Physical activity among children with Type 1 Diabetes: An exploration of children's experiences and development of an intervention to promote self-efficacy and participation

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Thesis summary

Regular physical activity among children with Type 1 Diabetes Mellitus (T1DM) can help optimise long-term health outcomes. The purpose of this thesis is to explore the experience of physical activity among children aged 9-11 years with T1DM and their parents, to adapt an existing evidence-based physical activity intervention and evaluate its feasibility for delivery with children who have T1DM in a pilot randomised controlled trial. Social cognitive theories have been drawn upon to develop an understanding of the influences acting upon children's behaviour and to inform theoretically-driven strategies to promote behaviour change.

First, a systematic review with meta-analysis critically evaluates existing physical activity interventions for children with T1DM. Intervention design and efficacy of the interventions are evaluated. The findings confirm the health benefits associated with regular physical activity for children with T1DM, including improved glycaemic control and lipid profile. Gaps in the existing literature are identified that are yet to be explored, such as the need for interventions to be underpinned by psychological theory.

Second, the experience of physical activity for children with T1DM from the perspective of i) parents and ii) paediatric diabetes healthcare professionals are explored. These qualitative research findings highlight the challenges faced by children with T1DM and their parents, as well as the methods used by families to overcome obstacles to physical activity. Important influencers on children's participation are identified. Healthcare professionals recognise their role in promoting physical activity, but perceive barriers to the successful fulfilment of this role. The findings highlight the potential for clinical and non-clinical supportive systems to help promote and maintain physical activity among children with T1DM.

Third, the feasibility and acceptability of ActiGraph GT3X+ accelerometers to detect change in the physical activity level of children with T1DM is explored. The findings demonstrate that the accelerometer protocol is feasible, acceptable to participants, sensitive to change in activity level and objective data correlates with the self-reported measure of physical activity. The findings suggest that wrist-worn accelerometers can be used to measure physical activity in children with T1DM.

Fourth, correlates of children's physical activity are explored alongside children's values, beliefs and expectations related to their participation. The findings suggest that self-efficacy and enjoyment have a potentially important role in physical activity and children perceive few diabetes-related barriers to participation. The findings demonstrate the factors influencing children's activity levels of the aspects of physical activity participation that children value.

Finally, the feasibility and acceptability of the Steps To Active Kids-Diabetes (STAK-D) programme for implementation among children with T1DM is explored using quantitative and qualitative methods. The capacity of measures to detect change over time in selected health outcomes (glycaemic control, physical activity, self-efficacy for physical activity and parental fear of hypoglycaemia) are also explored. The findings suggested that the intervention is feasible and recommendations are provided to help optimise the potential acceptability and efficacy of future implementation of the intervention.

The findings of this thesis are discussed in terms of the implications they have for our knowledge and understanding, a future definitive trial, future research and clinical practice.

Researcher contribution

The researcher produced the protocols and obtained ethical approval for all the studies within this thesis. The researcher's academic supervisor (Professor Cris Glazebrook, University of Nottingham) and research team developed the original Steps To Active Kids (STAK) programme. The thesis researcher made the necessary alterations to the STAK programme before implementing it in children with Type 1 Diabetes. The researcher developed the rationale for and chose the diabetes-specific measures used in this thesis. A research assistant contributed to the data collection and quality assessment of the systematic review in Chapter 2. Medical students assisted with data collection for the qualitative studies in Chapter 3 and Chapter 4, supervised by the researcher. The researcher conducted all analyses and interpretation of the data presented throughout the thesis and was lead author on all published papers.

Published papers

Quirk, H., Blake, H., Tennyson, R., Randell, T. and Glazebrook, C. (2014) Physical activity interventions in children and young people with Type 1 diabetes mellitus: A systematic review with meta-analysis. **Diabetic Medicine** 31(10): pp. 1163-1173.

Quirk, H., Blake, H., Dee, B. and Glazebrook, C. (2014) "You can't just jump on a bike and go": A qualitative study exploring parents' perceptions of physical activity in children with type 1 diabetes. **BMC Pediatrics** 14(1): p. 313.

Quirk, H., Blake, H., Dee, B., & Glazebrook, C. (2015). "Having diabetes shouldn't stop them": Healthcare professionals' perceptions of physical activity in children with Type 1 diabetes. **BMC Pediatrics**, 15(1), 68.

Quirk, H., Glazebrook, C., Martin, R. & Blake, H. (2016) "We don't worry about diabetes that much": A qualitative study exploring perceptions of physical activity among children with Type 1 Diabetes. **Advances in Pediatric Research**, 3 (2).

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Table of Contents

List of Figures

List of Tables

List of Appendices

List of abbreviations

ADEQ	Adequacy subscale (CSAPPA)
BMI	Body mass index
CASP	Critical Appraisal Skills Programme
CI	Confidence interval
CSAPPA	Children's self-Perceptions of adequacy in and predilection for physical activity scale
CVD	Cardiovascular disease
DCCT	Diabetes Control and Complications Trial
ENJ	Enjoyment subscale (CSAPPA)
EOI	Expression of interest (form)
ES	Effect size
FOH	Fear of hypoglycaemia
HbA1c	Glycated haemoglobin
HCP(s)	Healthcare professional(s)
HDL-C	High density lipoprotein cholesterol
HQ	Helen Quirk (researcher)
IFCC	International Federation of Clinical Chemistry
IMD	Index of multiple deprivation
IQR	Interquartile range
LDL-C	Low density lipoprotein cholesterol
LPA	Light physical activity
MI	Motivational Interviewing
MPA	Moderate physical activity
MRC	Medical Research Council
MVPA	Moderate-to-vigorous physical activity
NHANES	National Health and Nutrition Examination Survey
NICE	National Institute for Health and Care Excellence
NRS	Non-randomised study
PAQ	Physical activity questionnaire
PE	Physical Education
PHFS	Parental hypoglycaemia fear survey
PHFS-B	Parental hypoglycaemia fear survey-behaviour subscale

PHFS-W	Parental hypoglycaemia fear survey-worry subscale
PIS	Participant information sheet
PPI	Patient and Public Involvement
PRED	Predilection subscale (CSAPPA)
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomised controlled trial
SCT	Social cognitive theory
SDT	Self-determination theory
SED	Sedentary behaviour / sedentary activity
SMD	Standardised mean difference
STAK	Steps To Active Kids Programme
STAK-D	Steps To Active Kids Programme-Diabetes
T1	Time-point 1, baseline
T1DM	Type 1 Diabetes Mellitus
T2	Time-point 2, immediate post-intervention
T3	Time-point 3, long-term follow-up
TTM	Transtheoretical model
VM	Vector magnitude
VPA	Vigorous physical activity
WC	Waist circumference
YPAG	Young person's advisory group

Chapter One

Introduction

This chapter introduces and evaluates the key topics relating to children with Type 1 Diabetes Mellitus (T1DM) and their participation in physical activity. The complexity of physical activity for children with T1DM will be illustrated and the justification for promoting physical activity among children with T1DM will be outlined. A rationale for the importance of underpinning physical activity promotion strategies with psychological theory will be provided. An existing physical activity intervention is introduced before concluding with a summary of each thesis chapter. Detailed introductions to literature will be provided within each chapter.

1.1 Introduction to Type 1 Diabetes

Type 1 Diabetes is an autoimmune disease characterised by the inability to produce insulin from the pancreas. As insulin regulates blood glucose, the lack of insulin leads to hyperglycaemia (high levels of blood glucose) and the need for lifelong insulin therapy to control the level of glucose in the blood (International Diabetes Federation, 2013).

1.1.1 Prevalence and incidence of Type 1 Diabetes in children

In the UK T1DM is the third most common chronic illness affecting children, after asthma and cerebral palsy (Betts and Swift, 2003). The estimated prevalence of T1DM among children in the UK is one per 430-530 (Diabetes UK, 2014). Figures show the incidence of T1DM in children under 15 years in the UK has increased over the past two decades; from 13.5 per 100,000 per year in 1988 (Metcalfe and Baum, 1991) to 22.8 per 100,000 per year in 2014 (Diabetes UK, 2014). Reasons for increased incidence are not known, largely because the aetiology of T1DM is poorly understood. The peak age for diagnosis of T1DM is between 10 and 14 years (The Royal College of Paediatrics and Child Health (RCPCH), 2015), which highlights the importance of optimal diabetes management early in life. This thesis will focus on paediatric T1DM and 'children' will be used to refer to those aged 0-18 years with the specific term 'adolescent' being used where necessary.

1.2 Treatment and management of Type 1 Diabetes in children

The treatment of T1DM requires a lifelong commitment to achieving optimal blood glucose control. Until recently, the UK National Institute for Health and Care Excellence (NICE) recommended that children aim for a blood glucose level (herein referred to as HbA1c; glycated haemoglobin) of 58mmol/mol or below, with higher HbA1c indicating poorer diabetes control (NICE, 2004). The revised 2015 NICE guidelines state a HbA1c of ≤48mmol/mol is required for optimal diabetes control (NICE, 2015).

The treatment of T1DM in childhood is coordinated by healthcare professionals (HCPs), but its management in pre-adolescent children is usually the responsibility of parents, with mothers often taking most of the responsibility (Seiffge-Krenke, 2002). To achieve optimal blood glucose levels, frequent self-monitoring of blood glucose, adjustments in insulin dosages, monitoring diet and regular physical activity are required (International Diabetes Federation, 2013).

1.2.1 Blood glucose monitoring for children with Type 1 Diabetes

Blood glucose levels need to be monitored throughout the day with a blood glucose monitor to ensure the level of blood glucose is within the target range. HCPs advise frequent testing (e.g., a minimum of five tests a day), especially around meals and physical activity (NICE, 2015).

1.2.2 Insulin treatment for children with Type 1 Diabetes

Lifelong insulin treatment is required to regulate blood glucose levels. The insulin dosages required depend on the child's weight, health, food consumption and physical activity levels. Several types of insulin exist (broadly classified as fast-acting or slow-acting) which can be used in combination to achieve 24-hour blood glucose control. Insulin can be injected via a needle and syringe (multiple daily injection therapy) or continuously administered by a programmed insulin pump attached to the body via a cannula (insulin pump therapy) (NICE, 2015).

1.2.3 Dietary management for children with Type 1 Diabetes

Children with T1DM and/or their parents need to closely monitor dietary intake to prevent blood glucose levels becoming too high (hyperglycaemia) or too low (hypoglycaemia). Carbohydrate counting is the term given to the calculation of carbohydrates in food consumed. The accurate calculation of carbohydrate intake ensures that insulin dosages can be adjusted to help achieve optimal blood glucose level (NICE, 2015).

1.2.4 Exercise for children with Type 1 Diabetes

In the UK, the National Institute of Health and Care Excellence (NICE) guidelines advise HCPs to encourage children with T1DM to engage in regular exercise (NICE, 2015)(Box 1). The benefits and effects of physical activity and exercise for children with T1DM are described in more detail below (Section 1.3.2).

Exercise for children and young people with Type 1 Diabetes

1.2.47 Encourage all children and young people, including those with type 1 diabetes, to exercise on a regular basis because this reduces the risks of developing cardiovascular disease in the long term. [2004, amended 2015].

1.2.48 Explain to children and young people with type 1 diabetes and their family members or carers (as appropriate) that they can take part in all forms of exercise, provided that appropriate attention is given to changes in insulin and dietary management. [2004]

Diabetes (type 1 and type 2) in children and young people: diagnosis and management NICE guideline Published: 26 August 2015 *(*www.nice.org.uk/guidance/ng18*)* (NICE, 2015); p.19)

Box 1 NICE (2015) guidelines for exercise among children with T1DM

1.2.5 Type 1 Diabetes complications

Long-term complications of T1DM develop gradually over time and are more debilitating if blood glucose levels are poorly controlled in childhood. Figures from England and Wales in 2013-2014 show that less than 19% of children achieved the NICE guideline target for blood glucose control when it was set at 58mmol/mol (The Royal College of Paediatrics and Child Health (RCPCH), 2015). This puts children with T1DM at increased risk of serious health problems such as cardiovascular disease

(CVD), nerve damage, kidney failure and blindness (International Diabetes Federation, 2013 ; McVeigh et al., 2013). Cardiovascular disease is the leading cause of death in patients with T1DM (Sarwar et al., 2010). People with T1DM have at least twice the risk of developing CVD compared to those without diabetes and incidence of CVD risk factors (e.g., strokes, acute coronary events, and coronary revascularisations) are prevalent at a younger age in those with diabetes compared to the nondiabetic population (10-15 years earlier) (Soedamah-Muthu et al., 2006).

In summary, children with T1DM are at high lifetime risk of CVD due to a lack of insulin production resulting in hyperglycaemia (high blood glucose level) which damages the body's internal organs and tissues (International Diabetes Federation, 2013 ; McVeigh et al., 2013). Physical activity is one of the cornerstones of T1DM treatment and management has been recognised as essential for children to help achieve the target for blood glucose control and to delay the onset of cardiovascular complications (NICE, 2015). This thesis focuses on physical activity and its promotion in childhood as a means to help prolong the healthy lives of those with T1DM.

1.3 Introduction to children's physical activity

Physical activity is defined as bodily movement produced by skeletal muscles requiring energy expenditure (Caspersen et al., 1985). There are two main types of physical activity; acute physical activity refers to a single bout of activity and chronic physical activity refers to the repetition of bouts of activity over time (McAuley and Blissmer, 2000). Chronic physical activity is the focus of this thesis. The term 'physical activity' will encompass a broad range of chronic physical activity with the more specific terms of exercise, sport and Physical Education (PE) being used when appropriate.

Children generally have different physical activity patterns compared with adults. Children typically engage in spontaneous, intermittent bouts of activity, rather than sustained episodes of planned activity that is characteristic of adults (Bailey et al., 1995). Younger children may engage in more active play, which refers to unstructured outdoor physical activity in children's free time and can be accumulated throughout the day (Department of Health, 2011). It is essential to keep these differences in mind when exploring physical activity behaviours and, as such, the research presented in this thesis will focus on physical activity in children.

The current UK government guidelines recommend that children and young people aged 5-18 years attain at least 60 minutes of moderate-to-vigorous physical activity (MVPA) every day, and at least three days should involve muscle and bone strengthening activities (Department of Health, 2011). Activities that would meet the MVPA requirement include brisk walking, jogging, cycling, and active outdoor playing which result in the participant feeling warm and slightly out of breath (Biddle et al., 1998). The guidelines also recommend that children should minimise the time they spend being sedentary (Department of Health, 2011). Physical activity and sedentary behaviour are distinct behaviours with independent risk factors for disease (Tremblay et al., 2011), yet they should not be considered as functional opposites (Katapally and Muhajarine, 2015 ; Pearson et al., 2014). This thesis focuses primarily on physical activity.

1.3.1 Benefits of physical activity for children

The Department of Health suggests that 60 minutes of MVPA per day can improve cardiovascular health, maintain healthy bodyweight, improve bone health and self-confidence, and develop new social skills (Department of Health, 2011). The research evidence in support of these guidelines is strong. A number of reviews have demonstrated the beneficial effects of physical activity on a wide range of health and behavioural outcomes for children (Health Education Authority., 1997 ; Janssen and LeBlanc, 2010 ; Strong et al., 2005). The strongest evidence is for the dose-response relations between physical activity and beneficial effects on musculoskeletal health, cardiovascular health, adiposity, blood pressure and cholesterol (Janssen and LeBlanc, 2010 ; Strong et al., 2005). For psychological health, research has demonstrated associations between physical activity and reduced depression, reduced anxiety and improvements in self-esteem, although there is limited good quality research exploring the psychological benefits of physical activity for children (Biddle and Asare, 2011). It is beyond the scope of this thesis to go into further detail about physical activity among the general population of children. The rest of this thesis will refer specifically to physical activity among children with T1DM.

1.3.2 The health benefits of physical activity for children with Type 1 Diabetes

1.3.2.1 Physiological health benefits

Regular physical activity has important beneficial effects for children with T1DM, especially in the protection against CVD (Herbst et al., 2006 ; Trigona et al., 2010). The evidence suggests beneficial effects on blood glucose control (Salem et al., 2010b), insulin sensitivity (American Diabetes Association, 2004) and body composition (Michaliszyn and Faulkner, 2010). For example, children with T1DM who do less than 60 minutes MVPA per day have been found to have reduced flow-mediated dilation, which is an early sign of atherosclerosis (Trigona et al., 2010). The systematic review in Chapter 2 critically examines the research literature to date and further explores the potential health benefits of physical activity for children with T1DM.

1.3.2.2 Psychological health benefits

For children with T1DM, the potential psychological benefits of physical activity could be important in protecting against depressive symptoms (Johnson et al., 2013a). Research suggests that children with T1DM have higher depression and anxiety and lower health-related quality of life than children without diabetes (Mutlu et al., 2015), but collation of the evidence has not been conclusive (Johnson et al., 2013a). There is little research exploring the potential psychological benefits of physical activity among children with T1DM. Some research has suggested that physical activity can improve quality of life (Wiesinger et al., 2001 ; Zoppini et al., 2003) and satisfaction with diabetes (Heyman et al., 2007), whilst other research has found no significant association between physical activity and psychological wellbeing in children with T1DM (Edmunds et al., 2007). Regular physical activity by children with T1DM could protect against depression and anxiety, but further research exploring the role of physical activity to help maintain psychological health in children with T1DM is needed.

In summary, considerable health benefits could be achieved through promoting active lifestyles among children with T1DM. The identification of physical activity patterns is important in any attempt to implement physical activity promotion strategies (Caspersen et al., 1985). The next section seeks to identify the activity level of children with T1DM.

1.4 Physical activity levels of children

To produce health benefits, physical activity levels need to reach those recommended by the Department of Health (Department of Health, 2011). Determining children's activity levels is problematic due to the sporadic nature of children's activity and there being no 'gold standard' technique for accurate assessment (Tudor-Locke et al., 2011). Estimates of physical activity levels are dependent on the method used and criteria used to quantify the amount of activity performed. Physical activity levels can be measured either through self-report questionnaires or by objectively measuring the amount of activity a person is doing on a daily basis (see Chapter 5 for more details on objective measurement of physical activity). Self-report figures from the Health Survey for England in 2012 suggested that 21% of boys and 16% of girls aged 5-15 years met the recommendations for physical activity (Health and Social Care Information Centre, 2013a). Furthermore, physical activity levels tend to decline during adolescence, with figures demonstrating most decline after age 8-9 years (Health and Social Care Information Centre, 2013a), particularly between the ages of 9 and 12 (Dumith et al., 2011) and 11-15 years (OECD, 2013).

1.4.1 Physical activity levels of children with Type 1 Diabetes

Annual surveys such as the Health Survey for England (Health and Social Care Information Centre, 2013a) measure the levels of physical activity in children across the population. Such surveys have demonstrated small proportions of children meeting the recommended level of physical activity, but have not distinguished between those children with and without chronic conditions.

Current data on the physical activity level of children with T1DM is variable, partly due to differences in the way physical activity is measured. Research has sought to compare the activity levels of children with and without T1DM. Several studies using self-report measures of physical activity have reported children with T1DM to be less active than those without T1DM (Heilman et al., 2009 ; Sundberg et al., 2012 ; Valerio et al., 2007). Similar findings have been made with objective measures of physical activity (Fintini et al., 2012 ; Maggio et al., 2012 ; Sarnblad et al., 2005 ; Trigona et al., 2010). Other studies using objective measures of physical activity have reported similar levels of physical activity between those with and without T1DM (Fintini et al., 2012 ; Lobelo et al., 2010). In a review of epidemiologic literature, Liese et al. (2013) identified one out of a possible ten studies that found higher self-reported physical activity levels in children with T1DM compared with age-matched children without T1DM (Raile et al., 1999). It remains uncertain whether children with T1DM are more, less or equally active compared with children without diabetes.

Perhaps more conclusive is that a large proportion of children with T1DM do not meet current recommendations of 60 minutes of MVPA per day (Liese et al., 2013). For example, Michaliszyn and Faulkner (2010) objectively recorded the physical activity level of adolescents with T1DM across a 16-week physical activity intervention using an ActiGraph GT1M accelerometer (Pensacola, FL). This study found that on average, adolescents spent 10 hours per day in sedentary behaviour and 42 minutes per day in MVPA. Trigona et al. (2010) reported that 35% of children aged 6-17 years with T1DM accrued 60 minutes of MVPA per day.

It is apparent that the existing research evidence is equivocal, partly owing to small sample sizes (<100) and the noticeable absence of large, representative studies using objective assessment instruments such as accelerometers to measure children's physical activity (Liese et al., 2013). Furthermore, the studies have been conducted in Sweden (Sarnblad et al., 2005 ; Sundberg et al., 2012), Switzerland (Maggio et al., 2012 ; Trigona et al., 2010), Estonia (Heilman et al., 2009) and USA (Michaliszyn and Faulkner, 2010), and therefore may not be directly applicable to other countries.

In summary, regardless of the challenges with physical activity measurement, an insufficient level of physical activity puts children with T1DM at risk of short-term and long-term comorbidity and obesity, in addition to the pre-existent increased risk of CVD. The evidence suggests that children with T1DM should be encouraged to engage in a more active lifestyle to benefit their health and diabetes management. However, complications associated with physical activity may present challenges for children with T1DM. These complications are now discussed.

1.5 Complications associated with physical activity for children with Type 1 Diabetes

The complications associated with physical activity for children with T1DM are likely to relate to the body's physiological response to physical activity, particularly the effect on blood glucose level. When children with T1DM participate in physical activity, exercise or sport, the following factors must be considered:

- *Type, duration and intensity of the activity*

  Effective management of physical activity requires an understanding of how the body responds to aerobic, anaerobic, short duration and long duration exercise. The type, duration and intensity of the activity will determine the insulin dosage and carbohydrate intake required. It has been said that the management of diabetes and physical activity requires 'a sound understanding of the physiology of exercise' (Annan, 2013) (p. 238).

- *Insulin dosage*

  Changes in daily physical activity or exercise patterns may require insulin dose to be altered (NICE, 2015).

- *Site of the pump/injection*

  The site of insulin injection prior to participation needs to be considered with regards to the major muscle groups used during the activity.

- *Food eaten prior to participation*

  Carbohydrate intake is altered depending on the energy expenditure of the activity. The NICE (2015) guidelines advise that, "*additional carbohydrate should be consumed as appropriate to avoid hypoglycaemia and that carbohydrate-based foods should be readily available during and after exercise*" (NICE, 2015)(p20).

- *Age and weight*

  Energy expenditure and the amount of carbohydrate required will vary with the age and weight of the child (Annan, 2013).

- *Exercise-induced hypoglycaemia*

  Children with T1DM experience a drop in blood glucose levels during and after prolonged physical activity, known as hypoglycaemia (Riddell and Iscoe, 2006). Hypoglycaemia is the most common side-effect of exercise in children and adults with T1DM due to reduced plasma glucose, increased insulin sensitivity, and depletion of glycogen stores in muscle (Riddell and Burr, 2011).

These considerations often form part of a diabetes management plan for planned activities (Robertson et al., 2009). The complications of physical activity become particularly problematic when children engage in physical activity that is unplanned and sporadic. Adding to the complexity, there is no single technique or physical activity management plan that will suit every child (Annan, 2013).

1.5.1 Exercise-induced hypoglycaemia

Participation in physical activity and exercise changes glucose homeostasis, putting those with T1DM at risk of hypoglycaemia during and after episodes of increased activity. Episodes of hypoglycaemia are characterised by symptoms such as sweating, shaking, nausea, drowsiness, confusion, anger or tearfulness and unconsciousness (Wild et al., 2007). Delayed onset of hypoglycaemia is common due to increased insulin sensitivity in muscles after exercise (The Diabetes Research in Children Network Study, 2005). One study in children aged 10-18 years with T1DM has shown that following a low intensity late afternoon (4.00pm) exercise session (walking on a treadmill for 60 minutes), delayed onset of hypoglycaemia occurred overnight in 48% of 50 participants (The Diabetes Research in Children Network Study, 2005).

When exercise sessions are planned or form part of a structured routine, blood glucose regulation can be easier to manage (Robertson et al., 2009). Lifestyle physical activity (typically unplanned) also influences blood glucose levels, especially if the activity is novel, unusually strenuous or prolonged (Robertson et al., 2009). Thus, one of the major challenges for children with T1DM engaging in an active lifestyle is the balance of food, insulin and physical activity to limit blood glucose fluctuations (Riddell and Iscoe, 2006). In Section 1.5.1 of the current chapter, hypoglycaemia is discussed as a potential barrier to physical activity participation for children with T1DM.

In summary, there are complexities and complications associated with T1DM that have the potential to make participation in physical activity difficult. In this section, some complications, including exercise-induced hypoglycaemia, have been suggested as potential challenges for children wanting to engage in an active lifestyle. It is possible that these complications play a part in influencing children's level of physical activity, but to date, evidence supporting this is limited. Crucially, there remains a need to know *why* some children are less physically active than others and *how* physical activity can be promoted among children with T1DM. Research is needed to explore the factors influencing physical activity participation among children with T1DM. Without this knowledge, attempts to promote physical activity in children with T1DM could ignore influential factors.

1.6 The promotion of physical activity in children with Type 1 Diabetes

Physical activity interventions are attempts to promote and support physical activity in a target population. Chapter 2 will explore and critically evaluate existing physical activity and exercise interventions that have been implemented among children with T1DM. The challenge for physical activity promotion is in understanding how to support children to change their behaviour. This necessitates a greater understanding of the determinants of involvement in physical activity (Biddle and Mutrie, 2008), which can be facilitated by drawing upon psychological theory of behaviour change.

1.6.1 The role of theory in the promotion of physical activity

Psychological theory can help to explain behaviour as well as provide suggestions for effective ways to influence and change behaviour (Glanz et al., 2008). Theoretically driven interventions allow for the identification of intervention effects on potential mediators of behavioural change. It is known that physical activity interventions based on a psychological theory of behaviour change are more effective at promoting physical activity than strategies with no theoretical underpinning (King et al., 2002). What is less known is which of several competing theories is best to promote physical activity among children.

Choice of theory should be based on the identification of important variables in relation to the given behaviour in the population of interest, with identification of how the variables relate or interact to determine behaviour (Glanz et al., 2008). It has been argued that there is no dominant theoretical framework in health promotion research or practice (Glanz et al., 2008). Whilst it is beyond the scope of this thesis to offer an in-depth discussion of all the various psychological theories of behavioural change, it is beneficial to highlight theories and models that have been used advantageously to improve the understanding of children's physical activity.

1.6.2 Social cognitive approaches to physical activity promotion

Health behaviours such as participation in physical activity occur within a complex system of interacting influences. Cognitive based approaches consider behaviour as consequent to complex processes involving consideration of outcomes, attitudes, values and efficacy judgements (Buchan et al., 2012). Yet, behaviour does not occur in a cultural vacuum, meaning approaches must consider social influences such as family processes that may shape children's behaviour (Bennett and Murphy, 1997). The social cognitive approach combines the interactions of personal traits, thoughts, and social environment to help explain behaviour.

Social cognitive theories of behaviour change are of particular value in the area of children's physical activity. They explain the social, environmental and psychological underpinnings of children's physical activity. Three social cognitive approaches, self-determination theory (Deci and Ryan, 2000), social cognitive theory (Bandura, 2001) and the transtheoretical model (Prochaska and DiClemente, 1994) will be described in terms of how they can help explain and promote children's participation in physical activity. Descriptions of each theoretical model will be supported with examples of how an intervention underpinned by the theory might look in practice.

1.6.2.1 Self-determination theory

Self-determination theory (SDT) (Deci and Ryan, 2000) focuses on the processes through which children acquire motivation to initiate and maintain behaviours. Motivation refers to a child's drive to be physically active. The SDT proposes a multi-dimensional view of motivation, with different types of motivation being arranged on a continuum depending on the degree of self-determination (Deci and Ryan, 2000). Self-determined motivation (i.e., autonomous) is considered higher quality than less self-determined (i.e., controlling) motivation. At one end of the continuum, intrinsic motivation is considered the most autonomous form of motivation because it is based on the child's inherent interest and satisfaction derived from being active (e.g., fun and enjoyment). Extrinsic motivation focuses on the consequences not inherent in the activity. Extrinsic motivation can be autonomous (e.g., valuing the benefit of being physically active such as health outcomes) or controlling (e.g., being active to achieve participation-based reward). At the opposite end of the continuum from intrinsic motivation is amotivation, which is the absence of motivation or intention to act (Deci and Ryan, 2000).

1.6.2.2 Self-determination theory in practice

According to SDT, attempts to promote children's physical activity should optimise autonomous forms of motivation (Sebire et al., 2013). The SDT proposes that autonomous motivation requires satisfying the innate psychological needs of autonomy, competence and relatedness (Deci and Ryan, 2000). Promoting physical activity among children would benefit from helping children choose activities they enjoy (autonomy), feel competent and confident in their ability to be active (competence) and feel connected with or supported by significant others in their environment (relatedness) (Jago et al., 2013a).

An example of a physical activity intervention underpinned by SDT has been evaluated in a randomised feasibility trial (Jago et al., 2014a). Action 3:30 is an after-school physical activity programme led by teaching assistants among UK primary school children in Years 5 and 6 (ages 9–11) (Jago et al., 2014a). The programme used SDT constructs to encourage physical activity among children attending UK primary schools by increasing children's motivation and confidence in relation to physical activity. Teaching assistants were trained to use an autonomy-supportive style that supports children's autonomy, competence and relatedness whilst children participated in adaptable activities to improve hand-eye and limb coordination and agility skills in groups, pairs and alone (Jago et al., 2013a). Research to date has demonstrated that Action 3:30 was feasible to deliver, acceptable to children and teachers and could hold considerable promise in promoting children's physical activity (Jago et al., 2015 ; Jago et al., 2014a).

1.6.2.3 Social cognitive theory

An alternative social cognitive approach is offered by the social cognitive theory (SCT) (Bandura, 1986). The SDT and SCT both focus on the influence of the social environment and significant others on children's cognitions and behaviour. The SCT is described briefly below and in more detail in Section 1.6.3.

Bandura's SCT explains human functioning in terms of a model of triadic reciprocal interaction, in which behavioural, cognitive and environmental influences operate as interacting determinants of each other (Bandura, 1986). The model of triadic reciprocal interaction provides a framework for intervention development that targets both cognitive factors (e.g., self-efficacy) and environmental factors (e.g., social support) as potential mediators for behaviour change. Children may have little control over their environment, which is an important consideration when exploring the factors that influence physical activity. A supportive environment must be in place if a child is to succeed at becoming physically active, thus interventions to promote physical activity are likely to target the child's environment as well their cognitions.

1.6.2.4 Social cognitive theory in practice

An example of how SCT can be used to underpin a physical activity intervention for children is described below (see the Steps To Active Kids (STAK) programme described in Section 1.7). An example of a T1DM management intervention underpinned by SCT constructs has been evaluated in Scotland (Franklin et al., 2006). Franklin et al. (2006) implemented an e-health text-messaging intervention to promote diabetes self-management behaviours among children (8 - 18 years) with T1DM. The Sweet Talk programme drew upon SCT (Bandura, 2001), by promoting self-efficacy through goal-setting and social support. Research showed that the intervention had beneficial effects on clinical (e.g., HbA1c improvement) and psychosocial (e.g., self-reported adherence) outcomes and high acceptability and uptake. Improvement was demonstrated in children's diabetes self-efficacy and perceived diabetes social support from the diabetes team. Thus, an intervention underpinned by SCT could hold promise in promoting children's adherence to diabetes management behaviours.

A limitation of social cognitive theories such as SDT and SCT is that physical activity is more complex than individual constructs such as motivation and self-efficacy.

Behaviour emerges as a result of complex interactions between multiple levels of influence which are often unpredictable, spontaneous, uncontrolled and change over time. This calls for approaches that consider behaviour change as occurring in a dynamic or nonlinear manner.

1.6.2.5 Transtheoretical model

Models draw on a number of theories to facilitate understanding of a specific problem in a particular setting or context (Glanz et al., 2008). A dynamic advance to static theories is offered by the transtheoretical model (TTM) (Prochaska and DiClemente, 1994). The TTM is a stage-based approach proposing that individuals adopt and maintain physical activity in stages. The stages involve: pre-contemplation (i.e., not ready to change), contemplation (i.e., getting ready to change), preparation (i.e., ready to change), action (i.e., change) and maintenance (i.e., long-term change). The model proposes a cyclic rather than linear process.

TTM proposes that interventions to promote physical activity should be tailored to the child's stage of readiness to change. A valuable feature of TTM is that it indicates behaviour change strategies that are suitable for each stage of change, making it useful for underpinning physical activity promotion strategies. It is unique as an integrative model that incorporates key constructs from other theories such as self-efficacy.

For example, Motivational Interviewing (MI) is a patient-centred counselling approach to facilitate behaviour change that addresses the ambivalence and discrepancies between a person's current values and behaviours and their future goals (Rollnick et al., 2008). MI has the potential to benefit behaviour change interventions in paediatric health care (Erickson et al., 2005). It draws upon SDT by seeking to enhance a child's intrinsic motivation to change behaviour (e.g., become more physically active). It also aims to promote and support self-efficacy (e.g., the child's belief in their ability to be active). MI requires that HCPs understand the child's readiness to change to target their intervention effectively. Targeting the child's stage of change has potentially important implications for T1DM, which involves multiple daily management tasks. For example, if a child is in the action stage for dietary management, but is in the pre-contemplation stage for physical activity, clinical efforts to change behaviour should be tailored separately for each individual behaviour (Howe et al., 2005). MI has been shown to be effective in facilitating behavioural changes in adolescents with T1DM with subsequent improvement in diabetes control (Channon et al., 2007).

In summary, the above examples demonstrate the potential for social cognitive theories to underpin interventions aimed at promoting children's physical activity (Jago et al., 2014a) and also T1DM management behaviours (Channon et al., 2007 ; Franklin et al., 2006). The next section will describe Bandura's health promotion model (Bandura, 2004) and its related constructs, which offer a model for promoting physical activity via social cognitive means. An existing physical activity intervention underpinned by social cognitive constructs is then outlined in demonstration of how they translate into behaviour change techniques.

1.6.3 Bandura's health promotion model

Bandura (2004) proposed a model which depicts how social cognitive constructs affect health behaviour. This model suggests that self-efficacy has a direct effect on behaviour and works indirectly through outcome expectations, self-regulation (goal-setting) and socio-structural factors (barriers and facilitators) (Figure 1). Each of these constructs will be defined in terms of how they relate to children's physical activity.

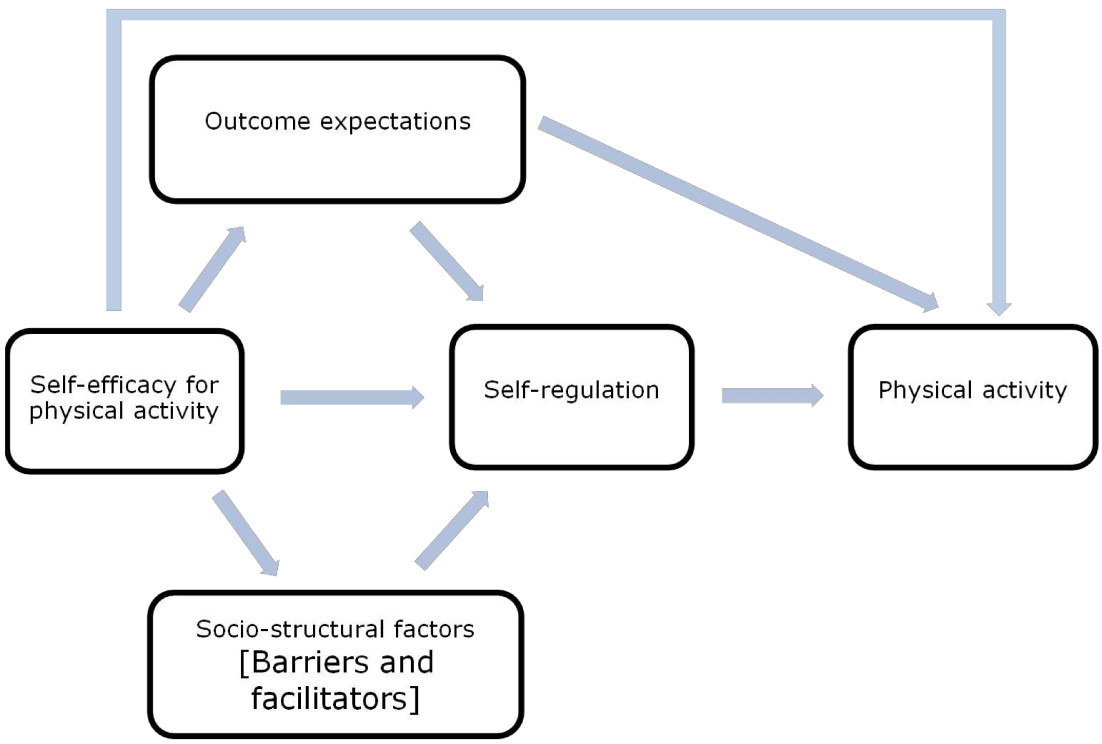

Figure 1 Bandura's health promotion model, adapted from Bandura (2004)

1.6.3.1 *Self-efficacy for physical activity*

To participate in physical activity, children must perceive that they are capable of doing so. Self-efficacy for physical activity refers to a person's belief in their ability to be physically active (Bandura, 1986). It concerns not just the skills they perceive themselves to have, but the judgement of what they believe they can do with those skills (Bandura, 1986). Bandura (1986) proposed that self-efficacy is a primary determinant of behaviour, suggesting that unless children judge themselves to be capable of physical activity, they will have little incentive to act. According to Bandura, a child's self-efficacy will affect the action they take, how much effort they exert, how long they persevere in the face of barriers or difficulties, their resilience to adversity, their thought patterns and affective response, their ability to cope with environmental demands and their level of accomplishment (Bandura, 1986).

Self-efficacy has been considered one of the strongest variables influencing the physical activity level of children in the general population (Salmon et al., 2009 ; Van der Horst et al., 2007). It has received support for mediating the relationship between interventions and physical activity among children and adolescents (Lubans et al., 2008). Self-efficacy for physical activity (also referred to as exercise self-efficacy) has been found to predict children's perceptions of exercise and increase after successful completion of exercise behaviours (Pender et al., 2002).

Self-efficacy for physical activity could be a promising focus for attempts to increase physical activity in diabetic populations. A physical activity intervention for adults with Type 2 Diabetes is underway in the Netherlands which gives extra support to people with low exercise self-efficacy (van der Heijden et al., 2012). Van der Heijden et al.'s study is the first of its kind to take levels of exercise self-efficacy into account when delivering a physical activity intervention to people with Type 2 Diabetes (van der Heijden et al., 2012). Unfortunately, similar research among children with T1DM is limited.

Targeting self-efficacy in interventions to promote physical activity has the potential to identify and benefit those people in need of extra support to adopt and maintain a physically active lifestyle (van der Heijden et al., 2012). It is theoretically plausible that once self-efficacy is established for a specific behaviour such as physical activity in childhood, there is potential for continuation of this desired behaviour in the long-term (Bandura, 1986). Therefore, targeting self-efficacy for physical activity in children with T1DM is a promising avenue of research.

1.6.4 Promoting self-efficacy for physical activity

Interventions aiming to build and sustain self-efficacy require an understanding of how self-efficacy beliefs form. Bandura proposed that self-efficacy beliefs are formed by interpreting information primarily from four sources; mastery experience, vicarious experience, social persuasion and emotional/physiological states (Bandura, 1986):

- *Mastery experience* involves experiencing success in challenging, yet attainable performances of desired behaviour. Thus, past experience of physical activity is important.

- *Vicarious experience* involves successful modelling of the desired behaviour, particularly by those regarded similar to the self.

- *Social or verbal persuasion* refers to the use of verbal and non-verbal cues to increase self-efficacy such as words of encouragement. The effectiveness of social persuasion depends on the credibility of the persuader and how knowledgeable they are about the nature of the task or behaviour.

- *Emotional and physiological states* involve enhancing self-efficacy through changing the perception of physiological and emotional reactions to specific tasks or behaviour. People rely on emotional and physiological states while judging capability and self-efficacy, e.g., positive affect or mood enhances self-efficacy whereas negative mood diminishes it.

Bandura's health promotion model (Bandura, 2004) suggests that self-efficacy can directly influence physical activity or indirectly influence the behaviour via outcome expectations, self-regulation perceived barriers and facilitators.

1.6.4.1 Outcome expectations

Bandura distinguished between efficacy expectations and outcome expectations (Bandura, 2004). An outcome expectation is an estimate that physical activity will produce certain outcomes (Bandura, 2004). Outcome expectations are formed through the child's past experiences and vicariously through the observation of significant others in their environment. Bandura suggested that the frequency of behaviour should increase when the outcomes expected are valued, whereas behaviours associated with unfavourable or irrelevant outcomes will be avoided.

Research findings suggest children's positive outcome expectations about physical activity are related to their participation in organised and free-time physical activity (Heitzler et al., 2006). Interventions targeting children's outcome expectations among other social cognitive constructs such as self-efficacy have been associated with positive changes in physical activity (Dishman et al., 2004 ; Haerens et al., 2008).

1.6.4.2 *Self-regulation*

Self-efficacy is theorised to influence physical activity through self-regulation strategies such as goal-setting (Bandura, 2004). According to (Bandura, 1997), there are six ways to achieve self-regulation: self-monitoring; goal-setting; feedback; self-reward; self-instruction; and enlistment of social support. Personal goals provide incentive to act, and can be long-term or short-term. Goal-setting is related to outcome expectations and self-efficacy. This is because goals are a function of the outcomes children expect from engaging in particular behaviours and the self-efficacy they have for completing those behaviours successfully (Bandura, 2004). Goals are useful for health behaviours such as physical activity because they provide objectives that children are trying to achieve and benchmarks against which to judge progress (Bandura, 2004).

