, parents generally felt a wrist-worn device would be more acceptable and would encourage more parents to give consent for their child to participate in the study. One parent stated that their child developed a mild rash when wearing the activPAL:

> It could be like Fitbits, but they don't take them off at night. Think they are a bit less hassle and people would be less bothered by them.

6. Discussion

This study investigated the acceptability of the ToyBox-Scotland obesity prevention intervention in preschools and children's homes. By using a mixed methods design, important aspects of intervention acceptability were identified that will assist with further development of the programme within Scottish preschools. Post intervention practitioner survey results suggested that the intervention was highly acceptable (80% acceptability score). This was reinforced in the qualitative findings, as practitioners identified a number of aspects of the intervention that aided delivery, namely user-friendly and informative classroom manuals, the programme being well aligned with preschool health and wellbeing curriculum objectives, and not overburdening staff with additional responsibilities or paperwork. Similar studies have highlighted time-consuming paperwork and additional workload as major barriers to intervention acceptability [25, 26]. Therefore, it appears that the extensive involvement of stakeholders during intervention development [13] has benefitted the acceptability of the intervention in Scottish preschools, a finding reported by similar studies which have actively involved practitioners during intervention development [27].

One aspect of the intervention that was highlighted as more difficult to implement by practitioners was changing the classroom environment, which specifically aimed to reduce sitting time and encourage more active-play. A related issue was the disparity between the level of implementation of movement breaks in comparison to physical activity sessions. A possible explanation for this is provided in a study by Alhassan and Whitt-Glover (2014) of a teacher-led preschool physical activity programme. Specifically, teachers incorrectly assumed that the classroom needed to be rearranged for each movement break, which discouraged regular implementation. Additionally, teachers also highlighted a need for more training regarding movement breaks [25]. Indeed, practitioners in our study stated that, prior to receiving the classroom activity guides, their confidence was low with regards to delivering classroom PA, but increased following training and the provision of classroom activity guides. Therefore, additional training on how best to incorporate movement breaks into the preschool routine, without disrupting other activities, may be of benefit in the future.

The acceptability of the home component of the intervention was lower (49% acceptability score) than the preschool component (80% acceptability score) based on parental survey responses, with the qualitative findings offering further explanation for this. Specifically, a major barrier identified during interviews was limited time to participate in the activities. This is a barrier commonly identified in family-based obesity prevention studies [28, 29]. It was apparent that parents did not perceive the intervention to have had any major effect on health behaviours possibly due to them feeling that they were not able to participate in activities fully based on the aforementioned barriers. However, parents had positive perceptions of the materials and activities concerning child enjoyment, acceptability of sticker incentives, and legibility of activity instructions, indicating that the lack of acceptability is likely an issue with method of delivery, rather than the content of materials. The Miranos study by Sosa and colleagues (2016) utilised a more engaging delivery approach, whereby parents were invited to short information sessions at their child's preschool, which were led by trained parents who acted as peer educators. Sessions were offered at multiple time slots, provided appealing visual materials and offered incentives for participation. The intervention achieved high attendance rates (mean attendance = 80%), and resulted in significantly increased parental knowledge of obesity-related health behaviours [30], indicating that such approaches may be more effective than solely distributing intervention materials to the home.

Both parents and practitioners offered extensive insights on acceptability of the trial procedures. Specifically, the activPAL accelerometer was perceived as invasive and caused a mild rash in some children, a finding supported by another study with preschool children (De Decker et al.[31]. Wrist-worn devices were regarded as a viable alternative by both parents and practitioners, with such devices having previously been shown to provide similarly valid estimates of physical activity and sedentary behaviour in comparison to the activPAL, however these devices do not provide postural data, and their accuracy varies [32, 33].

Recruitment to the feasibility RCT was somewhat low (18%), therefore practitioners were asked how best to engage parents to participate in future research. It was strongly suggested that having face-to-face interactions with parents, and providing information sessions as opposed to only distributing forms, was the most productive approach to take. This supports findings from a systematic review of childhood obesity prevention recruitment strategies, where higher recruitment rates were achieved than in the present study by using additional approaches such as parental presentations, phone calls, or home visits [34].

There are a number of limitations to this present study, which should be considered when interpreting the findings. Firstly, recruitment of parents to take part in interviews was low, and only included mothers. This may have biased results, as the parents who participated in the interviews may have had stronger perceptions of the intervention in comparison to parents who did not participate. Additionally, fathers may have offered differing perspectives regarding intervention acceptability compared to mothers. Recall bias is also a potential limitation within this study, as the focus groups and interviews took place approximately two months after the intervention had ended. Despite the limitations identified, these findings offer insight regarding the acceptability of ToyBox-Scotland, which can be used to further develop and adapt the programme before any future trials, and may assist the development of similar interventions.

The ToyBox-Scotland intervention appears to be acceptable in the preschool environment, based on the perceptions of preschool practitioners. Further development and adaptation measures are needed to improve the acceptability of the home-based component. Specifically, a new approach to intervention delivery in the home environment may be needed. Further development work with both parents and preschool practitioners will assist with optimising intervention content and delivery, and should be a priority before progression to further implementation and evaluation. The employment of feasibility and acceptability studies allows for the identification of issues with intervention acceptability. Such studies should be more widely used within intervention development and evaluation research.

7. References

1 WHO F. Global strategy on diet, physical activity, and health: obesity and overweight. 2006.

2 Chang J-H, Wang S-H, Kuo C-L, Shen HC, Hong Y-W, Lin L-C. Prevalence of flexible flatfoot in Taiwanese school-aged children in relation to obesity, gender, and age. *European journal of pediatrics*. 2010; 169: 447-52.

3 Reilly JJ, Armstrong J, Dorosty AR, Emmett PM, Ness A, Rogers I*, et al.* Early life risk factors for obesity in childhood: cohort study. *Bmj*. 2005; 330: 1357.

4 Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, Dyer A. Hip-hop to health Jr. for Latino preschool children. *Obesity*. 2006; 14: 1616-25.

5 Reilly JJ, Kelly L, Montgomery C, Williamson A, Fisher A, McColl JH*, et al.* Physical activity to prevent obesity in young children: cluster randomised controlled trial. *Bmj*. 2006; 333: 1041.

6 Sacher PM, Kolotourou M, Chadwick PM, Cole TJ, Lawson MS, Lucas A*, et al.* Randomized controlled trial of the MEND program: a family-based community intervention for childhood obesity. *Obesity*. 2010; 18: S62-S68.

7 Brown T, Moore THM, Hooper L, Gao Y, Zayegh A, Ijaz S*, et al.* Interventions for preventing obesity in children. *Cochrane Database of Systematic Reviews*. 2019.

8 Manios Y. The 'ToyBox-study'obesity prevention programme in early childhood: an introduction. *obesity reviews*. 2012; 13: 1.

9 De Craemer M, De Decker E, Verloigne M, De Bourdeaudhuij I, Manios Y, Cardon G. The effect of a kindergarten-based, family-involved intervention on objectively measured physical activity in Belgian preschool boys and girls of high and low SES: the ToyBox-study. *International Journal of Behavioral Nutrition and Physical Activity*. 2014; 11: 38.

10 De Craemer M, Lateva M, Iotova V, De Decker E, Verloigne M, De Bourdeaudhuij I*, et al.* Differences in energy balance-related behaviours in European preschool children: the ToyBox-study. *PLoS One*. 2015; 10: e0118303.

11 Latomme J, Cardon G, De Bourdeaudhuij I, Iotova V, Koletzko B, Socha P*, et al.* Effect and process evaluation of a kindergarten-based, family-involved intervention with a randomized cluster design on sedentary behaviour in 4-to 6-year old European preschool children: The ToyBox-study. *PloS one*. 2017; 12: e0172730.

12 Pinket A-S, Van Lippevelde W, De Bourdeaudhuij I, Deforche B, Cardon G, Androutsos O*, et al.* Effect and process evaluation of a cluster randomized control trial on water intake and beverage consumption in preschoolers from six European countries: the ToyBox-study. *PloS one*. 2016; 11: e0152928.

13 Malden S, Hughes AR, Gibson A-M, Bardid F, Androutsos O, De Craemer M*, et al.* Adapting the ToyBox obesity prevention intervention for use in Scottish preschools: protocol for a feasibility cluster randomised controlled trial. *BMJ open*. 2018; 8: e023707.

14 Fitzgibbon ML, Stolley MR, Schiffer LA, Braunschweig CL, Gomez SL, Van Horn L*, et al.* Hip-Hop to Health Jr. Obesity prevention effectiveness trial: postintervention results. *Obesity*. 2011; 19: 994-1003.

15 Østbye T, Krause KM, Stroo M, Lovelady CA, Evenson KR, Peterson BL*, et al.* Parent-focused change to prevent obesity in preschoolers: results from the KAN-DO study. *Preventive medicine*. 2012; 55: 188-95.
16 Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W*, et al.* Process evaluation of complex interventions: Medical Research Council guidance. *bmj*. 2015; 350: h1258.
17 Griffin TL, Pallan MJ, Clarke JL, Lancashire ER, Lyon A, Parry JM*, et al.* Process evaluation design in a cluster randomised controlled childhood obesity prevention trial: the WAVES study. *International Journal of Behavioral Nutrition and Physical Activity*. 2014; 11: 112.
18 Langford B, Jago R, White J, Moore L, Papadaki A, Hollingworth W*, et al.* A physical activity, nutrition and oral health intervention in nursery settings: Process evaluation of the NAP SACC UK feasibility cluster RCT. *BMC Public Health*. 2019.
19 Barber SE, Jackson C, Hewitt C, Ainsworth HR, Buckley H, Akhtar S*, et al.* Assessing the feasibility of evaluating and delivering a physical activity intervention for pre-school children: a pilot randomised controlled trial. *Pilot and feasibility studies*. 2016; 2: 12.
20 Verloigne M, Ahrens W, De Henauw S, Verbestel V, Mårild S, Pigeot I*, et al.* Process evaluation of the IDEFICS school intervention: putting the evaluation of the effect on children's objectively measured physical activity and sedentary time in context. *obesity reviews*. 2015; 16: 89-102.
21 Durlak JA, DuPre EP. Implementation matters: A review of research on the influence of implementation on program outcomes and the factors affecting implementation. *American journal of community psychology*. 2008; 41: 327-50.
22 Braun V, Clarke VJQrip. Using thematic analysis in psychology. 2006; 3: 77-101.
23 Ritchie J, Lewis J, Nicholls CM, Ormston R. Qualitative research practice: A guide for social science students and researchers: sage 2013.
24 Carter N, Bryant-Lukosius D, DiCenso A, Blythe J, Neville AJ. The use of triangulation in qualitative research. *Oncology nursing forum*: 2014.
25 Alhassan S, Whitt-Glover MC. Intervention fidelity in a teacher-led program to promote physical activity in preschool-age children. *Preventive medicine*. 2014; 69: S34-S36.
26 Whitt-Glover MC, Porte AT. Do short physical activity breaks in classrooms work?: Robert Wood Johnson Foundation 2013.
27 Howie E, Brewer A, Brown W, Pfeiffer K, Saunders R, Pate R. The 3-year evolution of a preschool physical activity intervention through a collaborative partnership between research interventionists and preschool teachers. *Health Education Research*. 2014; 29: 491-502.
28 Staiano AE, Marker AM, Comeaux J, Frelier JM, Hsia DS, Broyles ST. Family-based behavioral treatment for childhood obesity: caretaker-reported barriers and facilitators. *Ochsner Journal*. 2017; 17: 83-92.
29 Berge JM, Arikian A, Doherty WJ, Neumark-Sztainer D. Healthful eating and physical activity in the home environment: results from multifamily focus groups. *Journal of nutrition education and behavior*. 2012; 44: 123-31.
30 Sosa ET, Parra-Medina D, He M, Trummer V, Yin Z. ¡ Miranos!(Look at Us! We Are Healthy!) Home-Based and Parent Peer–Led Childhood Obesity Prevention. *Health promotion practice*. 2016; 17: 675-81.

31 De ED, De MC, Santos-Lozano A, Van EC, Cardon G. Validity of the ActivPAL™ and the ActiGraph monitors in preschoolers. *Medicine and science in sports and exercise*. 2013; 45: 2002-11.
32 An H-S, Kim Y, Lee J-M. Accuracy of inclinometer functions of the activPAL and ActiGraph GT3X+: A focus on physical activity. *Gait & posture*. 2017; 51: 174-80.
33 Koster A, Shiroma EJ, Caserotti P, Matthews CE, Chen KY, Glynn NW*, et al.* Comparison of sedentary estimates between activPAL and hip-and wrist-worn ActiGraph. *Medicine and science in sports and exercise*. 2016; 48: 1514.
34 Cui Z, Seburg EM, Sherwood NE, Faith MS, Ward DS. Recruitment and retention in obesity prevention and treatment trials targeting minority or low-income children: a review of the clinical trials registration database. *Trials*. 2015; 16: 564.

Chapter 10: thesis discussion and conclusions

1. Preface

This chapter will summarise the thesis as a whole, considering the chronological structure of the work, the rationale for each study conducted, and the results obtained and how these will likely impact on policy and any future research efforts relating to the thesis. As this thesis contains five separate discussion sections for each manuscript presented, this chapter will not be an exhaustive discussion of the research findings, but will instead serve as an overview of the thesis and its main recommendations, limitations and conclusions.