1.6.4.3 *Perceived facilitators and barriers*

Perceived facilitators are the factors that assist children in working towards goals and engaging in physical activity. Perceived barriers are determinants or correlates believed to impede participation in physical activity. Perceived barriers form an integral part of self-efficacy assessment because children assess their personal efficacy to be active in the face of obstacles such as the appeal of alternative behaviours (e.g., watching television) (Bandura, 2004).

Qualitative research has identified facilitators and barriers to children's physical activity across a range of demographic, psychological, social and environmental domains. These lists are not exhaustive, but facilitators of physical activity include being male (Rees et al., 2001), self-efficacy (Mulvihill et al., 2000), time spent with friends and parental influence, (Tannehill et al., 2015) and time spent outdoors (Tannehill et al., 2015). Barriers to physical activity include parents not owning a car (i.e., socio-economic status) (Brunton et al., 2003), not feeling competent (Rees et al., 2001), parental constraints (NICE, 2007b) and lack of facilities (Rees et al., 2001).

These studies have identified strong and consistent correlates of children's physical activity which, if targeted in physical activity interventions, should result in more effective behaviour change (Baranowski et al., 1998 ; Sallis et al., 1999). However, it has been recognised that children with chronic conditions are often excluded from research (Ferreira et al., 2007), and thus results from reviews should be generalised to children with T1DM with caution. Due to the complexity of living with and managing diabetes, it cannot be assumed that the same facilitators and barriers will be perceived by children with T1DM. The next section describes potential facilitators and barriers to physical activity for children with T1DM.

1.6.5 Facilitators and barriers to physical activity among children with Type 1 Diabetes

Whilst research has explored the barriers to physical activity participation among adults with T1DM (Thomas et al., 2004), few studies have explored the barriers and facilitators of physical activity among children with T1DM. It could be that children with T1DM perceive similar barriers and facilitators to adults with T1DM and to children without a chronic condition (Pivovarov et al., 2015), but to date we know little about what helps and hinders participation in physical activity among children with T1DM.

Fereday and colleagues (2009) used qualitative interviews to explore how children with chronic conditions (T1DM, asthma and cystic fibrosis) and their parents perceived and managed physical activity. This study revealed high participation in a wide variety of physical activities, accompanied by beliefs that participation was not hindered by the chronic condition. Parental planning and vigilance to manage the child's condition, supervision, and emotional and financial support were integral to the children having a physically active lifestyle. It was common for parents to transport and accompany their child to activities and school camps and invest time and money to enable their child to participate in physical activity and sport (Fereday et al., 2009).

The findings of Fereday and colleagues (2009) suggest that there are similarities between the facilitators of physical activity for children with T1DM (and other long-term conditions) and those identified in children without diabetes. The importance of parental planning and vigilance and the need for parental supervision identified by Fereday and colleagues (2009) suggests parental support may be particularly important for children with chronic conditions. Given that parents play an important role in the management of their child's condition, the facilitative role of parents in the physical activity of children with T1DM warrants further exploration (the role of parents has been explored further in Chapter 3).

In addition to having T1DM-specific facilitators, children with T1DM may perceive particular challenges related to their condition that limits their engagement in physical activity (Pivovarov et al., 2015). In Section 1.5.1, exercise-induced hypoglycaemia was introduced as a common side-effect and complication of physical activity among children with T1DM. The next section discusses fear of hypoglycaemia (FOH) as a potential barrier to physical activity for this population.

1.6.5.1 Fear of hypoglycaemia as a potential barrier to physical activity for children with Type 1 Diabetes

Previous researchers have proposed that fear of hypoglycaemia (FOH) may act as a barrier to physical activity among children with T1DM (Leclair et al., 2013 ; Pivovarov et al., 2015). This proposition, however, has been inferred from studies on adults with T1DM (Brazeau et al., 2008) and parents of children with T1DM (Patton et al., 2008). Such research suggests that the most common perceived barrier to physical activity in adults with T1DM is fear of exercise-induced hypoglycaemia (Brazeau et al., 2008). Similarly, parents of children with T1DM have concerns about exercise-induced hypoglycaemia and avoidance of hypoglycaemia is a high priority during and after participation in physical activity (Fereday et al., 2009). Further studies in children with T1DM would help identify the barriers to physical activity that are specific to children.

Questionnaire studies have demonstrated that children (8–18 years) experience FOH in everyday life, but the research has not examined FOH that is specific to children's participation in physical activity (Johnson et al., 2013b). Recent qualitative studies that have explored children's perceptions of physical activity suggest that children perceive few diabetes-specific barriers to physical activity (Fereday et al., 2009 ; MacMillan et al., 2014b). Further research is therefore required to understand whether children with T1DM have unique perceptions of physical activity outcomes and barriers.

In summary, the unique physiological (e.g., blood glucose levels) and psychological (e.g., FOH) responses to physical activity among children with T1DM present potential barriers to children's participation. Attempts to promote physical activity in this population would need to further explore and take into consideration these potential barriers. The next section introduces an existing theoretically-driven intervention targeted at children who may face unique challenges to physical activity.

1.7 An intervention to promote self-efficacy for physical activity: The Steps To Active Kids (STAK) programme

The Steps To Active Kids (STAK) programme is an empirically tested physical activity programme targeted at children aged 9–11 years who have low levels of customary physical activity. It has been delivered through UK primary schools and targets children in Year 5 and Year 6 (aged 9-11 years) who have low self-efficacy for physical activity, demonstrate low levels of physical activity, are overweight or have asthma (Glazebrook et al., 2011). The adapted STAK programme will be described in Chapter 7, Section 7.3.

1.7.1 Components of the original STAK programme

The STAK programme combines school-based physical activity sessions with home-based components. It comprises a 10 week programme delivered in three steps:

- Step 1 includes specially developed educational material delivered through a STAK activity diary, a Street Dance DVD and activity diary over 4 weeks.

- Step 2 involves weekly group activity sessions alongside the activity diary for 4 weeks. During this step, children are also given a pedometer and are encouraged to record the number of steps they take per day in the activity diary.

- Finally, Step 3 runs over the final 2 weeks of the intervention and involves individual goal-setting and review of goals (Motivational Interview). Each component is described in more detail below.

1.7.1.1 Children's STAK activity diary

A STAK activity diary, in the form of a loose-leaf folder, informs children about physical activity and raises awareness about their level of physical activity. Children are encouraged to personalise the folder and a number of interactive inserts are included.

The STAK activity diary recommends that children aim to collect at least five physical activity points a day (5-a-day). The promotion of '5-a-day' aims to bring about an accumulation of the recommended target of at least 60 minutes of MVPA per day (NICE, 2009). Diary inserts provide examples of how activity points can be achieved (Figure 2b). Walking to school, for example, would represent one of the '5-a-day'. There

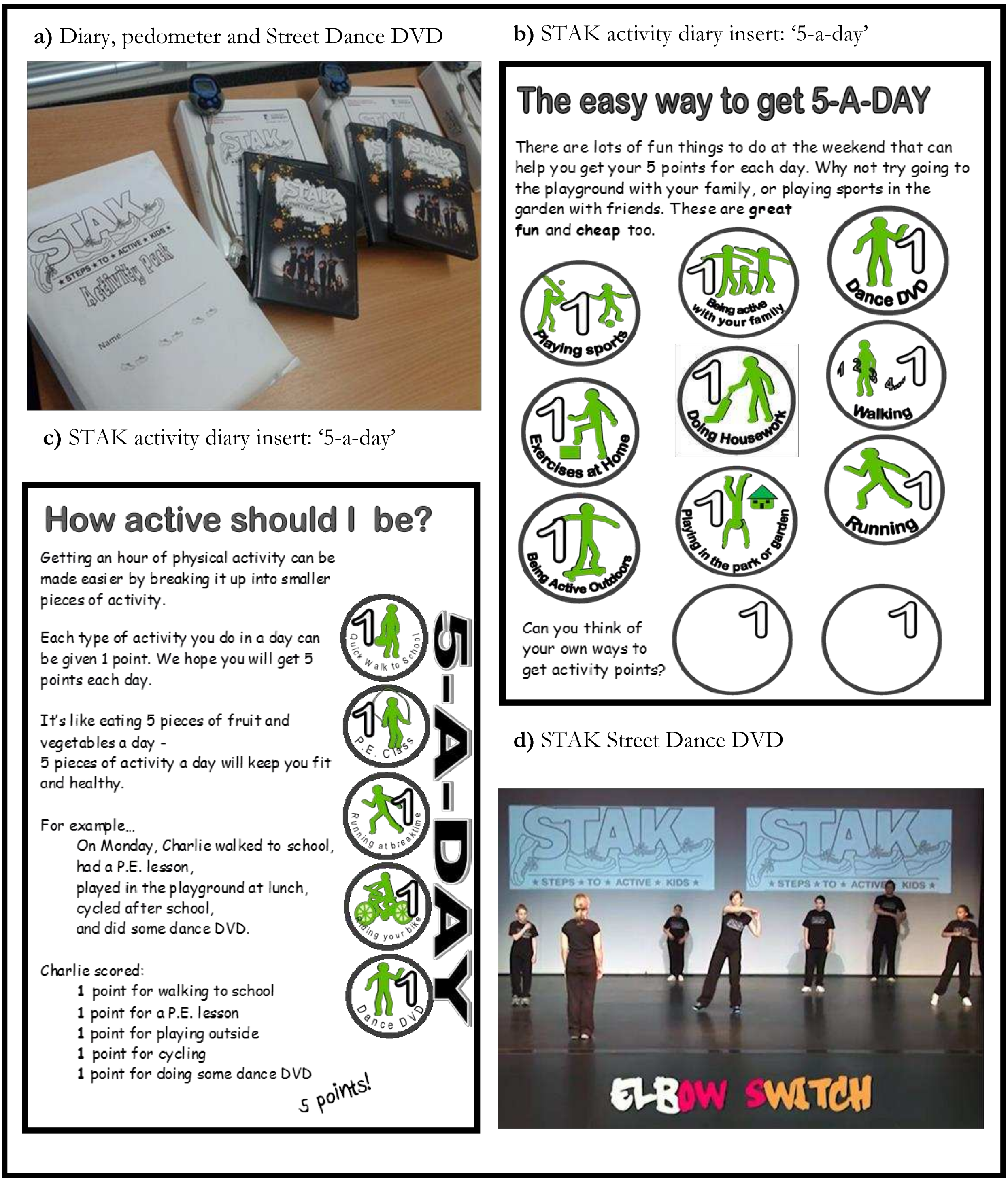

Figure 2 a–d Components of the STAK programme is a focus on everyday behaviours such as 'doing housework', 'playing in the garden', and 'running at break-time in school' and less emphasis on structured sports and exercises, although these also count towards the '5-a-day'. The STAK diary includes a log book within which children can monitor their '5-a-day' for the duration of intervention. Children are encouraged to personalise their STAK diary, engage with the inserts and suggested activities and monitor their daily activities at school and at home.

1.7.1.2 *STAK street dance DVD*

The street dance DVD was developed specifically for the STAK programme. It shows a group of ethnically diverse children aged 9–11 years being taught a street dance routine by dance teachers (Figure 2d). The children featured on the DVD have no previous dance experience and at times can be seen to make mistakes. The aim of the street dance DVD is to teach children a complete dance routine over a four-week period and provide role models that the children can relate to. Children are encouraged to complete the guided warm-up, 10-minute dance lesson and cool-down once a day at home either on their own or with a friend or family member; each dance session earns the child one activity point.

1.7.1.3 *Pedometer and step-count log*

Children are given a pedometer and encouraged to record daily step count in a log within the STAK activity diary over the course of the programme. Pedometers have been shown to increase physical activity in children (Lubans et al., 2009) and are useful tools in the STAK programme to promote goal-setting and self-monitoring.

1.7.1.4 *STAK group activity sessions*

To complement the home-based components, group activity sessions are scheduled for Step 2 of the STAK programme. The group activity sessions are held during the school day and last 50–60 minutes. The activity session, designed by a paediatric physiotherapist, uses circuit training to music. After a guided warm-up (10 minutes), children complete each activity station for two minutes, recording their score for each activity (20–30 minutes) on a score sheet provided. Between each station, a 1-2 minute break provides time for rest and score recording. Children perform each activity station alone, under the supervision of volunteers and are discouraged from comparing scores with other children. Instead, the session aims to encourage children to focus on individual effort and improvement rather than comparison with peers. Each activity station is designed to require both high and low intensity movements, to target a range of muscle groups and to develop a range of motor skills such as balance, co-ordination, movement skills and basic fitness (see Appendix 1 for activity stations). The aim is to provide a positive experience of physical activity and to increase self-efficacy for physical activity outside of the STAK programme as well as an improvement on these core competencies. The session concludes with a cool-down (10 minutes). The group activity session is delivered by a sports coach with supervision from trained volunteers. The coach and volunteers reinforce and model positive physical activity behaviours and aim to create an engaging and enjoyable environment for physical activity. Children are asked to bring their STAK diary to group activity sessions for volunteers to provide feedback and encouragement on the child's '5-a-day' progress and daily step count.

1.7.1.5 Motivational interview

Towards the end of the STAK programme, children with at high risk of obesity (above the 91st BMI centile at baseline) are involved in a one-to-one session with a researcher based on the principles of motivational interviewing (MI) (Rollnick et al., 2008). This MI technique seeks to promote physical activity through a collaborative, person-centred approach that elicits and strengthens the child's intrinsic motivation to engage in a physically active lifestyle. The main MI principles in the STAK programme are; expressing empathy (e.g., accepting and understanding the child's position) and supporting self-efficacy (e.g., providing support to develop the child's competence in physical activity and overcoming barriers to physical activity) (Rollnick et al., 2008).

The MI session primarily aims to facilitate discussion around physical activity between the researcher and the child. It aims to uncover the child's readiness to change by exploring whether they demonstrated 'change talk', e.g., "*I would like to do x with my mum*". Activity rulers encourage children to rate how active they believe themselves to be on a scale of 0-10, how happy they are with this amount of activity and how confident they are at being able to be more active (all on a 0–10 scale ruler) (Figure 3). The MI technique of developing discrepancy is used to generate further discussion and highlight the difference between the child's present activity/happiness level and their personal goals and values, e.g., *"what makes you an 7 and not an 8 or 9?"*. The session also seeks to elicit the child's perceived barriers to and facilitators of activity. The children are guided through goal-setting, how to set achievable goals and how to pre-empt what might be a barrier to successful goal attainment. By the end of the session, the child has set a physical activity-related goal and is encouraged to discuss the goal with their parent. Goals are reviewed one week after the first MI session.

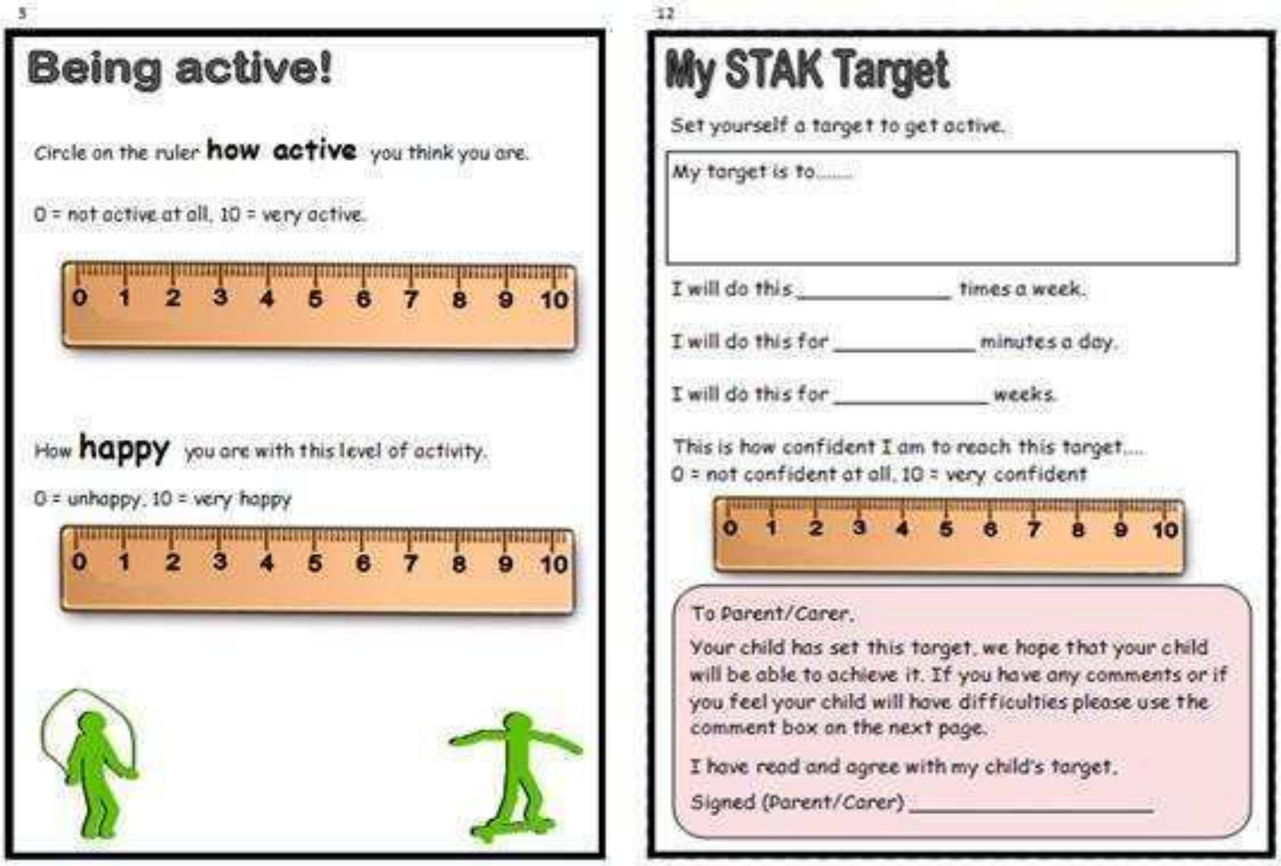

Figure 3 Motivational interview inserts

1.7.2 Theoretical underpinning of the STAK programme

The STAK programme combines educational (information sheets, physical activity guidance, safety information), behavioural (circuit training, pedometer step counting and physical activities) and cognitive-behavioural (physical activity monitoring and goal-setting) strategies to promote children's self-efficacy for physical activity. Steps 1 and 2 of the STAK programme draws upon SCT constructs of self-efficacy and observational learning (Bandura, 1986). The intervention targets children who have barriers to physical activity and aims to promote self-efficacy via observing successful role models, mastery experience and persuasion (via education). Step 3 of the STAK programme draws upon the TTM of behaviour change (Prochaska and DiClemente, 1994) and uses the technique of MI to establish barriers to exercise, elicit readiness to change and set realistic, achievable physical activity goals for the individual. The STAK programme components, content and theoretical underpinning are outlined in Table 1.

Table 1 Components, content and theoretical underpinning of the STAK programme

Component	Content	Theoretical underpinning
Children's STAK Activity Diary (Home-based)	Information about physical activity	Outcome expectations Persuasion (education)
	5-a-day target and activity log	Self-regulation (goal-setting, self-monitoring) Mastery experience
Street dance DVD (Home-based)	28 x 10 minute dance sessions gradually developing into complete dance routine	Vicarious experience (role model) Mastery experience Social support
Pedometer (Home-based)	Pedometer and step-count log	Self-regulation (self-monitoring and goal setting) Mastery experience
Group activity sessions (Supervised, group based)	Circuit training to music in a group	Vicarious experience
	Monitor personal progress	Mastery experience
	Volunteers (at least one volunteer per three children)	Social support Vicarious experience Verbal persuasion
Motivational interview (Supervised, individual)	Child-centred, supportive conversation about physical activity	Readiness to change Social support
	Identifying facilitators and barriers	Social support
	Personalised goal-setting	Self-regulation (self-monitoring and goal setting)

The original STAK programme has been tested in a cluster-randomised trial with 424 children from 24 UK primary schools (aged 9–11 years) screened for overweight, low exercise self-efficacy or asthma. The STAK programme improved children's self-efficacy for physical activity in the intervention group. In the group of children who were overweight at baseline (>91st centile), those in the STAK intervention group had smaller waist circumference and lower BMI at 4 month follow-up (Glazebrook et al., 2012). At 12 months, the intervention group had significantly increased children's exercise self-efficacy and self-reported physical activity scores compared with the control group (Glazebrook et al., *in press*).

1.7.3 Implementation of the STAK programme among children with Type 1 Diabetes: would it be possible?

The success of the STAK programme for children with barriers to physical activity, including those with asthma, would imply that similar outcomes might be achieved if applied to children with T1DM. Further research is required to test this assumption and to establish the potential benefit of the STAK programme for this population.

In its existing form, the STAK programme will need adaptations before it can be evaluated for feasibility and acceptability among children with T1DM. For example, given the prevalence of T1DM (one per 430-530; Diabetes UK (2014)), it is unlikely that school-based recruitment would generate sufficient numbers of children with diabetes. Therefore an important adaptation to the existing intervention would be recruitment and implementation via paediatric diabetes clinics. It has been suggested that healthcare settings have an important role to play in the promotion of physical activity (Salmon and King, 2010). Research is needed to establish whether the STAK programme can be adapted for delivery in a clinical setting.

A further adaptation to the STAK programme regards the level of parental involvement. In this chapter, the importance of parental involvement in the management of children's T1DM, especially pre-adolescent children, has been highlighted. It is proposed that the adapted version of the STAK programme will need to engage parents more and encourage parental involvement. Again, further research is required to test this assumption.

1.8 Significance and purpose and of the thesis

The promotion of physical activity in children with T1DM should be prioritised to optimise long-term health outcomes. Understanding behaviour and the likely process of change is complex and requires careful consideration of the influences contributing to the behaviour. The aim of this thesis is to expand our current understanding of how children with T1DM experience physical activity, to advance our knowledge of how to promote active lifestyles in this population and to adapt an existing physical activity intervention and subsequently evaluate its feasibility in a sample of children with T1DM. Social cognitive theories of behaviour change are drawn upon to help develop our understanding and produce replicable implications for future research and clinical practice.

1.9 Research paradigm

Paradigms refer to worldviews that shape how researchers design and implement their research studies (Guba and Lincoln, 1994). It has been suggested that researchers adopt the paradigm and methods which best reflect the purpose of inquiry, the questions being investigated and the resources available (Patton, 1990). The research paradigm used in this thesis is pragmatism. This pragmatic paradigm judges the merit of an evaluation not on philosophical tenants, but by the extent to which it is useful and practical (Johnson and Onwuegbuzie, 2004). The pragmatic stance enables researchers to draw upon the relative strengths of different research methods to satisfy their research aims. Equal value is given to quantitative and qualitative methods, which provides researchers with the opportunity to choose the methods to best address the research question (Greene et al., 1989). A pragmatic viewpoint is warranted because there is a strong focus on the practicality of the results derived from this research. Findings are being sought that are intended to be applicable in practice to optimise the health outcomes of children with T1DM.

1.10 Research design

The research design follows the UK medical research council (MRC) framework for the development of complex interventions (Campbell et al., 2000 ; Craig et al., 2008) (**Figure 4**). According to this framework, the development phase is important to establish an empirical and theoretical understanding of the given behaviour in the population of interest. This preliminary work informs the feasibility phase of the intervention before evaluation and implementation phases. The research studies within this thesis are situated within the Development and Feasibility phase of the MRC framework. The thesis uses a multiphase mixed-methods design (Creswell and Clark, 2007) and consists of six studies (**Figure 5**).

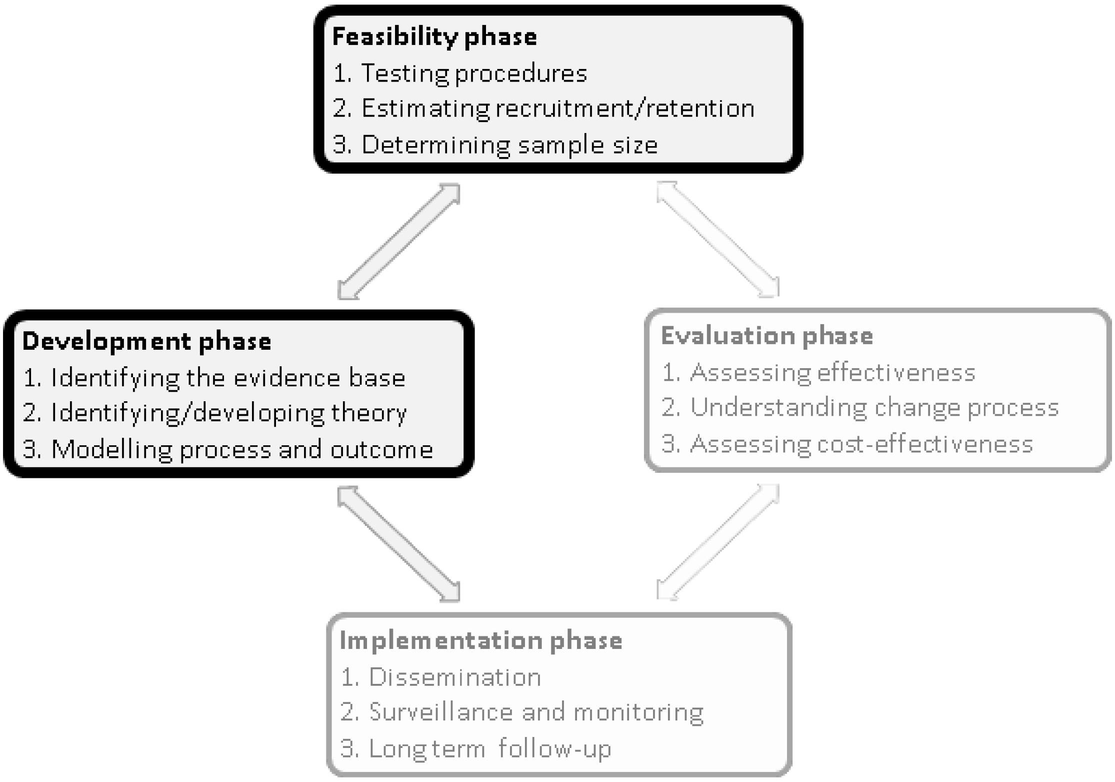

Figure 4 The MRC framework adapted from Craig et al. (2008)

1.11 Conclusions

This chapter has provided the theoretical background and justification for this the empirical exploration of physical activity among children with T1DM. The literature to date indicates that T1DM is a complex condition, which can be managed, in part, by regular physical activity. The figures reported have shown that levels of physical activity among children with and without T1DM are not sufficient to maximise potential health benefits. The value of social cognitive theories of behaviour-change to help explain and promote physical activity among children has been put forward. Bandura's construct of self-efficacy has been introduced as a valuable theoretical basis to help understand physical activity among children.

An existing intervention (the STAK programme; Glazebrook et al., 2011) has been presented as an example of a theoretically driven intervention with potential for promoting physical activity participation among children with T1DM. This thesis aims to develop our knowledge and understanding of the factors influencing physical activity for children with T1DM and how best to promote active lifestyles among this population, before attempt is made to evaluate and implement an adapted STAK programme tailored to the needs of children with T1DM.

1.12 Summary of thesis chapters

The first study in this thesis (described in Chapter 2) systematically reviews physical activity and exercise interventions for children and young people with T1DM. This study documents the strategy for literature searching, subjects the evidence to a quality evaluation and combines the evidence in meta-analyses where possible. It aims to establish the existing evidence base for the thesis, with particular attention being given to gaps in the existing literature.

Chapters 3 and 4 use qualitative methods to interview parents (Study 2) and HCPs (Study 3) and explore their perceptions of physical activity for children with T1DM. These studies seek to explore how parents and HCPs perceive physical activity for children with T1DM, including barriers and facilitators to participation. The findings will be used to advance understanding, provide recommendations for clinical practice and inform adaptations to the existing STAK programme to optimise its feasibility and acceptability when implemented among children with T1DM.

Chapter 5 explores the feasibility and acceptability of wrist-worn accelerometers to measure physical activity in a sample of 13 children aged 9–11 years with T1DM. This study primarily seeks to evaluate whether wrist-worn accelerometers can be used in this population. In addition, it will report the physical activity levels of the sample of children who participated in the feasibility study. Interviews with children and their parents are used to determine the acceptability of accelerometers for this population.

Chapter 6 explores the experience of physical activity and variables associated with participation among the sample of children who participated in the feasibility study (Study 5). This study identifies correlates of physical activity alongside children's values, beliefs and outcome expectations related to their participation. The study aims to advance our existing theoretical understanding of participation in physical activity among children with T1DM and describes the sample used in the subsequent feasibility study (Study 6, Chapter 7).

Chapter 7 describes the adaptations made to the existing STAK programme based on developmental research and patient and public involvement (PPI) activities. The study evaluates the feasibility of the adapted STAK programme for children aged 9–11 years with T1DM. This feasibility study (Study 6) includes a qualitative process evaluation to investigate children's, parents' and HCPs' views of the acceptability of the STAK programme for children with T1DM.

The final chapter of this thesis (Chapter 8) synthesises the conclusions from all studies and discusses the implications of the findings for a future definitive trial, future research and clinical practice.

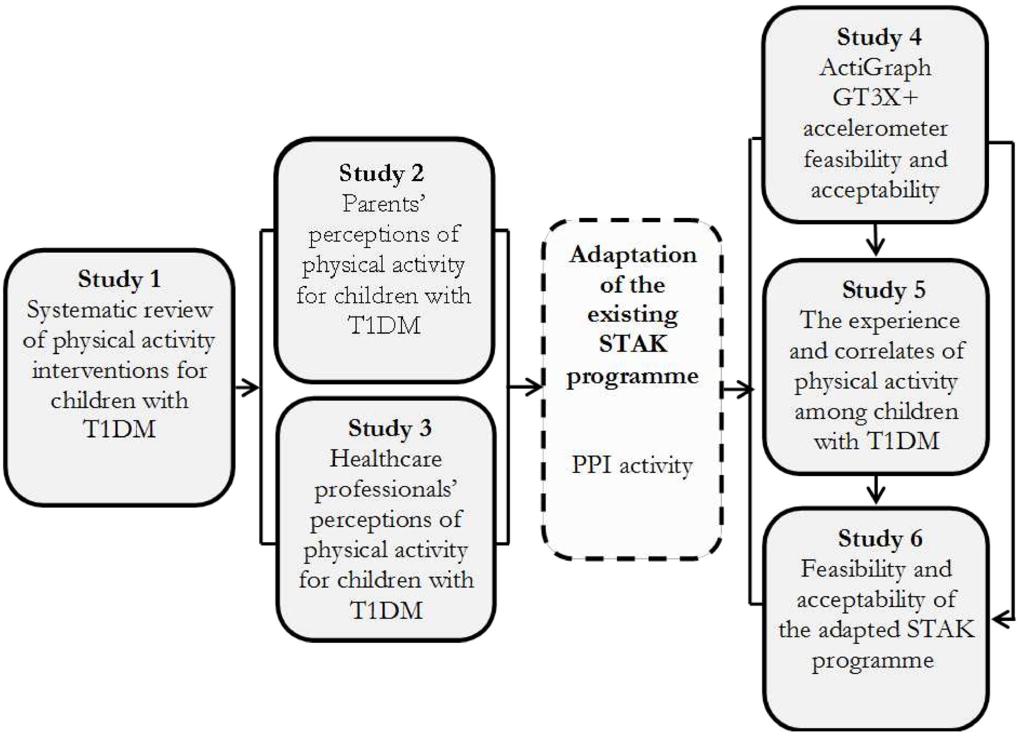

Figure 5 Overview of the studies within this thesis

Chapter Two

Physical activity interventions in children with Type 1 Diabetes: A systematic review with meta-analysis

2.1 Introduction

In Chapter 1, theoretical and empirical evidence was presented that supported the need for physical activity promotion among children with Type 1 Diabetes Mellitus (T1DM). This chapter explores and critically evaluates previous intervention studies in a systematic literature review. Medical Research Council (MRC) guidelines recommend a systematic review during the development of an intervention to collate the existing evidence (Craig et al., 2008). Until recently, no systematic review of physical activity interventions for children with T1DM had been published.

Kennedy et al. (2013) reviewed randomised controlled trials (RCTs) and non-randomised studies (NRS) of physical activity interventions, with a focus on the outcome of glycaemic control in both adults and children with T1DM (Kennedy et al., 2013). MacMillan et al. (2013) conducted a systematic review that explored a wider range of health outcomes, but focussed on RCTs only. Both reviews suggested that physical activity interventions had positive effects for children with T1DM, yet important information may have been missed regarding intervention design, implementation and potential health outcomes due to restrictive inclusion criteria. Thus, a synthesis of evidence from other study designs on a wider variety of health outcomes is warranted.

The current review is unique because it synthesises NRS and RCTs and, therefore, covers a wider range of studies and outcomes than previous reviews. Valuable insights and additional information can be gleaned from including NRS provided that attention is given to the risk of confounders and heightened bias (Higgins et al., 2011 ; Reeves et al., 2013). This inclusivity enables evaluation of a larger selection of interventions, which can inform future physical activity promotion.

2.2 Study aims

The aim of this chapter is to review synthesised evidence from RCTs and NRS of physical activity interventions in children and adolescents with T1DM. First, it examines the characteristics of existing interventions, including research processes such as recruitment and retention. Second, it seeks to explore the clinically relevant health outcomes associated with physical activity interventions. Finally, it will use the findings to inform strategies for physical activity promotion in this population. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al., 2009) guide the planning, conduction, and report of this review.

2.3 Methods

This section will describe the methods used to conduct this review, including the study eligibility criteria, data extraction procedure, quality assessment procedure, measures of treatment effect, assessment of heterogeneity and publication bias methods and subgroup and sensitivity analyses.

2.3.1 Study eligibility

Study eligibility criteria are reported in accordance with the PICOS principles for systematic reviews (Petticrew and Roberts, 2008); Population, Intervention, Comparison, Outcomes and Study design.

2.3.1.1 Population

The population of interest was children aged ≤18 years of age clinically diagnosed with T1DM.

2.3.1.2 Intervention

Studies reporting physical activity or exercise interventions were included for review. Interventions were more than a one-off activity session, with a programme of physical activity or exercise delivered through scheduled sessions, educational resources, or both. Physical activity interventions involved monitoring or promoting lifestyle physical activities whereas exercise interventions involved prescribed, planned, structured, repetitive bodily movements undertaken for the purpose of improving or maintaining physical fitness or health, such as swimming laps or circuit training (Caspersen et al., 1985).

2.3.1.3 *Comparison groups*

Studies were eligible if comparison groups involved children who were not exposed to any physical activity intervention, children partaking in their usual daily activity, or children without T1DM also exposed to the intervention. A distinction was made between control groups and comparison groups. A control group was defined as participants with T1DM who did not participate in the intervention. A comparison group was defined as participants without T1DM who participated in the intervention.

2.3.1.4 *Outcomes*

Physiological, psychological, behavioural and social outcomes were all considered of interest.

2.3.1.5 *Study designs*

The review included RCTs and NRS. RCTs refer to studies including a control group with T1DM, in which participants were randomly assigned to their group at the beginning. NRS refer to a controlled, before-and-after study with a control or comparison group (no randomisation), or a prospective cohort study (no control or comparison group).

Peer-reviewed, published articles in English were included with no limitation on the year of publication or length of follow-up.

2.3.2 Search methods

The following databases were searched using the search strategy detailed in Figure 6: CINAHL Plus, Cochrane Library, EMBASE, MEDLINE, PsycINFO, SCOPUS, SportDiscus, Web of Science. Search terms included: "type 1 diabetes" OR "type 1" OR "type I" OR T1DM OR "insulin dependent" OR IDDM OR "diabetes mellitus" AND child* OR teen* OR juvenil* OR young OR adolescen* AND exercis* OR activit* OR training OR sport* OR "strength training" OR "resistance training" OR endurance OR fitness OR "physical activit*" OR "physical education". Searches were conducted between October 2012 and December 2012. Reference lists of review articles and included studies were hand searched.

Two reviewers, the thesis researcher and a research assistant independently reviewed abstracts of potentially relevant articles identified from the search. Abstracts not fitting the inclusion criteria were excluded. When the abstract suggested potential eligibility, the full article was retrieved. Inclusion was based on mutual agreement between reviewers and reasons for exclusion were recorded. Disagreements were presented to a third reviewer (thesis supervisor), who made the final decision to include or exclude the article.

2.3.3 Data extraction and study quality

The two reviewers independently extracted the data and variations in data extraction were resolved through discussion. Wherever there was insufficient detail reported, the authors of the article were contacted by the researcher via email for clarification of study methods or data (17 authors were contacted, 10 authors provided information). Methodological quality of articles was assessed independently by the reviewers, based on the quality criteria specified by the Cochrane Collaboration (Higgins et al., 2011) and Critical Appraisal Skills Programme checklists (Critical Appraisal Skills Programme (CASP), 2010). Alterations were made to the Cochrane Collaboration risk of bias tool to accommodate the NRS included. The types of bias explored included selection bias, detection bias, measurement bias, attrition bias, reporting bias and confounding bias.

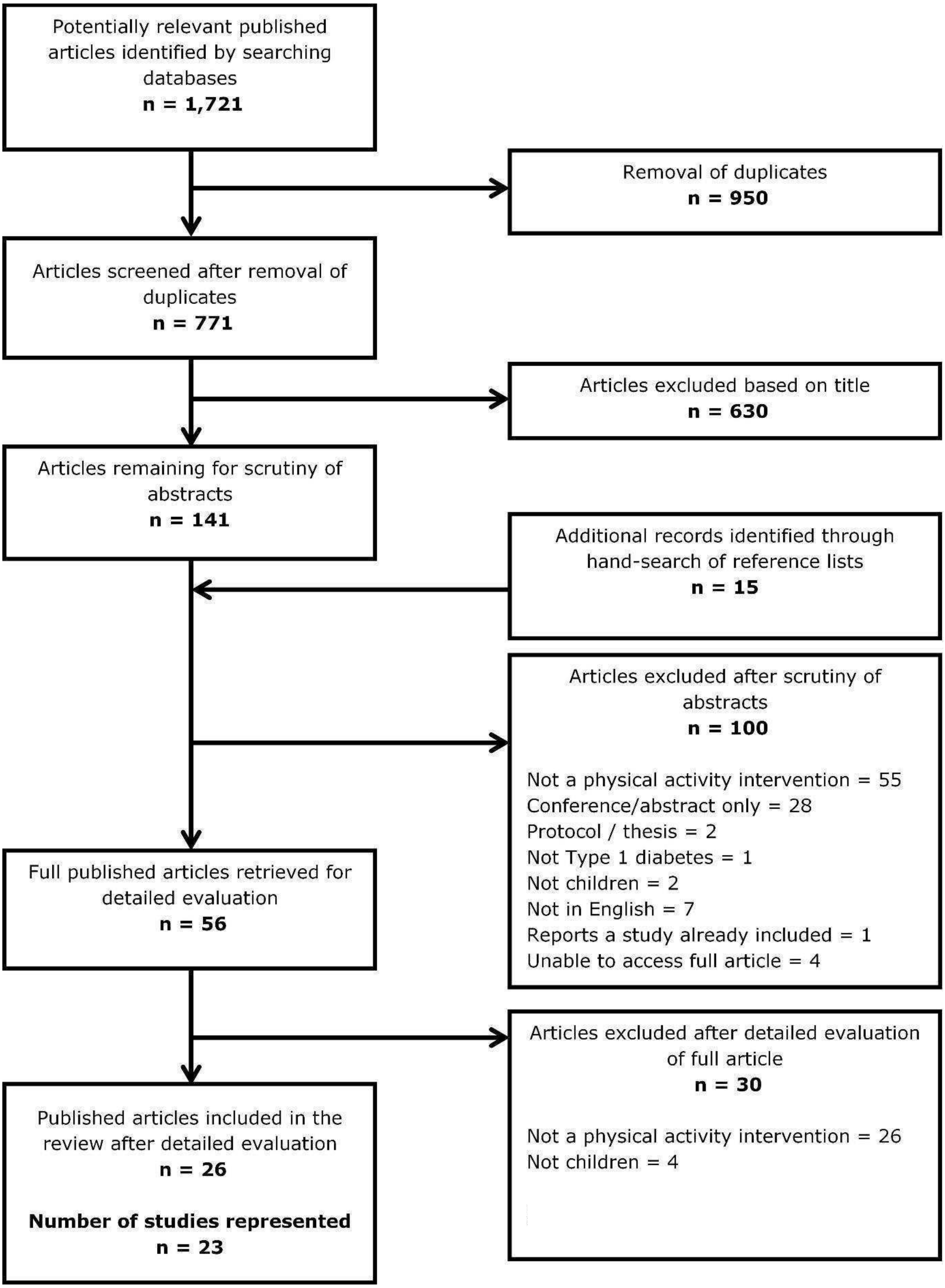

Figure 6 Flowchart to summarise the study selection process

2.3.4 Measures of treatment effect

Wherever possible, findings from RCTs or NRS with a control group were synthesised in meta-analyses using the Review Manager software (Review Manager (RevMan), 2012). The effect size for an intervention was defined as the observed difference in a measurement from pre- to post- intervention between an intervention group (exercise) and control group (no exercise). Standardised mean difference (SMD) was used as the summary statistic for the overall effect size. Associated 95% confidence intervals (CI) were expressed. Studies measuring outcomes with different units of measurement were not synthesised in meta-analyses, with the exception of glycated haemoglobin (HbA1c), where measurements of HbA1c or HbA1 differ only for a constant multiplier. HbA1c is now commonly reported in International Federation of Clinical Chemistry (IFCC) units (mmol/mol), but was previously reported as a percentage. All studies under review expressed glycated haemoglobin as HbA1 or HbA1c (%). The current guideline of HbA1c ≤48mmol/mol equates to ≤6.5 DCCT %.