2. Background

The present thesis aimed to explore the feasibility and acceptability of an adapted pre-school based intervention to prevent obesity in young children in Scotland. After introducing the reader to the proposed aims of work (chapter 1), the thesis then presented a strong case for early prevention of obesity through the conduct of a comprehensive systematic review and meta-analysis which highlighted the numerous co-morbidities which are associated with excess adiposity in young children (Chapter 3), which was preceded by an in-depth methodology chapter detailing the steps taken to conduct this review (Chapter 2). This systematic review used more stringent inclusion/exclusion criteria (i.e. explicitly defined obesity and distinction between children and adolescents) than previous reviews typically have in this area [1-3], which provides further understanding of the relationship between some co-morbidities of true obesity in relation to childhood. This review has subsequently been accepted for publication in the journal *Obesity Reviews*. Once obesity had been identified as a clear risk factor for multiple health conditions in childhood, a literature review was conducted to summarise the interventional research which has been published to date with regards to obesity prevention in childhood (Chapter 4). This chapter identified important studies in the field [4-7], and discussed key components of childhood obesity prevention interventions which should be considered when developing such programmes. The literature review also discussed the importance of feasibility and pilot studies in refining intervention and evaluation efforts, and introduced the reader to the fairly under-researched area of adapting existing interventions for use in other contextually different settings. The thesis then presents three methodology chapters, the first detailing the steps taken to adapted the ToyBox preschool obesity prevention intervention for use in Scottish preschools (chapter 5) [8], the second providing an in-depth rational for the evaluation methods used (chapter 6) and the third presenting a protocol for a feasibility cluster randomised controlled trial of the adapted intervention which was implemented in Glasgow preschools in 2018 (chapter 7) [9]. Two of these chapters (chapters 5 and 7) were published in the peer reviewed journals *Sage Research Methods Cases*, and *BMJ Open*, respectively. The thesis then presents the findings from the feasibility study and its accompanying process evaluation in two distinct results chapters. The first (chapter 8) was published in the journal *BMC Pilot and Feasibility Studies* and presents results from the cRCT, detailing intervention recruitment rates and intervention fidelity, and the intervention's effect on health and behaviour-related outcomes [10]. The second results chapter (chapter 9) used both qualitative and quantitative methods to investigate the acceptability of intervention components and trial procedures, and was published in the journal *Child: care, health and development* in 2019 [11]. The thesis is then concluded by this present chapter, which summarises the work, highlights important findings, acknowledges limitations, and makes recommendations for future research efforts relating to the work presented in this thesis.

3. Summary of findings

This thesis has produced a number of novel research findings, which add to the current understanding of both the impact of obesity in childhood on health outcomes, and novel methods for adapting existing interventions in obesity prevention research. Firstly, the systematic review and meta-analysis of the co-morbidities of childhood obesity further supported the findings of similar reviews in this area [2, 3, 12, 13], and also added further to the knowledge base. Asthma was further validated as an important co-morbidity of childhood obesity in the review, and the meta-analysis demonstrated a moderate association in line with other reviews [2, 12]. Our findings that childhood obesity appears to considerably increase the odds of both vitamin D and iron deficiency in children is a particularly important finding considering it has not been extensively investigated in meta analyses of child populations [14]. Collectively, the results of the systematic review present a strong justification for early intervention to prevent obesity in young children, as it highlights a clear association between childhood obesity and a number of health conditions. An important finding of the systematic review, is that the majority of the evidence available concerning this topic appears to be cross sectional in nature, and there is a dearth of high quality, longitudinal research or experimental studies which consider obesity as a distinct condition from overweight, which can further highlight the causal relationships between the conditions discussed in the systematic review presented in this thesis.

Other important findings of this thesis are the lessons learned during the journey from identifying a study to adapt, and making the necessary adaptations to it in the absence of guidance, to then testing the feasibility of the adapted intervention in the new context. To our knowledge, this is one of the first interventions for which each step in this process has been described in a series of peer reviewed published papers [8-11]. In order to achieve this, we followed the steps taken by only a small number of studies to successfully adapt an intervention to date [15-17]. Similar to these studies, we ensured that the relevant stakeholders were represented from the outset during intervention adaptation exercises by using a co-production approach [18]. Kipping et al adapted the US-based NAP SACC obesity prevention intervention for use in English preschools, adding an additional home-based component and matching the intervention components with current UK guidelines on nutrition, physical activity and oral health in pre-school children [16]. The adaptations were informed by workshops, interviews and focus groups with preschool managers, parents, local authority staff, health visitors and public health practitioners, representing a broad range of the relevant stakeholders who could potentially influence the intervention's success in the new setting. In a feasibility study and process evaluation of NAP SACC UK, the intervention was found to be acceptable to preschool staff, parents and programme partners [17]. However, the web-based parental component was implemented with low fidelity in comparison to other pre-school based components.

Preschool staff, local authority workers, and children were included in the adaptation process through workshops, co-production efforts and activity trialling with children, which led to considerable adaptations to the original ToyBox intervention [8, 9, 19]. During evaluation of ToyBox-Scotland, the intervention was found to be acceptable to preschool staff, and procedures of the cluster RCT were feasible [10, 11]. Similarly to Langford et al. (2019), the parental component of the intervention was also found to have been the most challenging to implement, and fidelity scores were considerably lower for the home-based aspects of the intervention compared to the pre-school aspects [10, 11]. This reflects the findings of other early years' intervention research, which has reported challenges in engaging parents with intervention materials and activities.

The lessons learned from the adaptation of the ToyBox study for use in Scottish preschools are therefore important to consider for other researchers who are looking to adapt an intervention for use in another context.

4. Thesis limitations

While the stringent systematic review inclusion criteria and engagement with a range of stakeholders during intervention adaptation are strengths of this thesis, there are a number of limitations to the work that should be highlighted. A major challenge which remained consistent throughout each stage of intervention adaptation and evaluation was the difficulties in engaging parents in the research. This was apparent during the initial efforts to recruit parents to participate in adaptation workshops which proved to be more time-consuming than anticipated. Therefore, due to time constraints related to a PhD timeline, we were required to abandon efforts to engage with parents directly and relied on preschool practitioner's experiences of interacting with parents during intervention adaptation activities. Difficulties also presented when recruiting parents for both the trial and post intervention interviews during process evaluation, managing only an 18% recruitment rate for the cRCT (i.e. only 43 parents provided consent for their child to participate out of a potential sample of almost 300), and four parental interviews, respectively. A number of reasons were discussed regarding the difficulties in recruiting parents. One theory was that the study took place primarily within areas of low SES, with previous research showing this can present a number of challenges that make recruitment more difficult such as mistrust of researchers, chaotic lifestyles, or long/unsociable working hours [20, 21]. It must also be conceded that the strategies employed to engage parents may have been too passive in their approach, and more interactive engagement with parents during recruitment may have yielded better results [7], however this would also have been more time-consuming.

Another limitation of the research was low compliance with some outcome measures, specifically BIA and accelerometery [10]. However, as this was a feasibility study, these limitations are important outcomes in themselves as they now allow for the reconsideration of these methods if any future trial is conducted, as recommended by guidelines on the conduct of feasibility studies and evaluation of complex interventions [22].

5. Future research and recommendations

Based on the results of the feasibility study, coupled with the limitations identified above, there remains a number of aspects of the ToyBox Scotland intervention which require further investigation and adaptation before progression to a full effectiveness trial can be recommended. While the pre-school components of the intervention were implemented with high fidelity and were generally well received by practitioners, it is clear from the recruitment difficulties and the low fidelity and acceptability of the intervention within children's homes, that more development work is needed in this area with parents. Additionally, alternative methods of measuring activity levels and adiposity should be explored, considering the poor compliance with the activPAL device and failure to collect accurate BIA data.

While it is not recommended to progress to efficacy testing at present, ToyBox-Scotland still demonstrates aspects of a potentially viable intervention for wider implementation in Scottish preschools, and it could therefore still be considered worthwhile conducting further development work, rather than abandoning implementation completely. If additional adaptations to the home component of the intervention can be explored with the input of parents, then further feasibility and pilot testing could be undertaken in the future. As MRC guidance on developing and evaluating complex interventions recommends, feasibility testing can be treated as an iterative stage of the process, where additional development work can be undertaken until the intervention is deemed ready for further testing [22].

It should also be acknowledged that due to a lack of published guidance on adapting interventions, there is currently no consensus on the extent to which an intervention can reasonably be adapted without undermining the core components and theories that define the programme. We considerably adapted the ToyBox programme by removing or adapting numerous components, it is therefore feasible that this may have significantly altered the underlying theories that were used to develop the original intervention.

6. Policy implications

While the findings of this thesis for the most part are preliminary due to the majority of the research being exploratory feasibility studies, there are still aspects of the research which may contribute to important policy implications in the future. Firstly, the findings of the systematic review reiterate the beliefs of a growing number of physicians, epidemiologists and general healthcare practitioners that obesity in the early years has potential to cause related conditions as early as childhood, and should therefore be prevented as a priority [23]. While the shift in policy to preventing obesity as early as possible is already well-established globally [24], our findings add further to the evidence suggesting that childhood obesity can cause serious morbidity long before adulthood, giving policymakers a stronger case when advocating for preventing obesity in early life. If the associations identified in the systematic review can be shown to have a causal relationship with obesity, this would have important implications for health care costs and impacts on families considering the high prevalence of the conditions investigated in the review.

Our feasibility study aligns with the Scottish Government's pledge to "half childhood obesity by 2030" [25], in that it offers a potential programme that can be implemented nationally in preschools, offering opportunities to engage in PA, reduce SB, and influence snacking behaviours, all of which are priorities in Scottish early years healthcare [25]. However, before ToyBox Scotland can be recommended as a viable intervention to combat childhood obesity, there remains a need to further adapt the intervention and test its effectiveness before making any such recommendations. Specifically, as mentioned previously, the mismatch between the relative fidelity and acceptability of the intervention between the preschool and the home environment needs to be addressed. The intervention appears feasible within preschools, and additional adaptation in this setting would be minimal. However, the intervention was generally not well received or extensively implemented in the home environment, which if it were to be implemented at present, may negate any benefits to children's health behaviours addressed in preschool that are not then continued in the home.

7. Conclusions

This thesis aimed to present a case for early obesity prevention, and to adapt the ToyBox obesity prevention intervention for use in Scottish preschools. The studies presented in this thesis achieved these aims while also increasing the evidence base with regards to co-morbidities in childhood obesity, and contributed some of the first literature concerning an adapted public health intervention implemented in another setting/country. With additional adaptation and development of the intervention components, the programme will be suitable for further testing of efficacy in the future.

8. References

1 Friedemann C, Heneghan C, Mahtani K, Thompson M, Perera R, Ward AM. Cardiovascular disease risk in healthy children and its association with body mass index: systematic review and meta-analysis. *Bmj*. 2012; 345: e4759.

2 Noal R, Menezes A, Macedo S, Dumith S. Childhood body mass index and risk of asthma in adolescence: a systematic review. *Obesity reviews*. 2011; 12: 93-104.

3 Paulis W, Silva S, Koes B, van Middelkoop M. Overweight and obesity are associated with musculoskeletal complaints as early as childhood: a systematic review. *Obesity Reviews*. 2014; 15: 52-67.

4 Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, Dyer A. Two-year follow-up results for Hip-Hop to Health Jr.: a randomized controlled trial for overweight prevention in preschool minority children. *The Journal of pediatrics*. 2005; 146: 618-25.

5 Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, Dyer A. Hip-hop to health Jr. for Latino preschool children. *Obesity*. 2006; 14: 1616-25.

6 Reilly JJ, Kelly L, Montgomery C, Williamson A, Fisher A, McColl JH*, et al.* Physical activity to prevent obesity in young children: cluster randomised controlled trial. *Bmj*. 2006; 333: 1041.

7 Yin Z, Parra-Medina D, Cordova A, He M, Trummer V, Sosa E*, et al.* Miranos! Look at us, we are healthy! An environmental approach to early childhood obesity prevention. *Childhood Obesity (Formerly Obesity and Weight Management)*. 2012; 8: 429-39.

8 Malden S, Reilly J, Gibson A-M, Bardid F, Hughes A. Procedures and challenges of adapting an existing public health intervention for use in another setting: the ToyBox-Scotland preschool obesity prevention programme. *SAGE Research Methods Cases*. 2019.

9 Malden S, Hughes AR, Gibson A-M, Bardid F, Androutsos O, De Craemer M*, et al.* Adapting the ToyBox obesity prevention intervention for use in Scottish preschools: protocol for a feasibility cluster randomised controlled trial. *BMJ open*. 2018; 8: e023707.

10 Malden S, Reilly JJ, Gibson A-M, Bardid F, Summerbell C, De Craemer M*, et al.* A feasibility cluster randomised controlled trial of a preschool obesity prevention intervention: ToyBox-Scotland. *Pilot and feasibility studies*. 2019; 5: 128.

11 Malden S, Reilly JJ, Hughes A, Bardid F, Summerbell C, De Craemer M*, et al.* Assessing the acceptability of an adapted preschool obesity prevention programme: ToyBox-Scotland. *Child: Care, Health and Development*. 2019; n/a.

12 Papoutsakis C, Priftis KN, Drakouli M, Prifti S, Konstantaki E, Chondronikola M*, et al.* Childhood overweight/obesity and asthma: is there a link? A systematic review of recent epidemiologic evidence. *Journal of the Academy of Nutrition and Dietetics*. 2013; 113: 77-105.

13 Pereira-Santos M, Costa PRdF, Assis A, Santos CAdST, Santos DBd. Obesity and vitamin D deficiency: a systematic review and meta-analysis. *Obesity reviews*. 2015; 16: 341-49.
14 Cepeda-Lopez AC, Aeberli I, Zimmermann MB. Does obesity increase risk for iron deficiency? A review of the literature and the potential mechanisms. *International journal for vitamin and nutrition research*. 2010; 80: 263.
15 Gillespie J, Hughes A, Gibson A-M, Haines J, Taveras E, Reilly JJ. Protocol for Healthy Habits Happy Homes (4H) Scotland: feasibility of a participatory approach to adaptation and implementation of a study aimed at early prevention of obesity. *BMJ open*. 2019; 9: e028038.
16 Kipping R, Jago R, Metcalfe C, White J, Papadaki A, Campbell R*, et al.* NAP SACC UK: protocol for a feasibility cluster randomised controlled trial in nurseries and at home to increase physical activity and healthy eating in children aged 2–4 years. *BMJ open*. 2016; 6: e010622.
17 Langford R, Jago R, White J, Moore L, Papadaki A, Hollingworth W*, et al.* A physical activity, nutrition and oral health intervention in nursery settings: process evaluation of the NAP SACC UK feasibility cluster RCT. *BMC public health*. 2019; 19: 865.
18 Greenhalgh T, Jackson C, Shaw S, Janamian T. Achieving research impact through co-creation in community-based health services: literature review and case study. *The Milbank Quarterly*. 2016; 94: 392-429.
19 Manios Y. The 'ToyBox-study'obesity prevention programme in early childhood: an introduction. *obesity reviews*. 2012; 13: 1.
20 Heinrichs N, Bertram H, Kuschel A, Hahlweg K. Parent recruitment and retention in a universal prevention program for child behavior and emotional problems: Barriers to research and program participation. *Prevention Science*. 2005; 6: 275-86.
21 Miranda J, Azocar F, Organista KC, Muñoz RF, Lieberman A. Recruiting and retaining low-income Latinos in psychotherapy research. *Journal of Consulting and Clinical Psychology*. 1996; 64: 868.
22 Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *Bmj*. 2008; 337: a1655.
23 Kraak VA, Liverman CT, Koplan JP. Preventing childhood obesity: health in the balance: National Academies Press 2005.
24 Han JC, Lawlor DA, Kimm SY. Childhood obesity. *The Lancet*. 2010; 375: 1737-48.
25 Scottish Government. A healthier future: Scotland's diet and healthy weight delivery plan. 2018.

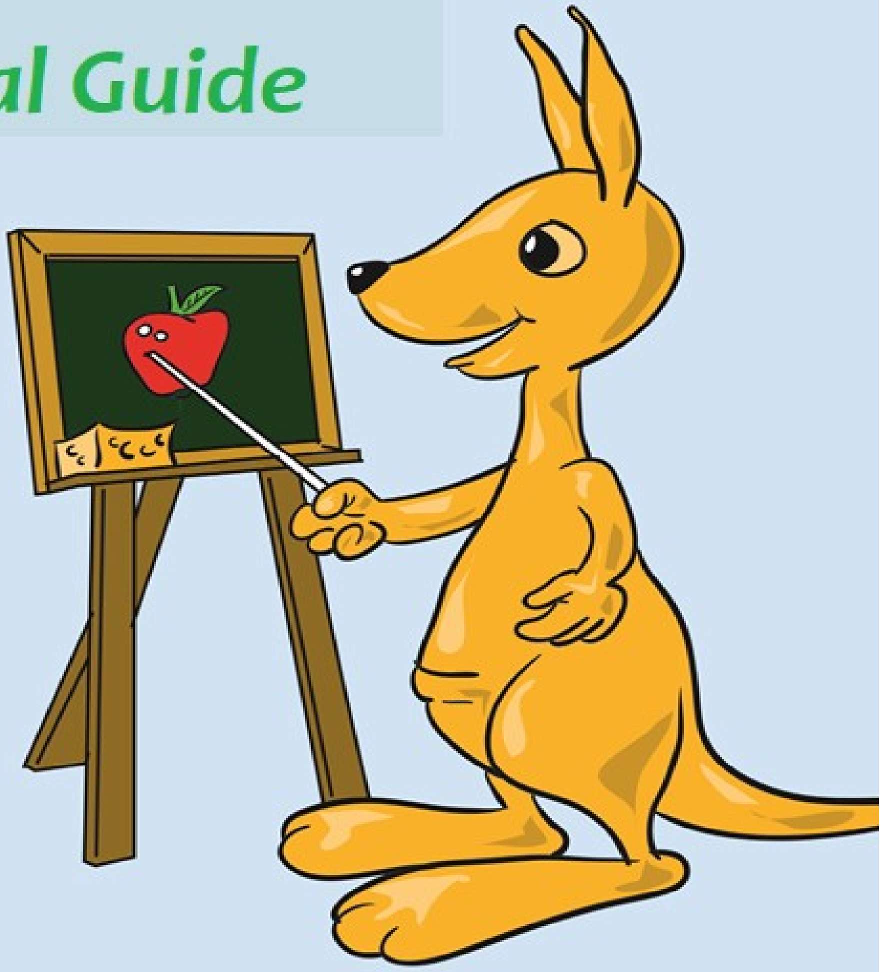
Appendix Glossary

A. ToyBox-Scotland General Practitioner's Guide
B. cRCT study information sheet and consent form
C. Interview/focus group information sheets and consent forms
D. Food Frequency Questionnaire
E. Primary Caregiver Questionnaire
F. Post-intervention parental feedback survey
G. Topic guide for parent/caregiver interviews
H. Topic guide for preschool practitioner focus groups
I. Parental activity pack 1
J. Parental activity pack 2
K. Parental activity pack 3
L. Parental activity pack 4
M. Parental activity pack 5
N. Parental activity pack 6
O. Parental activity pack 7
P. Parental sticker wallchart

Appendix A

Taste and move adventures

Practitioner's General Guide



Authors:
Ludwig-Maximilians-University (LMU), Munich, Germany: Kristin Duvinage, Sabine Ibrügger, Berthold Koletzko
State Institute of Early Childhood Research (IFP), Munich, Germany: Andreas Wildgruber, Susanne Kreichauf
Ghent University (UGent), Ghent, Belgium: Marieke De Craemer, Ellen De Decker, Lea Maes, Greet Cardon, Ilse De Bourdeaudhuij
Harokopio University (HUA), Athens, Greece: Yannis Manios, Odysseas Androutsos, Eftychia Apostolidou
Medical University of Varna (MUV), Varna, Bulgaria: Mina Lateva, Violeta Iotova, Natalya Usheva, Sonya Galcheva, Vanya Marinova Children's Memorial Health Institute (CMHI), Warsaw, Poland

Contributors:
Roehampton University (RoU), London, United Kingdom: Leigh Gibson
VU University Medical Center (VUMC), Amsterdam, The Netherlands: Mai Chin A Paw, Saskia te Velde
AOK-Publishing Company (AOK), Remagen, Germany
Durham University (UDUR), Durham, United Kingdom: Carolyn Summerbell, Helen Moore, Catherine Nixon
University of Zaragoza (UniZar), Zaragoza, Spain: Luis A. Moreno Aznar, Theodora Mouratidou, Maria Isabel Mesana Graffe

Nursery activity packs adapted by Stephen Malden, Jacqui Glover, Adrienne Hughes, Ann-Marie Gibson, Farid Bardid and John Reilly for use with Scottish nurseries.

Home intervention components for ToyBox-Scotland were designed and created by Stephen Malden and Miruna-Diana Mateescu.

Photographs:
AOK-Publishing Company, Remagen, Germany

Publisher/ Illustrations, Graphic and Sales:
AOK-Publishing Company, Lilienthalstr. 1-3, 53424 Remagen, Germany

We acknowledge the adoption of concepts and ideas from previous programmes such as ENERGY, POP, Cretan Health and Nutrition Intervention programme, and of text and material from TigerKids.

The research leading to these results and the creation of this material has received funding from the European Union's Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 245200.

The adaptation of materials and implementation of the Toybox intervention in Scotland is funded by the Cunningham Trust through a PhD studentship for Stephen Malden

For further information and reproduction purposes please visit the Toybox website: www.toybox-study.eu

Contents

The programme- ToyBox-Scotland: Taste and Move Adventures…………………… 4
Why we need ToyBox……………………………………………………………………………… 4
How has the programme been developed?...4
Part 1: Implementation of the ToyBox programme………………………………..5
What does the ToyBox programme consist of?...5
What are the aims of ToyBox?...5
How is ToyBox aiming to promote these four behavioural objectives?....................................6
Which material will be used in the pre-school settings?...6
Part 1: Setting environmental changes in the nursery…………………………………..6
Part 2: Child performing the actual behaviour……………………………………………..6
Part 3: Playroom experiences………………………………………………………………………….6
Which material will be used at home?..6
How to implement the ToyBox programme?...7
Physical activity……………………………………………………………………………………………...7
Sedentary Behaviour (sitting time)………………………………………………………...7
What about safety issues during ToyBox?...8
ToyBox-Scotland Timetable………………………………………………………………..9
Part 2: How ToyBox can contribute to children's learning and development……….10
How does ToyBox fit with the Curriculum for Excellence Health and Wellbeing Experiences and Outcomes?..10

The Little Kangaroo: role model and friend………………………………………………………….10
Part 3: Home elements of ToyBox…………………………………………………………………11
Collaboration with parents in ToyBox…………………………………………………………..11
What materials will parents receive?...11
References……………………………………………………………………………………………….12

The programme- ToyBox-Scotland: Taste and Move Adventures

Why we need ToyBox

In Scotland, the number of overweight children has significantly increased over the past two decades. Specifically, recent reports have indicated that almost one in three Scottish primary school children are overweight or obese. Targeting the causes of overweight and obesity at an early age can help to prevent more children becoming overweight as they get older.

The main causes of obesity in childhood are a lack of physical activity, long periods of sitting, and unhealthy diets consisting of sugary snacks and fatty foods. Pre-schools and nurseries have been at the forefront of trying to change this for a number of years in Scotland, and are a good setting to focus on changing these behaviours for the better. There is also a need to address some of these behaviours in the home too.

In order to actively support children's health and development, and minimise the risk of overweight and obesity, we have developed the programme "ToyBox Scotland – Taste and move adventures". With ToyBox we provide you with a programme that helps you to promote and incorporate more physical activity and movement breaks into the daily nursery routine. We have also developed some materials and activities for parents/guardians to do with children in the home or outside of nursery, to target all behaviours that contribute to obesity at home as well.

How has the programme been developed?

A multidisciplinary team of researchers from ten countries originally joined forces to develop this programme. As it was originally developed in Europe, the team here in Scotland has spent a year adapting and altering the programme so that it fits better with Scottish nursery policies and practices. We have worked with an early years' practitioner to develop the materials, and have tried out the experiences and activities in a Scottish nursery to get feedback on what works, and what does not work.

We hope you as early years practitioners enjoy delivering the programme and we especially hope the children enjoy being involved in ToyBox-Scotland!

Part 1: Implementation of the ToyBox programme

What does the ToyBox programme consist of?

The ToyBox programme was developed based on the latest scientific evidence regarding childhood obesity. We have been careful in the development of the programme to ensure that it does not create an extra workload for practitioners, but instead should make adding physical activity and movement breaks into the daily nursery routine easier than it has been in the past. The activities developed for ToyBox-Scotland are designed to meet a number of the health & wellbeing experiences and outcomes set out by Education Scotland in the Curriculum for Excellence.

Your pre-school will receive a number of materials that will enable delivery of the programme. The ToyBox intervention material consists of:

- **The practitioner's General Guide:** This handbook gives you an overview of the ToyBox-Scotland programme and some general tips on implementation.
- **The Playroom Experiences Guides:** two handbooks, one focusing on physical activity and the other on sedentary behaviour.

- **Materials for parents/guardians:** the research team will provide different materials throughout the course of the programme to be given to parents/guardians.
- **Additional material:** such as the kangaroo puppet and different play equipment for specific playroom experiences.

What are the aims of ToyBox?

ToyBox-Scotland aims to promote the healthy growth and development of pre-school children, and minimise the risk of early onset obesity. To reach these goals, the current programme has set four behavioural objectives outlined here.

Objectives:

1. Children drink water instead of sugary drinks to quench thirst*
2. Children consume healthy snacks*
3. Children are physically active
4. Children interrupt prolonged periods of sitting with active breaks

*Most Scottish nurseries already have their own policies in place, which address water consumption and healthy eating. ToyBox-Scotland will target these behaviours in the home environment.

How is ToyBox aiming to promote these four behavioural objectives?

By assisting early years practitioners and parents to create a supportive social and physical environment both at pre-school and at home to promote these behaviours.

Which material will be used in the pre-school settings?

The two Playroom Experience Guides, each one focusing on one of the targeted behaviours, contain all the information and instructions on how the programme can be delivered in the pre-school setting. Each of the Playroom experience guides is divided into three parts.