2.3.5 Assessment of heterogeneity and publication bias

Heterogeneity between studies was determined using the Chi-Square test. Random-effects analysis was performed when significant heterogeneity was present. Where possible, publication bias was assessed using funnel plots.

2.3.6 Subgroup and sensitivity analyses

Subgroup analyses for activity type, intensity and frequency, duration of intervention and supervision were planned, depending on availability of data. Sensitivity analyses were planned to explore the influence of different factors on effect size by repeating analyses: i) excluding studies with imputed values; ii) excluding NRS; and iii) excluding studies rated as being at high risk of bias.

2.4 Results

The search identified 1,721 records and 56 full articles met the inclusion criteria for further examination (Figure 6). Thirty articles were excluded and reasons recorded. The remaining 26 articles (representing 23 studies) were selected for review (Appendix 2). Studies included 10 RCTs and 16 NRS (nine controlled before-and-after studies, seven prospective cohort studies), published between 1964 (Larsson et al., 1964b ; Larsson et al., 1964a) and 2012 (Maggio et al., 2012 ; Tunar et al., 2012). Studies were conducted in 15 different countries; none were UK-based (Appendix 2).

2.4.1 Participants

Sample sizes ranged between 10 (Marrero et al., 1988) and 196 (Salem et al., 2010a), with a total of 756 participants, 661 with T1DM. Six NRS had a comparison group of participants without T1DM (Larsson et al., 1964b ; Larsson et al., 1964a ; Mosher et al., 1998 ; Sideravičiūtė et al., 2006 ; Sideravičiūtė et al., 2006a ; Woo et al., 2010). Three NRS had a control group with T1DM that did not participate in the intervention (Aouadi et al., 2011 ; Dahl-Jorgensen et al., 1980 ; Wong et al., 2011). All RCTs involved participants with T1DM only, with the exception of one involving participants with and without T1DM randomised to either an intervention or a control group (i.e., four groups) (Maggio et al., 2012). The age of participants with T1DM ranged from mean=8.5 years (SD=0.57) years (Campaigne et al., 1984) to mean=17 years (SD=1.2) years (Mosher et al., 1998). Most studies included both sexes, except five male-only studies (Aouadi et al., 2011 ; Larsson et al., 1964b ; Larsson et al., 1964a ; Mosher et al., 1998 ; Woo et al., 2010) and three female-only studies (Heyman et al., 2007 ; Sideravičiūtė et al., 2006 ; Sideravičiūtė et al., 2006a).

2.4.2 Interventions

2.4.2.1 Recruitment and setting

Studies recruited participants via diabetes clinics, but eight studies did not report the location of recruitment (Aouadi et al., 2011 ; Dahl-Jorgensen et al., 1980 ; Larsson et al., 1964b ; Larsson et al., 1964a ; Mosher et al., 1998 ; Sideravičiūtė et al., 2006 ; Sideravičiūtė et al., 2006a ; Stratton et al., 1987 ; Woo et al., 2010), and one study recruited via a diabetes summer camp (Ruzic et al., 2008). Only one study reported the recruitment method (i.e., invitation (Ruzic et al., 2008)). Eighteen interventions were delivered under supervision from an athletic coach or trainer, physiotherapists, physicians or study personnel. Supervised interventions were delivered at a hospital (Salem et al., 2010a ; Stratton et al., 1987 ; Tunar et al., 2012), swimming pool (Sideravičiūtė et al., 2006 ; Sideravičiūtė et al., 2006a), gymnasium (Aouadi et al., 2011), sports centre (Baevre et al., 1985), college (Dahl-Jorgensen et al., 1980), performance laboratory (Mosher et al., 1998 ; Woo et al., 2010) or outdoors (Aouadi et al., 2011). Five interventions were unsupervised, involving home-based pedometers (Newton et al., 2009), video programmes (Marrero et al., 1988 ; Wong et al., 2011) and personalised activities (Faulkner et al., 2010 ; Michaliszyn and Faulkner, 2010). Three interventions included both unsupervised and supervised sessions (Dahl-Jorgensen et al., 1980 ; Heyman et al., 2007 ; Seeger et al., 2011).

2.4.2.2 *Duration*

The length of interventions ranged from 2 (Ruzic et al., 2008) to 39 weeks (Maggio et al., 2012). The most common duration of intervention was 12 weeks. Two interventions lasted fewer than 12 weeks (Ruzic et al., 2008 ; Stratton et al., 1987), 15 lasted longer than 12 weeks. All studies used a single post-intervention follow-up. Two studies used a maintenance follow-up: Ruzic et al. (2008) took HbA1c and blood glucose measurements at 10 days and 2 months after cessation of a summer camp intervention; and Wong et al. (2011) took HbA1c, peak oxygen uptake and perceived exertion measures at six, nine and 12 months after a home-based aerobic activity intervention.

2.4.2.3 *Time and frequency*

Activity sessions ranged between 30 minutes (Baevre et al., 1985 ; Campaigne et al., 1984 ; Stratton et al., 1987 ; Wong et al., 2011) and 120 minutes (Heyman et al., 2007). Sessions of at least 60 minutes occurred in 13 studies and there was a tendency for the sessions lasting less than 60 minutes to be published prior to 1990 (Baevre et al., 1985 ; Campaigne et al., 1984 ; Landt et al., 1985 ; Marrero et al., 1988 ; Stratton et al., 1987). The number of sessions varied between 1-5 days per week, except one study where activities took place three times per day during a 2-week diabetes summer camp (Ruzic et al., 2008). Two studies (Aouadi et al., 2011 ; Salem et al., 2010a) had two active intervention groups, one low and one high frequency activity (e.g., twice and four days a week, respectively (Aouadi et al., 2011). Home-based interventions required an accumulation of activity to meet a goal (e.g., 10,000 steps per day (Newton et al., 2009)).

2.4.2.4 *Type of activity*

Interventions were aerobic or a combination of aerobic and strengthening activity. Single aerobic exercises included running and walking (Aouadi et al., 2011 ; Rowland et al., 1985), swimming (Sideravičiūtė et al., 2006 ; Sideravičiūtė et al., 2006a) and dance (Landt et al., 1985 ; Marrero et al., 1988 ; Wong et al., 2011). Other interventions varied the activities and included circuit training, cycling, skipping, ball and team games. Strengthening exercises included weight-bearing and resistance exercises such as weight training (D'hooge et al., 2011 ; Mosher et al., 1998 ; Salem et al., 2010a), jumping (Maggio et al., 2012) and sprinting (Seeger et al., 2011). Balance and flexibility activity, such as Pilates (Tunar et al., 2012) were also included. In four studies, the programme of activity was personalised to allow participants to choose the type of activity and when it was performed (Faulkner et al., 2010 ; Marrero et al., 1988 ; Michaliszyn and Faulkner, 2010 ; Newton et al., 2009). Ten interventions involved progression in the length (Wong et al., 2011) or intensity (Aouadi et al., 2011 ; D'hooge et al., 2011 ; Heyman et al., 2007 ; Larsson et al., 1964b ; Larsson et al., 1964a ; Mosher et al., 1998 ; Rowland et al., 1985 ; Salem et al., 2010a ; Woo et al., 2010) of the activity over time.

In studies with a non-intervention control group, participants were instructed to continue with normal daily activity (Aouadi et al., 2011 ; Campaigne et al., 1984 ; D'hooge et al., 2011 ; Dahl-Jorgensen et al., 1980 ; Heyman et al., 2007 ; Landt et al., 1985 ; Maggio et al., 2012 ; Newton et al., 2009 ; Salem et al., 2010a ; Tunar et al., 2012 ; Wong et al., 2011), except one group who participated in non-physical activities (Huttunen et al., 1989) and another who were simply given physical activity guidelines with no further advice or support (20-60 minutes, 3-6 days per week) (Stratton et al., 1987). Wong et al. (2011) reported that five control group participants were reassigned to a group of 'self-directed exercisers' after it became apparent that they had become involved in self-initiated exercise after enrolling onto the study, although no significant differences in outcomes were reported for this group.

2.4.2.5 *Intensity of activity*

The intensity of activity was reported in 19 studies (Appendix 2). Aerobic activities were performed at light (Ruzic et al., 2008 ; Woo et al., 2010), moderate-to-vigorous (D'hooge et al., 2011 ; Faulkner et al., 2010 ; Huttunen et al., 1989 ; Maggio et al., 2012 ; Michaliszyn and Faulkner, 2010 ; Mosher et al., 1998 ; Seeger et al., 2011 ; Sideravičiūtė et al., 2006 ; Sideravičiūtė et al., 2006a), vigorous (Campaigne et al., 1984 ; Heyman et al., 2007 ; Landt et al., 1985 ; Marrero et al., 1988 ; Rowland et al., 1985), or a combination of moderate activities and vigorous activities (Salem et al., 2010a). Strengthening activities were performed based on one repetition maximum values (D'hooge et al., 2011 ; Mosher et al., 1998), 10 repetition maximum values and 85-95% maximum heart rate (Salem et al., 2010a).

2.4.2.6 Diet or insulin advice

Seven studies provided the intervention group with advice about diet or insulin regimen (Baevre et al., 1985 ; Heyman et al., 2007 ; Landt et al., 1985 ; Marrero et al., 1988 ; Mosher et al., 1998 ; Rowland et al., 1985 ; Ruzic et al., 2008 ; Stratton et al., 1987). In five of these, participants were given specific advice, e.g., "add 30 to 40g of carbohydrate 30 minutes before exercising" (Rowland et al., 1985), but the advice differed across studies. In three studies participants were informed to continue their usual diet and insulin regimen (Heyman et al., 2007 ; Mosher et al., 1998 ; Stratton et al., 1987). Five studies monitored diet (Campaigne et al., 1984 ; Landt et al., 1985 ; Larsson et al., 1964a ; Ruzic et al., 2008 ; Stratton et al., 1987), but did not attempt to change diet, none of which reported any significant change in calorie intake. One study conducted during a diabetes summer camp provided a controlled diet to research participants and individualised changes to insulin dosages (Ruzic et al., 2008).

2.4.2.7 Theoretical underpinning

One study reported that the intervention had a theoretical underpinning (Michaliszyn and Faulkner, 2010) (social cognitive theory and family systems theory). Newton et al. (2009) used text messaging as a 'motivational tool', but did not refer to a theory of motivation.

2.4.3 Effect of interventions

The health outcomes that were measured among the studies are given in Table 2.

Table 2 Health outcomes measured in included studies in descending order

	Fitness/V02 max	HbA1c	Total Cholesterol	Weight	Triglyceride	HDL-c	Daily insulin requirement	Body mass index	Height	Other fitness measures	Heart rate	Blood Glucose	LDL-c	HbA1	Fat-mass	Urinary glucose	Quality of life	Physical Activity	Waist Circumference	Fat-free mass	Lean body mass	Blood pressure	Calorie intake	Other metabolites	Skinfolds	Hormones	Glucose utilisation rate	Exercise perceptions	Bone mass density	Endothelial function	Antioxidant enzyme activity	Oxidative stress
Aouadi		✓	✓		✓	✓							✓																			
Baevre	✓		✓	✓	✓		✓			✓		✓		✓										✓		✓						
Campaigne	✓										✓	✓		✓									✓									
D'hooge	✓	✓					✓	✓	✓	✓	✓	✓			✓		✓		✓	✓												
Dahl-Jorgensen	✓						✓					✓		✓		✓																
Faulkner	✓																✓	✓										✓				
Heyman	✓	✓	✓	✓	✓	✓		✓	✓				✓		✓		✓	✓	✓	✓				✓								
Huttunen	✓	✓								✓		✓				✓																
Landt	✓													✓							✓		✓				✓					
Larsson (a)	✓			✓						✓	✓					✓							✓									
Larsson (b)			✓		✓																			✓								
Maggio				✓				✓	✓												✓								✓			
Marrero	✓													✓																		
Michaliszyn	✓	✓	✓		✓	✓							✓		✓			✓		✓												
Mosher	✓	✓	✓	✓	✓	✓				✓		✓	✓		✓						✓				✓							
Newton		✓					✓	✓									✓	✓				✓										
Rowland	✓			✓						✓	✓	✓		✓		✓																
Ruzic		✓										✓																				
Salem		✓	✓		✓	✓	✓	✓	✓				✓						✓			✓										
Seeger	✓			✓				✓	✓	✓	✓								✓											✓		
Sideraviciute(a)		✓					✓				✓	✓																				
Sideraviciute(b)	✓		✓	✓	✓	✓		✓	✓				✓		✓																	
Stratton	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓													✓							
Tunar	✓	✓	✓		✓	✓	✓	✓	✓	✓			✓																			
Wong	✓	✓																														
Woo	✓	✓	✓	✓		✓	✓	✓	✓		✓				✓							✓									✓	✓
TOTAL	19	14	11	10	10	9	9	9	9	9	8	8	7	6	6	4	4	4	4	3	3	3	3	3	2	1	1	1	1	1	1	1

2.4.3.1 *Physical activity and fitness*

Four studies measured physical activity before and after the intervention in intervention and control or comparison groups (Faulkner et al., 2010 ; Heyman et al., 2007 ; Michaliszyn and Faulkner, 2010 ; Newton et al., 2009). One study, reported in two articles (Faulkner et al., 2010 ; Michaliszyn and Faulkner, 2010) measured intensity and frequency of activity during the intervention with accelerometers, and baseline level of physical activity with a seven-day physical activity recall questionnaire. Heyman et al. (2007) also used a self-report physical activity questionnaire to estimate the total weekly physical activity attributed to the intervention. Newton and colleagues (2009) used step-count as well as a self-reported physical activity questionnaire.

Among those studies using an objective measure of physical activity, Faulkner, Michaliszyn and colleagues (2010) found that adolescents adhered to 60 minutes of moderate-to-vigorous physical activity (MVPA) per day for a mean of 45.5% of days an accelerometer was worn during the 16-week home-based aerobic activity intervention; spending a daily average of 10 hours in sedentary activity and 42 minutes in MVPA. Heyman et al. (2007) reported a significant increase in total weekly physical activity in the intervention group, and a significant difference between the intervention and control group. Newton and colleagues (2009) found no significant difference in change in physical activity in adolescents after a 12-week pedometer intervention.

Nineteen studies measured changes in various parameters of fitness, 14 of which reported a beneficial effect of the intervention on some area of fitness, such as improved cardiovascular fitness (Table 2). Three studies (66 participants) were pooled in a meta-analysis which found a non-significant effect of physical activity on VO_2max (SMD 0.24, $p = 0.33$) (Figure 7a). Four studies did not measure any parameter of physical fitness or physical activity as an outcome (Aouadi et al., 2011 ; Maggio et al., 2012 ; Ruzic et al., 2008 ; Salem et al., 2010a).

2.4.3.2 *Glycated haemoglobin*

Glycated haemoglobin (HbA1c) reflects average blood glucose concentrations over the previous 2-3 months and is measured in clinic and research settings as an indicator of diabetes control. As mentioned in Chapter 1, lower HbA1c is indicative of better diabetes control. HbA1c was measured in 20 studies, 11 of which were appropriate for meta-analysis. A random effects model meta-analysis (11 studies, 345 participants) produced a SMD of -0.52 (95% CI -0.97 to -0.07), which was significantly different from 0 (Z=2.29, p=0.02). Effect sizes in nine of the eleven studies in the meta-analysis were less than 0 (Figure 7b), though there was significant heterogeneity between studies (chi square=33.94, p=0.0002). Sensitivity analyses excluding studies with imputed standard deviation (SD) values and NRS resulted in decreases in magnitude of the overall effect. Excluding studies rated high risk of bias (Dahl-Jorgensen et al., 1980) increased the magnitude of the overall effect to (SMD -0.62, 95% CI -1.07 to -0.17, p = 0.007).

From the studies that could not be pooled in the meta-analysis, two reported significant decreases in HbA1c following the physical activity intervention (Michaliszyn and Faulkner, 2010 ; Sideravičiūtė et al., 2006a) and six reported no significant change in HbA1c (Baevre et al., 1985 ; D'hooge et al., 2011 ; Mosher et al., 1998 ; Newton et al., 2009 ; Rowland et al., 1985 ; Woo et al., 2010). Ruzic et al. (2008) reported a significant initial decrease in HbA1c level 10 days after the intervention, followed by a significant increase in HbA1c two months later.

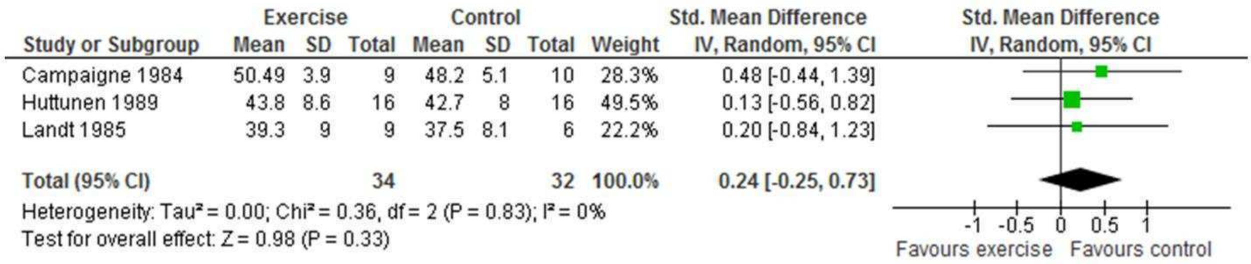

Figure 7a Forest plot showing estimate of the size of change in VO_2 max (ml/kg/min) after a physical activity intervention

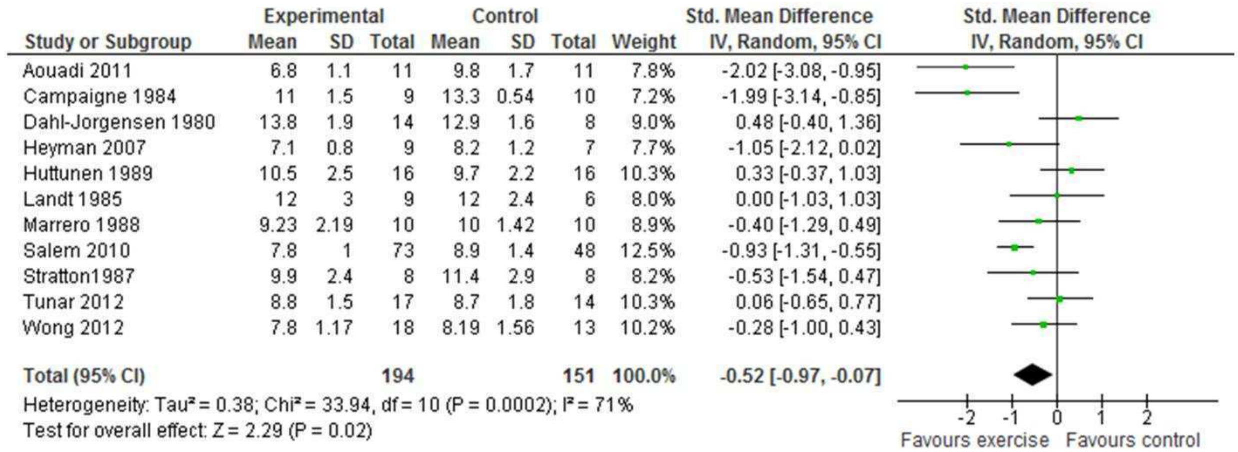

Figure 7b Forest plot showing estimate of the size of change in HbA1c (%) after a physical activity intervention

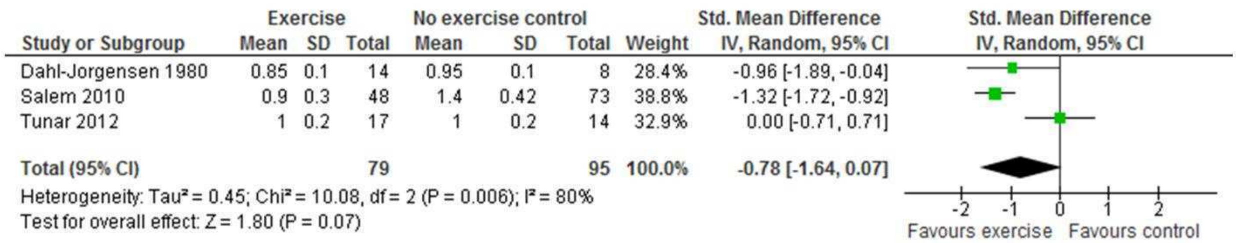

Figure 7c Forest plot showing estimate of the size of change in daily insulin dose (units/kg/day) after a physical activity intervention

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Aouadi 2011	60.7	6.9	11	79.5	9.2	11	14.7%	-2.22 [-3.33, -1.12]
Heyman 2007	55.8	8.9	9	71.7	34.5	7	16.1%	-0.64 [-1.66, 0.38]
Salem 2010	135.6	30.7	73	153.3	33.4	48	30.3%	-0.55 [-0.92, -0.18]
Stratton1987	85.6	51.7	8	123.6	95.9	8	16.5%	-0.47 [-1.46, 0.53]
Tunar 2012	89.9	46.8	17	95.1	57.5	14	22.4%	-0.10 [-0.81, 0.61]
Total (95% CI)			**118**			**88**	**100.0%**	**-0.70 [-1.25, -0.14]**

Heterogeneity: Tau² = 0.23; Chi² = 10.34, df = 4 (P = 0.04); I² = 61%
Test for overall effect: Z = 2.45 (P = 0.01)

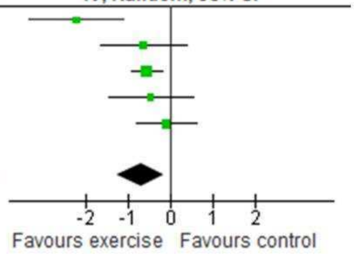

Figure 7d Forest plot showing estimate of the size of change in triglyceride level (mg/dL) after a physical activity intervention

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Aouadi 2011	150.1	16.3	11	163.7	19.4	11	19.4%	-0.73 [-1.60, 0.14]
Heyman 2007	164.7	24.36	9	186.4	20.1	7	17.3%	-0.91 [-1.96, 0.15]
Salem 2010	145.6	27	73	194.9	23	48	24.2%	-1.92 [-2.36, -1.48]
Stratton1987	214.5	66.1	8	223.3	65.4	8	18.1%	-0.13 [-1.11, 0.85]
Tunar 2012	167.5	25.8	17	196.1	62.1	14	21.1%	-0.61 [-1.33, 0.12]
Total (95% CI)			**118**			**88**	**100.0%**	**-0.91 [-1.66, -0.17]**

Heterogeneity: Tau² = 0.55; Chi² = 18.78, df = 4 (P = 0.0009); I² = 79%
Test for overall effect: Z = 2.41 (P = 0.02)

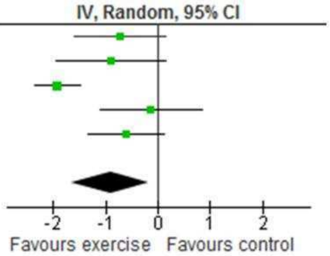

Figure 7e Forest plot showing estimate of the size of change in total cholesterol (mg/dL) after a physical activity intervention

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Heyman 2007	25.2	1.8	9	25.6	1.3	7	8.5%	-0.24 [-1.23, 0.76]
Maggio 2012	18.92	2.5	15	18.67	2.46	12	14.5%	0.10 [-0.66, 0.86]
Salem 2010	22.57	2.9	73	24.5	4.26	48	60.7%	-0.55 [-0.92, -0.18]
Tunar 2012	20.2	4	17	21.7	2.6	14	16.3%	-0.42 [-1.14, 0.29]
Total (95% CI)			**114**			**81**	**100.0%**	**-0.41 [-0.70, -0.12]**

Heterogeneity: Tau² = 0.00; Chi² = 2.37, df = 3 (P = 0.50); I² = 0%
Test for overall effect: Z = 2.76 (P = 0.006)

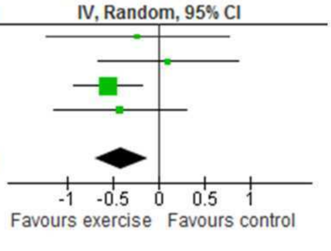

Figure 7f Forest plot showing estimate of the size of change in Body Mass Index (kg/m^2) after a physical activity intervention

Figure 7a-f Forest plots showing estimates of the size of change in outcomes after a physical activity intervention

2.4.3.3 Daily insulin dose

Nine studies measured daily insulin dose before and after the physical activity intervention. Three studies (174 participants) had data appropriate for meta-analysis. There was no overall difference in daily insulin dose (SMD -0.78, p = 0.07) (Figure 7c). In studies where data could not be pooled in the meta-analysis, three demonstrated decreases in insulin dose in intervention group participants (D'hooge et al., 2011 ; Sideravičiūtė et al., 2006a ; Stratton et al., 1987), although one found a reduction in short-acting insulin only (Sideravičiūtė et al., 2006a). Three studies reported no significant change in daily insulin dose (Baevre et al., 1985 ; Newton et al., 2009 ; Woo et al., 2010).

2.4.3.4 Lipid profile

Serum lipids were measured in eleven studies. Triglycerides, total cholesterol, high density lipoprotein cholesterol (HDL-C) and low density lipoprotein cholesterol (LDL-C) were reported. Five studies reporting triglycerides, total cholesterol, and HDL-C and four studies reporting LDL-C were appropriate for meta-analysis.

A random effects model meta-analysis for triglycerides (5 studies, 206 participants) produced a SMD of -0.70 (95% CI -1.25 to -0.14), which was significantly different from 0 (Z = 2.45, p = 0.01). Effect sizes in all five of the studies included in the analysis were less than 0 (Figure 7d), though there was significant heterogeneity between studies (chi square = 10.34, p = 0.04).

A random effects model meta-analysis for total cholesterol (5 studies, 206 participants) produced a SMD of -0.91 (95% CI -1.66 to -0.17), which was significantly different from 0 (Z = 2.41, p = 0.02). Effect sizes in all five of the studies included in the analysis were less than 0 (Figure 7e), though there was significant heterogeneity between studies (chi square = 18.78, p = 0.0009).

There was no significant effect of physical activity on HDL-C (SMD 0.36, p = 0.49) or LDL-C (SMD -0.54, p = 0.21). A sensitivity analysis excluding NRS did not change the inference of the meta-analyses.

Lipid data from four studies could not be pooled in the meta-analysis, Michaliszyn and Faulkner (2010) reported that time spent in light, moderate and MVPA was associated with decreases in total cholesterol, LDL-C and triglycerides. Mosher et al. (1998) found significant increases in HDL-C and decreases in LDL-C in adolescent males with and without T1DM. Woo et al. (2010) found no significant changes in total cholesterol or HDL-C in boys with and without diabetes. Sideravičiūtė et al. (2006) found no significant changes in lipid profile in adolescent girls with T1DM following a swimming intervention, whilst HDL-C significantly increased in girls without diabetes.

2.4.3.5 Body composition

Nine studies measured body mass index (BMI). A random effects model meta-analysis (4 studies, 195 participants) produced a SMD of -0.41 (95% CI -0.70 to -0.12), which was significantly different from 0 ($Z = 2.76$, $p = 0.006$). Effect sizes in three of the four studies included in the analysis were less than 0 (Figure 7f), with no significant heterogeneity between studies (chi square = 2.37, $p = 0.50$).

Results from five studies could not be pooled in the meta-analysis. Salem et al. (2010) reported a significant decrease in BMI in both groups of children who performed physical activity sessions once and three times per week, and the reduction was greater in those who participated three times a week. Sideravičiūtė et al. (2006) found an increased BMI in adolescent girls with T1DM compared to girls without diabetes before and after a swimming programme. The remaining studies found no significant change in BMI (D'hooge et al., 2011 ; Wong et al., 2011 ; Woo et al., 2010).

Nine studies measured body weight, three of which reported significant increases in body weight after physical activity (Baevre et al., 1985 ; Larsson et al., 1964a ; Sideravičiūtė et al., 2006a). Four studies reported waist circumference. Salem et al. (2010a) reported a significant decrease in waist circumference in children and greatest reduction in those who participated three times per week compared with once per week. Six studies measured fat-mass; three using bioimpedance techniques (D'hooge et al., 2011 ; Michaliszyn and Faulkner, 2010 ; Woo et al., 2010), and three computing fat-mass from skinfold measures (Heyman et al., 2007 ; Mosher et al., 1998 ; Sideravičiūtė et al., 2006a). Two studies found decreased fat-mass following the intervention (Mosher et al., 1998 ; Sideravičiūtė et al., 2006a). Three studies reported fat-free mass using bioimpedance (D'hooge et al., 2011 ; Faulkner et al., 2010 ; Michaliszyn and Faulkner, 2010) or computed from skinfold measures (Heyman et al., 2007). Fat-free mass was found to increase in the physical activity group (Heyman et al., 2007) and to be positively associated with time spent in moderate, vigorous and moderate-to-vigorous physical activity (Michaliszyn and Faulkner, 2010). Three studies reported lean body mass (Landt et al., 1985 ; Maggio et al., 2012 ; Mosher et al., 1998). Mosher et al. (1998) reported that adolescent males with T1DM gained lean body mass after 12 weeks of circuit training three times per week. Two studies reported no significant changes in skinfold thickness (Mosher et al., 1998 ; Stratton et al., 1987).

2.4.3.6 *Quality of life*

Quality of life was measured in four studies using three different measures. D'hooge et al. (2011) and Faulkner et al. (2010) found no significant changes in quality of life following the intervention. Heyman et al. (2007) reported improvement in 'satisfaction with diabetes' in the intervention group. Newton and colleagues (2009) found quality of life scores to be below the normative range at baseline in adolescents with T1DM, with no significant changes following the 12-week pedometer intervention.

2.4.3.7 *Exercise perceptions*

Faulkner et al. (2010) measured perceptions of exercise using scales for perceived self-efficacy, perceived benefits of action and perceived barriers to action (Pender et al., 1995). Faulkner et al. (2010) also used the exercise subscale of the Diabetes Social Support Questionnaire- family version (La Greca and Bearman, 2002). They reported that children's perception of normative family support for exercise increased significantly from pre- to post-intervention.

2.4.3.8 *Other effects of interventions*

Some physiological health indicators were explored in isolation and included serum apolipoproteins, lipoprotein(a), leptin, and adiponectin (Heyman et al., 2007), bone mineral density (Maggio et al., 2012), endothelial function (Seeger et al., 2011), and oxidative stress (Woo et al., 2010).

2.4.3.9 *Adverse effects*

Occurrence of hypoglycaemia was reported in nine studies (Aouadi et al., 2011 ; Campaigne et al., 1984 ; D'hooge et al., 2011 ; Faulkner et al., 2010 ; Landt et al., 1985 ; Maggio et al., 2012 ; Marrero et al., 1988 ; Mosher et al., 1998 ; Rowland et al., 1985 ; Ruzic et al., 2008 ; Salem et al., 2010a), two of which reported that hypoglycaemia did not occur (Landt et al., 1985 ; Maggio et al., 2012). Hypoglycaemic episodes were mild and varied in frequency, ranging from no episodes to at least one episode in most participants either during or after activity (Marrero et al., 1988). Following email contact, Heyman et al. (2007) reported 17 light episodes of hypoglycaemia. No other adverse effects of physical activity were reported.

2.4.4 Fidelity and adherence

Fidelity of the intervention, in terms of the delivery of the programme content, was not reported in any study. Adherence to the physical activity programme was reported as a percentage in five studies (Faulkner et al., 2010 ; Heyman et al., 2007 ; Michaliszyn and Faulkner, 2010 ; Newton et al., 2009 ; Salem et al., 2010a) and ranged between 52-100%. Attendance at activity sessions was reported in four studies (D'hooge et al., 2011 ; Maggio et al., 2012 ; Marrero et al., 1988 ; Rowland et al., 1985). Following email contact as part of the current review process, two authors provided further details about adherence (Mosher et al., 1998 ; Seeger et al., 2011). In three studies, the rate of adherence or attendance was not reported, instead, participants were required to attain a pre-specified percentage of attendance, which differed in each study (Campaigne et al., 1984 ; Mosher et al., 1998 ; Wong et al., 2011). Thirteen articles did not report adherence or attendance. During supervised activity sessions, adherence was assessed via heart rate monitoring (Heyman et al., 2007 ; Mosher et al., 1998 ; Salem et al., 2010a). In the home-based interventions, methods of monitoring adherence included telephone interviews and activity logs (Wong et al., 2011), measurement via accelerometers (Faulkner et al., 2010 ; Michaliszyn and Faulkner, 2010), text messages and daily step count charts (Newton et al., 2009), post-intervention interviews (Marrero et al., 1988), and an online log (Seeger et al., 2011).

2.4.5 Risk of bias

Most NRS were judged to be at unclear risk of bias and three studies were judged at high risk of bias. One study was rated unclear risk for 'selective reporting bias' as changes in the control group were not reported (Aouadi et al., 2011), although the author provided the control group data when contacted. One study was rated high risk of 'measurement bias' for limited detail in reporting of measurement and outcomes and potential bias in the way HbA1c was measured (Dahl-Jorgensen et al., 1980). The studies by Larsson and colleagues (Larsson et al., 1964b ; Larsson et al., 1964a) were rated high risk of selection bias due to unrepresentative intervention and control group samples (i.e., boys with an interest in sport and their friends) (Table 3).

Ten studies were described by the authors as randomised designs, but only two reported the method of randomisation or allocation concealment, e.g. closed envelopes (D'hooge et al., 2011 ; Maggio et al., 2012). After email contact, four authors revealed procedures such as drawing lots (Heyman et al., 2007), closed envelope (Salem et al., 2010a), computer randomisation (Campaigne et al., 1984) and a systematic sampling method (Tunar et al., 2012).

Table 3 Risk of bias table for NRS, adapted from the Cochrane Collaboration's tool for assessing risk of bias

NRS	**Selection bias**	**Detection bias**	**Measurement bias (exposure)**	**Measurement bias (outcomes)**	**Attrition bias**	**Reporting bias**	**Confounding factor bias**	**Other bias**	**Risk of bias within studies**
Aouadi 2011	?	−	?	−	−	+	?	−	**High**
Baevre 1985	?	−	?	−	?	−	?	?	**Unclear**
Dahl-Jorgensen 1980	?	−	?	+	−	?	?	?	**High**
Faulkner 2010	−	−	?	−	−	−	?	−	**Unclear**
Larsson 1964a	+	−	?	−	−	?	?	−	**High**
Larsson 1964b	+	−	?	−	−	?	?	−	**High**
Marrero 1988	?	−	?	?	−	?	?	−	**Unclear**
Michaliszyn 2010	−	−	?	−	−	−	?	−	**Unclear**
Mosher 1998	?	−	−	−	−	−	?	−	**Unclear**
Rowland 1985	?	−	?	−	−	−	−	−	**Unclear**
Ruzic 2008	−	−	−	−	−	?	?	−	**Unclear**
Seeger 2011	−	−	?	−	−	−	?	−	**Unclear**
Sideraviciute 2006a	?	−	−	−	−	?	?	−	**Unclear**
Sideraviciute 2006b	?	−	−	−	−	?	?	−	**Unclear**
Wong 2011	−	−	?	−	−	−	?	−	**Unclear**

Table 4 Risk of bias table for RCTs, adapted from the Cochrane Collaboration's tool for assessing risk of bias

RCTs	Selection bias	Selection bias (allocation concealment)	Detection bias	Attrition bias	Reporting bias	Other bias	**Risk of bias within studies**
Campaigne 1984	?	−	−	−	?	−	**Low**
D'hooge 2011	−	−	−	−	−	?	**Low**
Heyman 2007	−	−	−	−	−	?	**Low**
Huttunen 1989	?	?	−	−	?	?	**Unclear**
Landt 1985	?	?	−	−	?	?	**Unclear**
Maggio 2012	?	−	−	−	−	−	**Low**
Newton 2009	?	?	−	−	−	?	**Unclear**
Salem 2010	?	−	−	−	−	?	**Unclear**
Stratton 1987	?	?	−	−	?	?	**Unclear**
Tunar 2012	?	?	−	?	?	?	**Unclear**

2.4.5.1 Publication bias

Funnel plot asymmetry was assessed for the HbA1c outcome as there were inadequate numbers of studies in the other meta-analyses to properly assess funnel plots. Visual assessment of the funnel plot indicated bias (**Figure 8**). This may imply publication bias, but might reflect the methodological heterogeneity between studies.

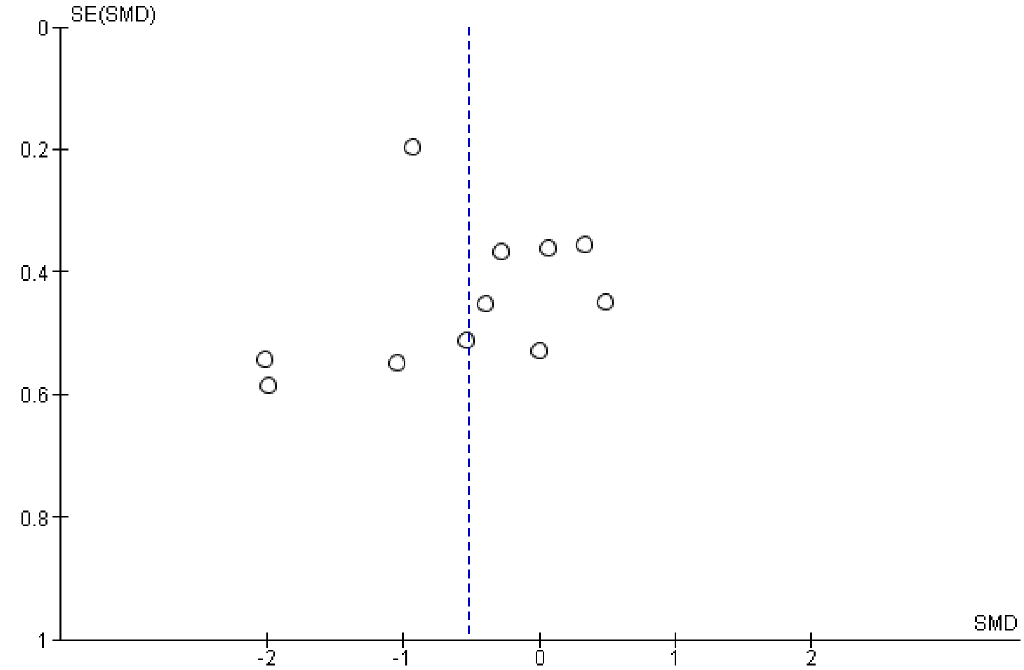

Figure 8 Funnel plot testing for publication bias in the HbA1c meta-analysis

2.4.6 Subgroup analyses

Subgroup analyses were performed for the HbA1c outcome when sufficient data were available. When only the studies in which physical activity was performed three or more days per week were included (8 studies, 275 participants), the effect size remained significant and increased (SMD -0.70, 95% CI -1.18 to -0.22, p = 0.004) (Figure 9). When only studies with physical activity on less than three days per week were included (5 studies, 215 participants), there was no significant effect on HbA1c. Based on subgroup analyses, the SMD for physical activity on three or more days per week was 0.18 units greater than for all the studies combined, providing potentially important information about the minimum dosage of physical activity required to produce clinical benefit for young people with T1DM.

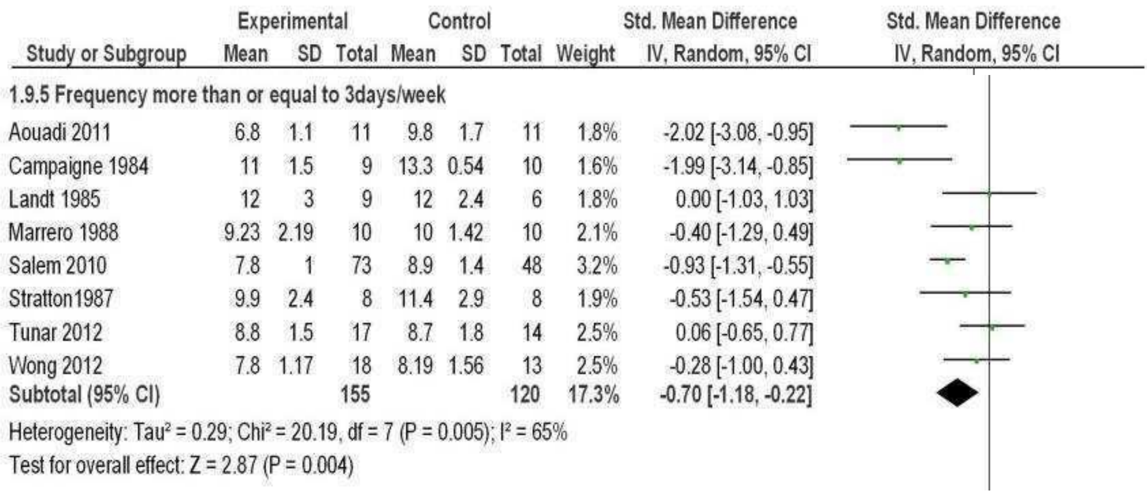

Figure 9 Forest plot for subgroup analysis for the outcome of HbA1c (%) including studies with physical activity performed three or more days a week

Subgroup analyses for interventions shorter (6 studies, 132 participants) and longer (5 studies, 213 participants) than 12 weeks in duration and interventions with (4 studies, 67 participants) and without (7 studies, 278 participants) diet or insulin advice did not reach statistical significance.