Part 1: Setting environmental changes in the nursery

This part will provide you with ideas on how you could change your playrooms and nurseries so that they are a physical activity-friendly environment. For a lot of preschools, this is already the case and only minimal changes will be needed. For others with less space, it may be a bit more difficult. However, ToyBox aims to provide you with tips and ideas to help you achieve this!

Part 2: Child performing the actual behaviour

This section includes various games, experiences and activities that can be incorporated into the daily pre-school day that will increase physical activity and reduce time spent sitting and being inactive.

Part 3: Playroom experiences

Part three of the packs contains various examples of additional playroom experiences that you can include in your daily/weekly nursery routine. Feel free to choose from these activities according to the needs of your class. However, we recommend combining activities for a minimum of one hour per week. For example, you could combine one kangaroo story and one game in one week. Of course, if the circumstances allow, it would be good to implement more activities!

More information on how to make the environmental changes (part 1), on how to perform the actual behaviour (part 2) or on playroom experiences (part 3) can be found in the playroom experiences guides.

Which material will be used at home?

ToyBox-Scotland aims to help parents/guardians make positive changes to their children's eating, drinking, physical activity and sitting time at home. Targeting these behaviours in the home environment can be very challenging, parents are often busy, or may not be aware of how best to go about changing their child's behaviour. ToyBox-Scotland will provide parent-child activity packs to be handed out to parents every 2-3 weeks during the programme. These packs contain simple parent-child games and experiences which promote healthy eating, water consumption, physical activity and movement breaks. Children will receive a Scottish Active Animal-themed sticker chart, which parents can award the provided stickers for when their child completes the weekly experiences.

How to implement the ToyBox programme?

What, When and How? On page 9 will see a diagram that gives a rough example of when to 1. Set up the nursery environment, 2. When to deliver physical activity experiences, 3. When to deliver sedentary behaviour experiences and 4. When to hand out parent/guardian activity packs.

Below is a diagram showing the basic structure of the ToyBox-Scotland programme. After making environmental changes to the nursery in the first week, you will then spend 3 weeks focusing on physical activity using the provided playroom experience guide and materials. The focus will then switch to sedentary behaviour, and you will spend the following 3 weeks using the experiences detailed in the sedentary behaviour playroom experiences pack. This pattern continues for the first 12 weeks, before the last six weeks are alternated between physical activity and sedentary behaviour on a fortnightly basis, then a weekly basis. As you can see in the diagram, while we only focus on physical activity and sedentary behaviour in nursery, we will also be focusing on eating/snacking and water consumption at home. The research team will provide the parent activity packs when they are due to be handed out, roughly every 3 weeks. A more detailed example of the timetable for ToyBox-Scotland is available on page 9.

	Implementation Phase (March 2018 to June 2018)															
	First Phase								Repetition Phase							
Weeks	3 weeks		3 weeks		3 weeks		3 weeks		2 week		2 week		1 week		1 week	
Nursery Focus	Physical activity		Sedentary behaviour		Physical activity		Sedentary behaviour		Physical activity		Sedentary behaviour		Physical activity		Sedentary behaviour	
Home Focus	DN	PA	WC	SB	DN	PA	WC	SB	DN	PA	WC	SB	DN	PA	WC	SB

DN= diet & nutrition, PA= physical activity, WC= water consumption, SB= sedentary behaviour

Physical activity

During these weeks, physical activity is in the spotlight. ToyBox has developed 11 structured physical activity experiences. During the first week that physical activity is being emphasised we ask you to start a structured physical activity program of 2 sessions per week. We realise that materials and space for such sessions are often limited; therefore ToyBox sessions require minimal materials and limited space or can also be organised outdoors. You can choose the sessions that are feasible in your setting. If you already have structured physical activity sessions in place, that’s great! The ToyBox physical activity experiences may give you some extra ideas. Unstructured play can be just as important as structured activity, feel free to allow the children to play with the materials provided on their own and come up with their own variations of the experiences to encourage child-led learning.

Sedentary Behaviour (sitting time)

During these weeks, ToyBox focuses on promoting less sitting. Again, you can choose from the fun playroom experiences and stories that address this behaviour and integrate this in your daily/weekly routine. It would be good if you could spend a minimum of one hour per week on these activities and stories. If you can do more, that’s even better! The environmental changes to the nursery will play a major role in changing sedentary behaviour. Removing or reducing the number of chairs in the playroom and creating “movement corners” will help you achieve this.

Along with the activities and stories, ToyBox has also developed movement breaks. It would be great if you could do at least two short movement breaks on a daily basis, one in the morning and one in the afternoon. When you focus on sedentary behaviour, it would be great if you could do four movement breaks each day: twice in the morning and twice in the afternoon. Of course, if you already have policies/activities in place for breaking up sitting time, that’s great. You can choose to continue using your own tricks to interrupt sitting time. Finally, ToyBox also suggests that you remind the children every 30 – 40 minutes throughout the day to interrupt their sitting behaviour.

What about safety issues during ToyBox?

ToyBox-Scotland was designed with safety in mind, so as long as you feel the particular activity or experience meets your nurseries' health and safety policy, there should be no issues with safety.

ToyBox-Scotland Timetable

Dates:	5th March																	26th June
Week	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Get familiar with materials	✓																	
Set-up nursery	✓																	
Physical activity	✓	✓	✓				✓	✓	✓				✓	✓			✓	
Sedentary behaviour				✓	✓	✓				✓	✓	✓			✓	✓		✓
Nursery visits			✓								✓							
Home activities 1	✓																	
Home activities 2				✓														
Home activities 3							✓											
Home activities 4										✓								
Home activities 5													✓					
Home activities 6															✓			
Home activities 7																	✓	

Legend	Term time	Easter break	Collect data

Part 2: How ToyBox can contribute to children’s learning and development

ToyBox has been designed with both health and learning in mind. In addition to increasing physical activity and preventing obesity, the original aims of the programme are to help children develop basic movement skills, social skills, and cognitive abilities. Preschool age children need hands-on experiences where they can be active themselves. You can support them by stimulating as many senses and early cognitive abilities as possible in through the games and experiences provided in the playroom experiences guides. In ToyBox we have included many such activities in the physical activity sessions or short movement breaks. The more a child participates and is involved, the more he/she will learn and develop.

How does ToyBox fit with the Curriculum for Excellence Health and Wellbeing Experiences and Outcomes?

When adapting the ToyBox programme for use in Scottish pre-schools, we worked with an early years’ practitioner to identify the health and wellbeing e’s and o’s that can be applied to the different sessions and experiences within the ToyBox programme. The e’s and o’s detailed below can be set against most of the activities in ToyBox, however they may differ depending on the practitioner’s delivery and the individual children.

ToyBox CfE Health and Wellbeing experiences and outcomes:

I value the opportunities I am given to make friends and be part of a group in a range of situations. HWB 0-14a
I am learning to move my body well, exploring how to manage and control it and finding out how to use and share space. HWB 0-21a
I am developing my movement skills through practice and energetic play. HWB 0-22a
By exploring and observing movement, I can describe what I have learned about it. HWB 0-24a
I am enjoying daily opportunities to participate in different kinds of energetic play, both outdoors and indoors. HWB 0-25a
I can describe how I feel after taking part in energetic activities and I am becoming aware of some of the changes that take place in my body. HWB 0-28a
I am aware of my own and others’ needs and feelings especially when taking turns and sharing resources. I recognise the need to follow rules. HWB 0-23a
I know that being active is a healthy way to be. HWB 0-27a
I am learning about where living things come from and about how they grow, develop and are nurtured. HWB 0-50a
In everyday activity and play, I explore and make choices to develop my learning and interests. I am encouraged to use and share my experiences.HWB 0-19a
I know and can demonstrate how to travel safely.HWB 0-18a

The Little Kangaroo: role model and friend

The Kangaroo stories that are used throughout ToyBox are designed to help the children learn about physical activity and sedentary behaviour. These sessions are designed to be interactive and enjoyable, and you can use the provided kangaroo puppet to engage the children in the stories.

Part 3: Home elements of ToyBox

The parents/guardians are the children's most important caregivers and therefore targeting the behaviours which lead to obesity in the home is critical if programmes like ToyBox are to be successful.

Collaboration with parents in ToyBox

It is important for parents to recognise that healthy eating and drinking, more physical activity and decreased sedentary time are important for the health and development of their child. In most Scottish pre-schools, unhealthy snacks and drinks are not permitted, so with ToyBox-Scotland we plan to target these behaviours in the home along with physical activity and sedentary behaviour. We will use the original posters and tip cards for parents, along with a newly designed programme of parent-child activities, which aim to increase children's consumption of healthy snacks, reduce their consumption of unhealthy snacks and drinks, increase water consumption, increase physical activity and reduce sedentary behaviours. These activities are designed to be simple and fun, and will hopefully increase parent's knowledge around these health behaviours and encourage them to make healthier choices regarding snacks, sugary drinks and physical activity at home.

What materials will parents receive?

Parents will receive activity packs roughly every three weeks from the preschool. These will contain a sticker chart, stickers, instructions for weekly activities, and any materials that are needed for the activities. All the activities are totally voluntary, but the more they and their child participate in them, the greater the benefits! Even if parents don't complete the activities, the materials may lead to an increase in their knowledge surrounding childhood obesity prevention.

Here are some examples of the materials that will be given to parents for interactive parent-child activities:

Children's Sticker chart

Poster

xample of parent-child ctivity- fruit highland ow

Appendix B

Participant Information Sheet for the Toybox study

Department: Physical Activity for Health Group,

School of Psychological Sciences and Health

Title of the study: **Increasing physical activity and healthy behaviours at nursery and at home: the Toybox Study**

Introduction

Hello, my name is Stephen Malden and I am a student researcher working with the Physical Activity for Health department at the University of Strathclyde in Glasgow. I am working on a project called Toybox, which is using fun, teacher-led activities in the nursery to increase children's physical activity and decrease the amount of sitting they do. We also want to try and change some of these behaviours in the home.

email: stephen.malden@strath.ac.uk

What is the purpose of this investigation?

The purpose of this study is to find out if the Toybox programme we have designed is suitable for use in Scottish nurseries, and whether it has positive effects on children's physical activity, sitting time, diet and sleep.

Does your child have to take part?

No your child does not need to take part in our study. Participation is voluntary and if you and your child decide to take part, you and your child are free to withdraw from the study at any time.

What will they do in the project?

If you AND your child are happy to be involved in this study, your child will be required to wear a small electronic device called an ActivPAL monitor for seven days in a row while at nursery and at home. The Activpal is a small device (about the size of a £2 coin) that is worn on the upper leg and fixed in place with a waterproof tape. This tape is hypoallergenic, (it rarely causes allergic reactions) and has been used with children of this age in other scientific studies without any problems. The device will be fitted by me with the assistance of your child's nursery teacher, and then they will wear the device for seven days before I come back to the nursery to remove it. The tape makes the device waterproof so your child can wear it in the bath/shower. This device will record all your child's movements and will provide us with information on the amount of time spent sitting, sleeping and moving around, and whether they are indoors or outdoors. You will also be asked to complete a short questionnaire about what your child eats and drinks while at home, and some general information about your family. We will also measure your child's height and weight, and will measure their body composition (fat mass and muscle mass) using a specially designed machine that uses sticky electrodes on the hands and feet. Your child will be asked to lie still for about one minute while we take the readings. While they do this we will chat to them about their day and hobbies etc. All the procedures are harmless and painless, and have been used in other studies involving young children with no issues.

Why has your child been invited to take part?

You are being asked to give permission for your child to participate in this study as your child's nursery is delivering the Toybox programme and we would like to see if it is having any effect on the health behaviours of children who have received the programme. Please be aware that your relationship with your child's nursery will NOT be affected by your decision to either take part or not.

What are the potential risks to your child in taking part?

There are no foreseeable risks in taking part in this study as all measurements are painless and safe. Nothing is likely to go wrong. But in the unlikely case that something does go wrong, for example if your child feels unwell, then their health will be the priority and the study will be stopped while they receive the appropriate care. Remember you can withdraw your child from the study at any time.

What happens to the information in the project?

At all times, participants' confidentiality will be maintained. Participant names or contact details will not be identifiable and participants will remain anonymous in any reporting of data.

The information collected as part of the study about your child will be downloaded onto a secure, password protected computer by the research team. The questionnaires completed by you will be given directly to the research team who will then look at all the results and write a short report. Once all the reports have been written, all the information collected will be deleted and paper copies will be locked in filing cabinets in the research department. Only the research team will have access to the information about you and your child, and this will not be shared with anyone.

What happens next?

If you understand the information and are happy for your child to be involved in the study, please sign and date the consent form below.

If you do not want your child to be involved in the study, thank you for your time and attention.

Researcher contact details:

Stephen Malden

PhD student

Physical Activity for Health Group

School of Psychological Science, Graham Hills Building,

University of Strathclyde, 50 George Street

GLASGOW

G1 1QE email: Stephen.Malden@strath.ac.uk

Chief Investigator details:

John J Reilly
Professor of Physical Activity and Public Health Science
Physical Activity for Health Group, School of Psychological Sciences and Health
University of Strathclyde,
Graham Hills Building (Room 531)
50 George Street
Glasgow
G1 1QE
Tel: 0141 548 4235

This investigation was granted ethical approval by the School of Psychological Sciences and Health Ethics Committee.

If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Dr Diane Dixon
Chair of the School of Psychological Sciences and Health Ethics Committee
School of Psychological Sciences and Health
University of Strathclyde
Graham Hills Building
40 George Street
Glasgow
G1 1QE Telephone: 0141 548 2571

Email: hass-psh-ethics@strath.ac.uk

Parent/guardian Consent Form

The Toybox Study

Department: Physical Activity for Health Group,

School of Psychological Sciences and Health

- ☐ I confirm that I have read and understood the information sheet for the above project and the researcher has answered any queries to my satisfaction.
- ☐ I understand that my participation, and that of my child/ren (named below) is voluntary and that I am free to withdraw from the project at any time, up to the point of completion, without having to give a reason and without any consequences. If I exercise my right to withdraw and I don't want my data to be used, any data which have been collected from me will be destroyed.
- ☐ I understand that my child will be asked to wear a small device on their leg for 7 days, and they will be asked to wear sticky electrodes for 1 minute to measure their fat mass and muscle mass.
- ☐ I understand that the measurements in this study are harmless, but that my child can stop at any time if they are uncomfortable
- ☐ I confirm that I have full parental rights over my child/ren (named below).
- ☐ I understand that I can withdraw myself and my child/ren (named below) from the study at any time.
- ☐ I understand that anonymised data (i.e. .data which do not identify me personally) cannot be withdrawn once they have been included in the study.
- ☐ I understand that any information recorded in the investigation will remain confidential and no information that identifies me will be made publicly available.
- ☐ I consent to being a participant in the project
- ☐ I consent to my child/ren (named below) to be a participant in the project

……………………………………………………………………

Parent/carer 1 sign: ____________________ Print name:____________________
Date:

Child

Name DOB

____

Researcher Sign: ______________________ Print name:

Appendix C

Participant Information Sheet for the Toybox study

Department: Physical Activity for Health Group,

School of Psychological Sciences and Health

Title of the study: **Increasing physical activity and healthy behaviours at nursery and at home: the Toybox Study**

Introduction

Hello, my name is Stephen Malden and I am a student researcher working with the Physical Activity for Health department at the University of Strathclyde in Glasgow. As you may know I am the researcher who has been working on the Toybox study which you have been delivering to your nursery class this term.

email: stephen.malden@strath.ac.uk

What is the purpose of this investigation?

We are testing the feasibility of the Toybox programme, and this study will provide us with further information regarding how teachers feel about the programme.

Do you have to take part?

No you do not need to take part in our study. Participation is voluntary and you are free to withdraw from the study at any time.

What will you do in the project?

If you are happy to be involved in this study, you will be asked to take part in either a focus group or interview with one of our researchers. This will involve having an informal discussion about topics such as your opinion on the Toybox programme including how it impacted on you/the children, any barriers to delivery or unforeseen issues that arose during delivery.

Why have you been invited to take part?

You are being asked to take part in this study as you are an early years education practitioner at a nursery which has been delivering the Toybox programme over the past 6 months.

What are the potential risks to you in taking part?

There are no foreseeable risks in taking part in the focus group/interview. Nothing is likely to go wrong. But in the unlikely case that something does go wrong, for example if you feel unwell, then the focus group/interview can be stopped at any time or you are free to leave the room at any time without giving any explanation.

What happens to the information in the project?

At all times, participants' confidentiality will be maintained. Participant names or contact details will not be identifiable and participants will remain anonymous in any reporting of data.

The voice recordings from the interview/focus group will be downloaded onto a secure, password protected computer by the research team and the recording will be deleted from the recording device. Once all the report has been written, all the information collected will be deleted and paper copies will be locked in filing cabinets in the research department.

What happens next?

After you have read this information sheet, you can then choose if you want to take part in the study or not. If you would like to take part, please complete the sheet labelled 'Consent form'.

If you do not want to be involved in the focus group/interview, thank you for your time and attention.

Researcher contact details:

Stephen Malden

PhD student

Physical Activity for Health Group

School of Psychological Science, Graham Hills Building,

University of Strathclyde, 50 George Street

GLASGOW

G1 1QE email: Stephen.Malden@strath.ac.uk

Chief Investigator details:

John J Reilly
Professor of Physical Activity and Public Health Science

Physical Activity for Health Group, School of Psychological Sciences and Health
University of Strathclyde,
Graham Hills Building (Room 531)
50 George Street
Glasgow
G1 1QE
Tel: 0141 548 4235

This investigation was granted ethical approval by the School of Psychological Sciences and Health Ethics Committee.

If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Dr Diane Dixon
Chair of the School of Psychological Sciences and Health Ethics Committee
School of Psychological Sciences and Health
University of Strathclyde
Graham Hills Building
40 George Street
Glasgow
G1 1QE Telephone: 0141 548 2571
Email: hass-psh-ethics@strath.ac.uk

Parent/guardian Consent Form

The Toybox Study

Department: Physical Activity for Health Group,

School of Psychological Sciences and Health

☐ I confirm that I have read and understood the information sheet for the above project and the researcher has answered any queries to my satisfaction.

☐ I understand that my participation is voluntary and that I am free to withdraw from the project at any time, up to the point of completion, without having to give a reason and without any consequences. If I exercise my right to withdraw and I don't want my data to be used, any data which have been collected from me will be destroyed.

☐ I understand that I can withdraw myself from the study at any time.

☐ I understand that anonymised data (i.e. .data which do not identify me personally) cannot be withdrawn once they have been included in the study.

☐ I understand that any information recorded in the investigation will remain confidential and no information that identifies me will be made publicly available.

☐ I consent to being a participant in the project

☐ I consent to having my voice recorded for this project

....

Participant 1 sign: ____________________ Print name:____________________
Date:

Researcher Sign: ______________________ Print name: ____________________
Date:

Participant Information Sheet for the Toybox study

Department: Physical Activity for Health Group,

School of Psychological Sciences and Health

Title of the study: **Increasing physical activity and healthy behaviours at nursery and at home: the Toybox Study**

Introduction

Hello, my name is Stephen Malden and I am a student researcher working with the Physical Activity for Health department at the University of Strathclyde in Glasgow. I am working on a project called Toybox which is looking to use fun, practitioner-led activities in the nursery to increase children's physical activity and decrease the amount of sitting they do. We also wanted to try and change some of these behaviours in the home too.

email: stephen.malden@strath.ac.uk

What is the purpose of this investigation?

As part of the Toybox programme, we wanted to target some behaviours in the home, specifically the amount of time children spend being active, watching tv or playing with electronic devices (tablets, games consoles), healthy eating, and sleeping. By speaking to you as part of this study, we hope to find out more about what parents thought of the activities and games we provided to parents as part of the programme this term.

Do you have to take part?

No you do not need to take part in our study. Participation is voluntary and you are free to withdraw from the study at any time.

What will you do in the project?

If you are happy to take part in this study, we will arrange for you to attend your child's nursery to take part in an interview with the researcher (Stephen Malden). This will be conducted in a private room with the researcher and will involve an informal discussion about various activities from Toybox and how you felt about these activities. This conversation will be audio recorded by the researcher and written down afterwards. Everything discussed will remain confidential and you won't be personally identified in any reports.

Why have you been invited to take part?

As you are a parent at one of the nurseries that has been delivering the Toybox programme, we would like to speak to you about some of the home-based activities and materials that were provided to parents over the course of the programme.

What are the potential risks to you in taking part?

There are no foreseeable risks in taking part in the interview. In the unlikely case that something does go wrong, for example if you feel unwell, then the interview can be stopped at any time or you are free to leave the room at any time without giving any explanation.

What happens to the information in the project?

At all times, participants' confidentiality will be maintained. Participant names or contact details will not be identifiable and participants will remain anonymous in any reporting of data.

The voice recordings from the interview will be downloaded onto a secure, password protected computer by the research team. Once all the report has been written, all the information collected will be deleted and paper copies will be locked in filing cabinets in the research department.

What happens next?

After you have read this information sheet, you can then choose if you want to take part in the study. If you do, please complete the consent form below and let a member of nursery staff know that you are interested and we will arrange a suitable time to do the interview.

If you do not want to be involved in the interview, thank you for your time and attention.

Researcher contact details:

Stephen Malden

PhD student

Physical Activity for Health Group

School of Psychological Science, Graham Hills Building,

University of Strathclyde, 50 George Street

GLASGOW

G1 1QE email: Stephen.Malden@strath.ac.uk

Chief Investigator details:

John J Reilly
Professor of Physical Activity and Public Health Science
Physical Activity for Health Group, School of Psychological Sciences and Health
University of Strathclyde,
Graham Hills Building (Room 531)
50 George Street
Glasgow

G1 1QE
Tel: 0141 548 4235

This investigation was granted ethical approval by the School of Psychological Sciences and Health Ethics Committee.

If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Dr Diane Dixon
Chair of the School of Psychological Sciences and Health Ethics Committee
School of Psychological Sciences and Health
University of Strathclyde
Graham Hills Building
40 George Street
Glasgow
G1 1QE Telephone: 0141 548 2571
Email: hass-psh-ethics@strath.ac.uk

Parent/guardian Consent Form

The Toybox Study

Department: Physical Activity for Health Group,

School of Psychological Sciences and Health

☐ I confirm that I have read and understood the information sheet for the above project and the researcher has answered any queries to my satisfaction.

☐ I understand that my participation is voluntary and that I am free to withdraw from the project at any time, up to the point of completion, without having to give a reason and without any consequences. If I exercise my right to withdraw and I don't want my data to be used, any data which have been collected from me will be destroyed.

☐ I understand that I can withdraw myself from the study at any time.

☐ I understand that information I provide may be used for publications, but that no identifiable information will be included in these publications

☐ I understand that any information recorded in the investigation will remain confidential and no information that identifies me will be made publicly available.

☐ I consent to being a participant in the project

☐ I consent to having my voice recorded for this project

....

Participant 1 sign: ______________________ Print name:______________________
Date:

Researcher Sign: ________________________ Print name: ______________________
Date:

Food Frequency Questionnaire for Young Children

This short questionnaire asks a few questions about your child's daily snacking and drinking habits. Please indicate your answer with a tick or an X next to the statement that most accurately describes your child.

Todays date:

Your current postcode:

<u>Treats and snacks</u>

1a How often does your child eat fresh fruit?

○ never or less than once per month
○ 1-3 days per month
○ 1 day per week
○ 2-4 days per week
○ 5-6 days per week
○ every day

1b. How many portions of fruit does your child usually eat *<u>per day?</u>* (one portion is roughly equal to the amount of fresh fruit they can fit in their hand)

○ less than one per day
○ 1
○ 2
○ 3
○ 4
○ 5
○ More than 5

2a. How often does your child eat sugary snacks (such as chocolate bars, chocolate biscuits or sweeties)?

○ Never or less than once per month
○ 1-3 days per month
○ 1 day per week
○ 2-4 days per week
○ 5-6 days per week
○ every day

2b. How many portions of sugary snacks does your child usually eat *<u>per week?</u>* (one portion is roughly equal to a small chocolate bar such as a mars milky way, or one chocolate biscuit)

○ Less than one per week
○ 1-2 portions per week
○ 3-4 portions per week
○ 5-6 portions per week
○ 7-8 portions per week
○ more than 8 portions per week

<u>Drinks</u>

3a. How often does your child drink water on its own? (without any other juices added)

○ never or less than once per month
○ 1-3 days per month
○ 1 day per week
○ 2-4 days per week
○ 5-6 days per week
○ every day

3b. How many cups of water does your child drink *<u>per day?</u>* (One cup is around 225ml)

○ Less than one per day
○ 1-2 per day
○ 3-4 per day
○ 5-6 per day
○ 7-8 per day
○ More than 8 per day

4a. How often does your child drink sugary drinks? (Some examples are coca cola, irn bru, non-sugar free diluting juice)

○ never or less than once per month
○ 1-3 days per month
○ 1 day per week
○ 2-4 days per week
○ 5-6 days per week
○ every day

4b. How many cups of sugary juice does your child drink *<u>per day?</u>* (One cup is around 225ml)

○ Less than one per day
○ 1-2 per day
○ 3-4 per day
○ 5-6 per day
○ 7-8 per day
○ More than 8 per day

Appendix E

Primary Caregiver's Questionnaire

Today's date

|__|__| |__|__| |__|__|__|__|

Day **Month** **Year**

The present questionnaire is available for free use with the obligation to explicitly reference the Toybox-study (www.toybox-study.eu)

Dear Parents/Caregivers,

Your child's nursery is participating in the ToyBox-Scotland study this term, and you have kindly agreed to allow your child to take part in the study. We very much hope that you are willing to fill in this questionnaire. Your participation is voluntary. All answers will be treated in strict confidence in accordance with the regulations regarding data protection, and the information will only be used for research purposes. No one will be given access to your answers except for the researchers. You do not need to put your name on the questionnaire. When you have answered the questionnaire please return it to your Child's nursery practitioner. If you have any

other queries or want further information please contact Stephen Malden at Stephen.malden@strath.ac.uk or by calling 07765486691. You can find out more info on the ToyBox website: http://www.toybox-study.eu/
Yours sincerely,
Stephen Malden and the research team

How to complete the questionnaire

- In sections B, C, D and E we ask firstly questions about YOU and then for YOUR child.
- Please complete the questionnaire using **a blue or black pen.**
- Most of the questions can be answered by placing a clear **X** in the answer box. Mark only one box per question unless multiple answers can be given. This will be indicated next to the question.
- In some questions we ask you to write your own answer.