2.5 Discussion

2.5.1 The effect of interventions on physiological outcomes

Most studies found significant improvement in at least one health outcome following a physical activity intervention, with only two studies observing no statistically significant health outcomes (Newton et al., 2009 ; Wong et al., 2011). A broad range of outcomes were reported, making direct comparison of intervention effects problematic. Nevertheless, meta-analyses identified significant effects of physical activity on reductions in HbA1c, BMI, triglycerides and total cholesterol, which reinforce the importance of a physical activity in the clinical management of diabetes, delaying or reducing the risk of microvascular complications (La Greca and Bearman, 2002) and cardiovascular disease (CVD) (NICE, 2004).

The moderate-sized effect of physical activity intervention on HbA1c could be clinically significant for young people with T1DM. Assuming a typical standard deviation (SD) of 16.4mmol/mol (1.5% HbA1c), the effect size from this meta-analysis (-0.52) would give a reduction of 8.5mmol/mol (0.78% HbA1c). For context, it has been suggested, albeit in adults with Type 2 diabetes, that a 1% higher HbA1c is associated with a 37% higher risk of developing advanced diabetes microvascular complications (Stratton et al., 2000). Thus any reduction in HbA1c is likely to reduce the risk of diabetes complications and improve long-term health outcomes.

The large and moderate-to-large effect sizes of physical activity on total cholesterol and triglycerides found in this review may also have important clinical implications for improving lipid profiles in children with diabetes. There is limited clinical trial evidence for lipid-improving interventions for T1DM (Soedamah-Muthu et al., 2006), yet research suggests that children with T1DM may have abnormal lipid levels compared to those without diabetes (Guy et al., 2009), which warrants further research into physical activity as a lipid-improving therapy. Findings must be interpreted with caution as some level of bias was present in all the studies included, with the additional unknown confounding effect of diet and insulin adjustments in children's treatment practices.

Only four studies measured physical activity as an outcome of the intervention. Studies were more likely to report changes in physical fitness, but four studies failed to measure either physical fitness or physical activity. This makes it difficult to demonstrate whether any health benefits found were related to change in physical activity, or to determine the dosage of physical activity required to bring about health benefits. Furthermore, measures of physical activity often relied upon self-reported recall rather than objective measures. Nevertheless, these studies suggest that physical activity interventions improve cardiovascular fitness and have potential to increase physical activity levels.

2.5.2 The effect of interventions on psychological outcomes

Four studies assessed the psychological influence of physical activity, each assessing quality of life and one demonstrating improvement in this psychological health outcome. Quality of life has been shown to be poorer in young people with T1DM compared with their peers without diabetes (Kalyva et al., 2011). In one study (D'hooge et al., 2011), participants had demonstrated good quality of life at the outset, which may have reduced the power of the study to detect a difference. There is a paucity of research exploring the relationship between physical activity and psychological outcomes in young people with diabetes.

2.5.3 *Characteristics of interventions*

Intervention characteristics were diverse. There was variation in total duration of the intervention, length of each session, type of activity performed, intensity of activity, delivery setting and supervision. No intervention delivered or accrued the UK guideline of 60 minutes of MVPA per day (Department of Health, 2011), although many were conducted prior to the release of physical activity guidelines for children and none were conducted in the UK.

Of those interventions involving a home-based component, only one study reported utilising influential factors in the home environment, by asking a parent to adopt an active lifestyle and thus provide their child with an active role model (Faulkner et al., 2010 ; Michaliszyn and Faulkner, 2010). In this study, the level of parental physical activity was unknown, precluding assessment of the influence of parental role models on the physical activity of children. It is well established that parents are important correlates of physical activity in young people without diabetes, especially as active role models and sources of emotional and logistical support (Lim and Biddle, 2012); parental influence on physical activity participation in children with T1DM has so far been overlooked.

Only two studies in this review reported any theoretical underpinning. Psychological theories of behaviour change can improve the development and delivery of interventions (Michie and Prestwich, 2010) and theoretically-driven physical activity interventions produce larger effect sizes (Webb et al., 2010).

The assessment of maintenance is particularly important when considering behaviour change interventions; and yet only two studies in this review implemented a maintenance follow-up (Ruzic et al., 2008 ; Wong et al., 2011), one of which found that lowered HbA1c levels after a two week physical activity intervention were not sustained at a two month follow-up (Ruzic et al., 2008). In children, sustained behaviour change may be more desirable than temporary behaviour change (Jones et al., 2011). For those with T1DM, sustained increases in physical activity will potentially benefit insulin requirement, weight management and blood glucose control, and help delay the onset of CVD.

2.5.4 Adherence rates and adverse events

Few studies reported adherence rates, and there was a tendency to report attendance at sessions rather than adherence to the activity programme. Those that did report adherence showed a good, if diverse, range of adherence (52-100%). This is comparable to rates of adherence in physical activity interventions in young people without diabetes (Ransdell et al., 2003), although the reporting of intervention exposure and adherence seems to be a common weakness in studies across the population (van Sluijs et al., 2007).

In interventions with unsupervised components, it is necessary that compliance to the programme is monitored. When participants choose their preferred activity, engagement may be enhanced through choice and independence, which have been found to facilitate participation in physical activity by young people (Brunton et al., 2003). Monitoring techniques (e.g., activity logs), however, have not been evaluated. It is difficult to draw firm conclusions about the effects of interventions on health outcomes when it is unclear whether participants fully adhered to the programme of activity.

It is encouraging that no severe episodes of hypoglycaemia were reported. Yet anxiety about hypoglycaemia can exist even in those with no history of severe hypoglycaemia (Johnson et al., 2013b), which emphasises that psychological factors associated with physical activity for young people with T1DM need further exploration.

2.5.5 Recommendations for future research

The findings from this review are summarised into the following recommendations for future research:

- Further explore the potential behavioural and psychological benefits of physical activity for young people with diabetes.

- Interventions should be theory-driven to include elements known to be associated with behaviour change and help explain *how* interventions bring about change.

- Interventions should be designed to encourage children and young people to be physically active for at least 60 minutes a day.

- The fidelity of intervention delivery should be monitored and reported.

- Maintenance follow-up data are required to explore whether changes in important health outcomes are sustained beyond the intervention period.

- Intervention studies should monitor adherence to the programme of activity and would benefit from evaluating the success of adherence strategies.

2.6 Evaluation

The findings should be considered in light of some methodological considerations. First, the inclusion of NRS increases risk of bias in this review, but the knowledge gained provides a valuable insight into existing interventions and the potential health-related outcomes of physical activity, which warrants their inclusion. Second, interpretation of the findings should consider the unknown, confounding effect of diet and insulin. Finally, the wide age-range included in this review means that some findings may not apply to all age groups of children. Future reviewers may wish to focus analyses on a more specific age group (e.g., 9–11 year olds); however limited data prevented the ability to compare age group differences in the current review.

2.7 Conclusions

This review suggests that physical activity interventions can have a range of health benefits for children and adolescents with T1DM. These findings are clinically important with regards to diabetes management and delaying premature onset of complications such as CVD. Despite promising findings, existing interventions have not used psychological theory of behaviour change or determined the long-term sustainability of positive health outcomes. Heterogeneity in study design, methods and reporting remains a barrier to fully understanding the influence of physical activity on health outcomes in young people with T1DM. The recommendations can be used by researchers to inform future interventions and will be used in the current research to inform the development, implementation and reporting of the physical activity intervention. Uncertainty remains about *which* elements of physical activity interventions are most effective for young people with T1DM, and *how* changes in physical activity might occur.

Chapter Three

"You can't just jump on a bike and go": A qualitative study exploring parents' perceptions of physical activity in children with Type 1 Diabetes

3.1 Introduction

The introduction chapter of this thesis highlighted the important role that parents of children with Type 1 Diabetes Mellitus (T1DM) have in the management of the condition. Yet the systemic review in Chapter 2 demonstrated how parents have had little involvement in existing physical activity interventions among this population. In order to engage parents in attempts to promote physical activity in children, research is needed that explores their beliefs and values related to their children's participation in physical activity.

The treatment of T1DM in childhood is coordinated by healthcare professionals (HCPs), but its management is usually the responsibility of parents, most often the mother (Seiffge-Krenke, 2002). After around ten years of age, children develop more independence with their diabetes management behaviour which appears to relate to declines in treatment adherence (King et al., 2014). By the age of 13, many children are able to manage most diabetes tasks, but parents continue to play an important role (Wysocki et al., 1996). It seems reasonable that strategies to enhance children's management behaviours are informed by the views of parents and that involving parents is an important element of interventions with children who have T1DM (Doherty et al., 2013).

Parents' perceptions of their children's T1DM may influence their decisions about parenting, which may have an effect on T1DM management behaviours such as physical activity and future health outcomes such as glycaemic control (Pattison et al., 2006).

Therefore, parents can be seen as gatekeepers to their child's physical activity experiences (Gustafson and Rhodes, 2006).

Social cognitive theories of behaviour change suggest that the environment and the individual affect one another in a process of reciprocal determinism to bring about any given behaviour. Bandura (2001) suggests that children establish patterns of normative behaviour through role models encountered in their environment and everyday interactions. Parents can influence children's physical activity through modelling attitudes, behaviour and providing encouragement (Määttä et al., 2014 ; Trost et al., 2003). Parents can also influence children's self-efficacy by providing rewarding opportunities to participate in physical activity and through encouragement and reinforcement (Trost et al., 2003). Furthermore, parents can help foster their child's intrinsic motivation towards being active by building an environment for their child that promotes autonomy, relatedness and competency (Deci and Ryan, 2000).

Opportunities for children's participation in physical activity may be shaped by parental concerns and attitudes, such as concerns over safety (Veitch et al., 2006). Chapter 1 of this thesis described how hypoglycaemia is a common side-effect of physical activity in children with T1DM (Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, 2010). During the night, nocturnal hypoglycaemia can be common (approximately twice per month) and prolonged (up to 2 hours) in children with T1DM, especially on days of increased physical activity (Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, 2010 ; Tsalikian et al., 2005). Parents of children with T1DM report anxiety and fear associated with hypoglycaemia (Barnard et al., 2010). Research has also suggested that avoidance of hypoglycaemia is a high priority for parents of children with T1DM partaking in physical activity (Fereday et al., 2009).

Two studies exist that have used qualitative methodology to explore parental beliefs about physical activity in children with T1DM (Fereday et al., 2009 ; MacMillan et al., 2014b). Fereday and colleagues (2009) conducted focus groups with 25 Australian parents of children aged 4-16 years with chronic conditions, 14 of whom had a diagnosis of T1DM. Parental encouragement and parental attitude towards physical activity emerged as important motivators for children's physical activity, which supports research findings from children without chronic conditions (Biddle et al., 2011 ; Sallis et al., 2000). In Fereday et al.'s study, some aspects of parental support, particularly parental vigilance in planning and involvement in the activity, were unique to parents of children who had T1DM. These were believed to be instrumental in allowing the children to overcome perceived barriers to physical activity such as hypoglycaemia. Fereday et al. attributed parental vigilance to the investment time and money to supervise their child's physical activity (e.g., thorough planning, driving long distances and providing equipment). This research is commended for providing an insight into how parents who have a child with a chronic illness perceive physical activity.

MacMillan et al. (2014b) interviewed parents, children and professionals from one diabetes clinic in Scotland and asked participants to share their experiences and interpretations of what should be included in a physical activity intervention for children with T1DM. In this research study, parent support, alongside peer support, was perceived as essential. Participants believed that interventions should target parents and families rather than patients alone to change physical activity in children with T1DM (MacMillan et al., 2014b).

The studies by Fereday et al. (2009) and MacMillan et al. (2014) have been important starting points for research exploring parents' perceptions qualitatively. As Fereday et al. (2009) explored different chronic conditions and MacMillan et al. (2014) explored perceptions specific to intervention content and delivery, further exploration of parental beliefs about physical activity for children with T1DM is warranted.

3.2 Study aims

In summary, it is believed that parents play an important role as facilitators of their child's physical activity and parents of children with T1DM have specific diabetes-related concerns. The purpose of this study is to understand parents' perceptions of what influences physical activity for their children with T1DM. The findings will be used to advance understanding, provide recommendations for clinical practice and inform strategies to help promote physical activity in this population.

3.3 Methods

The study employed qualitative research methods, collecting data through in-depth semi-structured interviews. This methodology was informed by interrelated concepts of interpretivism and reflexivity balanced with pragmatism and transparency. This was achieved by seeking to understand the experiences and perceptions of parents whilst demonstrating practical implications to inform the development of physical activity promotion strategies in this population.

3.3.1 Ethical Approval

The research was reviewed and approved by the University of Nottingham Medical School Research Ethics Committee (Reference No: B10012013 SNMP) (Appendix 3).

3.3.2 Participants

Parents were recruited using a purposeful sampling approach with snowball techniques (Patton, 1990). Parents who had a child aged 7-13 years with a clinical diagnosis of T1DM for at least three months were eligible. This age range was targeted because it captures the expected period of transition between parental management and child self-management. An advertisement was placed in the Diabetes UK "Balance" magazine and parents responding to the advert were invited to contact the researcher directly for more information. In addition, T1DM parent support groups across the UK were identified using an online search engine and support group leaders were emailed with request for an e-flyer to be distributed amongst group members. The e-flyer advertised the research and contained a web link to a survey site where parents could read about the study and provide their contact details confidentially. Those who supplied contact details were contacted by the researcher via email to confirm the parents' eligibility and provide eligible parents with the study information sheet and consent form (Appendix 4).

Participants were given the choice of a telephone interview or, where geographically feasible, a face–to-face interview. Face-to-face interviews took place in the participant's home. Interviews were conducted at a mutually convenient time by one of two interviewers; the researcher (n=16) or a medical student (n=4). The interviewer received consent from the participant in writing (if interviewed in person) or verbally (if interviewed via telephone) prior to the interview. Both interviewers were aged between 20 and 25 years, were female, and were trained in qualitative methods and interview techniques. With the participant's consent, interviews were recorded using an Olympus Dictaphone.

The interviewers aimed to create a free-flowing discussion directed by the interviewee in an informal conversational style. The questions were open-ended and to ensure the same topics were covered across all interviews, an interview guide was used (Appendix 5). The interview guide sought to explore parents' beliefs about physical activity with questions such as; i) what sorts of physical activities does your child take part in?, ii) what helps your child to be physically active?, and iii) what makes physical activity more difficult for your child? Interview length ranged from 15 to 120 minutes and the mean duration of interview was 50 minutes. Parents were offered a gift voucher after the interview as a gesture of appreciation.

Recruitment was guided by the number of participants needed to achieve theoretical data saturation (Strauss and Corbin, 1998). According to Strauss and Corbin (1998), theoretical data saturation refers to the point when; i) no new or relevant data seem to emerge regarding a theme, ii) the theme is well developed and demonstrates variation, and iii) the relationships among themes are well established. Based on these criteria, the researcher judged whether any new data were emerging that would inform our understanding of parents' perceptions or have practical implications for physical activity promotion strategies in this population. No new data emerged (and therefore data saturation was achieved) at 20 participants, at which point recruitment ceased.

Almost all parents interviewed were mothers (18/20), two were fathers, 18 were married, and the majority (17/20) had two or more children. The mean age of the child about whom the parent responded was 10.8 years (SD=2.2, range 7-14 years) and the mean length of diagnosis of T1DM was 4.7 years (SD=2.6, range 1-9 years) (Table 5). The study recruited parents of children between the ages of 7 and 13 years, however one parent's daughter had turned 14 years of age when the interview took place and was included based on the belief that responses would not be substantively different from those of the target age range. Eighteen interviews were via telephone and two were face-to-face. Whilst this led to methodological inconsistency, it was deemed an appropriate decision to achieve a diverse sample and derives from the pragmatic nature of this research.

Table 5 Summary of participant characteristics

Participant ID	Parent	Child age (years)	Length of diagnosis (years)	Child sex
P01	Mother	9	3	Male
P02	Mother	7	2	Male
P03	Mother	11	9	Male
P04	Father	11	7	Male
P05	Father	7	2	Male
P06	Mother	8	3	Male
P07	Mother	8	2	Female
P08	Mother	12	4	Female
P09	Mother	12	4	Male
P10	Mother	13	7	Male
P11	Mother	11	3	Male
P12	Mother	13	7	Male
P13	Mother	8	5	Female
P14	Mother	12	2	Male
P15	Mother	14	1	Female
P16	Mother	12	10	Male
P17	Mother	12	8	Female
P18	Mother	9	5	Male
P19	Mother	13	6	Male
P20	Mother	13	3	Male
N = 20	Mothers = 18 Fathers = 2	Mean = 10.8 years (SD=2.2)	Mean = 4.7 years (SD=2.6)	Female = 5 Male = 15

3.3.3 Data analysis

Audio recordings of the interviews were transcribed verbatim by the researcher, which enabled early familiarisation with the data. Participant anonymity was maintained by allocating participants an identification number and using pseudonyms for participants' names within interview transcripts. Data analysis was an iterative process using a method of thematic analysis (Figure 10) (Braun and Clarke, 2006). Thematic analysis is a method compatible with many different epistemological viewpoints, and therefore was appropriate for the balance between interpretivism and pragmatism in this study.

Thematic analysis involved identifying codes, themes and common threads across all interview transcripts (Braun and Clarke, 2006). Codes were meaningful groups of data that captured the essence of data and could be events (e.g., hypoglycaemia: night-time), emotions (e.g., hypoglycaemia: parental concern) or beliefs (e.g., hypoglycaemia: challenging). Codes could also refer to behaviours, values and attitudes. The software package NVivo version 10 (Qualitative Solutions and Research International) was used to facilitate the organisation of codes and themes, and has been used previously in similar research (Veitch et al., 2006).

Phase 1: *Familiarisation with the data*
Transcribe interviews verbatim, read and annotate transcripts.

Phase 2: *Generate initial codes*
List ideas about what is interesting about the data. Organise data into meaningful groups to form codes.

Phase 3: *Search for themes*
Sort codes into meaningful groups to form potential sub-themes.

Phase 4: *Review potential themes*
Refine potential themes, ensure codes within themes cohere together and ensure clear distinction between themes. Group related sub-themes and label with an overarching theme.

Phase 5: *Define and name themes in a code book*
Construct a code book with a theme description, an example of a quote to illustrate theme and an example of a quote which does not illustrate theme.

Phase 6: *Final analysis and write-up*
Write-up findings with extracts to demonstrate themes.

Figure 10 The six phases of thematic analysis, adapted from Braun and Clarke (2006)

Codes were derived primarily from the data (inductive) but could also be theory-derived (deductive) (Braun and Clarke, 2006). Codes arose through a deductive approach when the theoretical understanding found in the literature review allowed the researcher to be sensitive to certain topics that may arise in the data (Strauss and Corbin, 1998). Examples of a priori codes were the hypoglycaemia codes stated above, as previous research has suggested that hypoglycaemia could be a common side-effect of physical activity and cause of concern for parents. Inductive codes were induced from data and thus not anticipated in advance of data analysis. Data analysis began with an inductive approach to ensure important aspects of the data were not missed. Deductive codes relating to specific areas of interest were then identified in the data, but analysis was iterative rather than a rigid linear process.

3.3.4 Trustworthiness and reflective practice

Several approaches were used throughout the study to ensure methodological trustworthiness (Yardley, 2008). The researchers showed sensitivity, commitment and rigour (to theory, participants and data), transparency (e.g., reflective practice and being explicit with research decisions) and sought findings that would have practical implications (Yardley, 2000) This was in addition to utilising a rigorous approach to establish the consistency and replicability of the themes (Boyatzis, 1998).

Reflective practice refers to the process of critically reflecting on the knowledge produced during the research process and the researcher's role in producing that knowledge (Braun and Clarke, 2006). The researcher wrote reflective notes in a diary throughout the research process. Personal reflective practice entailed the researcher being careful to acknowledge personal background (e.g., "I am a white, middle-class woman with a background in Sport and Exercise Psychology") biases (e.g., "I am not a parent") and values (e.g., "regular exercise is important to me") prior to and during the research process. During data collection, the researcher made notes about the interview, including impressions of the interview (e.g., "Diane and I engaged well"), participant (e.g., "It was apparent that Diane was a strong character and a passionate and determined mother of her children") and emerging points of interest (e.g., "I was struck by Diane's determination"). In the early stages of data analysis, the researcher noted impressions, ideas and early interpretations of the data. This aided the generation of themes and served as a means for documenting the rationale for any changes or reassignment of codes and themes.

To counter bias and enhance the credibility of the data, consistency of themes were explored. In accordance with the recommendations of Boyatzis (1998), a codebook was developed which included a brief background to the study, a label for each theme, a theme and subtheme description and examples extracts that did and did not illustrate each theme (Boyatzis, 1998). Quotes belonging to each theme were selected at random and given to a second coder to code using the codebook. Boyatzis recommends that percentage agreement between two coders above 70% demonstrates acceptable reliability (Boyatzis, 1998). The percentage agreement between the two coders was established at 78%, indicating that the themes were consistent and reliable to a recommended standard (Boyatzis, 1998). This process resulted in minor amendments to descriptions of codes in the codebook, reassignment of some extracts to more appropriate themes and merging of two similar subthemes. Once the codebook was clarified, all previously coded transcripts were reviewed to ensure they were consistent with the revisions.

3.4 Results

The purpose of this study was to understand parents' perceptions of the influences on physical activity for children with T1DM. Factors believed to influence participation in physical activity among children with T1DM are presented as seven major themes and 15 corresponding subthemes (Table 6). Themes are supported by verbatim quotes from parents.

Table 6 Overview of themes, subthemes and codes

Theme	Subtheme	Codes
1. Conflict between careful planning and spontaneous activity	1a. Parents recognise the importance of having a predictable routine	Routine, planning and preparation, disruption to routine.
	1b. Parents perceive problems with the spontaneous nature of children's physical activity	Spontaneous activity, unplanned, unpredictable.
2. Parents' 'constant battle' for blood glucose control	2a. Blood glucose monitoring requires vigilance and commitment from parents	Constant battle, commitment, 24/7 job, interrupting, trial and error.
	2b. Hypoglycaemia is challenging and a cause of concern for parents	Hypoglycaemia challenges, physical effect, night-time, emotional effect, parental concern, length of diagnosis, hypoglycaemia avoidance.
3. Parents recognise the importance of physical activity	3a. Parents believe that physical activity is important for their child	Health benefits, fitness, prevention, longevity, diabetes-specific benefits.
	3b. Parents could see the positive effect of physical activity in their child's health or behaviour	Visible benefits, health, behaviour, diabetes-specific.
4. Parents are determined to overcome hurdles to physical activity	4a. Parents demonstrate assertiveness	Determination, forceful, resilience / overcome barriers.
	4b. Parents want their child to have as normal life as possible	Desire for normality.
5. Parents perceive their child's participation in physical activity as dependent on parental management and supervision	5a. Parents perceive difficulties allowing their child to achieve independence	Independence vs. dependence, independence / autonomy difficulties, parents as decision makers, parents supervising activities.
	5b. Parents are reluctant to give others responsibility	Reluctance giving others responsibility, 'Mum worries'.

6. Parents recognise the importance of support systems	6a. Parents perceive themselves as important in supporting and encouraging their child's participation in physical activity	Parental involvement, shared interactions, encouragement, logistical support.
	6b. Parents value the support received from the paediatric diabetes team	Individualised advice and guidance, health professionals being available and contactable, helpful, understanding, lack of support from health professionals.
	6c. Parents value the support received from school	Cooperation, inclusivity, lack of awareness / competence.
	6d. Parents perceive active role models as important for their child's participation in physical activity	Active role models.
7. Parents attribute participation in physical activity to their child's personal characteristics and preferences		'Sporty type', enjoyment, ability, preference, interest (or lack of).

3.4.1 Theme 1

Conflict between careful planning and spontaneous activity

Parents perceived diligent planning and preparation to be fundamental to their child's participation in physical activity, which conflicted with the spontaneous nature of children's physical activity.

Subtheme 1a) Parents recognise the importance of having a predictable routine

Parents in this study believed that planning and preparation enabled their child to participate in physical activity. Parents referred to everyday routines and also formal diabetes management plans, e.g., *"I write down every day what he has to do that's different, like today for PE [physical education] at what levels he can exercise at and what levels he can't exercise at"* (P02, Mother). When explaining what makes physical activity more difficult for children with T1DM, planning was mentioned e.g., *"it's a lot of effort and you've got to make sure you've* *got everything, and take extra stuff and you know, it's not fun to be perfectly honest with you"* (P16, Mother). When carefully prepared plans formed part of a routine, parents alluded to the predictability being facilitative, e.g., "*he will do everything because it's routine and he knows what to do and it's well-practiced and rehearsed"* (P11, Mother), whilst a disruption to routine was challenging for parents e.g., *"We do have struggles every now and again, particularly when something different is happening because obviously it's a change to routine…School trips spring to mind, sports day, fun days, swimming is a challenge"* (P01, Mother).

Subtheme 1b) Parents perceive problems with the spontaneous nature of children's physical activity

The importance of routine and the vigilant planning for physical activity conflicted with the unpredictable nature of physical activity. For example, the title of this chapter was taken from a quote that captured a viewpoint shared by many of the parents interviewed; *"You can't just jump on a bike and go, you have to think about how far you're going, what equipment you've got with you, has he tested beforehand, what [blood glucose] level he's at…"* (P02, Mother). Unpredictability was often discussed in reference to children's spontaneous play, but some parents found structured activity sessions, such as training for a sports team, difficult to manage. This was due to parents not knowing in advance what the training schedule would be and thus unable to anticipate what effect the activity would have on their child's blood glucose level. For example, one mother explained why sometimes her daughter's rowing training was difficult to manage; *"you don't know whether they're going to do a hard racing session or whether they're going to do a short one or whether it's going to be lazy or work on technique, or she's gonna go to the gym"* (P08, Mother).

3.4.2 Theme 2

Parents' 'constant battle' for blood glucose control

Parents perceived difficulty maintaining control of their child's blood glucose levels during periods of physical activity, described by one father as a "constant battle" (P05, Father).

Subtheme 2a) Blood glucose monitoring requires vigilance and commitment from parents

Parents described their continuous commitment to blood glucose monitoring, which included numerous blood glucose tests before, during and after activity and throughout the day in attempt to control blood glucose levels. The arduous nature of this task for parents was demonstrated through references to it being a, *"24/7 job"* (P08, Mother; P10, Mother) and a, "*constant balancing act"* (P20, Mother). This could disrupt physical activity by delaying it e.g., *"occasionally he has to join the [activity] class late because he's too low or too high"* (P02, Mother) or interrupting it e.g., *"I had to make her get out of the [swimming] pool half way through the lesson and dry off her finger and do a blood sugar, and that was quite awkward"* (P13, Mother).

Attempts to manage blood glucose levels and physical activity were sometimes characterised by the method of trial and error, as summarised by one mother; *"sometimes you get it right, sometimes you don't [laughs]. Sometimes he comes home and he's way too high because you've cut off too much [insulin], other times, you know, you've not cut off enough and he goes hypo"* (P01, Mother). Synonymous with the nature of trial and error, parents described how attempts to manage their child's physical activity can be unsuccessful e.g., *"you can only really make your best guess based on previous experience and it still sometimes goes wrong"* (P20, Mother) and difficult e.g., "*they do say when you exercise then you get better blood sugars, but I don't know, it just makes it more uncontrollable in some ways!"* (P08, Mother).

Subtheme 2b) Hypoglycaemia is challenging and a cause of concern for parents

Parents were aware that physical activity came with the risk of hypoglycaemia and highlighted that this was challenging to manage. The challenges faced by parents involved: i) the physical effect of hypoglycaemia, e.g., *"he'll just drop on the floor and become delirious"* (P02, Mother) or having to stop participation e.g., *"mid-way through a very impressive Frisbee session on Sunday morning when he pulled a spectacular hypo he had to come out for fifteen minutes"* (P01, Mother); ii) the emotional influence of hypoglycaemia, such as frustration when hypoglycaemia impedes physical activity e.g., *"he had a low and he missed break, and it's devastating"* (P01, Mother), or a lasting emotional influence of having a hypoglycaemic episode e.g., *"[the hypoglycaemic episode] then coloured her whole view that she didn't want to go into the PE lesson, to the point where she'd say she didn't feel very well on those days* *she's got PE"* (P07, Mother); and iii) worry about hypoglycaemia e.g., *"if she has a big hypo and she needs that extra assistance from outside and there's nobody there that knows what to do, is always the worry"* (P08, Mother). For some parents, the worry was more prominent earlier on in the diagnosis of T1DM, as one mother described her initial worries about skiing, *"We weren't too sure how a lot of activity, quite sustained activity for a couple of hours would affect her, so that was a worry I suppose at the time, but as time went on you know, we were able to learn and understand"* (P17, Mother). Yet another mother's worry had; *"got harder over the years"* (P13, Mother) because, *"the more parents I meet and talk to about checking in the night and stories that I hear about checks, I feel that I have to check her more often"* (P13, Mother). Parental worry about nocturnal hypoglycaemia was coupled with more vigilant blood glucose monitoring in the evenings after activity and throughout the night.

It was not common for parents to talk about maladaptive hypoglycaemia avoidance behaviours, but the mother above who had been concerned about her child skiing did allude to such behaviour; *"we probably chose to run her blood sugars high rather than low, take the view that we'll sort them out at lunchtime or whatever, sort them out later"* (P17, Mother). A small number of parents confided that the challenge of managing blood glucose fluctuations made it tempting to avoid physical activity e.g., *"the effect it has on her blood sugars, it's easier for me that she doesn't want to do [physical activity]"* (P13, Mother).

3.4.3 Theme 3

Parents recognise the importance of physical activity

Parents in this study recognised the importance of physical activity for its desirable effect on their child's health or behaviour.

Subtheme 3a) Parents believe that physical activity is important for their child

Parents attributed the importance of physical activity to its health benefits for people with and without T1DM. Those who believed physical activity was important for T1DM gave reasons such as: health and fitness e.g., *"they've got to keep themselves fit and healthy"* (P02, Mother); disease prevention e.g., *"because she's at higher risk of heart disease"* (P17, Mother); and longevity e.g., *"to live a long life"* (P06, Mother). Parents did not perceive T1DM to be the only reason why their child should keep physically active, but some believed that T1DM did provide an incentive to encourage their child to be active e.g., "*I think knowing that it's helping him stay healthy with his diabetes, obviously that's sort of what we take into account*" (P09, Mother).

Subtheme 3b) Parents could see the positive effect of physical activity in their child's health or behaviour

Some parents not only held beliefs about the importance of physical activity, but also described having observed benefits of physical activity in their child's health or behaviour. The overt benefits described by parents were physiological or psychological. Physiological benefits included improved blood glucose control, e.g., *"makes things easier to control"* (P09, Mother), *"the more sport he did that the less hypos he was having"* (P19, Mother) and body composition e.g., *"I just noticed his physique changing and I think slowly he's getting a thinner waist and broader shoulders"* (P19, Mother). Some parents noticed psychological benefits such as, giving the child space, energy or anger release e.g., *"a way of getting out his anger"* (P19, Mother) and developing knowledge e.g., *"[being active] makes him have a better understanding of the relationship between food and exercise and insulin*" (P11, Mother).

3.4.4 Theme 4

Parents are determined to overcome hurdles to physical activity

Parents demonstrated assertiveness, resilience and forcefulness to ensure that their child could have a 'normal' life and take part in any physical activity.

Subtheme 4a) Parents demonstrate assertiveness

Determination was evident in parents' accounts of being forceful and direct, particularly when negotiating diabetes management plans and arrangements with external bodies such as school and extracurricular activity groups. For example, one mother said; *"I think they [school] got supportive when I told them they had to be"* (P01, Mother). Examples of assertiveness involved being firm with requests e.g., *"I'm very direct [with teachers], not wishy washy about it"* (P06, Mother); setting clear boundaries e.g., "*I do the training for them [the teachers at school], because I don't trust anyone else to do it*" (P16, Mother); standing up for the child's rights e.g., *"I'm just determined that my child is going to be healthy in the long-term and I'm not prepared to settle for second best"* (P07, Mother); and expressing opinions or disagreeing with others or policies at a reasonable volume. For example, two parents had issued formal complaints when their child had been excluded from school activities such as swimming lessons or activity trips e.g., *"we did take them [school] to court and we did ring the disability related discrimination tribunal"* (P18, Mother). Assertive parents also tended to show resilience to overcome barriers to enable their child to be physically active, as summarised by one mother; "*if there's a barrier to it [activity], we find a way through it*" (P06, Mother). One mother conceptualised these barriers as 'hurdles', *"they [children with T1DM] just have some hurdles to get over to get active"* (P01, Mother).

Subtheme 4b) Parents want their child to have as normal life as possible

The majority of parents interviewed were determined for their child to experience normality, which entailed going to "*enormous effort*" (P11, Mother) to help their child overcome barriers to physical activity, e.g., *"it is a lot more work, I'll say that, but you do what you have to do for your child to have as normal life as possible"* (P20, Mother). Normality for some parents included a life without diabetes, e.g., *"we've always tried to think, if he didn't have diabetes, would we let him go [on activity/trip], and if the answer is yes then we should still let him go and try not to let it stop him"* (P09, Mother). For some parents, the desire for their child to experience a 'normal' life conflicted with safety concerns, e.g., *"[at rowing club] I need to know that the people taking her out on the water know that she's diabetic …Then it's sort of an issue, does everybody have to know?…an issue of privacy as well, although it is for her safety"* (P08, Mother).

3.4.5 Theme 5

Parents perceive their child's participation in physical activity as dependent on parental management and supervision

The parents believed that their child's participation in physical activity was dependent on parental supervision.

Subtheme 5a) Parents perceive difficulties allowing their child to achieve independence

Parents realised the need for allowing their child independence, but described children's dependence on them for diabetes management made this more difficult, e.g., *"to let him grow up independently, but at the same time make sure he's safe, it's a real challenge"* (P01, Mother). One father described; "*the biggest thing that you lose as a child with Type 1 Diabetes is independence and freedom*" (P05, Father). He attributed the loss of independence to the necessary safety precautions that needed to be in place when a child with diabetes was physically active away from parents, "*if we were confident of his ability to deal with [diabetes] himself, then yes potentially we wouldn't necessarily have the restrictions on clubs or wouldn't necessarily have to miss the occasional one because we [parents] couldn't sit outside*" (P05, Father).

Parents were involved in making important choices about physical activity, including the decision about whether to take part or not, e.g., *"we have to think, what his [blood glucose] levels are going to be before he starts, at what level we actually let him participate or not"* (P02, Mother). Several parents believed that this necessitated their presence during the physical activity, including structured external activities such as school activity holidays. For example, one mother described a conflict between her son's autonomy and his safety; *"we want Harry to have that freedom, so we literally sit outside the door in the car. Harry knows we're there and they [Cub Scout leaders] know we are there if there's a problem"* (P06, Mother). Whilst some parents were happy with this responsibility, one mother confided that accompanying her son to activities had become burdensome, e.g., *"We go through this again and again and again with everything he does whether it's like, he went to Beavers and Cubs and Scouts he did all that because we were there every flaming week with him, sitting there bored as hell, can't leave him"* (P16, Mother). Some parents believed that their presence during their child's physical activity influenced the child's confidence, e.g., *"He likes me being there for a bit, you know, it gives him a bit of security and confidence*" (P02, Mother).

Subtheme 5b) Parents are reluctant to give others responsibility

Parental responsibilities over their child's participation in physical activity was pressurised by a reluctance to give the responsibility of care to other people, such as school personnel, activity leaders and other family members, e.g., *"I'd prefer if she didn't want to do a lot of sporty things, because I'm not happy leaving her"* (P13, Mother). Reasons for this reluctance included the specialised knowledge required by the supervisor of the child, e.g.:

> *It's really hard for me to let anybody else take her to do anything…because you have to think about so many things like what she's had to eat and what her blood sugar was before you started and how many sweets she's had or how many glucose tablets or what other food she's had.*

P13, Mother

Other reasons for reluctance included; lack of skilled staff e.g., *"for Taekwondo I'm always there, because his teacher and everything, they're not trained in how to treat him if he suddenly has a hypo or comes hyper or his cannula comes out"* (P02, Mother); other people's negative perception of T1DM e.g., *"they'll be flippant and not take it serious"* (P06, Mother); others not willing to accept responsibility e.g., *"the people who took it would say oh no I'm not dealing with that you will have to stay and deal with it"* (P16, Mother) and; negative past experience of giving others the responsibility e.g., *"at holiday club…they didn't test him before dinner…and I said why didn't you do his tests, and they said 'oh we were busy'"* (P16, Mother). It was evident that limited understanding and awareness around T1DM in others, particularly those involved in the supervision of children's physical activity, was a problem for parents, as summarised by one mother; *"if Harry's PE teacher had been trained on how to deal with asthma and diabetes and it's part of their training, then surely me as a parent would feel more comfortable"* (P06, Mother).

3.4.6 Theme 6

Parents recognise the importance of support systems

Parents identified figures they perceived to be important sources of support for their child's participation in physical activity. Key supportive figures were the family, paediatric diabetes team, school teachers and active role models.

Subtheme 6a) Parents perceive themselves as important in supporting and encouraging their child's participation in physical activity

When asked to describe what helps their child be physically active, the vast majority of parents referred to their own involvement and encouragement. Involvement entailed direct involvement, e.g., *"I sit outside Beavers every Tuesday and I sit at tennis every week"* (P05, Father) and shared interactions, e.g., *"the family example…we're going to walk round the forest, going to go for a cycle ride"* (P08, Mother). Encouragement referred to parental attitudes e.g., *"I love sport…so I've always, you know, even when we first had kids we wanted to sort of encourage that"* (P05, Father) and verbal encouragement, e.g., *"we've both said 'you have to do something [active]'"* (P15, Mother). Logistic support, such as provision of equipment, transport and funding was also believed to be important contributor to an active lifestyle, e.g., "*we support him by financing the football things and taking him to various places that he needs to go"* (P09, Mother).

Subtheme 6b) Parents value the support received from the paediatric diabetes team

Parents valued the support received from their child's diabetes clinic, and were appreciative of the diabetes team providing individualised advice and guidance, e.g.:

> *We've always been able to contact them [the diabetes team] when we've had specific activities going on, like if we've been out on a long hike or he's done long exercise, then we can discuss which insulin to drop and how to alter the ratio of the food.*
>
> P12, Mother

Parents who described a positive experience of the support received from the paediatric diabetes team referred to the staff being: available e.g., *"you can contact [the nurse] most of the time, even outside office hours you can get hold of her"* (P09, Mother); helpful e.g., *"[they] help you work out ways for yourself to manage it"* (P17, Mother); and encouraging of the child's participation in physical activity. For example, one mother described how the nurse had supported her son in maintaining his previously active lifestyle, *"[the nurse] was good because she tried to get him back into the running, she was very encouraging and she really helped with that, giving him diaries of people that ran with diabetes and what helped and what doesn't"* (P14, Mother).

Some parents perceived the support they had received from the clinic as unhelpful or unaccommodating of their needs. For example, one mother believed that her concerns about night-time blood glucose testing were not supported; *"if I say when she does more activity I'll be checking even more at night, they don't think I need to check at all [during the night]. So they don't really understand"* (P13, Mother). Another mother expressed anger at her daughter not being offered the support that was available to children involved in higher-level sport, which resulted in her daughter's discontinuation of netball, e.g.:

> *[The doctor] said that children who play sport at a certain level are given intensive programmes of how to manage their diabetes when they go and play sport…and I felt quite strongly that, although Joanne would never be playing netball for England, she was quite a nice little club player and she deserved as much help with managing her diabetes as these other kids.*

P15, Mother

One mother described how inadequate information and support from the clinic had led to her son discontinuing Taekwondo after diagnosis because:

> *We hadn't been given the information to handle it properly or the information we were given about what to do didn't work for him and he became embarrassed about having hypos and having to sit out, so he did elect to stop that in the early days just after diagnosis because there wasn't enough support and information.*

P20, Mother

Subtheme 6c) Parents value the support received from school

Parents perceived that support and encouragement from school personnel was an important influence on their child's participation in physical activity. Supportive school practices included: being receptive to diabetes training and knowledge acquisition, e.g., *"they've learnt to use the technology that we've given them and they have made every effort to try and fit in with what we require"* (P07, Mother); providing the opportunity to be active (i.e., inclusivity) e.g., *"he's never not been allowed to be completely involved in anything and everything that's going on"* (P10, Mother); and facilitation of blood glucose testing in relation to physical activity, e.g., *"the PE teacher is like, 'Sam, check, make sure you've got enough energy to play this match', so he'll check himself"* (P19, Mother).

Generally, parents were satisfied with the support their child had received from school, but many parents could recall specific occasions when schools had been less supportive e.g., *"the teacher refused to deliver any care in relation to Harry's diabetes…very scary, everyday leaving him, wondering if he's having a hypo"* (P06, Mother). Parents perceived a lack of support when teachers demonstrated limited T1DM awareness and competence e.g*., "teachers lacking confidence in dealing with hypos…teachers are absolutely terrified of hypos in sporting activity and so they will not push or challenge him at all"* (P11, Mother). One mother described a time when her daughter missed her entitlement to PE due to the cold temperature of the swimming pool having a negative effect on the child's ability to regulate her body temperature. This mother was disheartened because no physical activity was offered as an alternative, "*she ends up doing extra handwriting which she isn't very happy about because she really would like to be more involved, she does like swimming*" (P07, Mother).

Subtheme 6d) Parents perceive active role models as important for their child's participation in physical activity

Parents believed that physically active significant others served as role models for their children. Examples of role models frequently involved active parents e.g., *"Role models. I mean when they started karate when they were five, their Dad joined with them"* (P11, Mother). Role models also included siblings and activity leaders, e.g., *"we found a martial arts instructor who is Type 1, so that's a role model. I think just everybody around him being active"* (P11, Mother). Peers were also cited as important role models for children, especially those who were physically active e.g., *"he's made friends with like-minded people and they play football at lunchtime"* (P09, Mother).

3.4.7 Theme 7

Parents attribute participation in physical activity to their child's personal characteristics and preferences

Parents often attributed their child's participation in physical activity to their personal characteristics and preferences. Several parents described their child as being or not being a 'sporty' type, referring to their child's enjoyment, ability and preference for sporting endeavours e.g., "*he'll do anything, he loves PE at school and he'll have a go at whatever they're doing, it doesn't matter what it is, he'll enjoy it and have a go"* (P09, Mother). Those parents who described their child as enjoying physical activity tended to emphasise that their child would not let T1DM stop them from being active, which was perceived as a positive influence e.g., *"I think if she can go out and do those things without the diabetes getting in* *the way too much then that's really promising, at least she'll continue when she gets bigger"* (P08, Mother).

When parents described their child's lack of enjoyment of physical activity, they often described alternative preferences such as sedentary screen-based activity, e.g., *"he likes his iPod, he likes his phone, he likes the telly [television], he likes the laptop, you know and I've tried lots of different things but can't get him interested in anything long-term things like skate-boarding, kick-boxing, karate"* (P04, Father). One mother alluded to enjoyment being akin with ability; *"it's not enjoyable if you're not good at it"* (P16, Mother). The same mother alluded to the idea that her son could use diabetes as an excuse not to be physically active; *"he will make up excuses about a hypo and check his bloods and get out of doing it"* (P16, Mother). Some parents were keen to point out that their child's interest in physical activity was not attributed to them having T1DM, as one father explained; *"he pretty much hated all them [activities] to start with, again this is part of just his make-up, nothing to do with diabetes"* (P05, Father).

3.5 Discussion

The purpose of this research was to understand parents' perceptions of what may influence physical activity for their children with T1DM. Interviews indicated that parents serve as gate-keepers for children's physical activity and perceive challenges relating to their child's participation in physical activity, but value the supportive systems that enable their child to overcome these hurdles. Themes that emerged included the conflict between planning and spontaneous activity, struggles to control blood glucose, recognition of the importance of physical activity, the determination of parents, children relying on their parents to manage physical activity, the importance of a good support system and individual factors about the children that influence physical activity participation.

The findings demonstrate how parents value the importance of routine and perceive a conflict between carefully arranged diabetes management plans and the sporadic, unpredictable nature of children's physical activity. Previous research with children who have chronic conditions has shown that having management plans as part of daily routine was perceived by their parents as fundamental to children having an active lifestyle (Fereday et al., 2009). Research exploring young people's (aged 13-16) and parents' perspectives on T1DM self-management and glycaemic control has suggested that implementation of structured daily routine gives parents a sense of being 'in control' of diabetes (Spencer et al., 2013). This suggests that guidance is needed to help parents to implement physical activity management plans within a daily routine, and thereby generate competence to respond to spontaneous activities.

Parents described the constant battle to achieve desirable blood glucose control and perceived the need for more vigilant blood glucose monitoring during periods of physical activity. This is a similar finding to previous research which examined the day-to-day experience of mothers with young children who have T1DM and identified that mothers use 'constant vigilance' to accomplish the daily management of their child's diabetes (Sullivan-Bolyai et al., 2003). Elsewhere, research has shown that parents who have children with chronic conditions feel the need for continual monitoring of their child's health status in relation to sport and physical activity (Fereday et al., 2009).

A trial and error system for managing blood glucose level seemed to be a useful learning method for parents, which has also been found to play an important part in decisions about children's asthma management (Callery et al., 2003). Trial and error could be advantageous because professional advice can be tested and adapted to fit with parents' own understanding of their child's diabetes. This depends on parents having the knowledge and confidence to implement new techniques and respond to different outcomes. Some parents may need ongoing advice and support when learning about their child's blood glucose level responses to physical activity.

Parents expressed concerns about the possible adverse side-effects of physical activity and spoke specifically about hypoglycaemia and nocturnal hypoglycaemia. Hypoglycaemia is more likely to occur after periods of physical activity (Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, 2010). Previous research has found that parents commonly report fear of nocturnal hypoglycaemia (Patton et al., 2007), and the current findings suggest that parental concern about hypoglycaemia may be heightened after physical activity. This highlights the importance of listening to parental concerns and providing education about how to manage the side-effects of physical activity. Designing interventions to support parents in normalising the hypoglycaemic response to physical activity could be beneficial.

Despite hypoglycaemia being perceived as a negative side-effect of physical activity, parents had observed benefits in their children such as improved blood glucose control, body composition and knowledge about the body's response to food, exercise and insulin which they attributed to physical activity participation. Observable benefits could serve to reinforce parental beliefs about the importance of physical activity for their children. Parents held beliefs about the importance of physical activity for everybody and specifically for children with T1DM for reasons such as protection against disease. Therefore, educational resources which promote awareness amongst parents of the short and long-term benefits of physical activity for children with T1MD may have a greater impact.

Parents wanted to optimise their child's physical activity opportunities, demonstrating a resilience to overcome or persevere in the face of challenges. Parents preferred to identify challenges as 'hurdles to get over' rather than barriers to stop their child participating in an active lifestyle. Resilience characteristics have been explored in families with a child who has T1DM and highlight that not all families have the qualities or resources to overcome adversity (Koegelenberg, 2013). Such families may require ongoing support and guidance to overcome hurdles to physical activity such as hypoglycaemia.

Parents acknowledged that physical activity participation could foster independence in their children, but found it difficult to reach a balance between promoting independence and ensuring their child's safety. Children's physical activity was believed to be dependent on parental management and supervision, fostering a reluctance to pass on responsibility of their child to other adults such as activity leaders, sports coaches and school teachers. This supports previous findings in parents of children with chronic conditions (Fereday et al., 2009). MacMillan et al. (2014b) also demonstrated that the parents, children and professionals interviewed in their study believed that it was important that physical activity interventions for children balanced parental involvement with giving children responsibility. Research in children with T1DM has suggested that parental responsibility is amplified due to the child's reliance on parents to make decisions about diabetes treatment and behaviour (Hackworth et al., 2013). This highlights the importance of identifying social networks that may provide parents with support that could reduce this burden of responsibility. The findings imply that parents may allow their child more independence if personnel involved in the supervision of children's physical activity, such as activity leaders, had an understanding of T1DM, its complications and physical activity side-effects.

Parents valued the supportive systems that enable their child to overcome some of the challenges relating to physical activity. The influential social agents included parents, school personnel, diabetes clinic staff and peers. Consistent with previous research in children with (Fereday et al., 2009) and without (Gustafson and Rhodes, 2006 ; Salmon et al., 2005) diabetes, parents acknowledged that their own involvement, encouragement and logistic support facilitated their child's physical activity. Active peers were also perceived as important enablers of children's participation in physical activity. Social cognitive theory can explain the influence of active parents and peers on children's physical activity (Bandura, 2001). Bandura (2001) suggests that children learn behaviours through role models and as such, parents and/or peers who endorse physically active behaviour or attitudes could promote physical activity in children. The findings also go some way to support Bandura's concept of self-efficacy, suggesting that a child's confidence or belief in their ability to be physically active might be enhanced in the presence of parents. Hence, targeting key influential figures such as parents and peers is warranted if attempts to promote physical activity in children with T1DM are to be successful.

Parents valued the support they received from their child's diabetes team, especially when the healthcare providers were deemed to be available, helpful and encouraging of physical activity. On occasions, the diabetes team were perceived as unsupportive due to a perceived lack of mutual understanding between the parent and HCPs or a lack of appropriate information provided, which had resulted in discontinuation of physical activity. This is consistent with findings that have shown positive relationships with HCPs are imperative for optimal management of T1DM in childhood (Herrman, 2006). This highlights the important position of the HCP to offer advice and support for children's prolonged participation in physical activity. Research with HCPs would be useful to explore their perceived competency to promote regular physical activity in children with T1DM and identify any support needs for communicating physical activity guidance.

Having a supportive school environment where physical activity was encouraged and supervised by trained and attentive teachers was perceived as facilitative of children's physical activity. Dissatisfaction with the support from school resulted from a perceived lack of teacher awareness of T1DM and competence in management techniques, which echoes previous findings demonstrating that more can be done to support children with T1DM in school physical activities (MacMillan et al., 2015). The school environment has been identified as an important correlate of physical activity (Biddle et al., 2005 ; Ferreira et al., 2007). A literature review investigating the effects of T1DM on schooling, including teachers' awareness of T1DM, suggested that teachers felt uninformed about T1DM, were unable or unwilling to offer support (e.g., could not recognise or properly treat hypoglycaemia) and students with T1DM and their parents were apprehensive about school personnel's limited understanding of diabetes (Wodrich et al., 2011). The current findings reinforce the point that people working with children (e.g., teachers) must be educated about T1DM and be trained to manage a child with T1DM during physical activity.

Parents perceived children's individual characteristics such as their preference for or enjoyment of physical activity as an important influence on their uptake and maintenance of physical activity. Children's enjoyment of physical activity has been perceived by parents as an important facilitator of physical activity (Bentley et al., 2012), implying that parents believe their children are intrinsically motivated to participate in physical activity. The current findings would suggest that parents of children with T1DM share this belief. Helping parents to facilitate their child's intrinsic motivation for physical activity could be a successful approach to physical activity promotion in children with T1DM.

3.6 Evaluation

The research provides an in-depth look at the specific challenges, hurdles and barriers that parents of children with T1DM may face when their child is participating in physical activity. The findings may be used to extrapolate practical implications for the teaching and caring of children with T1DM. The high consistency of themes support the credibility of the findings and the researcher's reflective practice enhances its methodological rigour.

The findings should be considered in light of methodological issues. The parents in this study were speaking mainly about boys' participation in physical activity, meaning that parents' perceptions of physical activity for girls with T1DM were underrepresented. In addition, the majority of the parents interviewed were married and were mothers and so the findings may not reflect the experiences of other family forms beyond the nuclear model or fathers. Research has demonstrated a difference between the influence of mothers and fathers on their child's physical activity (Määttä et al., 2014), warranting further research into the paternal perspective. Furthermore, due to the self-selected recruitment and the nature of the research question, the study may have reached the more motivated parents who actively seek assistance and information about physical activity. Parents with little interest or involvement in their child's physical activity may have been underrepresented. Nevertheless, the perceptions of parents with physically active children are valuable for demonstrating how barriers to physical activity can be overcome (Rees et al., 2006).

3.7 Conclusions

This study demonstrates the important role of parents in enabling children with T1DM to engage in physical activity. The findings provide insight into the need for T1DM knowledge and competence in personnel involved in the supervision of children's physical activities. The diabetes healthcare team have an ongoing opportunity to promote active lifestyles and collaborate with families to facilitate their understanding of how to manage physical activity. This sample was somewhat homogenous and further research is needed to investigate the experiences of parents who are in a less supportive position and less informed about physical activity. The findings inform those working with children (e.g., HCPs, school personnel and policy makers) to the issues confronted by children with T1DM and their parents, as well as the methods used to overcome obstacles to physical activity.

Chapter Four

"Having diabetes shouldn't stop them": Healthcare professionals' perceptions of physical activity in children with Type 1 Diabetes

4.1 Introduction

The findings from Chapter 2 suggested that regular physical activity for children with Type 1 Diabetes Mellitus (T1DM) is associated with improvements in glycaemic control, lipid profile and body composition (Quirk et al., 2014b). Despite its potential to delay the onset of cardiovascular disease (Herbst et al., 2006 ; Trigona et al., 2010), the figures presented in Chapter 1 suggest that, in common with the general child population, children with T1DM are not meeting the recommended 60 minutes of moderate-to-vigorous physical activity (MVPA) per day (Faulkner et al., 2010 ; Liese et al., 2013 ; MacMillan et al., 2015). Healthcare professionals (HCPs) potentially have an important role in encouraging children with T1DM to engage in regular physical activity. Yet little is known about how HCPs view this role and factors influencing physical activity in this population.

Provision of support and guidance from HCPs is important for children and parents to manage the complications associated with physical activity among children with T1DM. Previous research suggests that fear of hypoglycaemia is a potential barrier to physical activity among children with T1DM (Johnson et al., 2013b) and their parents (Barnard et al., 2010 ; Johnson et al., 2013b ; Quirk et al., 2014a). It is possible that HCPs have a valuable role in helping children and their parents manage the risk of hypoglycaemia and alleviating associated worries (Johnson et al., 2013b). MacMillan and colleagues (MacMillan et al., 2014b ; MacMillan et al., 2015) explored the perceptions of diabetes professionals together with teachers, youth with T1DM and their parents in Scotland to inform guidelines on how to improve physical activity support for young people with T1DM in the school setting. They found that HCPs recognised they could do more to encourage physical activity among children with T1DM and discussed various intervention delivery methods that might be effective in supporting physical activity in the Scottish diabetes clinic. This previous research, however, has not distinguished HCPs' beliefs from the views of other stakeholders, nor has there been an in-depth exploration of HCPs' perceptions of the factors influencing the physical activity levels of children who have T1DM.

Theoretical models provide a framework for understanding the role of HCPs in children's participation in physical activity. Social cognitive theories suggest that the environment and the individual affect one another in a process of reciprocal determinism to bring about any given behaviour (Bandura, 1986). Although HCPs may not be able to alter the physical environment, they can be sensitive to the social influences involved in helping or hindering children's participation in regular physical activity. To sensitise HCPs, further research is needed to explore HCPs perceptions of the influences involved in children's physical activity.

4.2 Study aims

The purpose of this study is to explore HCPs' understanding of factors influencing levels of physical activity for children with T1DM. The study aims to understand how HCPs perceive their role in relation to supporting physical activity for children with T1DM in an effort to inform attempts to promote physical activity in this population.

4.3 Methods

To satisfy these study aims, data were collected by semi-structured interview with HCPs involved in the care of children with T1DM. This study was informed by interrelated concepts of interpretivism and reflexivity, balanced with pragmatism and transparency. This was achieved by seeking to understand the perceptions of HCPs whilst demonstrating practical implications for physical activity promotion attempts among those working with children who have T1DM.

4.3.1 Ethical Approval

The research had been reviewed and approved by the University of Nottingham Medical School Ethics Committee (Reference No: B10012013 SNMP) (Appendix 3).

4.3.2 *Participants*

Participants were eligible if they worked as a healthcare professional in paediatric T1DM. HCPs were using a purposeful sampling approach with snowball techniques (Patton, 1990), whereby participants suggested colleagues who might be eligible. A recruitment poster was distributed amongst paediatric diabetes clinical network members and delegates at a professional diabetes conference. The poster contained a web link to a survey site where potential participants could read about the study and provide their contact details confidentially. Those who provided their contact details were contacted by the researcher and eligible HCPs were provided with the study information sheet (Appendix 6) and a consent form.

The number of HCPs recruited to this study was based on the number needed to achieve theoretical data saturation (Strauss and Corbin, 1998). With each interview, the researcher judged whether any new data were emerging that would satisfy the purpose of the research. Nineteen HCPs expressed an interest in being interviewed and no new data emerged during the tenth and eleventh interviews, at which point recruitment ceased.

The eleven participants who formed the study sample were recruited from eight different paediatric diabetes centres across the UK, four participants were recruited from the same centre, but held different roles (Dietician, Clinical Lead Dietician, Consultant and Specialist Nurse). The sample consisted of four Consultants, six Dieticians and one Specialist Nurse with an average 7.2 years of experience working in paediatric T1DM (mean = 7.2 years, range = 1-17 years) among them.

Table 7 Summary of participant characteristics

Participant ID	Job title	Years of experience
P01	Paediatric dietitian	6
P02	Consultant in paediatric diabetes	5
P03	Consultant in paediatric diabetes	15
P04	Paediatric diabetes specialist nurse	15
P05	Consultant paediatrician with interest in diabetes	8
P06	Clinical lead dietitian	2
P07	Diabetes specialist dietitian	3
P08	Paediatric dietitian	6
P09	Paediatric diabetes dietitian	1
P10	Consultant paediatrician with interest in diabetes	17
P11	Diabetes dietitian	1
N = 11	Consultants (n=4) Dietitians (n=6) Nurse (n=1)	Mean = 7.2 years

4.3.3 Data collection

The researcher received consent from the participant in writing (if interviewed in person) or verbally (if interviewed via telephone) prior to the interview. Interviews were arranged for a mutually convenient time and location; telephone interviews were offered if a face-to-face interview was not feasible. Two interviews were conducted face-to-face at the local institution, nine were conducted by telephone. Each interview was carried out by one of two interviewers; the thesis researcher and a medical student. At the time of interviews, both interviewers were aged between 20 and 25 years, were female, and were trained in qualitative methods and interview techniques. With the participant's consent, interviews were recorded using an Olympus Dictaphone. Interviewers followed an interview guide to ensure that the same topics were covered across interviews (Appendix 7). All interviewees were asked to speak freely and were assured that the interviews remained confidential. Interview length ranged from 18 to 85 minutes and the mean duration was 40 minutes.

The interviewers aimed to create a free-flowing discussion directed by the interviewee. Interview questions sought to explore HCPs' perceptions of physical activity for children who have T1DM with open questions such as: *How do you think children with*

T1DM feel about taking part in physical activities?; *How do you think having T1DM influences participation in physical activity? What could be done to help children with T1DM be more active?*.

4.3.4 Data analysis

Interviews were transcribed verbatim into Microsoft Word (Microsoft, Redmond, WA, USA) by the researcher, which facilitated early familiarisation with the data. Transcript analysis was an iterative process using thematic analysis (Braun and Clarke, 2006) (Figure 10, Chapter 3). This involved identifying codes, patterns (themes) and common threads across all transcripts. Codes were meaningful groups of data that captured the essence of the data. NVivo version 10 (QSR International Pty Ltd., 2012) was used to facilitate the organisation of codes and themes, and has been used previously in similar research (Veitch et al., 2006).

Codes were derived primarily from the data (inductive) but could also be theory-derived (deductive) (Braun and Clarke, 2006). Codes arose through a deductive approach when the theoretical understanding found in the literature review allowed the researcher to be sensitive to certain topics that may arise in the data (Strauss and Corbin, 1998). Examples of a priori codes were '*occurrence of hypoglycaemia*', '*children's concerns about hypoglycaemia*' and '*parental fear of hypoglycaemia*', as previous research has suggested that hypoglycaemia could be a potential barrier to physical activity. Inductive codes emerged from data and thus not anticipated in advance of data analysis. Data analysis began with an inductive approach. Deductive codes relating to specific areas of interest were then looked for in the data, but analysis was iterative rather than a rigid linear process.

4.3.5 Trustworthiness and reflective practice

Several approaches were used throughout the study to ensure methodological trustworthiness (Yardley, 2008). The researchers showed sensitivity, commitment and rigour (to theory, participants and data), transparency (e.g., being explicit with research decisions) and sought findings that would have practical implications. This was in addition to utilising a rigorous approach to establish the consistency and replicability of the themes (Boyatzis, 1998). A codebook was developed which included a brief background to the study, a label for each theme, a theme and sub-theme description and examples extracts that did and did not illustrate each theme (Boyatzis, 1998). Quotes belonging to each theme were given to a second coder to code blind using the codebook. Boyatzis (1998) recommends that percentage agreement between two coders above 70% demonstrates acceptable reliability. The agreement was 89.5%, indicating that the themes were consistent and reliable to a recommended standard (Boyatzis, 1998).

Through reflective practice, the researcher was careful to acknowledge personal biases, values and judgements explicitly in a diary prior to and during the research process (Braun and Clarke, 2006). During data collection, the researcher made notes about the interview, including insights about the interview, participant and emerging points of interest. In the early stages of data analysis, the researcher noted impressions, ideas and initial interpretations of the data. This aided the generation of themes and served as a means for documenting the rationale for any changes or reassignment of codes and themes.

4.4 Results

The purpose of this study was to explore HCPs' perceptions of what influences physical activity for children with T1DM in an effort to inform those working with children who have T1DM. Factors believed to influence participation are presented as five major themes and eleven corresponding sub-themes. Verbatim quotes are provided to demonstrate themes, labelled with the participant's professional role.

Table 8 Overview of themes, subthemes and codes

Theme	Subtheme	Codes
1. Social support is a positive influence on children's participation in physical activity	1a. Parental responsibility and support is believed to be the key to children's participation in physical activity	Parental influence, a family thing, encouragement, positive influence/role model, motivated, engaged, sedentary family.
	1b. Active friends are a positive influence on children's physical activity	Peer support, role model, active friends, social involvement.
2. Individual motivation to be physically active is the main influence on children's level of physical activity		Motivated, enjoyment, committed, interested, competence.
3. Formal organisations have the potential to support physical activity	3a. Schools are believed to have a "wonderful opportunity" (P10, Consultant) to promote physical activity	Teachers, concerns, opportunity, PE teachers,
	3b. Healthcare professionals' role to educate and advise around physical activity	Help, role, educate, support, communication, management plan, skills, reassure parents, children's commitment to the advice.
	3c. Professional expertise supports the child's existing lifestyle rather than promoting increased physical activity	Promote the guidance, sporty children, what they already do, targeting those who need it, overweight children.
4. Type 1 Diabetes presents specific challenges to physical activity	4a. Problems maintaining stable blood glucose control	It shouldn't interfere, testing frequently, spontaneous activities, hypoglycaemia.
	4b. Parental concern regarding hypoglycaemia limits children's physical activity	Parental fear of hypoglycaemia, concerns, worry more than children.
	4c. Concerns about Type 1 Diabetes being used as an excuse not to be active	Another excuse for not being active, get-out clause.

5. Perceived barriers to healthcare professionals fulfilling their role to promote physical activity	5a. Healthcare professionals perceive difficulty implementing physical activity guidelines	Standardised information, individualised advice (no off-the-peg solution), confidence, competence, difficult to translate information, physical activity an after-thought, time.
	5b. Healthcare professionals acknowledge the need for further training and resources	We don't do enough, resources would be good, training health professionals a priority.

4.4.1 Theme 1

Social support is a positive influence on children's participation in physical activity

Social support was the most commonly identified influence on children's physical activity, with parents and peers being perceived as important sources of practical and emotional support.

Subtheme 1a) Parental responsibility and support is believed to be the key to children's participation in physical activity

The majority of HCPs perceived parents as a powerful source of support for their child's physical activity. Parental support encompassed parents being encouraging and demonstrating a positive attitude toward physical activity, e.g.:

> *I think parental responsibility, so communicating with their children to say look, [physical activity] is important for you, for your development, to continue being social with your friends, obviously good for your health. So I think that parental role is extremely important, that supportive structure around them.*
>
> P09, Dietician

Parental support was believed to be emotional (e.g., encouragement) and/or logistical (e.g., providing transport); "*they would need their parents to take them to the activity, Mum to drive them*" (P02, Consultant). Some HCPs believed that it helped if parents were active and others believed an active parental role model was not necessary, e.g.; "*I don't think necessarily that parents have to be really sporty to get the children to be sporty, but they encourage them to be sporty and take them to their hobbies and support them*" (P01, Dietician). Overall, parents were perceived as the key to children being provided the opportunity to be active, e.g.:

> *I suppose parents' lifestyle influences…whether they have those opportunities to be active or whether their parents want to get on with other things and leave them to watch TV or play on the PlayStation.*
>
> P11, Dietician

The parents whom HCPs believed to be less engaged and supportive were perceived as "*likely to be the most reluctant*" (P01, Dietician) to encourage their child to be physically active and less likely to prioritise the importance of physical activity:

> *The main problem you're likely to face is not diabetes, it's just, when are we [the family] going to fit this [physical activity] into our busy lives and is it really a priority?*
>
> P03, Consultant

Subtheme 1b) Active friends are a positive influence on children's physical activity

Active friends were deemed an influential support network for providing socialisation opportunities and modelling active behaviour. One HCP believed that participation in physical activity depended on, "*who they make friends with and whether they are into [physical activity], if they've got friends who play football they'll go join them and play football after school*" (P11, Dietician).

Friends were also mentioned as valuable for providing children with support to manage and cope with diabetes. "Buddy systems" were mentioned as potentially valuable forms of social support and important to, "*bring the community of young people with diabetes together*" (P10, Consultant). One nurse mentioned how children with T1DM wishing to be more active could be "*buddied up with someone who does do sports*" (P04, Nurse).

4.4.2 Theme 2

Individual motivation to be physically active is the main influence on children's level of physical activity

Specific characteristics of the child were thought to facilitate participation in physical activity. The most pertinent characteristic referred to the child's motivation. Around half of the HCPs identified the child's motivation to be physically active as the main influence on children's participation in physical activity. Some HCPs believed that children are driven by "*what they're interested in and what they feel they're good at*" (P08, Dietician), implying that the motivation might be intrinsic, thus driven by feelings of enjoyment and competency to satisfy an inherent interest in being active. Others conceded that it is difficult to know what motivates some children: "*We don't really know what it is that drives some people into it [physical activity] and others into couch potatoes*" (P11, Dietician).

Children involved in structured activity or organised sports were described as being the most motivated and committed, e.g.; "*Taking part in competitive sport requires discipline anyway so you find that the patient and the family tend to be quite motivated and disciplined and that reflects on their diabetes control*" (P02, Consultant). Being active prior to T1DM diagnosis was perceived to help children overcome barriers to physical activity, e.g.; "*The ones that have always been active carry on and find a way to do that with the diabetes*" (P04, Nurse). The same nurse went on to say that these active children, "*know what they get out of the exercise already*" (P04, Nurse), which implies that experiencing some reward from previous participation or having an existing interest in being active can motivate children towards physical active after diagnosis with T1DM.

4.4.3 Theme 3

Formal organisations have the potential to support physical activity

The child's school and healthcare team were identified as having the potential to influence children's participation in physical activity.

Subtheme 3a) Schools are believed to have a "*wonderful opportunity*" to promote physical activity (P10, Consultant)

School teachers were believed to have an important role in the facilitation of physical activity for children with T1DM. As a mandatory part of the school curriculum, Physical Education (PE) was believed to be an accessible opportunity for all children to be active "*whether they like it or not*" (P09, Dietician). For teachers supervising children with T1DM, "*the priority is safety*" (P09, Dietician) and HCPs perceive that it is the role of the diabetes team to ensure that schools are adequately informed and prepared to supervise and support pupils with T1DM via training and school visits, e.g.:

> *That has occasionally been an issue, where teachers haven't understood or are frightened about what might happen and children are prevented from participating…well often the diabetes nurses can be quite helpful in those situations, going out to the school and talking to teachers, finding out their concerns and addressing those issues.*
>
> P03, Consultant

Subtheme 3b) Healthcare professionals' role to educate and advise around physical activity

The majority of HCPs believed that it was their role to educate and support children with advice and guidance around physical activity; "*to give them the skills to be able to manage their diabetes to the best of their ability and perform that activity*" (P07, Dietician). They believed they can reassure parents that physical activity is safe when diabetes management plans are in place, but implied that safe participation depended on the patient's commitment to the advice. For example, a dietician said, "*it's important that we have a role …we reassure them that anything is possible as long as they're willing to commit to what we say*" (P09, Dietician). The HCPs also believed they were in a position to normalise the experience of hypoglycaemic episodes:

> *We do tell the parents that having a couple of hypos a week is actually a sign of good control, as long as the child can recognise hypo symptoms…so it is normal as long as they're just checking blood sugars and know how to treat them.*
>
> P01, Dietician

The HCPs interviewed in this study described their tendency to discuss physical activity with specific children; e.g. overweight children, "*if it's a child who's got a weight problem as well then we might address it*" (P02, Consultant) and children who were regularly active prior to diagnosis, "*We talk about exercise if they're sporty*" (P01, Dietician). Furthermore, some HCPs identified themselves or specific colleagues as being more inclined or suitable to give advice around physical activity. One HCP described their centre as being proactive in offering exercise advice to children; "*I think compared to other centres we are probably quite proactive in advising on exercise in diabetes*" (P04, Dietician) and a colleague in the same centre explained, "*I think it's driven more by our personal interests as much as anything else*" (P03, Consultant).

Subtheme 3c) Professional expertise supports the child's existing lifestyle rather than promoting increased physical activity

The HCPs perceived that they were better placed to support the management of existing structured activities rather than promoting an increase in lifestyle physical activity. The management strategies described were individualised management plans, activity diaries and ongoing clinic discussions:

> *With most patients you can find a pattern to say look the child tends to go a bit hypo maybe two hours after the activity, so we need to make sure that we give them a good carbohydrate meal, we cut down the insulin or work out a strategy that works.*
>
> P02, Consultant

A minority of HCPs did promote lifestyle physical activity, describing how they encourage lifestyle activities such as walking to school and playing outside. One dietician perceived it easier to discuss physical activity with children who already had an interest being active, because then the HCP's role was "*to support [the child's] chosen lifestyle, but it's very different to actively promoting physical activity*" *(*P11, Dietician). Another dietician acknowledged; "*[healthcare professionals] forget about anything that may just be sort of everyday activities…, walking to school say, and we concentrate a lot more on what we call 'exercise'*" (P07, Dietician).

4.4.4 Theme 4

Type 1 Diabetes presents specific challenges to physical activity

There was consensus among HCPs that T1DM "*shouldn't really interfere*" (P01, Dietician) with lifestyle physical activities, but that structured, prolonged exercise and competitive sport participation need a diabetes management plan in place to ensure that participation is safe and performance is optimal. The current level of activity in children with T1DM was believed to be similar to their counterparts without diabetes. Nevertheless, HCPs recognised that diabetes presents unique challenges to children with T1DM engaging in active lifestyles.

Subtheme 4a) Problems maintaining stable blood glucose control

Blood glucose control was perceived as a challenge for children with T1DM and their parents due to the extra demands of monitoring and managing fluctuating blood glucose levels around times of physical activity. The majority of HCPs perceived one of the main challenges to be the frequent testing of blood glucose level, which they sympathised as being; "*difficult*" (P07, Dietician), "*boring*" (P04, Dietician), "*interfering*" (P01, Dietician) and "*a lot of effort*" (P01, Dietician). One HCP acknowledged that, "*I think our expectations of testing so frequently during physical activity are very difficult for people to keep up*" (P07, Dietician). Swimming and spontaneous activities were specific situations perceived to be problematic for maintaining a stable blood glucose level. Spontaneous activities were perceived as particularly difficult to manage due to the inability to pre-empt changes in blood glucose level:

> *You've got a child…who suddenly decides to go out and bounce on the trampoline for half an hour and then their blood sugars go low and then it's the parents that worry about sudden unpredicted exercise because that can make their sugars drop quickly.*
>
> P03, Consultant

Subtheme 4b) Parental concern regarding hypoglycaemia limits children's physical activity

Every HCP interviewed accepted the negative influence hypoglycaemia had on participation in physical activity for children with T1DM and agreed that the main challenge was the worry of hypoglycaemia, rather than its actual occurrence. Parental concern and worry about hypoglycaemia was the most commonly cited barrier to physical activity. One Consultant referred to parental worry as a normal response and "*part and parcel*" of being a parent of a child with T1DM, rather than a "*pathological worrying state*" (P02, Consultant). Yet acknowledged; "*that [parental concerns about hypoglycaemia] will definitely limit the child's participation*" (P02, Consultant). Nocturnal hypoglycaemia was identified as a specific cause of worry for parents:

> *When they do become a bit sporty, they do struggle, especially with getting hypos, their blood sugars drop at some point in the evening after the activity and parents worry a lot about hypos in the evening or at night and that can be something that deters them from doing activities.*
>
> P02, Consultant

A small number of HCPs perceived the child's concerns about hypoglycaemia to be a potential barrier to physical activity; "*maybe it is that some of them are less confident because of the fear of hypos*" (P01, Dietician), but the general consensus was that "*it's the parents that worry a lot more than the children*" (P08, Dietician). Some HCPs offered suggestions for the cause of parental concerns about hypoglycaemia; i) parental worries due to a historical emphasis on the risk of exercise-induced hypoglycaemia, ii) negative past experiences of hypoglycaemia, iii) being newly diagnosed, and iv) parents worrying on behalf of their child. For example, younger children may have limited awareness of the risks of hypoglycaemia, as suggested by one Consultant; "*the younger kids, they probably just don't have the awareness to worry about it [hypoglycaemia], so their parents worry on their behalf*" (P02, Consultant). No consistent reason was offered, but there was some agreement that most concerns are likely to follow an episode of hypoglycaemia, with the consequences for children being embarrassment or losing confidence and for parents having the lasting memory of the episode; "*[parents] have got the real scary situation in their head*" (P04, Specialist Nurse) and "*[hypoglycaemia] haunts them a long time later*" (P05, Dietician).

Four HCPs indicated that parents might attempt to avoid hypoglycaemia by keeping blood glucose higher than is recommended, termed 'maladaptive hypoglycaemia avoidance behaviour'. Amongst these HCPs, there was consensus that it was the role of the HCP to promote adequate levels of blood glucose rather than high levels:

> *Often parents like to have their children have relatively high blood glucose levels and we try to listen to those concerns and empathise with them, but at the same time, we try to have them, rather than highs, we try to promote adequate levels.*
>
> P09, Dietician

Subtheme 4c) Concerns about Type 1 Diabetes being used as an excuse not to be active

Five HCPs believed that the extra effort required when a child with T1DM participates in physical activity could be used as an excuse not to participate, particularly by children who do not have an inherent interest in being active; "*Sometimes the diabetes can be used as a nice convenient excuse but you usually find out that these were children who never did anything beforehand*" (P03, Consultant).

4.4.5 Theme 5

Perceived barriers to healthcare professionals fulfilling their role to promote physical activity

The majority of HCPs could readily identify barriers to the successful promotion of physical activity in children with T1DM.

Subtheme 5a) Healthcare professionals perceive difficulty implementing physical activity guidelines

Healthcare professionals confided that physical activity was not always a priority for discussion during clinic appointments, where time was prioritised to other aspects of diabetes care (e.g., diet and insulin management). The reasons suggested for not prioritising physical activity included; "*there's quite a bit to it*" (P10, Consultant), and "*you only get a small amount of time*" (P09, Dietician). The HCPs interviewed found it difficult to translate physical activity information into a comprehensible format, e.g.; "*difficult trying to translate that information into a digestible form for children*" (P11, Dietician). Two HCPs suggested that the limited time available during routine clinic appointments meant that details around physical activity promotion and management were often omitted. Also, it was acknowledged that the effective implementation of guidelines was dependent on there being commitment from the child and family:

> *If people are really going to manage their diabetes well during exercise that takes a lot of commitment in terms of what we may ask people to do. We might ask them to take blood glucose before and then every 20-30 minutes during activity and every hour afterwards.*
>
> P07, Dietician

Subtheme 5b) Healthcare professionals acknowledge the need for further training and resources

Healthcare professionals believed that standardised guidelines for physical activity participation would be beneficial to educate children with T1DM and their families about managing physical activity, however conceded that "*there's not an off-the-peg solution to anything*" (P11, Dietician). Instead, because advice needs to be tailored to the individual child, its effectiveness depends on the ability of parents to understand how blood glucose levels respond to physical activity; "*It can be quite individual for the patient and that can be quite overwhelming*" (P07, Dietician).

There was general agreement that resources or referrals were available for children participating in structured or high level exercise and sport, however a gap was perceived in the availability of resources to promote and manage everyday lifestyle physical activities.

> *It would be useful to get better resources…a nice hand-out that we could actually give out UK-wide would help families get the right support and education they need and make sure all centres are giving the same advice.*
>
> P05, Dietician

Another HCP suggested that a curriculum or resource aimed at school teachers would be useful, especially PE teachers, who are "*ideally placed to understand*" (P10, Consultant) exercise:

> *It might be useful to have a bit of a curriculum that is clear, directed at teachers for example, with a bit more for those that do sporting activities...they will be the ones to have a child go hypo if that's not properly planned or monitored.*
>
> P10, Consultant

Two HCPs described initiatives that had been developed in their respective centres to address this need for resources and facilitate the discussion and management of physical activity; i) an algorithm (not yet evaluated) giving instructions to children depending on their blood glucose level prior to physical activity and ii) an education programme for adolescents making the transition from paediatric to adult care (Eiser et al., 2013).

A small number of HCPs lacked confidence in their ability to implement physical activity guidelines and questioned the effectiveness of the guidelines they were implementing: "*I'm not quite sure how effective that education is*" (P10, Consultant). One dietician indicated that the complications associated with T1DM meant that she lacked confidence to promote physical activity, "*in a group of people that you know will have problems*" (P11, Dietician). Some suggested that further training might facilitate the promotion and management of physical activity in the clinic setting; "*I don't always feel I know all I need to know about it...and so I think educating healthcare professionals is a starting point*"

(P07, Dietician), and; "*I don't feel adequately informed, probably because I haven't studied [physical] activity*" (P11, Dietician). One dietician described a self-initiated solution to this lack of mainstream physical activity training was to attend physical activity conferences:

> *We don't get enough training as a dietician you don't get any training in Type 1 Diabetes particularly until you start doing it let alone on sports and exercise. So the way I've been trained is because I've gone to conferences on specific days and I've gone out my way to do that; it's not an essential part of the training.*
>
> P05, Dietician

4.5 Discussion

Interviews with HCPs indicated that they believed they had an important role in providing physical activity advice and support to children with T1DM and their parents. There was agreement that diabetes should not be a barrier to children participating in any physical activity, exercise and sport. Yet challenges were identified on a number of levels (individual, social and promotion) that were perceived to make regular participation problematic for some children with T1DM. Themes demonstrated perceived facilitators and barriers that are shared with the general population of young people, including the positive influence of social support, the child's motivation to be active and the potential for formal organisations such as school to promote and support active lifestyles. Themes alluded to the challenges faced by individuals with T1DM and their parents (individual level), the role of the diabetes team and teachers to support physical activity among children with T1DM (social level), and the perceived barriers to HCPs fulfilling their role of promoting physical activity (promotion level).

The findings demonstrate how HCPs perceived parental support to be an important influence on children's physical activity participation. Of particular importance was parents' emotional and logistical support. Parental factors, family life and the home environment have been shown to influence a child's physical activity behaviour (Gustafson and Rhodes, 2006) and specifically the positive influence of parents' emotional (Pugliese and Tinsley, 2007) and logistical (Lim and Biddle, 2012) support. Parents are often responsible for the day-to-day management of blood glucose control in children with T1DM, which suggests that they may have a unique influence on their child's physical activity behaviour. Previous research supports the important role of parents in the physical activity participation of children with T1DM (Fereday et al., 2009 ; MacMillan et al., 2014b). Findings from Chapter 4 have shown that HCPs perceive parents to be one of the main sources of social support for children with T1DM engaging in regular physical activity. This suggests that parents should be targeted as influential agents in any attempt to promote physical activity in children with T1DM.

The HCPs also identified children's friends as important for promoting participation in physical activity, particularly their active friends. Previous research suggests that peers have been used as "diabetes buddies" to support children with T1DM (Wagner et al., 2006) and that peer support could be an important component of physical activity interventions for children with T1DM (MacMillan et al., 2014b). Bandura's SCT (Bandura, 1986) proposed that individuals learn behaviours by observing and imitating others through vicarious experience and the current findings imply that active friends could serve as important role models to children and could be targeted in attempts to promote physical activity in children with T1DM. Healthcare professionals with awareness of children's values can use that information to build rapport and to promote physical activity among their patients.

Children's individual preference for physical activity was perceived to be an important influence on their uptake and maintenance of physical activity. In particular, HCPs observed that children's enjoyment of physical activity was important. Participation in regular physical activity after diagnosis with T1DM was related to their history of physical activity participation and accomplishment. This suggests that children might be motivated when they feel competent, experience mastery and expect that participation will bring enjoyment. Previous research has identified intrinsic motivation (Sebire et al., 2013) and enjoyment (Dishman et al., 2005) as positively associated with children's participation in physical activity. Mastery experiences, which involve some previous successful accomplishment, are proposed to be an antecedent of self-efficacy (Bandura, 1986). Self-efficacy could be a powerful drive influencing children's motivation and has been identified as a psychological determinant of children's physical activity participation (Dishman et al., 2004). These findings suggest that attempts should be made to uncover what motivates children with T1DM to be physically active and to foster children's self-efficacy for physical activity through fun and enjoyable ways to keep active.

Schools were perceived to have a valuable opportunity to enable and promote physical activity among children with T1DM, but this was dependent on teachers being trained and prepared to supervise children's physical activity. Previous research has highlighted that teachers, youth with T1DM, their parents and diabetes professionals valued the importance of teachers' T1DM knowledge and training for encouraging children with T1DM to be physically active in school (MacMillan et al., 2015). Similarly, the parents in the previous chapter of this thesis expressed the importance of competent and supportive school teachers (Quirk et al., 2014a). The HCPs believed that it was the role of the diabetes team to ensure that training and safety precautions are in place at school to facilitate physical activity and sport engagement in children with T1DM. This would not only rely on healthcare teams having the capacity to deliver intensive training to school teachers, but whether they feel confident in doing so. It is arguable as to whether there is a need for specific training on the management of long-term conditions such as diabetes as part of teacher training. In addition, whilst PE in schools was valued by HCPs for its widespread accessibility, it must be acknowledged that classes may occur infrequently and children may be relatively inactive during the class. This raises the issue as to whether schools can do more to promote physical activity throughout the course of the day (Dobbins et al., 2013). The notion of school teachers promoting physical activity in children with T1DM is consistent with MacMillan et al. (2014), who provide guidance on what teachers can do to support children with T1DM being active in school (MacMillan et al., 2015).