EXAMPLE:

How far is your child's preschool located from your home?

☐1 Up to 500 metres

☐2 From 500 metres to <1 kilometre

☒3 From 1 kilometre to <2 kilometres

☐4 From 2 kilometres to <3 kilometres

☐5 From 3 kilometres to <4 kilometres

☐6 4 kilometres or more

A. Socio-demographic Questions

The following questions are for the person who is answering this questionnaire. Ideally this person must be the child's primary caregiver. Please answer all

questions and fill in what applies to you or your situation. It is important to remember that there are no right or wrong answers.

This questionnaire is filled in by…

❑1 The mother
❑2 The stepmother
❑ 3The father
❑4 The stepfather
❑5 Other (please state by whom ....)

A0. What is your current postcode? ....

A1. Was your child born in Scotland?
❑1 Yes ❑2 No, he/she was born in: ....

A2. Was the biological mother of your child born in Scotland?
❑1 Yes ❑2 No, she was born in:
.... ❑3 I don't know

A3. Was the biological father of your child born in Scotland?
❑1 Yes ❑2 No, he was born in:
.... ❑3 I don't know

A4. In what language(s) do you usually/mainly speak with your child at home? ❑1 English
❑2 Other language, please specify: ....

A5. Which adults does your child live with? (You can mark more than one box)
❑1 With both his/her mother and father
❑2 Only with his/her mother
❑3 Only with his/her father
❑4 With his/her mother and her new partner
❑5 With his/her father and his new partner (more options on next page) ❑6 With his/her grandparents
❑7 Other adults (please specify)………………………

How many persons live permanently in the household where your child usually lives? A6. Number of persons 18 years or above: |__| person(s). **A7.** Number of persons below 18 years: |__| person(s).

How many years of school education did you and your spouse/partner complete? Please mark one option for you and one option for your spouse/partner (do not count years in preschool. Start from age 5)

	A8. Me	A9. Spouse/partner	A10. I do not have a spouse/ partner
Less than 7 years	❑1	❑1	❑1
7-12 years	❑2	❑2	
13-14 years	❑3	❑3	
15-16 years	❑4	❑4	
More than 16 years	❑5	❑5	

What is the main occupation of you and your spouse/ partner over the last 6 months?

	A11. Me	A12. Spouse/partner	A13. I do not have a spouse/ partner
Full time housework	❑1	❑1	❑1
Work full-time	❑2	❑2	
Work part-time	❑3	❑3	
Unemployed	❑4	❑4	
Full-time education	❑5	❑5	
Sick/disabled	❑6	❑6	
Something else	❑7	❑7	

A14. What is the gender of your child?

❑1Male ❑2 Female

A15. On which day/month/year your child was born?

|___|___| Day |___|___| Month |___|___|___|___| Year

A16. How many days per week does your child usually attend childcare? |___| Days

A17. How many hours per day does your child usually attend childcare?

|___|___| Hours

A18. What do you think about your child's weight?

❑1 My child's weight is very low

❑2 My child's weight is low

❑3 My child's weight is not too low/ not too high

❑4 My child's weight is high

❑5 My child's weigh is very high

How many hours of sleep does your child usually have during the night? (Please mark one box for weekdays and one box for weekend days)

A19. Weekdays **(average per night)**	**A20.** Weekend days **(average per night)**
❑1 Less than 6 hours	❑1 Less than 6 hours
❑2 6-7 hours	❑2 6-7 hours
❑3 8-9 hours	❑3 8-9 hours
❑4 10-11 hours	❑4 10-11 hours
❑5 12-13 hours	❑5 12-13 hours
❑6 14 hours	❑6 14 hours
❑7 More than 14 hours	❑7 More than 14 hours
❑8 I don't know	❑8 I don't know

Thinking on the number of times and the duration of naps your child usually takes; Please indicate the <u>TOTAL TIME SPEND TAKING NAPS PER DAY.</u> (Please mark one box for weekdays and one box for weekend days)

A21. Weekdays **(average per week day)**	**A22.** Weekend days **(average per weekend day)**
❑1 My child does not take naps on weekdays	❑1 My child does not take naps on weekend days

❑2 Less than 1 hour	❑2 Less than 1 hour
❑3 1-2 hours	❑3 1-2 hours
❑4 3-4 hours	❑4 3-4 hours
❑5 5-6 hours	❑5 5-6 hours
❑6 7-8 hours	❑6 7-8 hours
❑7 9 or more hours	❑7 9 or more hours
❑8 I don't know	❑8 I don't know

What is the age, height and weight of parents/caregivers with whom your child lives with?

	Me	Spouse/partner
A29. Age	|___|___| years	|___|___| years
A30. Height	|__|__|__|(cm)	|__|__|__|(cm)
A31. Weight	|__|__|__|.|__|(kg)	|__|__|__|.|__|(kg)

B. Drinking behaviour

The following part of the questionnaire aims to assess the drinking behaviour your child. Please answer all questions. It is important to remember that there are no right or wrong answers. Fill in what applies to you or your situation.

When we say:
- **Water: we mean tap water, mineral water, natural sparkling or still water**
- **Soft drinks: we mean all sugared or sweet-flavoured beverages, carbonated or not, plain or light e.g. Cola and Cola light/zero, Ice Tea, 7-up, Pepsi, Fanta, Fanta non-carbonated, Sprite, Orangina etc**
- **Pre-packed juices: we mean all fruit juice-based products including 100% fresh juice bottled or in paper-pack, 30% fruit-juice with added sugared (nectar), sports drinks, smoothies, canned juices e.g. Life, Tropicana, Lemonade, Lucozade**

➢ QUESTIONS ABOUT YOUR CHILD

Please read the following statements and tick the boxes most appropriate to your situation:

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
B6. My child is allowed to drink soft drinks or prepacked juices whenever he/she asks for	❑1	❑2	❑3	❑4	❑5
B7. I make water always available for my child	❑1	❑2	❑3	❑4	❑5
B8. It is bad for my child to drink soft drinks everyday	❑1	❑2	❑3	❑4	❑5
B9. It is bad for my child to drink pre-packed juices everyday	❑1	❑2	❑3	❑4	❑5
B10. I encourage my child to drink water	❑1	❑2	❑3	❑4	❑5
B11. If I would like to drink soft drinks or pre-packed juices, I would try to restrain myself because of the presence of my child	❑1	❑2	❑3	❑4	❑5
B12. I am pleased with my child's water consumption	❑1	❑2	❑3	❑4	❑5
B13. My child prefers to drink soft drinks or pre-packed juices instead of water	❑1	❑2	❑3	❑4	❑5
B14. During meals, water is always available on the table	❑1	❑2	❑3	❑4	❑5

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

B15. I find it difficult to give my child water if he/she wants soft drinks or pre-packed juices	❑1	❑2	❑3	❑4	❑5
B16. My child does not enjoy drinking water	❑1	❑2	❑3	❑4	❑5
B17. I make soft drinks or pre-packed juices always available for my child	❑1	❑2	❑3	❑4	❑5
B18. My child's water consumption is within the appropriate recommendations	❑1	❑2	❑3	❑4	❑5
B19. My child can drink soft drinks or pre-packed juices as much as he/she likes	❑1	❑2	❑3	❑4	❑5
B20. I give soft drinks or pre-packed juices to my child as a reward or to comfort him/her	❑1	❑2	❑3	❑4	❑5
B21. During meals, soft drinks or pre-packed juices are always available on the table	❑1	❑2	❑3	❑4	❑5
B22. My child drinks soft drinks or pre-packed juices only on certain occasions e.g., birthdays	❑1	❑2	❑3	❑4	❑5

B23. How often do you think your child should drink soft drinks and pre-packed juices? 'please note that portions per week is the same as times per week'

❑1 Never
❑2 On certain occasions e.g., birthdays
❑3 1 glass or less per week ❑4
2-4 glasses per week
❑5 5-6 glasses per week
❑6 1-2 glasses per day
❑7 3-4 glasses per day
❑8 5 or more glasses per day
❑9 I don't know

B24. How many glasses of water do you think your child should drink daily?

❑1 None
or scarce

❑2 1 glass
per day
❑3 2 glasses per day
❑4 3 glasses per day
❑5 4 glasses per day
❑6 5 glasses per day

❑7 6 glasses per day
❑8 7glasses per day
❑8 8 or more glasses per day
❑9 I don't know

C. Snacking behaviour

The following part of the questionnaire aims to assess the snacking behaviour of your child. Please answer all questions. It is important to remember that there are no right or wrong answers.

When we say SNACKING, we mean all food items consumed as snacks in between the main meals of the day i.e. between breakfast and lunch (morning snack), between lunch and dinner (afternoon snack) and before going to bed (evening snack).
Examples of snacks include:
- pieces of fruits or vegetables, biscuits, yogurt (plain and flavoured), cereal bar, bread, packet of crisps, bar of chocolate etc

➢ QUESTIONS ABOUT YOUR CHILD

Please read the following statements and tick the boxes most appropriate to your situation for morning, afternoon and evening snacks

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
C23. My child likes to eat fruits or vegetables as a snack	❑1	❑2	❑3	❑4	❑5
C24. My child likes to eat dairy as a snack	❑1	❑2	❑3	❑4	❑5
C25. My child likes to eat cereals/bread as a snack	❑1	❑2	❑3	❑4	❑5
C26. I often give fruits or vegetables as snacks to my child	❑1	❑2	❑3	❑4	❑5
C27. I often give dairy as snacks to my child	❑1	❑2	❑3	❑4	❑5
C28. I often give cereals/bread as snacks to my child	❑1	❑2	❑3	❑4	❑5

C29. I make fruit or vegetables snacks regularly available for my child	❑1	❑2	❑3	❑4	❑5
C30. I make dairy snacks regularly available for my child	❑1	❑2	❑3	❑4	❑5
C31. I make cereals/bread snacks regularly available for my child	❑1	❑2	❑3	❑4	❑5
C32. My child chooses sweet or salty snacks, when fruit or vegetables snacks are available	❑1	❑2	❑3	❑4	❑5
C33. My child chooses sweet or salty snacks when other children eat fruit or vegetables snacks	❑1	❑2	❑3	❑4	❑5
C34. I think eating sweet or salty snacks is not bad for my child	❑1	❑2	❑3	❑4	❑5
C35. I make sweet or salty snacks regularly available for my child	❑1	❑2	❑3	❑4	❑5
C36. My child is not allowed to snack while watching TV	❑1	❑2	❑3	❑4	❑5
C37. My child is allowed to eat fruits or vegetables as snacks without asking	❑1	❑2	❑3	❑4	❑5

	Strongly disagree	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**
C38. My child is allowed to eat dairy or cereals/bread as snacks without asking	❑1	❑2	❑3	❑4	❑5
C39. My child is allowed to eat sweet or salty snacks only at certain occasions i.e., birthdays	❑1	❑2	❑3	❑4	❑5
C40. I give sweet or salty snacks to my child as a reward or to comfort him/her	❑1	❑2	❑3	❑4	❑5

C41. If I prohibit my child to eat a sweet or salty snack, I find it difficult to stick to my rules if he/she starts nagging	❑1	❑2	❑3	❑4	❑5
C42. I find it difficult to restrain myself from eating sweet or salty snacks because of the presence of my child	❑1	❑2	❑3	❑4	❑5
C43. I am pleased with my child's snacking behaviour	❑1	❑2	❑3	❑4	❑5

When we say:

- Fruits or Vegetables: we mean pieces of fruits or vegetables (do not include juices)
- Bread or Cereals: we mean any kind of bread or breakfast cereals or cereal products
- Dairy products: we mean any kind of milk (plain and flavored), yogurt (plain and flavored) or cheese.
- Sweet or salty snacks: we mean any kind of chocolate, biscuits, candy, crisps, croissants, pizza or ice cream etc

What do you think is an acceptable consumption of the following food items for 3-5 year old children?

	Never	**On certain occasions i.e. birthdays**	**1 or less times per week**	**2-4 times per week**	**5-6 times per week**	**1-2 times per day**	**3-4 times per day**	**5 or more times per day**
C44. Sweets/candies/ chocolate	❑1	❑2	❑3	❑4	❑5	❑6	❑7	❑8
C45. Biscuits/cookies/ cakes/muffins	❑1	❑2	❑3	❑4	❑5	❑6	❑7	❑8
C46. Crisps and other similar salty snacks	❑1	❑2	❑3	❑4	❑5	❑6	❑7	❑8

C47. Fruit and vegetables	❑1	❑2	❑3	❑4	❑5	❑6	❑7	❑8
C48. Pizza, cheese pies/ meat pies	❑1	❑2	❑3	❑4	❑5	❑6	❑7	❑8
C49. Milk (plain)	❑1	❑2	❑3	❑4	❑5	❑6	❑7	❑8
C50. Yogurt (plain)	❑1	❑2	❑3	❑4	❑5	❑6	❑7	❑8
C51. Milk (flavored)	❑1	❑2	❑3	❑4	❑5	❑6	❑7	❑8
C52. Yogurt (flavored)	❑1	❑2	❑3	❑4	❑5	❑6	❑7	❑8
C53. Cheese	❑1	❑2	❑3	❑4	❑5	❑6	❑7	❑8

D. Physical Activity

The following part of the questionnaire is to assess the physical activity behaviour of your child.
Please answer all questions. It is important to remember that there are no right or wrong answers. Fill in what applies to you or your situation.