Healthcare professionals perceived themselves and their colleagues involved in the care of children with T1DM to be an important source of support for children with T1DM engaging in physical activity. They described their role in *facilitating* the management of children's existing activities and sport participation rather than *actively promoting* physical activity in children's daily lives (e.g., walking to school). Our findings suggest that HCPs recognised that their role was to reassure children and parents about physical activity, but admitted that their influence might be limited to those who were 'sporty' or had an existing interest in physical activity. Paradoxically, the children who would benefit the most from increased physical activity were perceived as the most difficult for HCPs to engage in conversation around physical activity. This goes some way to explain previous research findings that healthcare professionals do not perceive themselves to be influential in the physical activity participation of children with T1DM (MacMillan et al., 2014b). Healthcare professionals and policy makers may need to think beyond traditional sports and activities and consider the promotion of active lifestyles among children, especially those who may not have been active prior to their diagnosis.

The HCPs appreciated that the demands of managing blood glucose levels could be a deterrent to physical activity, especially in those children who lacked interest in or motivation for physical activity. Children typically engage in spontaneous, intermittent bouts of activity and this was perceived to be challenging because the fluctuation in blood glucose level cannot be anticipated or offset with pre-planned insulin or dietary adjustments. Parental fear of hypoglycaemia was a commonly cited barrier to physical activity perceived by HCPs, but was not considered a maladaptive worrying state. Given the potential danger of low blood glucose levels, some degree of fear around hypoglycaemia is considered appropriate and adaptive (Gonder-Frederick et al., 2011). Healthcare professionals involved in the care of children with T1DM should seek to uncover concerns and give children and parents the skills and confidence to manage hypoglycaemia during and after physical activity.

The HCPs in this study believed they had a role in the promotion and management of physical activity, but identified aspects of their work conditions that made it difficult to fulfil this role. Some HCPs lacked confidence in either their own physical activity knowledge or the information available to them, which suggests they might be inadequately trained to deliver the guidance. They also perceived difficulty in implementing physical activity guidelines, and identified barriers to doing so, such as time constraints, translating the advice into a digestible format and feeling inadequately equipped or confident to deliver the advice. The barriers identified by the HCPs were consistent with those identified by medical professionals in other health domains, including; time constraints (Douglas et al., 2006), their own interests and health behaviours (McKenna et al., 1998), lack of standard protocols and lack of financial incentive (McKenna et al., 1998 ; McPhail and Schippers, 2012). This consistency suggests that our findings may have implications for the promotion of physical activity across the population. Healthcare systems are natural settings for the promotion of physical activity as they often involve repeated contact between HCPs and patients (Whitlock et al., 2002). We do not understand whether advice to engage in physical activity given by HCPs is effective in changing children's behaviour. It would not be unreasonable to infer from the current findings that HCPs might benefit from training opportunities to foster competence in the implementation of guidelines, promotion and management of physical activity. Diabetes teams might benefit from having a staff member who is specifically trained in physical activity advice and guidance and who has the confidence to champion physical activity promotion within the clinic. The effectiveness of this approach could be explored in future research.

4.6 Evaluation

The high consistency of themes supports the credibility of the findings and ongoing reflective practice enhances the methodological rigour. The findings should be considered in light of the following methodological issues. The HCPs were self-selected and therefore the study may have reached those with a personal interest in physical activity. Self-selection, together with snowball techniques meant that the HCPs in this study may have held different perceptions to those HCPs who were not interested or able to talk about physical activity for children with T1DM. Also, the combination of telephone and face-to-face interviews meant there was methodological disparity which may have elicited different responses. Yet a range of opinions about physical activity were captured and telephone interviews allowed for more diversity in participant type and geographical location.

4.7 Conclusions

The findings from this study raise awareness of HCPs' perceptions of the difficulties faced by children with T1DM in relation to physical activity, and highlight the potential for clinical and non-clinical supportive systems to be sensitive to these challenges and facilitate children's regular participation. Challenges to children's participation in regular physical activity have been identified at the individual (e.g., lack of motivation), social (e.g., parental concerns about hypoglycaemia) and promotion level (e.g., HCPs' lack of competence and confidence to promote physical activity). Healthcare professionals and policy makers should be aware of these challenges when designing and implementing interventions to promote physical activity among this population.

Chapter Five

The feasibility of objectively measured physical activity in children with Type 1 Diabetes

5.1 Introduction

Given the importance of physical activity and the promotion of active lifestyles in children and young people, it is essential that healthcare professionals and researchers have access to valid, reliable and practical tools to measure children's free-living activity levels. The measurement of children's physical activity level is inherently difficult given the short bouts of sporadic, intermittent activity that characterises children's behaviour (Baquet et al., 2007 ; Rowlands and Eston, 2007). Accelerometers provide an objective measurement of physical activity and can accurately quantify short bouts of intense activity (Riddoch et al., 2007). This chapter seeks to consider the methodological issues of utilising accelerometers to measure children's physical activity and to explore the acceptability and feasibility of the measurement protocol in the sample of children with Type 1 Diabetes Mellitus (T1DM).

To the researcher's knowledge, this is the first study to explore the acceptability of wrist-worn accelerometers at two time points among children with T1DM, whilst assessing whether the measure is sensitive to change in physical activity over time. The current study is situated within the broader framework of the feasibility study reported in Chapter 7 (**Figure 11**).

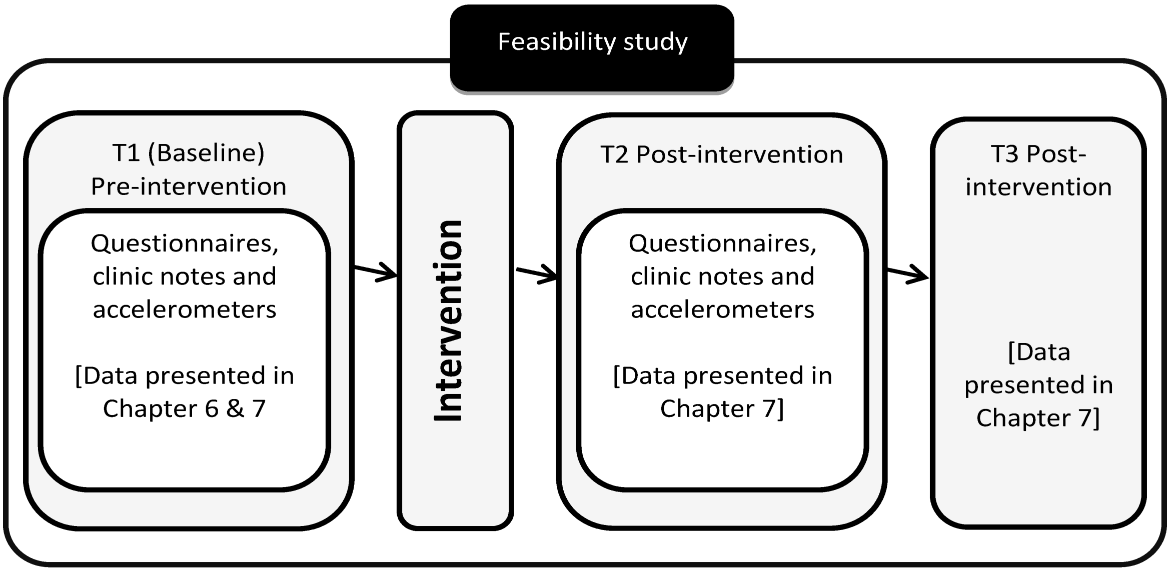

Figure 11 How the current study fits within the wider feasibility study design

5.2 Background to accelerometer methodology

Accelerometers measure physical activity through natural body movement. They provide a way of capturing non-structured daily activities that may be difficult to self-report, especially in children who may find it difficult to contextualise and/or recall physically active behaviours (Sirard and Pate, 2001). Accelerometers convert frequency and intensity of movement into a raw numerical output value (counts) summed over a specific period of time (epoch). The recorded counts for each epoch represent the intensity of the activity undertaken over a given measurement period.

A 60-second epoch has been commonly used in adult research measuring physical activity (Cain et al., 2013), but a shorter duration of epoch might be better able to reflect the sporadic nature of children's physical activity (Treuth et al., 2004). To date, conclusive evidence for the optimum epoch length for measuring physical activity in children does not exist. Baquet and colleagues (2007) showed that 80% of moderate physical activity (MPA) and 93% of vigorous physical activity (VPA) lasted less than 10 seconds in children aged 9-10 years. This would support the idea of using a shorter epoch in children.

The placement of the accelerometer is another important methodological consideration that can not only influence the ability to predict physical activity intensity, but also children' compliance to the monitoring protocol (Routen et al., 2012 ; Trost et al., 2014). Until recently, research in children has predominantly employed waist-worn accelerometers (Evenson et al., 2008 ; Freedson et al., 2005 ; Puyau et al., 2002). Recent research has suggested that wrist-worn accelerometers are less obtrusive than waist-worn devices in children and adults (Routen et al., 2012), may enhance participant compliance to the monitoring protocol (Centers for Disease Control and Prevention, 2011 ; Ekblom et al., 2012 ; Esliger et al., 2011 ; Schaefer et al., 2014), can reduce loss of data since the monitor can be worn overnight (Ekblom et al., 2012) and thus can be used to assess sleep (Crouter et al., 2015). The US population-based surveillance study, National Health and Nutrition Examination Survey (NHANES) has released an updated physical activity monitor protocol which recommends wrist placement on the non-dominant arm (i.e., the arm used less frequently) (Centers for Disease Control and Prevention, 2011). The non-dominant wrist has been used to reduce the possibility of increased activity counts during sedentary activities such as writing, drawing, or video games and has been recommended when measuring physical activity in children (Centers for Disease Control and Prevention, 2011 ; Chandler et al., 2015).

Wrist-placement has shown good validity regarding accelerometer counts and physical activity energy expenditure in school-aged children (Ekblom et al., 2012). Recently, Trost et al. (2014) has shown the wrist (non-dominant arm) accelerometer placement using the ActiGraph GT3X+ performed just as well in terms of activity classification accuracy as the waist placement in children and adolescents. Wrist-worn accelerometers have been shown to be acceptable among children without diabetes (Schaefer et al., 2014). Furthermore, there is a possibility that a wrist-worn accelerometer might be less likely to interfere with the insulin pump commonly worn around the abdominal area in children with T1DM.

5.3 Methodological considerations

For healthcare professionals and researchers, the aim is to achieve an accurate measurement of children's habitual physical activity, but care must be taken to ensure that the requirements are acceptable and not burdensome for participants. Numerous methodological criteria must be considered, included the non-wear time within a day, minimum number of wearing hours within a day and the minimum number of valid wear days for the data to be considered representative of habitual behaviour and therefore included in the analyses.

5.3.1 Non-wear time within a day

Non-wear time within a day refers to the number of consecutive zero counts that must be encountered before the period is considered to reflect removal of the accelerometer (e.g., through non-compliance or through legitimate removal for water-based activity). When making this decision it is important to be able to differentiate between 'wearing the accelerometer but sedentary' and true 'non-wear time' (Tracy et al., 2014). Misclassification of wear time and non-wear time will result in errors in estimates of physical activity level and thus bias in understanding the relationship between physical activity and outcomes (Zhou et al., 2015). There is currently no consensus for the minutes of continuous zero counts for identifying non-wear time in children. Criteria have ranged from 10 minutes in 11-year-olds (Riddoch et al., 2007) to 180 minutes in children aged 11-14 years (Van Coevering et al., 2005).

5.3.2 Definition of valid day

A valid day is defined as minimum number of wearing hours needed to provide a valid measure of daily physical activity (Herrman, 2006). This may differ for different age groups, different accelerometer placement (e.g., waist and wrist), and different days of the week (i.e., weekend and weekday) (Catellier et al., 2005). Criteria have ranged from less than 6 to over 12 hours to define a valid day (Cain et al., 2013). To date, little research has established a definition of a valid day when the accelerometer is worn 24 hours per day.

5.3.3 Minimum number of valid wear days

The minimum number of valid wear days refers to the number of valid days required to represent habitual activity. Seven consecutive days of accelerometer wear time is believed to provide a reliable estimate of habitual physical activity in children (Trost et al., 2005). Seven days also allows for differences between weekday and weekend days to emerge, as research suggests that children aged 10-11 years are less active and more sedentary at the weekend compared with week days (Fairclough et al., 2015 ; Jago et al., 2010).

5.3.4 Cut-point values

Physical activity is typically analysed using activity count thresholds derived from validated regression equations using the vertical axis, which measures the dominant plane of movement of the hip. A number of calibration studies using waist-worn accelerometers have established cut-off points or thresholds for sedentary, light, moderate and vigorous activity in children (Evenson et al., 2008 ; Freedson et al., 2005 ; Puyau et al., 2002). Researchers and healthcare professionals measuring physical activity using waist-worn accelerometers face difficulty described as a ‘cut-point conundrum’ (Trost, 2007), whereby there are many cut-point equations yielding vastly different outcomes when classifying physical activity intensities. There is little agreement in thresholds for different activity intensities, and the thresholds vary depending on the placement of the accelerometer, type of calibration activity used, age and maturational stage, sex, fitness level, leg length, and body composition of the sample (Freedson et al., 2005). This makes comparison between studies difficult. For example, according to accelerometer research in UK school children, there is a wide variation in the proportion reaching the Department of Health’s recommendation of 60 minutes of moderate intensity activity per day, from 2.5% in 11 year olds (Riddoch et al., 2007) to 92% in 13-14 year olds (Alexander et al., 2005).

Until recently, there has been no attempt at calibrating or validating a wrist-worn ActiGraph accelerometer in children. Chandler et al. (2015) conducted a field-based calibration study using a sample of 45 children aged 8-12 years to address this gap. The sample’s average age was nine years, 69% were Caucasian, 60% were normal weight and children were deemed “healthy” with no physical limitations that would restrict their movements during physical activities. Chandler and colleagues used a range of activities (sedentary to vigorous) in their testing protocol including; rest, enrichment/drawing, walking, and the progressive aerobic cardiovascular endurance run (PACER). Other activities performed by a subset of children included: swimming, splash pad and playing on fixed playground equipment. The testing period lasted between 60-90 minutes and each activity lasted 10 minutes. All activities were deemed to represent free-living, unstructured activities used to mimic children’s sporadic activity habits. Receiver operator curve (ROC) analyses and regression analyses were used on all 5-second epoch data to derive the cut-points for sedentary, light, moderate, vigorous and moderate-to-vigorous physical activity (MVPA) intensities (Table 9). Chandler et al. (2015) examined activity counts from three axes of the ActiGraph GT3X+ and also the vector magnitude (VM). VM combines the data from each axis and is calculated as the square root of the sum of squares of each of three ActiGraph axes. All three axes and VM were calibrated and cross-validated independently and demonstrated good to excellent classification for each intensity of activity. Distinguishing vigorous activity from moderate intensity activity yielded the lowest percentage of correct classifications, but given that most research looks at moderate-to-vigorous physical activity (MVPA), the classification accuracy is good (Chandler et al., 2015).

This calibration study by Chandler et al. (2015) is one of the first using wrist-worn ActiGraph GT3X+ for use with children aged 8-12 years, and the only one to use the non-dominant wrist. Problems with using the dominant wrist include the possibility of increased activity counts during sedentary activity, such as drawing, playing video games, which would lead to the overestimation of active time when the child is actually sedentary (Chandler et al., 2015). The researchers propose that these new cut-points can be used with the same accuracy as previously established waist-worn cut-points to determine time spent at various physical activity intensities. The table below shows the Axis 1 cut-points per 5 seconds derived from this calibration study.

Table 9 Axis 1 cut-points per 5 seconds

Cut points and age	Model and placement	Sedentary (SED)	Light (LPA)	Moderate (MPA)	Vigorous (VPA)	MVPA
Chandler (2015) 8-12 years	ActiGraph GT3X+ Wrist (non-dominant)	0-161	162-529	530-1461	1462-max	530 +

5.4 Evaluation of accelerometer data

ActiGraph accelerometers are among the most widely used and have been shown to be reliable and valid devices for capturing children's physical activity (Chandler et al., 2015 ; Evenson et al., 2008 ; Freedson et al., 2005 ; Puyau et al., 2002). The ActiGraph GT3X+ is light weight (19g), small in size (5 × 5 × 2 cm) and water resistant (i.e., it can withstand light splashes, but not submersion in water) making it portable and practical. It has been used on the waist in previous research with children who have T1DM (MacMillan et al., 2014c) and wrist placement has demonstrated good feasibility and acceptability in children without T1DM aged 6-10 years (Nyberg et al., 2009). There are no known risks associated with the use of accelerometers and the monitor does not emit radiation, electrical or magnetic current, vibration or heat.

There is currently limited cut-points for wrist placement and cut-points from waist-worn calibration studies are not comparable (Routen et al., 2012). Without standardised cut-point values, raw accelerometer data cannot be interpreted (Masse et al., 2005). Processing the raw data from wrist-worn accelerometers provides a challenge because of the wrist gesticulation and variability in movement (referred to as "noise"). Accelerometer noise refers to the movement and counts recorded on the accelerometer when the child is sedentary (e.g., by moving hands, jittering etc.). Accelerometer noise can impair the accuracy and quality of the data recorded and whilst it can be filtered out, to date, research has not explored the influence of noise on wrist-worn accelerometer data, nor has a noise-filtering algorithm been developed. Furthermore, the ActiGraph predominantly detects movement in the vertical plane meaning that some physical activities may be under-monitored (e.g., cycling, non-motorised scootering) or over-monitored (e.g., jumping on trampoline).

Whilst the body of literature using wrist-worn accelerometers is growing, previous research to address the wrist location in children has used a variety of devices including the ActiGraph (Chandler et al., 2015 ; Crouter et al., 2015), the Actical accelerometer (Schaefer et al., 2014), the Actiwatch (Ekblom et al., 2012) and GENEActiv (Esliger et al., 2011). Therefore to build upon the recent work of Crouter et al. (2015) and Chandler et al. (2015), there is need for guidance on how wrist accelerometer data from the ActiGraph accelerometer can be used and interpreted to predict children's time spent in physical activity.

The utility and feasibility of waist-worn ActiGraph accelerometers to measure physical activity in the general population of children has been explored (Robertson et al., 2011). Technical limitations relate mostly to data loss due to malfunction (Van Coevering et al., 2005). Participant factors include compliance to the data collection protocol and possible stigma associated with wearing the device within social contexts (Robertson et al., 2011). Using accelerometers in intervention studies to measure change in physical activity over time requires multiple measuring periods, posing potentially greater practical challenges for researchers and healthcare professionals. The utility and feasibility of using wrist-worn ActiGraph GT3X+ accelerometers to measure physical activity in children with T1DM has not yet been explored.

5.5 Study aims

The primary aim of the current study is to assess the feasibility and acceptability of using a wrist-worn accelerometer in children aged 9-11 years with T1DM at two time points (baseline (T1) and post-intervention (T2)). Secondary purposes of this study are to; i) explore the potential of a wrist-worn accelerometer to detect change in physical activity over time, and ii) explore the correlation between the objective measure of physical and a self-report assessment of physical activity.

5.6 Method

5.6.1 Feasibility

The feasibility of the accelerometers was evaluated by exploring response rates, compliance rates, wear times and practicalities. Response rates referred to the number of children recruited onto the study and number agreeing to wear the accelerometer at baseline (T1) and immediately post-intervention (T2). Compliance referred to the number of days the accelerometers were worn by children at each time point. Wear time referred to the number of hours the monitor was worn per day and the number of nights the accelerometer was worn. Practicalities referred to influential issues encountered during deployment, data collection and retrieval of accelerometers.

5.6.2 Acceptability

The acceptability of the accelerometers was assessed via interviews with children and parents. After T2, children and parents were asked to share their perceptions of the accelerometer measurement. Each child and parent involved in the research was asked to take part in the interview and reminded of their right to refuse the interview. Interviews with children were face-to-face at their home (n = 8) except for one child who completed a survey version of the interview (n = 1). Interviews with parents were on a separate occasion over the telephone (n = 8). The interview questions formed part of a longer interview described in Chapter 7 which explored participants' perceptions of the research processes involved in the feasibility study. The questions concerning the accelerometer included:

Questions for children:

- What did you think about wearing the activity monitor?
- Why did you like / not like wearing it?
- What do you think about having to wear it again?
- If appropriate: Probe why children are interested in finding out the results?

Questions for parents:

- What did you think about the accelerometer/activity monitor?
- What did your child think about the accelerometer?
- Why do you think they liked/did not like wearing it?
- If appropriate: Probe why parents are interested in finding out the results?

The interview questions sought to explore the appeal, burden and acceptability of the accelerometers experienced by the children and their parents. Interviews with children were not recorded, but instead answers were transcribed verbatim by the interviewer during the interview. Telephone interviews with parents were recorded, with permission, using an Olympus Dictaphone.

5.6.3 Accelerometer data

Physical activity was measured objectively with a wrist-worn ActiGraph accelerometer (ActiGraph GT3X+, Pensacola, FL, USA). Accelerometer data were collected at two time-points to measure physical activity levels before and after a physical activity programme in an intervention and control group: baseline (T1) and immediately post-intervention (T2). The measurement start day for each child was unlikely to be the same at each time-point, but the methodology adopted at each time point was the same. As far as was practically possible, the same accelerometer device was worn at each data collection time point to minimise 'between unit' variation (Robertson et al., 2011).

Activity monitors were initialised using the ActiLife 6 Data Analysis Software (ActiGraph, ActiLife version 6.7.1) and set to start collecting data at a pre-determined start time. The start time corresponded to the day that a home-visit had been arranged with each participant (12.00am on the day after the accelerometer had been put on until 12am seven consecutive days later). This meant that once the children put the monitor on, it did not start collecting data until 12.00am the following day. This was done in to minimise any 'reactivity' or potential changes in behaviour as a result of wearing the device (Mattocks et al., 2008). Data at T1 were collected in September and early October 2014. All children were asked to wear the accelerometer for seven consecutive days. The data collection week was not the same across all participants due to pragmatic reasons such as the number of devices available. Data at T2 were collected in November 2014.

Figure 12 ActiGraph GT3X+ accelerometer and placement on the non-dominant wrist

Accelerometers were distributed via home-visits by the researcher. Children were familiarised with the accelerometer, given some simple information about what the purpose of wearing it was, and given the opportunity to ask questions. Children were asked to wear the accelerometer on their non-dominant wrist for seven consecutive days and nights, unless the child experienced discomfort. To determine the non-dominant wrist, children were asked "which hand do you write with?" The monitor was attached to the wrist using an adjustable woven nylon wrist strap with a buckle resembling that of a watch strap. The monitor was positioned on top of the wrist, proximal to the ulnar styloid process, so that the vertical axis (y-axis) of the ActiGraph was parallel to the longitudinal axis of the lower arm (Crouter et al., 2015) (Figure 12). Children were asked to continue with normal daily activities during the week they wore the accelerometer. They were asked to remove the accelerometer during water-based activities such as swimming or bathing, or in certain other cases such as heavy contact sports.

Participants were provided with written instructions for the parent; written instructions for the child (Appendix 9) and a letter for teachers/activity leaders to explain the purpose of the accelerometer. Accelerometers should eliminate the burden of log books (Peeters et al., 2013), therefore children were given the option of keeping a log book, should they feel it was necessary to report when the monitor had been taken off, for example when swimming.

5.6.4 Promoting compliance

To maximise the quality of the data, a number of techniques were employed by the researcher to encourage compliance to the accelerometer protocol. The researcher had established rapport with children and their parents which facilitated the organisation of home-visits. It was also useful to enlist the support of parents. Parents were made aware of the importance of wearing the accelerometer and a successful approach was to frame the importance of the accelerometer in terms of the results parents would have access to (e.g., daily activity graphs).

The researcher wore an activity monitor for home visits in an attempt to 'normalise' the wearing of the activity monitor. Children were encouraged to fasten the device to their wrist with assistance from the researcher. As well as the clear written instructions, explanations were also given in person. The researcher explained to children and parents the data that can be obtained from wearing the monitor. Children were told that the monitor could be worn under clothing. A simple reminder was sent to parents via text message and three text messages were sent throughout the data collection week (mid-way through the week, towards the end of the week and at the end of the week). In the first two of these text messages, the importance of wearing the accelerometer for as many full days as possible was emphasised.

Previous research has been criticised for not reporting the accelerometer methodology 'decision rules' (Cain et al., 2013). The methodological issues reported below include: 1. accelerometer model; 2. epoch length; 3. non-wear time; 4. valid days; 5. minimum number of valid wear days; and 6. cut-points.

1. Accelerometer model

The ActiGraph GT3X+ (Pensacola, FL, USA) measures acceleration in three directions and records with a frequency of 100 Hz. The accelerometer was placed on the wrist of the non-dominant arm.

2. Epoch length

A recording epoch of 5 seconds was used.

3. Non-wear time

Periods of ⩾60 minutes of zero values, with an allowance of up to 2 minutes of interruptions between 0 and 100 counts, were classified as non-wear time and thus removed from analyses (Troiano et al., 2008).

4. Definition of a valid day

Children must have provided at least nine hours of activity during the "wake hours" of 7.00am-11.00pm used in the analyses.

5. Minimum number of valid wear days

A 7-day monitoring period was used and children had to provide a minimum of three valid days of activity data to be included in the analysis.

6. Cut-points

The cut-points established in a methodologically rigorous comparison study were used (Chandler et al., 2015) (Table 9).

5.6.4.1 *Wake hours and sleep times*

Due to the nature of wrist-worn accelerometers and the high data storage ability of the ActiGraph accelerometers, accelerometer wear time has taken a 24-hour approach which can lead to more detailed measurement of children's activity patterns, including sleep patterns (Tracy et al., 2014). This approach requires the researcher to be able to discriminate bedtime rest from activity. Until recently, there has been no algorithm to differentiate between sedentary and sleep time in wrist-worn accelerometer data. Thus, it is difficult to differentiate bedtime rest (e.g., reading) from other sedentary activity or sleep. Bedtime rest refers to inactive periods of time longer than 60 minutes spent in forms of rest other than sleep such as lying and viewing television or short naps (Tracy et al., 2014). In the absence of an algorithm for the accelerometer used in the current study, a crude measure was to select "wake hours". To ensure that sleep data were not included, only data recorded between 7.00am and 11.00pm were included in analyses.

5.6.5 Self-reported physical activity

Children's self-reported physical activity level was measured with a physical activity questionnaire (PAQ) (Appendix 10). This was a revised version of an original (Thompson et al., 2001) modified for use in the UK with children who have long-term conditions by (Glazebrook et al., 2006). Children were asked to rate a range of activities on a three-point scale representing how much of that activity they did (none, a little, a lot) at three time points in the previous 24 hours; today before school (22 items), yesterday after school (22 items), and yesterday during school (11 items). Scores were summed to form a total score for physical activities (possible range 41-123) and a total score for sedentary activities (possible range 14-42), with higher scores indicating greater physical activities and sedentary activities, respectively. The authors of the original questionnaire demonstrated good agreement between questionnaire responses and observed activities (Thompson et al., 2001). Furthermore, probing activity in the recent past (e.g., one day recall) is likely to obtain results that correlate with objective measures of activity (Sirard and Pate, 2001).

5.6.6 Data analysis strategy

The aim of this study was to assess the feasibility of the wrist-worn accelerometers and the analyses focussed on addressing key issues of feasibility. The secondary aim of the analyses was to estimate the sensitivity of the measure to detect change over time in MVPA.

5.6.7 Feasibility analysis

Response rates, compliance and wear time were calculated and expressed as percentages. Data from interviews with children and parents were transcribed verbatim and analysed using content analysis. Content analysis was chosen to attain a condensed description of participants' perceptions of the accelerometer. The qualitative software package NVivo version 10 (QSR International Pty Ltd., 2012) facilitated the organisation of interview data and the identification of relevant quotations to illustrate the main findings. The evaluation questions generated the initial ideas for categories of data and these were then refined during analysis of the data (inductive) to depict the content of participants' responses.

5.6.8 Accelerometer data analysis

Accelerometer data were downloaded using data analysis software ActiLife 6 Data Analysis Software (ActiGraph, ActiLife version 6.7.1). Downloaded files were visually checked for compliance (wear and non-wear time) using the wear time validation tool in ActiLife. Sustained ≥60 minute periods of zero counts was used as an indicator that the accelerometer had been removed and thus flagged as non-wear or 'missing' counts (Troiano et al., 2008). Total 'missing' counts represented the duration of time that accelerometers were not worn and thus removed from the analysis. If available, completed log sheets were inspected to identify when the accelerometers had been removed for legitimate reasons such as water-based activities.

Data were imported into SPSS version 22 for Windows (IBM Corp., 2013) for statistical analyses. Change over time between T1 and T2 in each group was calculated as the difference between means at T1 and T2 for each activity intensity (T2 minus T1). Physical activity at each time point (T1 and T2) is presented as estimates of time spent in physical activity according to cut-point thresholds provided by Chandler et al. (2015). The mean daily time spent in each physical activity intensity category: sedentary (SED), light (LPA), moderate (MPA), vigorous (VPA) and moderate-to-vigorous (MVPA) were calculated and presented as minutes per day. MVPA was assessed by summing the time spent in MPA and VPA.

Missing items on the PAQ (n=1) were scored as zero. Descriptive statistics were reported (mean and standard deviation). To describe the association between MVPA and self-reported physical activity, Pearson correlation analyses were conducted. Due to the exploratory nature of the study, no hypotheses were made and a two-tailed analysis was conducted. Attention was given to effect size, but for completeness, p-values were also reported with statistical significance set to ≤.05.

5.7 Results

5.7.1 The sample

Full characteristics of the sample involved in the feasibility study are described in Chapter 7. In brief, accelerometer data were collected from 11 children at T1 (five female, six male) aged mean=10.7 years (SD=0.9 years) and eight children at T2 (two female, six male) aged mean=10.6 years (SD=0.8 years).

5.7.2 Response rates

Twelve children were asked to wear the accelerometer at T1. The acceptance rate was 92% at T1 and 73% at T2. The reason for lack of acceptance to wear the monitor at T1 was disengagement with the feasibility study. At T2, those who did not accept the accelerometer had withdrawn from the feasibility study (n=1) and failed to respond to follow-up (n=2).

5.7.3 Compliance

Compliance was high. At T1, all 11 children had accelerometer data for seven days (100% compliance). At T2, six of the eight children had accelerometer data for all seven days and two children had data for five days (100% compliance to the three-day protocol criterion). A completed logbook was collected from one child at T1 and no children at T2. Overall, less data were collected at T2 compared with T1 due to n=3 participants being lost to follow-up and participant non-compliance. Nevertheless, the data available at T2 fulfilled the criteria for analysis.

5.7.4 Wear time

The criterion for at least nine hours of wear time per day was met by all children at T1 (100% compliance) and seven children at T2 (87.5%). Despite participants being given an information sheet for school teachers, children may not be able to wear devices during Physical Education (PE) class in school, as experienced by one child in this study. This has clear implications for measuring physical activity in children and may lead to the underestimation of children's activity levels. Children were told that they could keep the monitor on for 24 hours per day. At T1, eight children (73%) wore the accelerometer for seven nights, one child wore the accelerometer for five nights and one child wore it for three nights. At T2, five children (63%) wore the accelerometer for seven nights, two wore the accelerometer for five nights and one did not wear it during any night. It was beyond the purpose of the current study to analyse the sleep patterns of children with T1DM, but further research could explore sleep using this data.

5.7.5 Practicalities

Accelerometers were deployed by the researcher during visits to participants' homes. This required agreement of visiting times when children and their parents were home and resulted in high researcher burden. In studies with small sample sizes such as the current study, for example, n<15, home visits may be feasible and beneficial for rapport and compliance, but for larger trials postal delivery or clinic deployment would need to be considered. All accelerometers were retrieved in-person by the researcher and all were retrieved undamaged at both T1 and T2. Two accelerometers became faulty after T1 and had to be returned to the manufacturer, but no data were lost.

5.7.6 Acceptability

Nine children (six male, three female) and eight parents (five mothers, two fathers, and one mother-father pair) shared their perceptions of the accelerometer. Children's interview data was categorised into six main groups: positive feedback; willingness to wear again; comfort; risk of damage; stigma; and interest in results. Eight (89%) children gave positive feedback about the accelerometer. All except one (89%) expressed a willingness to wear the monitor for the second time. Three children thought the accelerometer was sometimes uncomfortable to wear (comfort), e.g., "*fun, but uncomfortable*" (P06), "*itchy because of the strap, nothing else*" (P10) and "*the wrist band was too big, kept slipping*" (P04). One expressed concern about having to be careful around water (risk of damage), e.g., "*it was alright but I couldn't put water on it, so had to be careful*" (P09). And whereas one boy did not like other children asking what the monitor was (stigma), another child "*liked telling people [about it]*" (P01). All of the children interviewed were interested in receiving the results about their physical activity level. Reasons offered for being interested in the results included:

> *"Because I want to see how active I am"* (P09, Natasha, aged 11)
>
> *"Interesting to see how active I am"* (P01, Amelia, aged 10)
>
> *"To see how much I'm moving around"* (P02, Ryan, aged 11)
>
> *"I think I might be 100% active, so I want to see how active I am"* (P07, Matthew, aged 9)
>
> *"So I know I'm getting healthier"* (P12, Andrew, aged 9)

Parents' interview data were categorised into three main groups: positive feedback; interest in results; and comfort. Eight out of eight parents gave positive feedback about the accelerometer, describing it as "*brilliant*" (P02, Mother), "*good*" (P09, Father) and "*really interesting*" (P04, Mother). All the parents interviewed were "*quite interested in the results*" (P07, Mother) from the accelerometer. Reasons offered for the parents' interest included:

> *Give insight into…matching up activity and blood sugars… get a feeling for how much more [activity] and the intensity of it*
>
> Ryan's mother, P02

> *We can compare that to the [insulin] pump downloads and we can compare that to activity and see what caused that, will be really interesting*
>
> Amelia's mother, P01

[we do not] know whether their PE sessions are actually really active or they're just sat around watching [which] makes a big difference on whether she needs any extra carbs

Amelia's father, P01

It's good to know are you active or not? … useful to see her activities, when she's active doing exercise or not

Natasha's father, P09

Just to see how active he really is because he does a lot of after-school activities, but it is just an hour at the end of the school day. I mean, there's six, six and a half hours at school where I don't know whether he's sat about or whether he's walking up and down the classroom and corridors, what he's doing at lunchtime, at times that I'm not with him really

Matthew's mother, P07

It might encourage him, if you're not doing enough exercise you should be doing more, it would encourage him to do a bit more as well

Craig's mother, P08

Parents were asked if their child had experienced any difficulties when wearing the accelerometer. Two reported that their child experienced discomfort from the device or wrist-strap and one parent thought the strap was too small. By observation it appeared difficult for some children to fasten the buckled wrist strap without assistance. Two parents said their child was unhappy about wearing the monitor during the night. One parent said their child had been concerned about wearing it in school.

5.7.7 Accelerometer results

The secondary purpose of this study was to explore the ability of the accelerometer methodology to detect change over time. Data will be presented as the full sample rather than by intervention group. Table 10 shows time in different intensities of physical activity at each time point for each participant.

Table 11 shows the average scores across the group. At T1, the mean sedentary time over the 16 hours between 7.00am and 11.00pm in the full sample (n = 11) was 658.1 minutes (SD=47.3 minutes) (11 hours). The mean time in MVPA was 84.8 minutes (SD=26.9 minutes). Overall the children engaged in less MVPA at T2 compared with T1. As a whole group, there was a decrease in mean MVPA between T1 and T2 from 84.8 minutes (SD=26.9 minutes) to 69.5 minutes (SD=24.2 minutes); a decrease of 14.6 minutes (SD=12.1 minutes). Indicating that the measurement was sensitive to a reduction in MVPA over time.

Table 10 Average time spent in activity intensities per participant at each time point

Participant	Time	Sedentary	Light	Moderate	Vigorous	MVPA	Days ≥60 minutes MVPA (full days worn)
P01 Amelia	T1 T2	639.6 (33.1) 659.9 (57.4)	241.4 (23.9) 225.8 (41.4)	74.1 (11.0) 72.1 (19.1)	4.8 (1.6) 2.2 (1.6)	78.9 (12.0) 74.3 (19.9)	7 (7) 3 (5)
P02 Ryan	T1 T2	727.1 (41.5) 753.0 (39.5)	187.1 (29.0) 168.7 (30.1)	43.0 (11.4) 37.8 (10.9)	2.7 (5.4) 0.5 (0.3)	45.8 (15.7) 38.2 (10.8)	1 (7) 0 (7)
P04 Calum	T1 T2	703.0 (19.3) 770.3 (93.4)	196.7 (20.0) 149.2 (73.2)	57.1 (10.4) 38.0 (22.1)	3.1 (2.0) 2.5 (1.8)	60.2 (12.2) 40.5 (23.3)	4 (7) 0 (5)
P05 Ava	T1	639.5 (57.4)	218.0 (25.1)	96.2 (32.1)	6.3 (5.3)	102.4 (36.6)	7 (7)
P06 Sophia	T1	607.5 (38.0)	244.0 (29.1)	87.8 (16.6)	20.6 (7.3)	108.4 (13.5)	7 (7)
P07 Matthew	T1 T2	644.7 (52.6) 693.9 (53.0)	202.1 (37.0) 190.9 (35.8)	98.8 (18.0) 68.6 (20.5)	14.3 (4.8) 6.5 (2.7)	113.2 (22.3) 75.1 (22.8)	7 (7) 5 (7)
P08 Craig	T1 T2	673.1 (28.7) 704.8 (60.5)	222.5 (15.0) 193.6 (37.4)	61.6 (18.5) 59.6 (23.8)	2.8 (2.2) 1.9 (1.9)	64.3 (20.5) 61.5 (25.6)	4 (7) 3 (7)
P09 Natasha	T1 T2	625.4 (62.2) 665.0 (61.6)	247.7 (48.1) 217.8 (40.2)	81.3 (15.4) 73.4 (20.9)	5.4 (2.3) 3.7 (3.0)	86.7 (17.0) 77.0 (23.1)	7 (7) 5 (7)
P10 Daniel	T1 T2	587.1 (26.7) 633.1 (35.2)	248.4 (11.2) 211.8 (21.9)	114.1 (13.1) 105.4 (16.8)	10.3 (5.0) 9.6 (6.3)	124.4 (17.6) 115.0 (22.6)	7 (7) 7 (7)
P11 Lauren	T1	734.5 (48.7)	175.7 (34.1)	46.2 (14.0)	3.5 (2.3)	49.7 (16.1)	2 (7)
P12 Andrew	T1 T2	657.3 (65.7) 707.8 (89.4)	203.6 (44.0) 178.0 (55.4)	90.2 (26.2) 68.8 (31.6)	8.8 (7.4) 5.3 (5.9)	99.0 (30.0) 74.1 (35.9)	6 (7) 3 (7)

NB: Intensity data presented as mean minutes (SD)
T1 = Time point 1 (baseline); T2 = Time point 2 (post-intervention); MVPA = moderate-to-vigorous physical activity

Table 11 Summary table of minutes spent in each intensity of activity at each time point (mean and SDs)

	n	Sedentary	Light	Moderate	Vigorous	MVPA
T1	11	658.1 (47.3)	217.0 (25.9)	77.3 (23.0)	7.5 (5.7)	84.8 (26.9)
T2	8	698.5 (46.5)	192.0 (26.1)	65.5 (21.6)	4.0 (3.0)	69.5 (24.2)
Mean difference	8	41.31 (15.2)	-26.71 (11.8)	-12.06 (10.3)	-2.5 (2.4)	-14.6 (12.1)

NB: Intensity data presented as mean minutes (SD)
T1 = Time point 1 (baseline); T2 = Time point 2 (post-intervention); MVPA = moderate-to-vigorous physical activity

5.7.8 Meeting physical activity guidelines

The current UK guidelines recommend at least 60 minutes of MVPA each day for children with and without T1DM (NICE, 2004 ; NICE, 2009). At T1, six children achieved at least 60 minutes of MVPA on every day the accelerometer was worn compared to one child at T2. At T2, two children did not attain 60 minutes of MVPA on any day the accelerometer was worn. At T1, 60 minutes of MVPA was achieved on an average of five days per week. At T2, this reduced to an average of three days per week (Table 12).

Table 12 Summary table of children meeting physical activity guidelines

	T1	T2
Mean number of days >60minutes of MVPA (SD)	5.36 (2.25)	3.25 (2.43)
Number of children achieving 60 minutes MVPA every day (%)	6 (55%)	1 (13%)
Number of children failing to obtain 60 minutes MVPA on any day (%)	0 (0%)	2 (25%)

This study also sought to explore the correlation between objectively measured physical activity and self-reported physical activity scores. Children in this study scored a mean of 54.1 (SD=8.5) out of a possible score of 41-123 on the self-reported physical activity scale. The correlation coefficient is presented in Table 13, described in terms of Cohen's (1988) classifications of effect sizes; .1 small, .3 moderate, .5 large. Children who had higher levels of MVPA as measured by the accelerometer had higher self-rated scores for physical activity (r=.568, p=.068).

Table 13 Correlation between objective and self-reported measures of physical activity

	Objective moderate-to-vigorous physical activity		
	r	n	p-value
Self-reported physical activity	**.568***	**11**	**.068**

*Large effect size

5.8 Discussion

This study is the first to explore the feasibility and acceptability of using a wrist-worn accelerometer to measure physical activity in children with T1DM. It provides insight into the utility of accelerometers to measure habitual physical activity in children aged 9-11 years, including the acceptability of their use and sensitivity to change in MVPA in this population. In studies where physical activity is measured multiple times, it is important that accelerometers are feasible and acceptable. The utility of an instrument includes factors relating to the participants such as adherence to data collection protocols and experience of wearing the monitor, and factors relating to the monitor itself, such as technical limitations and data loss due to malfunction (Perry et al., 2010).

Overall the wrist-worn ActiGraph GT3X+ accelerometer showed low participant burden and high participant acceptability. Previous researchers have suggested that wrist-worn accelerometers provide a significant advantage with respect to compliance (Trost et al., 2014) and the current findings support this. The children were interested and keen to wear the accelerometer and compliance was good at both time points, although better at T1. The main motivation shared by children and their parents was the feedback they would receive on the children's daily physical activity. Parents valued the opportunity to see how active their child was, especially for periods of the day when they could not be sure how active their child was being (i.e., at school). The accelerometer results were perceived by some parents as something that could benefit blood glucose management. The difficulty faced by parents in predicting children's activity levels was echoed in the parents' perceptions reported in Chapter 3 of the current thesis (Quirk et al., 2014a) and the healthcare professionals' perceptions in Chapter 4 (Quirk et al., 2015). Parents in the qualitative study admitted to finding children's physical activities difficult to manage due to the unpredictable nature of the activity intensity (Quirk et al., 2014a). Similarly, the healthcare professionals believed that children's spontaneous activities were difficult to manage and that tailored advice for specific activities was required (Quirk et al., 2015). This suggests that accelerometer data might have a valuable role in demonstrating to parents and healthcare professionals the intensity of children's physical activities and help towards the development of individualised management plans to pre-empt activity intensities and subsequent changes in blood glucose levels.

Previous research exploring the utility of accelerometers to measure physical activity in children aged 7-13 years who are overweight or obese found that in some cases, the waist-worn ActiGraph monitor had the unintended consequence of stigmatising the children in the school environment (Robertson et al., 2011). The current findings found one child to be concerned about stigmatisation prior to wearing the monitor, but generally the children found the wrist-worn ActiGraph GT3X+ acceptable to wear during their daily lives, two children likened it to wearing an insulin pump. The wrist seemed to be a favourable site for these children, which supports previous findings (Schaefer et al., 2014).

The findings from this study suggest the ActiGraph GT3X+ may be able to detect change in physical activity over time among children aged 9-11 years with T1DM. Further research in a larger sample with more statistical power is needed.

Whilst on average children seemed highly active, large portions of the day were occupied by sedentary behaviour. This might be expected given that data were collected during term-time, so children were in school for six or more hours of the day during weekdays. Further research using a larger dataset could investigate the difference between weekday and weekend activity levels in children to explore the influence of the school day on children's physical activity. Another consideration is that children are likely to spend some of the time between 7.00am and 11.00pm sleeping, which is not considered sedentary behaviour. Nevertheless, a large amount of sedentary behaviour is likely to have detrimental health consequences independent of children's level of physical activity (Tremblay et al., 2011 ; Tremblay et al., 2010). This warrants the need for research and policies aimed at promoting active rather than sedentary lifestyles among children with T1DM.

Findings between waist-worn and wrist-worn accelerometer data are non-comparable. To the researcher's knowledge, the only previous study to use the same ActiGraph GT3X+ accelerometers in children with T1DM employed waist-worn measurement (MacMillan et al., 2014c). MacMillan et al. (2014) measured physical activity in children aged 7-9 years and 12-14 years with T1DM over seven days. They found that mean sedentary time was 10.2 hours (SD=1.7 hours) per day and MVPA was 43.2 minutes (SD=23.8 minutes) per day. More research is required using wrist-worn accelerometer data and established cut-points to enable comparison between different populations.

The current study measured physical activity at two time points and the findings showed that the measure was sensitive to change over time, suggesting that children's activity declined from T1 to T2. Possible explanations for these findings need to be considered. Among children in the UK, for example, small but significant seasonal variations in objectively measured physical activity have been identified (Fisher et al., 2005 ; Mattocks et al., 2007 ; Rich et al., 2012) that may have important implications. In the current study, baseline (T1) data were collected in late September-early October and T2 was in mid-to-late November. Whilst both of these periods are in autumn, November evenings are darker, which may limit the amount of time children have for outdoor play after school. This was supported anecdotally by parents and also in the post-research interviews with parents, where some parents acknowledged that their child was less active during the darker winter evenings. For example:

> *Wearing the wrist strap [accelerometer] at the end of the summer [T1; September] and the second time in winter [T2; November], I think that makes a massive difference on his activities… he comes in from school now and I'm not letting them out [to play] now it's dark! Whereas when the first time he wore the wrist strap he was playing out until 6:30 at night, it's three hours after school and he's running about, whereas now it's an hour after school and he's sitting down in front of the telly [television].*

Matthew's mother, P07

This quote captures the parent's perceptions of the influence of the darker evenings on her son's level of activity and offers a potential explanation for the lower activity levels at T2 which should be explored in future research. It also draws attention to the mother's role in "*not letting them out [to play]*", which reiterates the findings from Chapter 3 and 4 which demonstrated the influential role of parents' on children's level of physical activity. Seasonal effects have influenced participant adherence to accelerometer wear time in a previous study whereby adolescents had concerns about wearing accelerometers on an elastic belt around the waist during the summer (Audrey et al., 2013). Future research timetables must carefully consider the seasonal influences on accelerometer adherence and physical activity levels.

This research suggests that compliance declines with the number of times participants are asked to wear the device, which supports previous studies in adolescents (Audrey et al., 2013) and adults (Perry et al., 2010). Audrey et al. (2013) found that adherence to waist-worn accelerometers in adolescents fell from 75% at baseline to 56% at follow-up. As such, strategies are needed that promote compliance to accelerometer wear time. The children and parents in the current study expressed a desire to see their results, as did the adolescents in the Audrey et al. (2013) study. For example, one mother in the current study said, "*it would be quite good to get [results] a little bit quicker, because we haven't had any results yet*" (P08, Mother). Thus, a tangible sign of the child's efforts at baseline may encourage greater adherence to the accelerometer at follow-up, although this would need to be carefully considered in intervention studies as the feedback itself may influence children' activity levels.

The accelerometer measure of MVPA correlated strongly with the self-reported physical activity data, suggesting agreement between the objective and self-report measures. The results support the utility of accelerometers for measuring what children recognise and contextualise as being physical activity. It also suggests that 24-hour recall questionnaires might be a feasible method of physical activity measurement in children aged 9-11 years, and could be used to supplement objective data to provide information about the types of activities children participate in (e.g., organised sports, free play, active transportation).

5.9 Evaluation

The findings should be considered in light of methodological considerations. The children in this study volunteered to take part in a physical activity intervention study. This may have influenced the levels of physical activity reported as the sample may have been more active than the average child with or without T1DM, although comparison data using the same methodology is not available. Convenience sampling is characteristic of physical activity and exercise interventions, but it does limit the extent to which findings can be generalised. Due to the small sample size in the current research, the researcher had some influence over adherence by being able to maintain contact with participants and encourage personalised adherence via text message to children's parents. Such close contact would be less feasible in a larger-scale trial.

The strengths and limitations of accelerometers to capture physical activity in children have been discussed elsewhere (Cain et al., 2013 ; Perry et al., 2010 ; Van Coevering et al., 2005). Accelerometer methodology has been described as chaotic (Cain et al., 2013) due to the lack of agreement on how to analyse and interpret the data. Wrist-worn accelerometer methodology in children is in its infancy and data may be vulnerable to misclassification errors when the target activity involves a relatively static position but with significant arm movement (Trost et al., 2014). Furthermore, to date there is no consensus on the most accurate cut-points to use. The cut-points used in the current study were calibrated with activities performed in a controlled free-living experiment (Chandler et al., 2015), thus may not accurately reflect the activity patterns of free-living children. The focus of the present study was to evaluate the feasibility and acceptability of wrist-worn accelerometers among children with T1DM and the results provide useful guidance for future research.

The findings imply that wrist-worn ActiGraph GT3X+ accelerometers are feasible and acceptable for this sample of children aged 9-11 years with T1DM and sensitive to change over time. Yet strategies to promote compliance over multiple assessment periods are required and further research should investigate the effectiveness of compliance promotion techniques. Participants may benefit from feedback on their results after baseline assessment. A correctly-sized wrist strap made easy to fasten and from comfortable materials should be used to optimise acceptability and a waterproof device may be more convenient for wearers. Future implementation of research must take into consideration the potential influence of seasonal effects on physical activity levels. For future research to accurately interpret the data, validation and calibration of wrist-worn accelerometer cut-points for children is urgently needed. Additionally, longitudinal validity studies comparing the classification accuracy of different cut points over time are required (Trost et al., 2011). Self-reported measures of physical activity could be used in this population in the absence of objective measures or to supplement objective measures.

5.10 Conclusions

Accelerometers can provide an important measure of physical activity in free-living conditions among children aged 9-11 years with T1DM. Yet wrist-worn accelerometer protocols are in their infancy meaning that our ability to interpret and generalise the findings is limited. Little research has explored the acceptability of accelerometer use in pre-adolescent children and the current findings suggest that children with T1DM perceive accelerometers as acceptable tools to measure physical activity, although multiple testing poses greater challenges for adherence and compliance rates. This chapter has set out a number of challenges and has suggested implications which will be of value to future studies.

Chapter Six

The experience and correlates of physical activity among children with T1DM

6.1 Introduction

The systematic review in Chapter 2 of this thesis confirmed the potential effectiveness of physical activity interventions for children with Type 1 Diabetes Mellitus (T1DM). The meta-analyses found physical activity interventions to have positive influence on glycated haemoglobin (HbA1c), body mass index (BMI), triglycerides and total cholesterol. The review identified that only four out of 23 studies had investigated the influence of interventions on level of physical activity and only one out of 23 studies had underpinned the intervention with psychological theory. As such, current understanding of the effective mechanisms underlying physical activity among children with T1DM is limited. Chapter 3 and 4 demonstrated that parents and healthcare professionals (HCPs) endorse the importance of physical activity for children with T1DM, yet they perceive potential barriers and challenges to participation and promotion. The successful promotion of physical activity requires an understanding of children's construction of their experiences of physical activity as well as influential variables associated with the behaviour. These issues are currently not well understood for children with T1DM.

It is accepted from a social-cognitive perspective that children's physical activity results from the dynamic interplay between the child (cognitions) and their social and physical environment (socio-cultural factors) (Bandura, 1986). Cognitions are targeted as the most proximal factors to behaviour and openness to change. At the heart of the social cognitive theory (SCT) are the cognitive constructs of self-efficacy and outcome expectations (Bandura, 2001) (see Chapter 1, Section 1.6.3 for detailed description).

Prior quantitative and qualitative research has examined factors associated with physical activity behaviour in children without diabetes. Such evidence suggests that children's intention and preference for physical activity have been found to be correlated with their physical activity behaviour, along with self-efficacy, perceived competence and attitudes (Sallis et al., 2000). Perceived barriers were the most consistent negative correlate of physical activity (Sallis et al., 2000). The barriers to physical activity identified through qualitative research include parents not owning a car (i.e., socio-economic status) (Brunton et al., 2003), the child not feeling competent (Rees et al., 2001), lack of facilities (Rees et al., 2001) and parental constraints (NICE, 2007b).

Research is required to further our understanding of the way in which children with T1DM perceive facilitators and barriers to physical activity. Due to the challenges associated with their physical activity participation, such as hypoglycaemia, and it being a prescribed element of diabetes management, children with T1DM may have a unique perception of physical activity (Edmunds et al., 2007). For example, the parental constraints identified by children without diabetes as a barrier to their physical activity (NICE, 2007b) may be different for children with T1DM, whose parents are gatekeepers to their diabetes management behaviours and supervision of physical activity (Chapter 3 and Chapter 4). These ideas warrant further exploration through the perspectives of children, as they could influence the effectiveness of physical activity promotion strategies in this population.

Fear of hypoglycaemia (FOH) has been identified as a potential barrier to physical activity among children with T1DM, although the evidence is conflicting (Fereday et al., 2009 ; Johnson et al., 2013b ; MacMillan et al., 2014b). Questionnaire data suggests that children with T1DM may have FOH (Johnson et al., 2013b), whereas qualitative studies that have explored children's perceptions of physical activity suggest that children do not demonstrate worries or concerns about hypoglycaemia (Fereday et al., 2009 ; MacMillan et al., 2014b). Further exploration among children with T1DM is needed to aid our understanding of how they perceive physical activity and its influences.

In the current study, the combined strengths of quantitative and qualitative methodologies are used to explore children's cognitions and beliefs, putting their experience of physical activity participation into context using descriptive statistical data. The advantages of mixed-methods in health-related research have been argued (Creswell et al., 2011). The current research aims to achieve a more complete understanding of physical activity among children with T1DM, by exploring their experiences alongside outcomes (Plano Clark, 2010). The ontology of pragmatism accepts that using different approaches to data collection and analysis whilst giving primacy to the importance of the research question can provide contextual understandings of behaviours and constructs (Creswell et al., 2011). The researcher seeks to integrate data by reporting qualitative and quantitative results together in the discussion section of this chapter.

6.2 Study aims

This study explores the physical activity beliefs, values and outcome expectations of children with T1DM through interviews. Concurrently, variables that may influence children's activity are explored through questionnaires and clinical data. The study aims to integrate the quantitative and qualitative data in an attempt to develop our understanding of the motivations behind participation choices in this population and to help inform theoretically-driven approaches to behaviour change.

6.3 Methods

6.3.1 Mixed-methods design

This study used one sample of children to collect qualitative and quantitative data. The timing of qualitative and quantitative data collection is an important methodological consideration in mixed-methods research and can have implications on the knowledge gained (Creswell et al., 2011). In the current study, quantitative data was collected at the baseline phase of the feasibility study described in Chapter 7. Qualitative data was collected during the intervention period of the feasibility study. The quantitative and qualitative strands were conducted at different time-points, but the data were given equal priority and were integrated during data analysis (Figure 13 (Creswell and Clark, 2007).

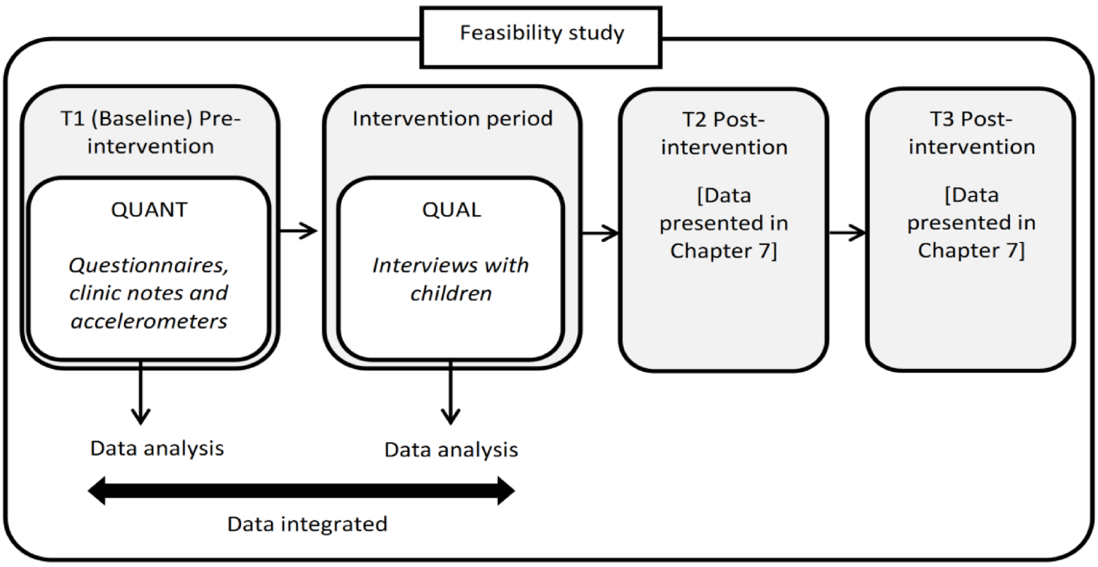

Figure 13 The research phases within the wider feasibility study design

6.3.2 Ethical Approval

The study protocol and all prepared study documents were submitted to the Nottingham 1 Research Ethics Committee (REC) and ethical approval was granted (REC reference number: 14/EM/0057) (Appendix 8). NHS Trust permissions (R&D approval) were sought from one site in the East Midlands (UK) and granted.

6.3.3 Inclusion criteria and exclusion criteria

Informed consent was received from parents of children aged 9 to 11 years and 10 months who had been diagnosed with T1DM for at least three months. Children and parents who were not fluent in English were excluded, as the study documents and intervention materials were not available in other languages. Other exclusions were applied to those children who medical professionals deemed were unable to comply with the research protocol.

6.3.4 Recruitment of children

Children were recruited from one paediatric diabetes clinic within Nottingham University Hospitals Trust. The clinic serves all children with T1DM in Nottinghamshire. At the onset of recruitment there were 64 children aged 9–11 years on the clinic register and of these 50 children were potentially eligible for the study, with a further three children becoming eligible during the recruitment period. Recruitment posters were displayed in the clinic waiting area. The 53 eligible participants were sent a postal information pack including participant information sheets (PIS) and an expression of interest (EOI) form (Appendix 11; Appendix 12). Formative research with a Young Person's Advisory Group (YPAG) informed the content and format of the PIS (Appendix 18). Children's parents were asked to return the EOI form to the researcher indicating their interest and details of their child's next clinic appointment. Thirty parents expressed an interest to hear more about the research. The researcher met the interested parents and children at the clinic before or after their routine appointment and explained the research in more detail. The researcher was unable to make further contact with 12 interested parents and one parent opted out. Seventeen interested parents provided consent and their child provided assent to participate (32% recruitment rate). Further detail about the recruitment process, included recruitment rates and reasons for failure to recruit are covered in Chapter 7, Section 7.8.1.

6.3.5 Data collection procedures

Quantitative and qualitative data were collected within the broader framework of a feasibility study (Figure 13).

6.3.6 Quantitative data

Quantitative data were collected via questionnaires, accelerometers and from each child's clinic notes at baseline. In total, 17 sets of questionnaires were distributed and 13 were returned completed (76% completion rate). Reminders were sent to the remaining four families; the research failed to establish contact with two families and two families opted out.

6.3.6.1 *Self-reported physical activity*

Children's self-reported physical activity level was measured with a physical activity questionnaire (PAQ) (Glazebrook et al., 2006), as described in Chapter 5 (Appendix 10).

6.3.6.2 *Objective physical activity*

An objective measure of children's daily physical activity was achieved with wrist-worn accelerometers. All children were asked to wear the ActiGraph GT3X+ accelerometer (Pensacola, FL, USA) on their non-dominant wrist for seven consecutive days and nights except during water-based activities. Eleven children were willing to wear the monitor and sufficient data was collected from all 11 children. Full details of the accelerometer methodology can be found in Chapter 5.

6.3.6.3 *Self-efficacy for physical activity*

Self-efficacy for physical activity was measured using the Children's Self-Perceptions of Adequacy in and Predilection for Physical Activity (CSAPPA) scale (Hay, 1992) (Appendix 13). The CSAPPA scale measures generalised self-efficacy and attitudes towards participation in physical activity. The scale was designed by Hay (1992) for 9–16 year-olds to identify those children who have low self-efficacy for physical activity (Hay, 1992).

The 19-item CSAPPA scale measures factors that may result in children's poor self-efficacy for physical activity. It measures children's perceived adequacy, predilection and enjoyment towards physical activity. Perceived adequacy refers to the perception of one's ability to achieve some acceptable standard of success, that standard being influenced by the self, parents, peers, teachers and society's expectations. Predilection refers to the preference for being active over being sedentary when given the choice. Enjoyment refers to enjoyment of Physical Education (PE) class. Each item is scored from 1 to 4 and total CSAPPA scores range between 19–76 with higher scores indicative of greater self-efficacy. Each subscale is also given a score; adequacy (7 items 7–28), predilection (9 items 9-36), and enjoyment (3 items 3–12). The CSAPPA scale is based on the Harter technique of questioning by employing a structured alternative choice format (Harter, 1982). Children were asked to choose the option that best describes them from pairs of statements about other children such as; "Some kids like to play active games outside on weekends" and "Some kids like to relax and watch TV on weekends" by indicating whether the sentence was either "sort of true for me" or "really true for me". In this technique, the child does not need to self-identify and can shift any negative connotations to a separate group.

The CSAPPA scale and its subscales have demonstrated high test-retest reliability and strong predictive and construct validity (Hay, 1992 ; Sharma et al., 2013). Total CSAPPA scores have been found to moderately relate to children's performance on aerobic fitness assessment and self-reported participation in physical activity (Cairney et al., 2005 ; Cairney et al., 2008).

6.3.6.4 Clinically relevant outcome measures

With consent from the child and parent, the researcher was permitted access to the child's clinic notes for HbA1c, height and weight measurements taken at the clinic appointment that corresponded most closely with the T1 data collection period.

6.3.6.5 Glycated haemoglobin (HbA1c)

Glycated haemoglobin (HbA1c) is used to assess glycaemic control in diabetes. HbA1c tests indicate average glycaemia over the preceding six to eight weeks. In children with T1DM, HbA1c is tested during routine clinic appointments every two to three months and results are retained on clinic notes. At the time this research data was collected, the UK National Institute for Health and Care (NICE) guideline for HbA1c in children with T1DM was <58mmol/mol (NICE, 2004). NICE recently lowered the recommended HbA1c target for children with T1DM to <48mmol/mol (NICE, 2015).

6.3.6.6 *Body composition*

Height (cm) and weight (kg), measured during routine clinic appointments by trained nurses, were retrieved from children's clinic notes. Body mass index (BMI) (mass in kg/height in m^2) and BMI-for-age percentile were calculated by the researcher (NHS, 2013). The percentile indicates the relative position of the child's BMI among children of the same sex and age. BMI is a well-established methodology to determine weight status and was selected in this study for pragmatic reasons. Central adiposity in children may be more relevant to health outcomes than BMI and waist circumference (WC) or waist-to-height ratio are alternative methods to assess body composition (Griffiths et al., 2012).

6.3.7 Parent measures

6.3.7.1 *Parent demographic questionnaire*

A demographic questionnaire invited parents to provide information regarding their child and themselves (Appendix 14). Questions asked for the child's age, sex, ethnicity, insulin delivery method, insulin monitoring method, family composition, mother and father's education, mother and father's occupation and annual family income. Participant postcode was used to derive the Index of Multiple Deprivation (IMD) ranking for the area the participant lived (Department for Communities and Local Government, 2010). The IMD is an area level measure of deprivation that takes into account income, employment, health and disability, education, skills and training, barriers to housing and other services, crime and living environment. It has been used in similar studies as a measure of socio-economic status (Jago et al., 2013c). Areas are put into a rank order based on their IMD score. A rank of 1 is the most deprived.

6.3.7.2 *Parental fear of hypoglycaemia*

Parental fear of hypoglycaemia (FOH) was assessed using the parental hypoglycaemia fear survey (PHFS; Gonder-Frederick et al. (2006), (Appendix 15). The 26-item PHFS measures parents' FOH and the negative consequences of these episodes, as well as behaviours used to avoid hypoglycaemia and its negative consequences. The measure has 11 items on a PHFS-B (behaviour) subscale (score range 0–44) that assess the behaviours that parents may engage in to reduce the chance and consequences of hypoglycaemia (e.g., 'avoid having my child being alone when his/her sugar is likely to be low'). The PHFS-W (worry) subscale (15 items, score range 0–60) addresses specific worries that parents may have in relation to various aspects of hypoglycaemia (e.g., ‘child not having food, fruit or juice with him/her’). Total scores range from 0–104 with higher scores reflecting greater FOH. Internal consistency of the behaviour and worry subscales of the PHFS has been good (Gonder-Frederick et al., 2006 ; Patton et al., 2008), but a recent study suggested that the validity of the behaviour subscale requires further investigation (Haugstvedt et al., 2015).

6.4 Qualitative data

6.4.1 Semi-structured interviews

Qualitative data were collected through semi-structured interviews to explore the perceptions and experiences of physical activity among children with T1DM. The interviews were informed by interrelated concepts of interpretivism balanced with pragmatism, seeking to understand children’s experience whilst having practical implications for the development of physical activity promotion strategies for children with T1DM.

Once informed consent was received from parents, and assent was received from the child, face-to-face interviews were conducted by the researcher (female, aged 25 years, trained in qualitative research and interview techniques) at the family home. One child involved in the wider feasibility study (Chapter 7) refused the interview, 12 children were interviewed (Table 17). The researcher gave no requirement for parents to be present (or not) during the interview, this decision was made by the children and their parent. Eight interviews were conducted whilst a parent was present and on four occasions the child was alone with the interviewer; although this may give rise to some inconsistency, it was deemed an appropriate ethical decision. With permission from the child and parent, on nine occasions the interviewer (HQ) was accompanied by a second researcher who observed the interview (RM)[1].

All children and parents agreed to the conversation being recorded on an Olympus dictaphone. The dictaphone was shown to the child and then placed out of sight during the interview. Before the interview commenced, the interviewer reassured the children that there was no right or wrong answer and of their right not to answer questions. The interviewer adopted an informal conversational style. Interview questions were guided

[1] RM: a female medical student aged 20 years who observed interviews and conducted an independent analysis of the data as part of a Bachelor of Medical Sciences (BMedSci) undergraduate degree

by an interview guide to ensure that the same topics were covered across all interviews, yet the agenda was kept flexible (Appendix 16).

The interview guide had been previously pilot tested with a 9-year-old boy with T1DM (Appendix 18). Broadly, the questions explored what the child perceived 'physical activity' to be, how being active made them feel, what they liked and disliked about physical activity and what or who helped and hindered their participation. Interviews used open questions, e.g., "*What does physical activity mean to you?*" Prompts were used where necessary to elicit more details or clarify responses. The concept of 'physical activity' was not defined by the interviewer. Children were asked about physical activity experiences only, any mention of health or diabetes came from the child. The interviewer was known to the child because of the child's involvement in the feasibility study, thus rapport had been established (Creswell, 2012). A thought-bubble sheet was available during the interview as a visual prompt. Ten children chose to utilise the thought-bubble worksheet and an example is provided in Appendix 17. Interview durations ranged between 13 and 40 minutes, with the mean duration being 23 minutes.

6.5 Data analysis

6.5.1 Quantitative data analysis strategy

Quantitative data were analysed using IBM SPSS Statistics version 22.0 (IBM Corp., 2013). The distribution of the data for each outcome measure was assessed for normality required for parametric statistical analyses. All data were checked for extreme values and boxplots were scanned for outliers. Non-parametric analyses were used if data were deemed to depart from normality. Descriptive analyses were performed to summarise characteristics about the sample and the outcome variables (frequencies, means, standard deviations, and ranges), including subscales of questionnaires. The mean and standard deviation (SD) were reported for normally distributed outcome measures and median and interquartile range (IQR) for non-normally distributed data.

6.5.1.1 Accelerometer data analysis

Chapter 5 provided a detailed account of the accelerometer methodology. Briefly, a recording epoch of five seconds was used. Data analysis was filtered to only include activity measured between 7.00am and 11.00pm. Data showing zero counts implied that the monitor had not been worn and were removed from analyses. Cut-points for wrist-worn accelerometer data developed by Chandler et al. (2015) were used to determine time spent in moderate-to-vigorous physical activity (MVPA) (Chandler et al., 2015). The cut-points were deemed to have acceptable classification accuracy across the range of physical activity intensities and are appropriate for use with 9–11 year-olds (Chandler et al., 2015).

6.5.1.2 Correlation between variables

To describe the association between variables, Pearson correlation analyses were conducted for normally distributed data and Spearman's Rho for non-normally distributed data. Due to the exploratory nature of the study, no hypotheses were made and two-tailed analyses were conducted. Attention was given to effect size. The p-value is reported with statistical significance set to $\leq .05$.

6.5.1.3 Data screening

Returned questionnaires were checked for missing data. The researcher described missing data in a logbook to help identify any patterns in the missing items. Two children incorrectly completed the CSAPPA scale and although attempt was made to re-send the questionnaire, they were not returned completed. Based on the presumption that some children were experiencing difficulty completing the CSAPPA scale, the researcher developed clear completion instructions that accompanied all further administrations of the CSAPPA scale. For the remaining data, missing data counts were low and a visual scan of the data identified only single items as missing. Given the small number of missing data, it was not deemed necessary to statistically test whether the items were missing in a random or systematic manner. Instead, the PAQ missing items (n=1) were scored as zero, missing items in the CSAPPA scale (n=2) were given a value equal to the child's mean score on that subscale and where data were missing in the PHFS (n=2) the mean for that subscale was calculated by dividing by the number of questions answered.

6.5.2 Qualitative data analysis strategy

6.5.2.1 Thematic analysis

The qualitative data were analysed using the six phases of thematic analysis (Braun and Clarke, 2006) described in Chapter 3, Section 3.3.3. Transcribed documents were read in full repeatedly by the researcher (HQ) and the second researcher and annotated based on recurring concepts and points of interest. Codes could be events (e.g., behaviour: sedentary pursuits), emotions (e.g., feeling happy) or beliefs (e.g., physical activity keeps you healthy). Codes were derived primarily from the data (inductive) but could also be theory-driven (deductive) (Braun and Clarke, 2006). Data analysis began with an inductive approach to ensure important aspects of the data were not missed. Inductive codes arose purely from the data and thus were not anticipated in advance of data analysis. Codes arose through a deductive approach when the theoretical understanding found in literature review allowed the researcher to be sensitive to certain topics of interest that may arise in the data (Strauss and Corbin, 1998). For example, an initial code; 'hypoglycaemia' was deductive as previous research suggested that hypoglycaemia could be a potential barrier to physical activity. Although the sample size was purposeful, the researchers believed that data saturation had been reached because the last interviews did not provide additional understanding of children's experience of physical activity (i.e., no more codes emerged).

6.5.3 Trustworthiness and reflective practice

Evaluative criteria were used as a guide to ensure methodological trustworthiness (Yardley, 2008). Interpretivism regards researcher preconceptions and subjectivities as something used creatively in the research process to advance knowledge, rather than as a problem of bias. The researcher was sensitive to the power imbalance between child participant and adult researcher. Through reflective practice, the researcher critically reflected on her assumptions and role as the adult researcher. Reflections took place; prior to data collection (e.g., to reflect on personal values, beliefs and motivations), immediately after each interview with a second researcher when possible (RM) (e.g., to reflect on methodological decisions and impressions of the interview, the interviewee and emerging points of interest) and during data analysis (e.g., to reflect on early impressions of the data and to document rationale for assignment of codes and themes). A codebook was developed and the percentage of agreement with a second coder, who was not affiliated with the research, was calculated. Agreement was 71%, suggesting that the theme analysis had been reliably conducted to a recommended standard (Boyatzis, 1998).

6.6 Results

6.6.1 Characteristics of the sample

Children who completed the questionnaires were also interviewed with the exception of one participant who completed the questionnaires but was unwilling to provide an interview. The children in the study had a mean age of 10.1 years (SD=0.9 years).

Gender distribution was approximately equal (54% female). The sample was predominantly White-British (85%). Whilst there was spread across all quartiles of IMD ranking, participants were weighted towards the highest IMD rank (46% in the highest IMD rank), indicating low levels of deprivation (Table 14).

Table 14 Demographic characteristics of feasibility study sample (n=13)

Characteristic	**Value**
Child age (years), mean (SD), range	10.1 (0.9), 9.2–11.9
Child gender, n (%)	
Male, n (%)	6 (46%)
Female, n (%)	7 (54%)
Ethnicity, n (%)	
White British	11 (85%)
Black African	1 (8%)
Mixed race	1 (8%)
Index of Multiple Deprivation (IMD) rank, n (%)	
1st quartile (highest deprivation)	3 (23%)
2nd quartile	3 (23%)
3rd quartile	1 (8%)
4th quartile (lowest deprivation)	6 (46%)
Height (cm), mean (SD), range	146.01 (7.8), 135.8–159.3
Weight (kg), mean (SD), range	42.8 (10.0), 29.6-63.0
BMI (kg/m^2), mean (SD), range	19.9 (3.5), 15.6–26.8
BMI <5th percentile, n (%)	0 (0%)
BMI 5th-85th percentile, n (%)	8 (62%)
BMI 85th–95th percentile, n (%)	2 (15%)
BMI ≥ 95th percentile, n (%)	3 (23%)
HbA1c (mmol/mol), mean (SD), range	56.5 (10.4), 41–72
≤ 2014 target HbA1c of 58mmol/mol, n (%)†	7 (54%)
> 2014 target HbA1c of 58mmol/mol, n (%)	6 (46%)
≤ 2015 target HbA1c of 48mmol/mol, n (%)	4 (31%)
> 2015 target HbA1c of 48mmol/mol, n (%)	9 (69%)
Age at diagnosis, mean (SD), range	6.2 (3.0), 0.8–10.8
Years diagnosed, mean (SD), range	4.3 (2.9), 0.4–10 .6
Insulin delivery method, n (%)	
Multiple daily injections	5 (38%)
Insulin pump	7 (54%)
Insulin pen	1 (8%)
Number of siblings, n (%)	
0	1 (8%)
1	6 (46%)
2	4 (31%)
3	1 (8%)
4	1 (8%)

*Mothers n=13; **Fathers n=11; † NICE (2004) guideline at the time of data collection

The mean BMI of the children was 19.9 kg/m^2 (SD=3.5kg/m^2). Over half of the children (62%, n=8) were classified as healthy weight according to BMI percentiles (5^{th} and 85^{th} BMI percentile), 15% (n=2) were classified as overweight (between 85^{th} and 95^{th} BMI percentile) and 23% (n=3) as very overweight or obese (at or above 95^{th} BMI percentile). Mean BMI for all potentially eligible children in the clinic population was lower (n=50, mean BMI =18.9kg/m^2) than those who participated in the current study.

6.6.1.1 Type 1 Diabetes status

Children had been diagnosed with T1DM with a mean duration of 4.3 years (SD=2.9 years), which ranged between 0.4 and 10.6 years. The mean HbA1c was 56.5mmol/mol (SD=10.4mmol/mol) (range of measurements 41–72mmol/mol). Mean HbA1c for all potentially eligible children from the clinic population was higher, (n=50, mean HbA1c=62.7mmol/mol) than the current sample, suggesting that the current sample had better glycaemic control on average. Fifty-four percent of the sample were considered to have good diabetes control at the time of data collection based on the NICE recommendation of ≤58mmol/mol current at the time of the data collection (NICE, 2004). Based on the revised 2015 NICE recommendation of ≤48mmol/mol, 31% of the current sample would be considered to have good diabetes control. The predominant method of insulin delivery was with an insulin pump (54%).

Table 15 shows the means and standard deviations (SD) for the physical activity, self-efficacy and parental fear of hypoglycaemia data.

Table 15 Average scores for outcome measures and subscales (n=13)

Measure	Mean (SD)	Median (IQR)	Range of scores
Physical Activity (PAQ)			
Physical activity	54.1 (8.5)	-	42–74
Sedentary behaviour	20.3 (4.3)	-	16-31
Objective physical activity			
MVPA (minutes)	84.8 (26.9)	-	45.8–124.4
Self –efficacy (CSAPPA)			
CSAPPA total	60.8 (7.1)	-	50–73
Adequacy	21.5 (3.1)	-	14–26
Predilection	28.8 (4.1)	-	23–36
Enjoyment	10.5 (1.6)	-	7–12
Parental hypoglycaemia fear survey (PHFS)			
PHFS total	42.7 (13.3)	40.0 (18.3)	13–70
Behaviour	21.9 (4.4)	21.5 (7.0)	7–29
Worry	20.8 (12.2)	18.0 (15.5)	5–50

6.6.1.2 *Children's self-reported physical activity*

Children in this study scored a mean of 54.1 (SD=8.5) out of a possible score of 41–123 on the self-reported physical activity scale. On the sedentary behaviour subscale, children scored a mean of 20.3 (SD=4.3) out of a possible score of 14–42. There was a wide range of scores for both physical activity and sedentary behaviour.

6.6.1.3 *Children's objectively measured physical activity*

Eleven children wore the accelerometer and all eleven provided seven days of accelerometer data. As shown in Table 15, children spent a mean of 84.8 minutes (SD=26.9 minutes) in MVPA per day, ranging from 45.8 to 124.4 minutes.

6.6.1.4 *Children's self-efficacy for physical activity*

Children scored a mean of 60.8 (SD=7.1) for total CSAPPA out of a possible score of 19–76. On the predilection subscale, children scored a mean of 28.8 (SD=4.1) out of a possible score of 9-36. Four children (31%) were considered to have low self-efficacy, based on the criterion of a score of 27 or below, on the predilection subscale used in a previous study (McWilliams et al., 2013). On the adequacy subscale children scored mean of 21.5 (SD=3.1) out of a possible 7–28 and on the enjoyment subscale children scored mean of 10.5 (SD=1.6) out of a possible score of 3-12. All these scores were above the mid-point for that scale, indicating relatively high perceived adequacy in and enjoyment of physical activity.

6.6.1.5 *Parental Fear of Hypoglycaemia*

Overall, parents of children in this study scored low on the PHFS (median=40.0). Parents scored 21.5 (median) out of a possible score of 0–44 on the behaviour subscale and 18 (median) on the worry subscale out of a possible 0–60. There was a wide range of total scores (13–70) and scores on each subscale (PHFS-B; 7–29 and PHFS-W; 5–50). Two parents' PHFS scores appeared to deviate from other observations in the sample, but these cases were not removed given the small sample size.

6.6.2 *Correlational analyses*

Correlation coefficients are presented in Table 16 described in terms of Cohen's (1988) classifications of effect sizes; .1 small, .3 moderate, .5 large (Cohen, 1988).

Table 16 Factors associated with total levels of moderate to vigorous physical activity: correlation coefficients (r) with level of statistical significance (p-value) and number of participants (n)

	Moderate to vigorous physical activity (MVPA)		
	r	n	p-value
Age	**-.831**	**11**	**.002***
HbA1c	-.108	11	.751
BMI	.010	11	.976
CSAPPA total self-efficacy	**.758**	**10**	**.011***
CSAPPA Adequacy	**.577**	**10**	**.081**
CSAPPA Predilection	**.830**	**10**	**.003***
CSAPPA Enjoyment	.103	10	.778
Self-reported physical activity	**.568**	**11**	**.068**
Self-reported sedentary behaviour	.314	11	.347
Parental total fear of hypoglycaemia (PHFS)	-.109	11	.749
PHFS-behaviour	.080	11	.800
PHFS-worry	-.447	11	.168

*significant at p<.05 level (two-tailed)
Note: Large effect sizes in **bold**.

Children who had higher levels of MVPA as measured by accelerometer were younger, (r=-.831, p=<.01), had higher self-rated scores for physical activity (r=.568, p=.068) and had higher self–efficacy for physical activity (r=.758, p=<.05). There was a particularly strong relationship between predilection for physical activity and children's objective levels of physical activity (r=.830, p<.01). There was some evidence of negative correlation between parental hypoglycaemia worry (PHFS-w) and children's MVPA ($r=-.447$, $p=.168$).

6.6.3 Qualitative results

Twelve children were interviewed and their characteristics are provided in Table 17. Evidence of the major themes that emerged during analysis are presented and supported with verbatim quotations from the raw data, using fictitious names for each child.

Table 17 Participant characteristics

Participant*	Gender	Age (years)	Diagnosis (years)	HbA1c (mmol/mol)	BMI (kg/m^2)	MVPA (minutes)	PAQ physical activity	PAQ sedentary behaviour	CSAPPA total	CSAPPA Adequacy	CSAPPA Predilection	CSAPPA Enjoyment	PHFS total	PHFS behaviour	PHFS worry
P01 Amelia	F	10.8	8.0	54	18.8	78.9	53	23	53	20	23	10	52	24	28
P02 Ryan	M	11.4	10.6	61	17.0	45.8	48.24	17	61	22	28	11	29	14	15
P03 Jay	M	11.8	4.8	67	20.3	-	47	18	59	21	29	9	40	18	22
P04 Calum	M	11.1	3.0	59	19.1	60.2	53	16	55	20	26	9	34.9	20.9	14
P05 Ava	F	11.1	2.1	60	26.8	102.4	52	17	67	22	33	12	41.9	20.9	21
P06 Sophia	F	9.4	3.3	43	22.2	108.4	57	20	62	23	32	7	40	28	12
P07 Matthew	M	9.9	5.8	51	15.6	113.2	67	24	70	26	32	12	36	26	10
P08 Craig	M	11.3	0.4	41	25.5	64.3	42	20	50	14	25	11	36	22	14
P09 Natasha	F	10.8	1.6	72	16.2	86.7	54	25	62	22	29	11	70	20	50
P10 Daniel	M	9.8	0.8	45	21.3	124.4	50	18	73	25	36	12	22	17	5
P11 Lauren	F	12.2	6.1	47	21.7	49.7	49	17	57	22	24	11	57	29	28
P12 Andrew	M	9.4	5.6	65	16.3	99.0	57	18	-	-	-	-	54	23	31

NB: *All names are fictitious HbA1c=glycaemic control, BMI=body mass index, MVPA=moderate-to-vigorous physical activity, PAQ=physical activity questionnaire, CSAPPA=Children's self-perceptions of adequacy in and predilection for physical activity scale, PHFS=Parental hypoglycaemia fear survey

Table 18 Overview of themes, subthemes and codes

Theme	Subtheme	Codes
1. Children's understanding of physical activity varied across the group		Beliefs about what physical activity is; being healthy, games and playing, running and moving, sport. How much is enough?
2. Children's physical activity is motivated by friendship and social interaction	2a. Co-participation in physical activity with friends is important for children	Socialisation, co-participation, friends help initiate activity, social benefits, teamwork.
	2b. Sometimes peers limit physical activity	'Other people', teasing.
3. Children have positive outcome expectations for physical activity		Positive perceptions; fun, enjoyment. Outcome expectations; physiological, psychosocial. Positive feelings; happy, cheerful, other feelings.
4. Children describe how their family helps them to be active	4a. Children describe family involvement in physical activity	Parents join in, active with siblings.
	4b. Children describe parental encouragement of physical activity	Verbal encouragement, feeling supported.
	4c. Children are dependent on parents for some physical activities	Transport, funding, supervision.
5. School provides children with an opportunity to be active	5a. Children are influenced by physical education (PE) and extracurricular activities provided by school	PE class, break-time at school, afterschool clubs, lunchtime clubs.
	5b. Children believe teachers can help them to be active	Teachers' encouragement, teacher support.
6. Children refer to personal mastery and competence in physical activity	6a. Children value physical activity practice and learning to master skills	Observational learning, mastery, learning, practising skills.
	6b. Children talk about their perceived competence at physical activities	Ability, being good.
7. Children perceive things that make physical activity difficult	7a. Children recall difficulties related to diabetes	Blood glucose checking, hypoglycaemia, pump.
	7b. Children can be distracted by sedentary activities	Screen time, homework.