In the following questions, when we say PHYSICAL ACTIVITY we mean:
Activities that you do including practicing a sport or exercising

In the following questions, when we say **PHYSICAL ACTIVITY including practicing a sport or exercising** we mean:
Activities that YOUR CHILD does before and after school and that make him/her breathe harder or sweat

Examples of physical activities are: walking, cycling, playing in the playground, team sports like football and organized activities such as swimming or dance lessons

➢ QUESTIONS ABOUT YOUR CHILD

D8. Is your child member in a sports club?

❑1 Yes

❑2 No ➔➔➔ **Please continue with question D11**

D9. How much time does your child spend doing sport in a sports club per week?

|___|___| hours |___|___| minutes

D10. What kind of sport does your child do in a sports club?

Please tick all appropriate.

❑1 Football

❑2 basketball

❑3 running

❑4 general ball games

❑5 Other, please specify:

D11. How does your child usually get to/from preschool and how long does it take him/her?

	D12. Travel forth	D12a.Time (minutes)	D13. Travel home	D13a.Time (minutes)
Walking	❑1		❑1	
Cycling (himself/herself)	❑2		❑2	
By guardians bicycle	❑3		❑3	
By school bus and/or public transport	❑4		❑4	
By car/motorbike	❑5		❑5	
Other, please specify:	❑6		❑6	

Think about where your child spent his/her time *YESTERDAY*.

Note: If yesterday was a Saturday or Sunday, then this question refers to the *last* WEEK

DAY (i.e. Friday)

D14. What was the weather like YESTERDAY? (please tick *one* response)

❑1 Fine to play outdoors
❑2 Too wet to play outdoors
❑3 Too hot or humid to play outdoors
❑4 Too cold to play outdoors

D15. How much time did your child spend outdoors in active play (skipping, cycling) YESTERDAY? (record "0" if your child did not spend time playing outside)

|___|___| hours |___|___| minutes

D16. What was the weather like on that WEEKEND-DAY? (please tick *one* response)

❑1 Fine to play outdoors
❑2 Too wet to play outdoors
❑3 Too hot or humid to play outdoors
❑4 Too cold to play outdoors

D17. How much time did your child spend outdoors in active play IN THE LAST WEEKEND DAY?
(record "0" if your child did not spend time playing outside)

|___|___| hours |___|___| minutes

D18. How far is your child's preschool located from your home? ❑1 Up to 500 metres
❑2 From 500 metres to <1 kilometre
❑3 From 1 kilometre to <2 kilometres
❑4 From 2 kilometres to <3 kilometres
❑5 From 3 kilometres to <4 kilometres
❑6 4 kilometres or more

D19. I think that the recommendations on PHYSICAL ACTIVITY for 3-5 year old children are

❑1 To be physically active one day a week
❑2 To be physically active 2-3 days a week
❑3 To be physically active every day for 30 minutes to 1 hour
❑4 To be physically active every day for 1-2 hours
❑5 To be physically active every day for 3 hours
❑6 To be physically active every day for 5 hours
❑7 To be physically active every day for 7-8 hours
❑8 To be physically active every day for more than 8 hours
❑9 I don't know

Please read the following statements and tick the boxes most appropriate to your situation:

	Strongly disagree	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**
D20. My child likes to be physically active	❑1	❑2	❑3	❑4	❑5
D21. My child enjoys taking part in sports	❑1	❑2	❑3	❑4	❑5
D22. My child prefers doing passive activities (like playing with cars, dolls, drawing,..) rather than physical activities	❑1	❑2	❑3	❑4	❑5
D23. If my child has the choice, he/she rather chooses to go somewhere in a passive (e.g. by car) rather than an active (walking, cycling) way	❑1	❑2	❑3	❑4	❑5
D24. Being physically active is good for my child	❑1	❑2	❑3	❑4	❑5
D25. I plan physical activity for my child on a regular basis	❑1	❑2	❑3	❑4	❑5
D26. I find it difficult to organize our family so that we have enough time for active transport.	❑1	❑2	❑3	❑4	❑5
D27. Toys or equipment/material (ball, rope, bike, swing, …) are available for my child to play actively outside or inside	❑1	❑2	❑3	❑4	❑5

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
D28. I find it difficult to let my child be physically active if I want my child to be quiet so that I can do my household or work	❑1	❑2	❑3	❑4	❑5
D29. I find it difficult to let my child be physically active if the weather conditions are bad or it is very cold/hot outside.	❑1	❑2	❑3	❑4	❑5
D30. I find it difficult to let my child be physically active outside as I always have to be there to supervise him/her	❑1	❑2	❑3	❑4	❑5
D31. I encourage my child to be physically active	❑1	❑2	❑3	❑4	❑5
D32. I like doing physical activities together with my child	❑1	❑2	❑3	❑4	❑5
D33. I reward my child or comfort him/her by being physically active together with him/her	❑1	❑2	❑3	❑4	❑5
D34. I find it difficult to insist that my child is physically active if he/she does not want to and starts nagging	❑1	❑2	❑3	❑4	❑5
D35. I try to be physically active together with my child regularly	❑1	❑2	❑3	❑4	❑5
D36. My child is allowed to run around and be physically active inside our house	❑1	❑2	❑3	❑4	❑5
D37. I am pleased with my child's physical activity level	❑1	❑2	❑3	❑4	❑5

E. Sedentary activities

The following part of the questionnaire aims to assess the sedentary behaviour of your child. Please answer all questions. It is important to remember that there are no right or wrong answers. Fill in what applies to you or your situation.

When we say SEDENTARY activities, we mean all sitting and lying activities, such as watching television and/or DVD, using the computer, drawing and looking into books.

E5. How often do <u>you or your spouse/partner</u> watch television, DVD/video together with your child?

❑$_1$ Never
❑$_2$ Less than once a week
❑$_3$ Once a week
❑$_4$ 2-4 days a week
❑$_5$ 5-6 days a week
❑$_6$ Every day, once a day
❑$_7$ Every day, more than once a day

E6. Is there internet connection available in your household?

❑$_1$ Yes
❑$_2$ No

Are the following devices available in your child's room?

	Yes	No
E7. TV	❑$_1$	❑$_2$
E8. DVD player	❑$_1$	❑$_2$
E9. Game consoles i.e., Play Station	❑$_1$	❑$_2$
E10. Computer	❑$_1$	❑$_2$

➢ QUESTIONS ABOUT YOUR CHILD

In the following questions, when we say SEDENTARY BEHAVIOUR we mean:

All sitting and lying activities, such as television viewing, playing games on a computer, game consoles and quiet play (drawing, construction, dolls), looking into books

By screen viewing activities, we refer to the usual time spend in a range of activities including TV/DVD/Video, electronic games and recreational computer use per day.

About how many hours a day does your child usually watch television (including DVDs and videos) in his/her free time? (Please mark one box for weekdays and one box for weekend days)

E11. Weekdays (average all weekdays)	**E12.** Weekend days (average per weekend days)
❑1 Never	❑1 Never
❑2 Less than 30 minutes/day	❑2 Less than 30 minutes/day
❑3 30 minutes to <1 hr/day	❑3 30 minutes to <1 hr/day
❑4 1- 2 hrs/ day	❑4 1- 2 hrs/ day
❑5 3-4 hrs/ day	❑5 3-4 hrs/ day
❑6 5-6 hrs/ day	❑6 5-6 hrs/ day
❑7 7-8 hrs/ day	❑7 7-8 hrs/ day
❑8 8 hrs/ day	❑8 8 hrs/ day
❑9 More than 8 hrs/ day	❑9 More than 8 hrs/ day
❑10 I don't know	❑10 I don't know

About how many hours a day does your child use the computer for activities like playing games on a computer, game consoles (e.g.Playstation, Xbox, GameCube) during leisure time?

E13. Weekdays (average all weekdays)	**E14.** Weekend days (average per weekend days)
❑1 Never	❑1 Never
❑2 Less than 30 minutes/day	❑2 Less than 30 minutes/day
❑3 30 minutes to <1 hr/day	❑3 30 minutes to <1 hr/day
❑4 1- 2 hrs/ day	❑4 1- 2 hrs/ day
❑5 3-4 hrs/ day	❑5 3-4 hrs/ day
❑6 5-6 hrs/ day	❑6 5-6 hrs/ day

❑7 7-8 hrs/ day	❑7 7-8 hrs/ day
❑8 8 hrs/ day	❑8 8 hrs/ day
❑9 More than 8 hrs/ day	❑9 More than 8 hrs/ day
❑10 I don't know	❑10 I don't know

About how many hours a day does your child have quiet play (looking into books, playing with blocks, playing with dolls, drawing, construction) during leisure time?

E15. Weekdays (average all weekdays)	**E16.** Weekend days (average per weekend days)
❑1 Never	❑1 Never
❑2 Less than 30 minutes/day	❑2 Less than 30 minutes/day
❑3 30 minutes to <1 hr/day	❑3 30 minutes to <1 hr/day
❑4 1- 2 hrs/ day	❑4 1- 2 hrs/ day
❑5 3-4 hrs/ day	❑5 3-4 hrs/ day
❑6 5-6 hrs/ day	❑6 5-6 hrs/ day
❑7 7-8 hrs/ day	❑7 7-8 hrs/ day
❑8 8 hrs/ day	❑8 8 hrs/ day
❑9 More than 8 hrs/ day	❑9 More than 8 hrs/ day
❑10 I don't know	❑10 I don't know

Please read the following statements and tick the boxes most appropriate to your situation:

	Strongly disagree	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**
E17. I think screen viewing activities are beneficial and educational for my child	❑1	❑2	❑3	❑4	❑5
E18. My child likes to watch TV/DVD/ Video	❑1	❑2	❑3	❑4	❑5
E19. My child prefers to watch TV for a long time instead of doing other activities	❑1	❑2	❑3	❑4	❑5

E20. I find it difficult to limit my child's screen viewing activities if he/she does not want to and starts nagging	❑1	❑2	❑3	❑4	❑5
E21. I like watching TV/DVD/Video together with my child	❑1	❑2	❑3	❑4	❑5
E22. I make sure that there are other activities available for my child to do instead of screen viewing	❑1	❑2	❑3	❑4	❑5
E23. My child does not like to do activities while standing up	❑1	❑2	❑3	❑4	❑5
E24. My child's TV viewing levels are within the appropriate recommendations	❑1	❑2	❑3	❑4	❑5
E25. I think it is necessary to limit the screen viewing activities for my child	❑1	❑2	❑3	❑4	❑5

	Strongly disagree	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**
E26. I encourage my child to do something else instead of watching TV/DVD/Video	❑1	❑2	❑3	❑4	❑5
E27. It is a habit to organise my family so that we can see programs we like at TV	❑1	❑2	❑3	❑4	❑5
E28. I try to restrain myself from watching TV/DVD/Video while my child is present	❑1	❑2	❑3	❑4	❑5
E29. My child is allowed to watch TV for as long as he/she wants	❑1	❑2	❑3	❑4	❑5
E30. I punish my child by forbidding him/her to watch TV	❑1	❑2	❑3	❑4	❑5
E31. I do not think it is necessary to limit TV viewing for my child if he/she look at the appropriate children programs	❑1	❑2	❑3	❑4	❑5
E32. I am pleased with my child's screen viewing activities	❑1	❑2	❑3	❑4	❑5

E33. I think that the recommendation for TV VIEWING for 3-5 year old children is:

❑1 Not to watch television at all
❑2 To watch television not more than a few times per week
❑3 To watch television for maximum 1 hour per day
❑4 To watch television for 1 to 2 hour per day
❑5 To watch television for 3 to 4 hours per day
❑6 To watch television for 5 to 6 hours per day
❑7 To watch television for 7 to 8 hours per day
❑8 To watch television for more than 8 hours per day
❑9 To watch television as often as he/she likes
❑10 I don't know

How often does your child watch television during the following meals?

	Never	Rarely	Sometimes	Often	Always
E34. Breakfast	❑1	❑2	❑3	❑4	❑5
E35. Morning snack	❑1	❑2	❑3	❑4	❑5
E36. Lunch	❑1	❑2	❑3	❑4	❑5
E37. Afternoon snack	❑1	❑2	❑3	❑4	❑5
E38. Dinner	❑1	❑2	❑3	❑4	❑5
E39. Evening snack	❑1	❑2	❑3	❑4	❑5

THANK YOU VERY MUCH FOR FILLING IN THE QUESTIONNAIRE!

Appendix F

Post intervention parental feedback survey

The questions below ask about the materials that accompanied the ToyBox programme. Please tick **one** box for each question	**Yes**	**No**	**Not sure**
Did you receive the ToyBox-Scotland sticker wallchart from your child's preschool?			
If so, did you use the wallchart?			
Did you receive the home activity pack called "fun in the forest"?			
Did you receive the home activity pack called "leaping at the loch"?			
Did you receive the home activity pack called "fun on the farm"?			
Did you receive the home activity pack called "adventures at loch ness"?			
Did you receive the home activity pack called "moving in the mountains"?			
Did you receive the home activity pack called "flying with the eagles"?			
Did you receive the home activity pack called "Fox's games"?			

The next two questions are about your use of the ToyBox home materials. Please tick **one** box for each question	**None**	**Some**	**Not sure**	**Most**	**All**
How many of the ToyBox home activities that you received did you use at home with your child?					
Did you award the provided stickers to your child after they completed an activity?					

The next questions are about your feelings towards the ToyBox home materials. Please tick **one** box for each question	**Strongly disagree**	**disagree**	**Not sure**	**agree**	**Strongly agree**
Overall, did your child enjoy the activities in the programme?					
Overall, did your child like the stickers and wallchart provided?					
Did you enjoy doing the activities with your child?					
Do you think the activities helped your child be more physically active?					
Do you think the activities helped your child spend less time sitting/being inactive?					

Do you think the activities helped your child to eat healthier snacks?					
Do you think the activities helped your child drink more water instead of sugary juices?					
Were the instructions provided for the games/activities easy to read and clear?					

Please provide any additional comments that you would like to make about the ToyBox home materials and activities in the box below:

Appendix G

Parent/caregiver interview topic guide

1. Your child has been taking part in the ToyBox programme at nursery for the last 6 months or so. What information have you received from the nursery about this? (Have you spoken to nursery practitioners etc?)

2. Thinking back to before you took part in the ToyBox programme, what would the typical daily routine be for your child?
   - Have any of these materials influenced your ability to provide PA, healthy drinks and snacks for your child throughout the day? If so, how?
   - Is there anything that has made it difficult/not possible to do any particular activity?
   - Have you got any suggestions for how we could make the materials better/more easy for parents to use in their daily routine?

3. As part of the programme you will have received seven home activity packs from the nursery (recap each one). The next few questions are going to focus on these materials. Firstly, what were your initial thoughts about these materials?

   - How was the language? How clear were the instructions?
   - Did you find the materials visually appealing? If so, how so?
   - Engagement with the materials- did you and your child do any of the activities provided? Which ones? What were your thoughts on these?
   - What did your child think of the activities?
   - Do you think it changed their behaviour? If so, how? (PA, SB, diet, water. probe for ways in which they may have changed their behaviour since receiving the materials I.e. what were their PA patterns like before, did they watch much TV, snacking behaviours etc).
   - Did you learn anything new from the materials? If so, what?
   - Did you/your child use the provided wallchart and stickers? How did you use them? What were your overall thoughts on these? What did your child think of it? Did their stickers have any effect on their engagement with the activities?

4. Has your approach to your child's activity levels, diet and screen time changed since receiving these activity packs? If so, in what way?

Thank you for your time

Appendix H

Practitioner focus group topic guide

The Toybox Study:

1. How long have you been a nursery teacher? (follow-up questions: what aspects of the job do you enjoy/not enjoy? How has the role changed since you started as a teacher?)
2. Since you started working in nurseries, what have you seen change with regards to health and wellbeing? (follow up questions: was PA/diet/SB always a major focus? How has the focus on these behaviours changed over time?
3. You have been delivering the toybox programme for the last 6 months or so. What were your initial thoughts on this when you were first asked to deliver it? (follow-up questions: did it fit well with the nursery's ethos regarding physical activity/H&W, if so, how?) did you feel that there was a need for it at this nursery/in this particular area of Glasgow? How well does Toybox fit with the Health and wellbeing focus at this nursery?
4. You were provided with a training session prior to delivering the toybox programme, what are your thoughts on this? (follow-up questions: based on responses improvements, good, bad, worthwhile etc) did you feel adequately prepared to deliver the programme following this training? Suggestions for improvements?
5. You received materials to assist you with delivering toybox. What are your thoughts on these materials (follow-up questions based on responses. E.g. were they clear? Too long/ too short? how much time did you spend familiarising yourself with the material, was this long enough? Did you feel confident to deliver a session, if not why, if yes why?
6. Toybox contained a number of sessions on physical activity and sedentary behaviour that were designed to be easy to implement in the classroom or in the playground. Of the indoor sessions, which ones in particular did you use and why? Were there any that you did not use/hardly ever used and if so why?
7. Same questions as above but for outdoor activities
8. Was your nursery appropriately equipped/designed to accommodate the toybox programme effectively? Barriers to implementation? Facilitators?
9. Toybox also included some environmental changes to be made to the classroom, did you make any of these changes? If so what was your experience with them and if not, why?
10. You were required to keep a log of Toybox activities, how did you find this task (was it time consuming, easy to use?)
11. Was your ability to deliver Toybox affected by the fact that it was part of the curriculum for excellence? If so how?
12. Toybox was developed with the input/assistance of an experienced early years practitioner, as you may have been aware. Do you think this is reflected in the programme content/design? How do you think this has impacted on the programme?
13. Considering everything we have discussed, what is your personal opinion of the Toybox programme? How does it compare to other nursery-based initiatives with the same objectives? Did you enjoy delivering it? (follow up as required)
14. Did any of your colleagues voice any strong opinions regarding the programme?

15. Did the children enjoy the programme, and did they learn anything?
16. If you were in charge of your own nursery, would Toybox be part of your curriculum? If so, why, if not, why?

Thanks you very much for your time.

Appendix I

ToyBox Scotland: Home activities block 1

Fun in the Forest!

Activity A- Help the squirrels find their cones!

- Let the children decorate their pine cones
- Hide the cones around the house or garden
- Give the children clues to find the cones!
- Set a time limit for a bigger challenge!
- Do this 3 times in one week, and award a sticker for the chart!

Activity B- The squirrels share their food

- Try and find some nuts and seeds at the supermarket- some suggestions are cashews, peanuts, walnuts, almonds, Brazil nuts, and pecan nuts
- Let the children try each kind of nut/seed instead of their usual snacks
- When each nut and seed has been tried, award a sticker for the chart!
- Avoid nuts and seeds if the child has a nut allergy

Activity C- Tree Acrobats

- Go for a walk in the park or to the garden to find a tree
- Get the children to jump up and touch the trunk of the tree, as high as they can
- Measure how high they reached with the measuring paper or with a measuring tape
- Find more trees to do this with and record the highest score
- Do this 3 times in one week, then award a sticker for the chart!

SAFETY FIRST

Always supervise children's activities and don't leave them unattended

Avoid nuts and seeds if

Appendix J

ToyBox Scotland: Home activities block 2

Leaping at the Loch

Activity A- Island hopping with the kangaroo!

- Decorate the five islands with your child
- When watching tv or playing with a tablet, get the children to sit on the islands.
- Every 5 minutes, get the children to move to a different island
- after 30 minutes have passed, get your child to move to a different island every 2 minutes, or move the islands further apart
- Get the children to stand on the islands instead of sitting to make it more of a challenge!
- Do this 3 times in one week, and award a sticker for the chart!

Activity B- Water wagon

- Get the children to decorate the kangaroo's water wagon, and try the sparkling water instead of fizzy juice
- Place a one litre bottle of water on the wagon picture, and encourage the children to drink as much as they can throughout the day. Use a pen to mark how much they drink each day to show them their progress!
- Replace children's meal-time drink with water 3 times during the week, and then award a sticker for the chart!

Activity C- The movement game

- While the child is watching tv or playing with a tablet, hold up one of the movement cards provided and get them to copy the activity for 30 seconds
- Change the movement every 3 to 4 minutes for 30 minutes
- Do this 3 times in one week, then award a sticker for the chart!

Appendix K

ToyBox Scotland: Home activities block 3

Fun at the farm

Activity A- Highland cow's fruit portrait

- At the supermarket, buy one banana, two oranges or satsumas, grapes and blackberries
- With the children, tell them that they are going to help you create the highland cow's face out of tasty fruits!
- Help the children to arrange the fruits as they are shown in the picture
- Encourage the children to eat the fruit instead of sugary/salty snacks throughout the day. When it is all gone, award a sticker for the chart! Repeat this activity regularly if the children want to

Activity B- Harvesting the crops

- Cut out the paper fruits and vegetables. Let the children decorate them if they want, and teach them the names of each one
- Spread all the pieces on the floor (outdoors or indoors)
- The aim of the game is for the children to collect all of crops as fast as they can and bring them to you
- Shout which crop you want the children to collect, for example "carrots!" or "broccoli!" and get the children to run and pick up all the carrots and bring them back to you. Play this game 3 times in one week, then award a sticker for the chart!

Activity C- Veggie tasting

- **At the supermarket, buy a selection of 4 or 5 vegetables. Some options are carrots, broccoli, courgettes, cauliflower, sweetcorn or peppers.**
- **Cut each vegetable into small pieces, and boil for 20 minutes**
- **Let the children try each vegetable and decide which one they like best**
- **After eating their favourite vegetable on 3 days in the week, award a sticker for the chart!**

ToyBox Scotland: Home activities block 4

Adventures at loch ness

Activity A- Fruity water

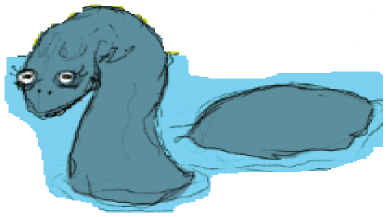
- At the supermarket, buy a an orange, lime, lemon and cucumber- let your child choose some fruits too
- Cut a wedge from each of the pieces of fruit/veg, and show the children
- With the children, add each wedge to cups of water, and let the children try each one
- Try squeezing the juices from each fruit into the water to add more flavour!
- Swap these fruity juices for children's usual drinks 3 times in a week, then award a sticker for the chart!

Activity B- Hide and seek around the castle

- Play hide and seek with the children around the house
- Take turns to be the hider and the seeker
- To keep everyone active, the hider has to change their hiding place every 30 seconds!
- Play this game 3times in a week and award a sticker for the chart!

Activity C- Daily water challenge

- Using the provided water cup checklist, see if the children can drink 6 cups of water a day, and award a sticker for the chart!



Appendix M

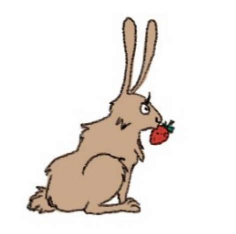
ToyBox Scotland: Home activities block 5

Moving in the mountains

Activity A- Mountain hare hill races

- Go outside and try to find a hill with space to safely run
- Get the children to run from the bottom of the hill to the top, as fast as they can
- If you have a watch, why not time them to see their best times!
- If friends or brothers/sisters are also there, why not have a race
- Find 3 different hills to do this on in one week, and award a sticker for the chart!

Activity B- The mountain climber's snack pack



- Go for a walk with the children and bring some healthy snacks to have on the way, tell them this is what explorers eat!
- Some options are oatcakes, fruit (apples, oranges, pears, grapes, bananas etc), nuts/seeds
- Let the children try these snacks whenever they feel hungry on the walk
- Do this 3 times in one week, and award a sticker for the chart!

Activity C- High hoppers

- Go for a walk in the park or to the garden to find objects to jump over, some examples are small pieces of wood or stones, paths or patches of grass
- Allow the children to try and jump over these objects
- Measure how far they jumped with the measuring paper or with a measuring tape
- Find more objects to do this with and record the highest score
- Do this 3times in one week, then award a sticker for the chart!

ToyBox Scotland: Home activities block 6

Flying with the eagles

Activity 1- High flyers

- Help the children make a paper eagle using the lines on the paper provided
- Let the children decorate their eagle if they want
- Go to a local park or playing field and fly the eagle. Teach the children how to throw to get the best flight!
- Why not take the measuring paper or measuring tape to see how far it flies!
- Try do this on 2 days out of the week, and award a sticker for the chart!

Activity 2- Water wagon 2

- Get the children to decorate the water wagon, and try the sparkling water instead of fizzy juice
- Place a one litre bottle of water on the wagon picture, and encourage the children to drink it in one day
- Cut up some slices of lemon, orange and lime and allow the children to squeeze these into the water for more flavour
- Replace children's meal-time drink with water 3 times during the week, and then award a sticker for the chart!

Activity 3- No tv, no problem!

- Encourage the children to watch less tv or use devices such as tablets.

- **Start by reducing the children's daily screen time by half (if they watch tv for one hour a day, drop it to 30 minutes), use this time to do other fun activities from the ToyBox Scotland packs!**
- **Reduce the time each day, and when the children do a whole day without watching tv, award a sticker for the chart!**

Appendix O

ToyBox Scotland: Home activities block 7

Foxes fun games

Activity 1- The sneaky fox game

- Go to the garden, or a park or playing field with plenty of space, set out a playing area of about 10 metres
- The aim of the game is for the children to sneak up on you with your back turned, without you catching them moving
- You can turn around at any time, if they are standing still, they stay in the game, but if you catch them moving, chase them back to the start line!
- After 3 games, award a sticker for the chart!

Activity 2- Fox's food face

- At the supermarket, buy a selection of eggs, ham, cheese, carrots, sweetcorn and strawberries
- With the children, make the fun fox's face out of the food shown in the picture here.
- Encourage the children to try each piece of food throughout the day. When they have tried each piece, award a sticker for the chart!

Activity 3- ball games

- Go for a walk to the park or out in the garden
- With the ball provided in the pack, play a variation of some popular ball games.

- **Some examples are catch, dodgeball, football/penalties and basket shooting. Instructions are included in this pack**
- **When the children have played 3 different games in one week, award a sticker for the chart!**

SAFETY FIRST

When playing games outside, avoid areas near main roads or dangerous surfaces

Remember to wash any fresh foods before eating

Appendix P

ToyBox-Scotland Sticker wallchart