6.6.4 Theme 1

Children's understanding of physical activity varied across the group

Children's interpretations of physical activity generally involved a list of favourite activities, often sports. Movement of the body or "moving around" (P09, Natasha) was also a common way of defining and conceptualising physical activity. Matthew suggested that, "*Xbox is active [because] it makes your fingers go fast*" (P07, Matthew) whilst Calum recalled a definition he had learnt in school; "*physical activity is doing exercise and increasing your heart rate*" (P04, Calum). Other less common responses involved references to health, such as "*being healthy, keeping in shape*" (P11, Lauren).

Children were asked, 'how much physical activity should a child like you do?' to which there was a variety of responses. Some children did not know how to answer the question whilst others provided vague answers such as, "*quite active*" (P01, Amelia). Daniel gave a vague response suggesting, "*quite a bit…just a lot... Adults, they don't need to do as much*" (P10, Daniel). Among the children who provided a definitive answer, some suggested 30 minutes and others suggested one hour or more. Calum scored relatively low on self-efficacy and did not agree with a 30-minute recommendation, "*I read that about 30 minutes every day, but I don't think it's necessary to do that every day*" (P04, Calum). Jay, who scored low on self-reported physical activity, was hesitant about a 60-minute recommendation; "*about 60 minutes a day, at least…but if you can't manage it all, it doesn't need to be 60 [minutes]*" (P03, Jay).

6.6.5 Theme 2

Children's physical activity is motivated by friendship and social interaction

Physical activity was regarded as a social experience, with some children considering themselves part of an active social group.

Subtheme 2a) Co-participation in physical activity with friends is important for children

Socialisation was a common rationale for participating in activities. Children conceptualised activities, such as walking to school, as a social experience, e.g., "*I walk with my friends*" (P08, Craig). Social benefits such as "*working as a team*" (P08, Craig) were also mentioned. Lauren was the oldest child and achieved suboptimal levels of MVPA, but suggested that her active friends were a positive influence for her, "*because all my friends, they're running across fields and well, since all my friends are active, I am. Just makes me want to be like them*" (P11, Lauren). Children specifically identified school friends or neighbourhood friends as important in their participation in physical activities.

Subtheme 2b) Sometimes peers can limit physical activity

For some, the importance of identifying with their social group could at times limit their physical activity participation. Craig said he would co-participate in sedentary activities with friends at school break time, e.g., "*I sit and talk to friends*" (P08, Craig). Craig had the lowest self-efficacy score in the group. He expressed an interest in trampolining club, yet his rationale for not joining was, "*but none of my friends do that*" (P08, Craig). Sophia said "I *generally talk to people [at break time], sometimes play Pokémon [playing cards]*" (P06, Sophia). This group of children distinguished 'other people' (e.g., school peers or other children in the neighbourhood) who were detrimental to their enjoyment of physical activity. Children described how these 'other people' would "*be mean*"; "*tease*" (P09, Natasha); "*be really annoying*" (P03, Jay); "*make fun*" (P07, Matthew); and be "*horrible to my friends*" (P08, Craig) in physical activity contexts.

6.6.6 Theme 3

Children have positive outcome expectations for physical activity

Overall, this group of children spoke positively about physical activity and many reported being active because of the perceived "*fun*" (P09, Natasha) or because they "*enjoy*" or "*like*" it (P02, P03, P11, P08). When probed, children often found it difficult to explain why physical activity was fun, but friendships were offered by some children as a reason for enjoyment, e.g., "*because I get to play with my friends*" (P01, Amelia). Generally, children expected physical activity to be fun and this was perceived as a good reason to be active.

Irrespective of their self-efficacy or level of physical activity, children described positive feelings derived from participation, mostly feeling "*happy*" (P01, P05, P06, P08, P10, P12). Daniel, who scored highest on self-efficacy said, "*I feel quite happy when I'm doing it [playing football]…like I've enjoyed it*" (P10, Daniel). Explaining why physical activity makes him feel happy, Matthew, who also had high self-efficacy stated, "*Sometimes it makes me feel happy because it's not about winning or losing, it's just fun and having a great time, that's what it's all about*" (P07, Matthew). Other positive feelings derived from physical activity included satisfaction, cheerfulness and relaxed; "*I feel quite satisfied*" (P03, Calum); "*cheerful*" (P12, Andrew); and "*I like walking because it really relaxes me*" (P11).

Children also mentioned physiological outcomes such as health and fitness and psychosocial outcomes such as teamwork. Children's perceived physiological health outcomes included, "*it keeps you healthy and fit*" (P01, Amelia), "*when you do sport you can be healthy*" (P12, Andrew) and "*you get longer to live and when you don't do exercise you have a shorter life*" (P08, Craig). Some children also acknowledged the preventive effect of physical activity, such as, "*because otherwise you could have a heart attack*" (P08, Craig) and, "*so you don't get fat*" (P05, Ava). It was more common for children to cite outcomes not related to diabetes. Only Natasha, who had the highest HbA1c (i.e., poorest diabetes control) acknowledged that physical activity could benefit diabetes control; "*my blood sugar gets better*" (P09, Natasha). Four children mentioned psychosocial outcomes and they were all in the older age range (11-12 years). Psychosocial examples included, "*if people aren't happy, physical activity makes them feel better I suppose*" (P11, Lauren) and, "*it can help teamwork*" (P02, Ryan).

6.6.7 Theme 4

Children describe how their family helps them to be active

All children referred to certain family members who helped them to be active.

Subtheme 4a) Children describe family involvement in physical activity

Children often referred to parents or siblings co-participating in physical activity with them, e.g., "*my two brothers play on the trampoline and what we got to do is see who jumps the highest*" (P09, Natasha). All except one child lived with siblings, yet it was more common for children to describe being active with parents than it was for them to describe being active with siblings; "*sometimes I play football with my Dad…Sometimes golf, my Grandad's* *teaching me* (P07, Matthew). Some described whole family activities, such as, "*family bike ride*" (P02, Ryan).

Subtheme 4b) Children describe parental encouragement of physical activity

Parental encouragement was perceived as a motivation for children to participate in physical activity. For example, Lauren, who had excellent diabetes control said, *"[Mum] she keeps motivating me, so if I'm on my bed lying down she's like 'ok do you wanna, ok you should go out. Lauren don't lie down on your bed all day, go out'*" (P11, Lauren). Parental encouragement was not only verbal; children felt encouraged if they believed their parents were in favour of physical activity, e.g., "*they [parents] want me to be healthy*" (P12, Andrew) and "*My Mum's all for it*" (P04, Calum). Craig acknowledged how his mother encouraged him to be active by allowing him to go outside to play, "*not many people just let them [their children] go out, but Mum lets me go out quite a lot*" (P08, Craig), similarly Sophia stated, "*they [parents] don't stop me from doing it*" (P06, Sophia).

Subtheme 4c) Children are dependent on parents for some physical activities

Children's participation in physical activity was sometimes dependent on parents for fees, transport and accompanying them to the activity. Jay acknowledged that this logistical support helped him to be active, "*Parents driving me to places to play football*" (P03, Jay). It was common for children to indicate logistical support, e.g., "*We spent fifty pounds on new jodhpurs*" (P04, Calum), "*My Mum or her [friend's] Mum takes me [ice skating]*" (P11, Lauren), and "*She [Mum] takes me to the park*" (P05, Ava). Some children also described times when their parents were not available, were ill, or could no longer fund the activity, which had a detrimental effect on the child's activity, e.g., "*Mum wasn't well, so we didn't go [horse riding]*" (P04, Calum). All the children who referred to their parents' logistical support were in the older age range (11-12 years). It was not common for children to talk about their parent's role in diabetes management. Lauren described a school activity holiday and mentioned how her mother had "*travelled an hour and a half to get there every day*" and when probed added, "*she's really like OTT [over the top] about me checking my blood sugar and stuff. So she'll always be like talking to the teacher, 'has she done her blood glucose?'*" (P11, Lauren). Lauren's narrative was supported by her parent scoring the highest on hypoglycaemia-related behaviour (i.e., behaviour in attempt to reduce the chance and consequences of hypoglycaemia).

6.6.8 Theme 5

School provides children with an opportunity to be active

Children associated school with opportunities to be physically active.

Subtheme 5a) Children are influenced by physical education (PE) and extracurricular activities provided by school

The majority of children mentioned PE as an example of how they kept active. Children spoke positively about PE and Daniel, who had the highest enjoyment score valued the chance to try "*different stuff every time*" (P10, Daniel). Extracurricular activities were also mentioned as physical activity opportunities, including indoor games club, cheerleading, athletics and basketball. Jay had one of the lowest enjoyment of PE scores and described "*getting bored*" in PE, yet appreciated its importance by saying, "*I feel [PE] it's good to actually do it in the curriculum and having clubs and stuff afterschool and that's encouraging people to do sport*" (P03, Jay).

Subtheme 5b) Children believe teachers can help them to be active

Most of the children spoke positively about the encouragement they received from their PE teachers. Andrew described feeling motivated by his teacher, "*there's an assistant called Mr Rogers at PE …He helps you get healthy and make it, make you really want to do it*" (P12, Andrew) and Sophia valued being taught netball skills from a role model, "*Mrs Patterson*[2] *does netball with us and she shows us the perfect way to do it and helps us try and get better at it*" (P06, Sophia). Natasha used the phrase "*people I trust*" to describe the teachers in school, and when probed she clarified that she trusted teachers with her "*diabetes and in general*" (P09, Natasha). Daniel suggested that his teachers were helpful when he had to test his blood glucose level. Few children had anything negative to say about PE teachers; three children expressed concern about, "*strict*" teachers at Secondary school (P11, Lauren), teachers "*focusing on other people*" in class (P06, Sophia) and teachers giving afterschool detention "*if you accidentally forget your PE kit*" (P04, Calum). Matthew, who had the second highest self-efficacy score, said he did not feel influenced by PE teachers, "*no, they [teachers] don't help me to be active*" (P07, Matthew) and Jay, who described "*getting bored*" in PE (above), seemed indifferent when asked about his PE teachers, "*they're fine*" (P03, Jay).

[2] Names are fictitious

6.6.9 Theme 6

Children refer to personal mastery and competence in physical activity

Children expressed a desire to learn, practice and develop competence in physical activities.

Subtheme 6a) Children value physical activity practice and learning to master skills

Regardless of their self-efficacy or physical activity level, children seemed to value the experience of learning about physical activities. For example, Amelia said, "*I like doing my street dance because I know stuff about street dance I didn't know about street dance before*" (P01, Amelia). Ryan referred to "*wanting to do it to get better*" (P02, Ryan) and Matthew valued the opportunity to try handball in school, "*I knew nothing about handball, and now I do*" (P07, Matthew). Matthew went on to discuss mastering skills through practice, "*I really like skipping because it helps you jump and I'm not a very good jumper, but skipping makes me better*" (P07, Matthew). Children would recall situations in which they had mastered a physical activity successfully and how that made them feel, e.g., "*Ice skating it's just, you do the tricks and you feel like, "wow, I can actually do that" and then, it's just really good I guess*" (P11, Lauren).

Subtheme 6b) Children talk about their perceived competence at physical activities

Children had an awareness of their competence or level of ability to perform certain activities. It was more common for children to mention a perceived lack of competence in an activity, rather than proclaiming themselves as good at an activity. Calum, who scored below average in perceived adequacy, assessed his competence in comparison to others, "*There's a coach and a few people [at tennis lessons] but the people are quite good, so I'm quite challenged because I'm not as good as them*" (P04, Calum). Craig scored the lowest on perceived adequacy and assessed his competence based on his own performance, "*I'm not that good at gymnastics so I'm not sure, roly-polys... I don't like hitting my head*" (P08, Craig). Natasha scored above average on adequacy and implied that she enjoyed physical activity irrespective of perceived competence, e.g., "*I like it [basketball] but I don't know if I'm good at it… just as long as you have fun*" (P09).

6.6.10 Theme 7

Children perceive factors that make physical activity difficult

This theme captures the issues raised when children were asked what makes it harder for them to be physically active.

Subtheme 7a) Children recall difficulties related to diabetes

Half of the children mentioned hypoglycaemia in interviews, four of whom perceived it as something that could impede their participation (P02; P03; P09; P10). Yet it was not common for the children to talk in depth about the influence of diabetes on their ability to be active. Ryan, who had the lowest MVPA level alluded to physical activity having negative consequences for blood glucose control, "*it sort of burns off calories and unfortunately carbs and sugar…if it burns off the carbs, you go hypo*" (P02, Ryan). Episodes of hypoglycaemia were perceived as a practical inconvenience by children, particularly when they would miss part of the activity whilst they waited for a quick-acting carbohydrate (e.g., energy drink) to take effect on blood glucose level. Children described how this made them feel, "*awkward*" (P10, Daniel), "*annoyed*" (P03, Jay) and "*sad*" (P09, Natasha). For example, Jay said:

> *Sometimes with football when my bloods go low...I have to you know, come off or not go on or don't go on, just need to wait for them to come back up. [Interviewer: How does that make you feel?] Annoyed because not so long ago, there was a football match and I was supposed to be coming on at half-time, so I had to delay that as well, so I ended up not playing as long.*

P03, Jay

Over half of the children used an insulin pump and three suggested that it could be an inconvenience, especially if it needed to be removed during physical activity, e.g., "*we don't worry about diabetes that much apart from swimming where I have to take my pump off because it's not waterproof*" (P04, Calum). Jay suggested that finding somewhere safe to keep his pump made physical activity more difficult, "*I have to find somewhere safe to put it because I can't play rugby with it on*" (P03, Jay).

Subtheme 7b) Children can be distracted by sedentary activities

Over half of the children mentioned screen-time activities, such as television and video games, impeded their physical activity level. Children acknowledged that sedentary activities were a "*distraction*" (P10, Daniel) from being active, e.g., "*when I'm away from home I think I am a bit more active, because there's not the screen to distract me!*" (P04, Calum). Lauren, who was the oldest child, scored low compared with other children on MVPA and said, "*If I see something really good on television, I'll really want to watch it even though I'm supposed to be going out on my bike. So that's kind of hard to say like 'oh don't watch it'*" (P11, Lauren). Sedentary behaviours were perceived to co-exist with the children's active lifestyle. For example, Matthew scored above average on MVPA and also had the second highest self-reported sedentary behaviour score, which was illustrated with his quote, "*When our 45 minutes [outside being active] is over, we come in and play Minecraft, which is an Xbox game*" (P07, Matthew).

6.7 Discussion

The present study sought to integrate quantitative and qualitative data in attempt to develop our understanding of the motivations behind participation choices in children with T1DM.

6.7.1 Characteristics of the sample

6.7.1.1 Diabetes control

The children in the current study had good diabetes control at the time of data collection based on the mean HbA1c, 56.5mmol/mol, being below the 2014 recommended level of 58mmol/mol (NICE, 2004). The mean HbA1c is below the current UK national average (71.6mmol/mol) (The Royal College of Paediatrics and Child Health (RCPCH), 2015), which suggests better than average diabetes control. However, the average HbA1c is above the new 2015 NICE recommendation of ≤48mmol/mol (NICE, 2015). The findings gave no indication of a relationship between HbA1c and physical activity, which concurs with previous studies (Edmunds et al., 2007).

6.7.1.2 Physical activity level

The children in this study would be considered highly active based on their average time spent in MVPA. A mean of 84.8 minutes (SD=26.9 minutes) of MVPA per day meets the current recommendation of at least 60 minutes of MVPA per day (Department of Health, 2011). As reported in Chapter 5, six children (55%) achieved 60 minutes MVPA every day the accelerometer was worn. As children's age increased, MVPA decreased suggesting that the physical activity level declined between the ages of 9 and 11 years in the sample. This is consistent with figures from the general population of children without diabetes in England (Health and Social Care Information Centre, 2013a). Wrist-worn accelerometer data collection is in its infancy and previous research using ActiGraph accelerometers to measure physical activity among children with T1DM has used waist placement (MacMillan et al., 2014c) meaning that the findings cannot be compared with previous studies (see Chapter 5). Further, the lack of control group means that it is not possible to compare with the physical activity level of children without T1DM. More research is needed using wrist-worn accelerometers to enable comparison with other samples and populations of children.

Self-reported physical activity, as measured by the PAQ, was similar to scores recorded in previous studies using the same instrument (McWilliams et al., 2013). McWilliams et al. (2013) measured self-reported physical activity in a sample of children aged 9–11 years, who had been targeted as being less active than their peers. The children McWilliams et al.'s study scored two points higher (mean=56.1, SD=8.3) for physical activity than the sample in the current study (mean=54.1, SD=8.5) As the objective measure of physical activity in the current study suggested the sample was active, it is possible that either the self-reported findings underestimated physical activity or the accelerometers overestimated physical activity. More research is required in a larger sample of children with T1DM to enable comparisons with other research and populations.

6.7.1.3 Body Composition

Despite being an active sample, over a third of the sample was overweight and the 1kg/m^2 difference in mean BMI between the study sample (mean=19.9 kg/m^2) compared with the clinic sample (mean=18.9 kg/m^2) would be considered clinically significant for cardiometabolic risk markers in children (Danielsson et al., 2012). Previous research has also identified high activity levels yet high incidence of excess weight in youth with T1DM. Heyman et al. (2007) had a sample of adolescent girls aged 13-15 years (n=16) from France who had good diabetes control and were physically active, yet half of the sample were rated overweight or obese (Heyman et al., 2007).

Levels of obesity in children with T1DM are demonstrating concerning trends. The National Paediatric Diabetes Audit 2013-2014 suggested that among children under 12 years of age with T1DM in England and Wales, 18.5% were overweight and 18.1% were obese, and figures increased for those aged 12 years and older (The Royal College of Paediatrics and Child Health (RCPCH), 2015). When these audit figures were compared with the Child Measurement Programme (Health and Social Care Information Centre, 2013b), the prevalence of overweight and obesity was higher compared with children without diabetes (40.2% compared to 33.3%).

6.7.2 Children's perceptions and experience of physical activity

The children in this study had positive perceptions of physical activity and understood it in terms of sport and 'moving'. They demonstrated awareness of the physiological health benefits of physical activity (physical outcome expectations), but there was limited understanding of the specific benefits of an active lifestyle for T1DM outcomes. Children were generally unaware of the physical activity recommendations for children, which has been found in young people with (MacMillan et al., 2014b) and without T1DM (Roberts and Marvin, 2011). It is important to explore children's interpretation of physical activity in this way to facilitate physical activity discussions in clinical practice and promote physical activity health messages among children with T1DM.

6.7.3 Children's self-efficacy for physical activity

Overall, CSAPPA scale scores were not suggestive of low self-efficacy, but individually over a quarter of the children were deemed to have low self-efficacy based on their predilection for physical activity scores. When compared with previous studies, total CSAPPA scores in the current study were: marginally higher than overweight and obese African American children aged 9–11 years (mean=57.4, SD=1.04; Sharma et al. (2013)); higher than children aged 9–11 years targeted as having low self-efficacy for physical activity (mean=50.65; Glazebrook et al.(2012)); similar to ten Canadian children aged 8–14 years with epilepsy (mean=60.1, SD=9.2; Whitney et al.(2013)) and marginally higher than young people aged 5–25 years with leukaemia (mean=57.72, SD=12.30), but lower than a comparison group aged 5-25 years considered 'normative' (mean=63.72, SD=8.46; Wright et al. (2003)). This suggests that the children in the current study scored similarly on the CSAPPA scale to other populations deemed to have barriers to physical activity (e.g., overweight or long term condition), but lower than children considered a 'normative' sample. This supports the implementation of initiatives to promote perceived adequacy and predilection for physical activity among children with T1DM.

The strong positive correlation between predilection and MVPA is suggestive of a higher preference for physical activity being associated with higher levels of activity. Predilection refers to the likelihood that one would choose a physical activity as opposed to a sedentary activity if given the choice. The interviews identified that children perceived positive outcome expectations from participation in physical activity. Particularly, children were more likely to perceive social benefits and feelings of fun and enjoyment than physiological benefits such as better blood glucose control. The SCT posits that children will act in ways that they believe will lead to positive and valued outcomes (Bandura, 2004). Thus, identifying children's valued outcomes is important for successful behaviour change. The interviews also revealed that even the most active children would sometimes prefer sedentary behaviours such as watching television and considered them to co-exist with their active lifestyle. This suggests that initiatives to target children's predilection for physical activity might improve children's tendency to be distracted by appealing sedentary alternatives. A broader package of initiatives may benefit from education around sedentary behaviour alongside the promotion of children's predilection for physical activity.

The positive correlation between perceived adequacy and measures of physical activity is also in line with the SCT. It suggested that children's belief in their ability to achieve some degree of success in physical activity relates to their actual participation. Bandura (1997) proposed that mastery was an important source of self-efficacy. In the interviews, children described deriving pleasure and enjoyment from learning and mastering physical activity skills and demonstrating competence. A similar finding has been demonstrated in youth with cystic fibrosis who perceived the opportunity to experience mastery was a key motivator to engagement in physical activity (Moola et al., 2012). Interviews also demonstrated that perceived competence was salient to children's understanding of physical activity; they recognised their strengths and limitations. The findings suggest that a supportive, mastery-oriented environment could increase children's enjoyment of physical activity, intrinsic motivation and promote a sense of competence and self-efficacy for physical activity.

The interview findings provide good support for the SCT premise of a supportive environment, showing that children perceive their peers, family and school as important in their participation in physical activity. The importance of social interaction and friendship in physical activity has been identified in children with (MacMillan et al., 2014b) and without T1DM (Dismore and Bailey, 2010 ; Jago et al., 2009 ; Veitch et al., 2013) and would suggest that children value the social outcome expectation of physical activity (Bandura, 2004). The findings from Chapter 6 also show that in some circumstances peers can be detrimental to a child's enjoyment of physical activity. Strategies to promote physical activity in children with T1DM could use peer groups as social support and motivation, but this requires careful consideration. There may be scope for research to explore peer's perceptions of physical activity for those with T1DM to help understand how best to use friendship groups and networks.

Children described how parents provided encouragement that was facilitative to their engagement in an active lifestyle and valued being allowed to go outside and play. Longitudinal research has demonstrated that in children ten years old, early parental encouragement and positive attitudes towards physical activity were associated with higher levels of physical activity in adolescence (Verloigne et al., 2013). The children in this study did not relate parental support to diabetes management specifically, but rather acknowledged their parents for transport and funding (i.e., logistical support). The findings implied that children may become more aware of their parents' role in their own physical activity participation as they get older. The qualitative research in Chapters 3 and 4 demonstrated that parents and healthcare professionals place great importance on the role of parents to support physical activity among children with T1DM (Quirk et al., 2014a ; Quirk et al., 2015). Overall the findings suggest that parents influence children's experience of physical activity and could set standards that influence their child's self-perceptions of adequacy in physical activity (Hay, 1992).

Children referred to the school environment as instrumental in their engagement in physical activities, particularly through PE lessons. Most children valued the variety of activities offered through PE and the support and encouragement received by PE teachers. Having trust in teachers supervising physical activities was touched upon by a child in the current study and has been identified as important in previous research (MacMillan et al., 2014b ; Quirk et al., 2014a). The positive perceptions of these children toward school physical activity engagement is encouraging, especially given research which indicated that diabetes support in schools is inadequate (MacMillan et al., 2014a ; MacMillan et al., 2015). Parents of children with T1DM have previously reported positive attitudes towards the support received for their child's physical activity participation in school, although many could recall specific occasions when schools had been less supportive (Quirk et al., 2014a). Overall, teachers influence children's experience of physical activity; and should be supported to promote and encourage physical activity in children with T1DM.

The interviews provided evidence for the influence of children's enjoyment on their participation in physical activities. Children seemed motivated by positive outcome expectations such as fun, enjoyment, satisfaction, happiness and cheerfulness, captured by the comment, "*it's not about winning or losing, it's just fun and having a great time, that's what it's all about*". The findings concur with previous research exploring the perceptions of children with (MacMillan et al., 2014b) and without T1DM (Mulvihill et al., 2000). MacMillan et al. (2014) identified enjoyment as a strong influencer of physical activity in children with T1DM and suggested children benefit from being given 'ownership' to choose activities they enjoy. This is consistent with the idea that children are driven by the innate psychological drive of autonomy (Deci and Ryan, 2000). For prolonged participation in physical activity, research suggests that enjoyment should be prevalent (Allender et al., 2006) and in other chronic conditions enjoyment has been shown to be a key facilitator of physical activity (Moola et al. (2012); cystic fibrosis). The findings suggest that children's individual preferences, outcome expectations and motivation should be considered in attempts to promote active lifestyles in this population. Providing an environment that is autonomy-supportive may enhance children's enjoyment of physical activity experiences and foster prolonged participation.

6.7.4 Perceived barriers to physical activity

Diabetes-related barriers to physical activity participation were mentioned by half of the children interviewed, which included blood glucose testing and hypoglycaemia. Yet the children did not perceive diabetes to hinder their participation in physical activity, which aligns with previous research in children with T1DM (Fereday et al., 2009 ; MacMillan et al., 2014b). Generally, children believed hypoglycaemia was a practical inconvenience during participation rather than a negative outcome expectation or deterrent to further participation. This finding contrasts with previous research which implied that children aged 8–18 years with T1DM fear hypoglycaemia (Johnson et al., 2013b), however, this may reflect the wider age range than that used in the current study. The inconclusive evidence suggests further research should seek to explore children's perceptions of physical activity barriers to better understand how to promote efficacious beliefs for participation.

6.7.4.1 *Parental fear of hypoglycaemia*

Children's low concern about hypoglycaemia corresponds with their parents' level of FOH. Parents in this study scored substantially lower on FOH (mean=42.7, SD=13.3) compared with scores reported in previous literature, where it is common to see mean total PHFS scores above 60 (Barnard et al., 2010 ; Haugstvedt et al., 2015 ; Hawkes et al., 2014). In the current study, there was a large SD around the mean score, suggesting that some parents within the sample had more worry about hypoglycaemia. The findings from Chapter 3 of the current thesis suggested that parents worry about exercise-induced hypoglycaemia, especially during the night after active days (Quirk et al., 2014a). The potential correlation between parental worry about hypoglycaemia and children's MVPA suggests that more research is needed to help understand whether parental worries or behaviours influence children's physical activity beliefs and preferences.

6.7.5 Implications of the findings for the promotion of active lifestyles in children with T1DM

Overall the current study has provided support for the social cognitive constructs of intrinsic motivation and self-efficacy (Bandura, 1997 ; Deci and Ryan, 2000), including the CSAPPA scale subdomains of adequacy, predilection and enjoyment (Hay, 1992). If HCPs, researchers and physical activity providers are to be in a position to promote active lifestyles among children with T1DM, they need to be sensitive to modifiable influencers and respond to children's physical activity-related values and desires. The findings from the current study would suggest that children with T1DM would benefit from:

- Environments that promote and maintain self-efficacy beliefs (including adequacy, predilection and enjoyment), autonomy, physical activity practice and mastery.

- Fun opportunities to be active with their friends.

- Support from parents and opportunities to be active with family members.

- A school environment in which teachers promote and support physical activity opportunities.

- Support for those who have concerns about blood glucose control and hypoglycaemia in relation to physical activity.

6.8 Evaluation

The study demonstrates the value of mixed-method studies to gain insight into the physical activity experience of children with T1DM. Integrating the results from questionnaires and interviews has elucidated a rich understanding of how children with T1DM perceive and experience physical activity and the influences acting upon their participation. The researcher has been transparent in the conducting and reporting of methods and delineation of the analytical processes to enable the reader to discern for themselves the characteristics of this sample and of the themes identified in interviews. Qualitative findings, supported by excerpts from the raw data, ensured that the interpretation of the data remained directly linked to the words and experience of the children (Fereday and Muir-Cochrane, 2008). This integration gives a better insight into children's physical activity experience than using a single method alone.

The findings from the current study must be considered in light of methodological considerations that may influence the interpretation and implications of the results. The initial analyses provide new information on the factors that influence physical activity in children with T1DM, but research in a larger dataset is required to identify how associations may differ by participant characteristics and the extent to which the findings can be generalised to the wider population. Children were purposefully recruited from one diabetes clinic in the UK and had self-selected to enrol onto a physical activity intervention study. It is possible therefore that these children (and/or their parents) had an existing interest in physical activity and may have been more active than those who declined to take part. Furthermore, only twice did the child's father complete the PHFS and so the current findings provide a better representation of maternal concerns around hypoglycaemia.

The sample consisted of predominately white British children living in areas of low deprivation. The National Paediatric Diabetes Audit Report (2013) found that the majority of young people with T1DM (<25 years of age) were from White ethnic groups. In this audit, 86.4% of young people with T1DM in the East Midlands were of white ethnicity (The Royal College of Paediatrics and Child Health (RCPCH), 2015). Whilst the current sample is reflective of these statistics, a number of factors should be considered when interpreting the diabetes control observed. First, white ethnic groups typically achieve better control of diabetes when compared with other ethnicities. Second, children with T1DM living in the least deprived areas have better HbA1c on average compared with those in the most deprived areas (The Royal College of Paediatrics and Child Health (RCPCH), 2015). Therefore further research with a larger sample is needed in attempt to recruit a more diverse sample. Nevertheless, the wide range of individual HbA1c scores indicates heterogeneity in the sample and clear scope to improve glycaemic control and long-term health outcomes in almost half of the children studied.

6.9 Conclusions

This study has explored how physical activity is experienced and perceived by children with T1DM in attempt to inform our understanding of how to promote active lifestyles in this population. The findings implied that social cognitive constructs such as self-efficacy, preference for and enjoyment of physical activity play an important role in children's participation. Children perceived few diabetes-related barriers and future research should further explore children's perceptions of hypoglycaemia and how parental concerns may influence children's behaviour. The findings should sensitise healthcare professionals, activity providers and policy makers to the factors influencing children's activity levels and the aspects of physical activity participation that children value.

The study in the next chapter will use the same sample of children with T1DM. The feasibility of an intervention to promote physical activity in this population will be evaluated.

Chapter Seven

An intervention to promote self-efficacy for physical activity among children aged 9-11 years with Type 1 Diabetes: A feasibility study

7.1 Introduction

Previous chapters in this thesis have highlighted the needs and desires of children with Type 1 Diabetes Mellitus (T1DM) and their parents that could help inform the implementation of initiatives aimed at promoting active lifestyles in this population. The systematic review in Chapter 2 demonstrated that among physical activity and exercise interventions for children and adolescents with T1DM to date: none have been implemented in the UK; few have used important social agents such as parents and peers; many have failed to explore the long-term effects of the intervention; few have been underpinned by psychological theory of behaviour change; and little attention has been given to potential psychological outcomes of physical activity and exercise for children with T1DM. The current chapter aims to evaluate the feasibility of delivering a physical activity intervention for children with T1DM: that is empirically informed; that is theoretically driven; implemented in the UK; that uses important social agents; and where the outcomes measured include psychological constructs.

Feasibility studies have an important role in the development of the next generation of interventions (Jago and Sebire, 2012). Medical Research Council (MRC) guidelines emphasise the importance of performing process evaluations alongside the effect evaluation (Craig et al., 2008). Process evaluations document each research process in detail; allow appropriate interpretations and conclusions to be drawn about positive or negative trial results; can help to explain why an intervention did or did not work and how it can be optimised; and can explain the discrepancies between expected and observed outcomes (Reelick et al., 2011). Process evaluations help to ensure that research funds are invested in interventions and full randomised controlled trials (RCTs) that have been appropriately designed and evaluated.

7.2 Study aims

The aim of this study is to evaluate the feasibility of implementing an adapted intervention to promote self-efficacy for physical activity among children with T1DM. Adaptations to the original Steps To Active Kids Programme (STAK) (Glazebrook et al., 2011) described in Chapter 1, Section 1.7 are necessary before it can be implemented in children with T1DM.

7.3 Adaptations to the original STAK programme

The adaptations to the original STAK programme (Glazebrook et al., 2011) are informed by formative research and patient and public involvement (PPI) activities conducted by the researcher. After systematic consideration of what is known about physical activity interventions for children with T1DM (Chapter 2) (Quirk et al., 2014b), the researcher sought the views of: i) a Young Persons Advisory Group (YPAG); ii) a child aged nine years with T1DM; iii) parents of children with T1DM; and iv) healthcare professionals (HCPs) who specialise in paediatric diabetes, to gather expert opinion and real life experiences that would inform the adaptations made to the original STAK programme. Full details of this formative research can be found in Appendix 18. In brief, all the groups were asked to share their perceptions of the original STAK programme and offer suggestions for what they would like to see in an adapted programme specifically aimed at promoting physical activity among children with T1DM. The main findings from this PPI activity highlighted:

- The importance of family and peer involvement, including the opportunity for children to meet other children with T1DM.

- The lack of agreement on whether children would be encouraged or discouraged from a diabetes-only group, with some concerns around stigma.

- The importance of the programme being fun for children (i.e., activities they enjoy).

- The need for the programme content and delivery to be tailored for children with T1DM, especially having personnel who were trained in T1DM.

- The programme's potential to promote the importance of blood glucose monitoring, form physical activity habits and develop routines for children.

- Concerns about whether families would have time to attend group activity sessions.

- Doubts about whether activities would engage children in the long-term.

The research presented in Chapters 2, 3, 4, and 6 of this thesis play an important role in informing changes to the original STAK content and its active ingredients for behaviour change. The table below summarises the main empirical findings and PPI outcomes from the development research and demonstrates how each finding informed the intervention adaptation (Table 19).

Table 19 Summary of development research and how it informed the STAK-D intervention

Development research	Research purpose	Research findings	How the findings informed the new STAK-Diabetes intervention
Patient and public involvement (PPI) (Appendix 18)	Explore potential changes, confounders, barriers and research design challenges		
• Young Person's Advisory Group (YPAG)		Logistics of the group activity sessions; venue and time	Use the clinic setting for group activity sessions and explore a convenient time for families to attend
• Interview with 9-year-old boy with T1DM		Concerns about an exclusive T1DM group	Invite children to bring a friend or sibling to the group activity session
• Interviews with parents and HCPs		Unique demands of T1DM necessitate specific tailoring of the	Include information about T1DM and side-effects of physical activity on blood

		programme and utilisation of social support networks	glucose levels, ensure volunteers are trained in T1DM management, schedule blood glucose testing breaks during the group activity session and engage parents and peers within the intervention
Systematic review Chapter 2 (Quirk et al., 2014b)	Identify and evaluate similar interventions	Existing interventions lack a theoretical underpinning and there is limited exploration of psychological factors in existing interventions and research Limited exploration of the role of potentially important social figures such as peers and parents Limited success of previous interventions in increasing children's physical activity and psychological wellbeing, especially in the longer term	Implement a theoretically-driven intervention targeting self-efficacy as a potential mediator of physical activity behaviour change among children with T1DM Introduce a parents' booklet and invite children to bring a friend or sibling to weekly activity sessions Conduct ongoing Motivational Interviews with all children and encourage parents to promote physical activity at home
Parents' perceptions Chapter 3 (Quirk et al., 2014a)	Gain insight into the perceptions of parents and their role	Complex nature of T1DM for children and their parents and unique demands on parents for management and care	Involve health professionals (e.g., encourage children and parents to discuss physical activity with their health

			professional)
		Dependence of children with T1DM on family and social support to promote adherence to diabetes management behaviours	Encourage parental involvement via STAK-D parents' booklet and social support networks via the group activity sessions
		Parents may experience worries and concerns about the occurrence of hypoglycaemic episodes during or after their child's participation in physical activity	Encourage parents to discuss worries or concerns with their health professional and include an outcome measure of parental fear of hypoglycaemia
HCPs' perceptions Chapter 4 (Quirk et al., 2015)	Gain insight into the perceptions of HCPs and their role	Complex nature of T1DM for children and their family and unique demands on self-care	Engage parents and encourage parental involvement via STAK-D parents' booklet
		Dependence of children with T1DM on family and social support to promote adherence to diabetes management behaviours	Engage peers and encourage social support networks via group activity sessions
		Limitations of current clinic arrangements including; time demands, lack of competence or confidence and difficulty encouraging physical activity to children,	Develop an informative resource package that is available for HCPs to distribute among all children and parents

		especially those without an existing interest in physical activity or sport	
Children's perceptions Chapter 6	Gain insight into the perceptions of children with T1DM	Importance of fun and enjoyment of physical activities	Conduct ongoing Motivational Interviews with all children to identify personal interests, individual barriers to and motivations towards engaging in an active lifestyle

The adapted version of the STAK programme implemented in the current chapter is referred to as STAK-Diabetes (STAK-D); a 6-week supervised and home-based physical activity programme utilising educational, behavioural and cognitive-behavioural strategies to promote self-efficacy for physical activity among children with T1DM.

7.3.1 STAK-D components

The next section focuses on elements of each STAK-D component where adaptations have been made.

7.3.1.1 Children's STAK-D activity diary

The STAK-D activity diary aims to inform children about physical activity, raise awareness about their physical activity level and provide a daily target for activity ('5-a-day'). The STAK-D activity diary consists of educational and interactive inserts including: *What is being active?*; *What does being active mean to me?*; *How active should I be?*; *Why is it good to be active?*; *Why is physical activity good for diabetes?*; *Tips for being active with diabetes*; and *Being active at home*. The educational information has been altered by the researcher for this study to be relevant to children with T1DM. All the information contained within the STAK-D activity diary has been reviewed and approved by HCPs at the diabetes clinic where the programme would be implemented to ensure that the messages are consistent with those delivered to patients in standard care (e.g., information around blood glucose testing and appropriate snacks).

7.3.1.2 STAK street dance DVD

The street dance DVD component of the STAK-D programme is as described in the original programme (Chapter 1, Section 1.7.1.2).

7.3.1.3 Pedometer and step-count log

Additional STAK-D diary inserts, produced by the researcher, provide examples of how to set realistic step count targets based on the child's total step count from the previous day or week. With guidance from a researcher, the children are encouraged to set step count goals and record daily step count in the step-count log.

7.3.1.4 STAK-D group activity sessions

STAK-D group activity sessions take place in a leisure room situated in the hospital from where children are recruited. Travel expenses, including car parking fee at the hospital, are offered to parents. Children are given the option to bring a friend or sibling to participate in the session for social support. Parents have the opportunity to stay during the session and are encouraged to voice any questions, comments or concerns. Attendees of the group activity session are required to bring their preferred drink, blood glucose testing equipment and hypoglycaemia treatment.

The group activity session circuit training format is the same as the original STAK programme described in Chapter 1 (Section 1.7.1.4). The main changes to the STAK-D group activity session are the time and location, the invite to bring a friend and consideration of the importance of blood glucose monitoring during the session. The researcher sought advice and guidance from HCPs at the diabetes clinic regarding blood glucose monitoring during the activity session. Circuit training is useful as the regular breaks in activity provide a natural time for children to recover and assess how they feel before continuing. Water will be available to drink throughout the session and a scheduled 10-minute water and blood glucose testing break will take place halfway through the session.

7.3.1.5 STAK-D group activity session volunteers

The STAK-D group activity sessions will be led by the researcher and up to four trained volunteers. Volunteers will be pre-registered HCPs, with Disclosure and Barring Service (DBS) clearance and trained in delivery of the STAK-D and treatment of T1DM. There will be at least one volunteer per three children and their role is to encourage and support the children, assist with counting and scoring activities, provide easier or harder alternatives to activities and monitor the children's physical state (e.g., looking for signs of hyper- or hypoglycaemia).

7.3.1.6 Motivational interview

During the first two weeks of the intervention period, children will be involved in a one-to-one session with the researcher based on the principles of motivational interviewing (MI) (Rollnick et al., 2008). The original STAK programme implemented the MI at the end of the intervention, with a selected sub-set of the intervention group (Chapter 1, Section 1.7.1.5). The STAK-D programme schedules the MI at the start of the intervention with every child in the intervention group to establish each child's perceptions of physical activity and readiness to change. The researcher is trained in MI techniques. The content of the MI will be delivered as described for the original STAK programme.

7.3.1.7 STAK-D Parent's booklet

A booklet for parents, developed by the researcher for the STAK-D programme, provides parents with information and advice about safe participation in physical activity. The inserts include: *How active should my child be?*; *Why is it good to be active?*; *Are there benefits for diabetes?*; *What can I do to help my child keep active?*; *What can I say to help my child keep active?*; and *Tips for being active with diabetes*. 'Top Tips' are provided throughout the booklet, such as: "Speak to your child's diabetes team about managing blood glucose levels when having a physically active lifestyle." The aim of the parent's booklet is to engage parents in their child's pursuit of an active lifestyle. It seeks to encourage parents to think about providing an environment for their child that promotes intrinsic motivation and self-efficacy towards physical activity, e.g., emphasising the importance of enjoyment and praising effort rather than outcomes. All the information contained within the parent's booklet has been reviewed and approved by HCPs at the diabetes clinic.

Table 20 Comparison of the original and adapted STAK-D programme content

Original STAK programme content (Glazebrook et al., 2011)	**STAK-D programme adapted content**
Activity diary (weeks 1-10)	Activity diary: Information aimed specifically at T1DM (weeks 1-6)
Information letters home to parents	Parent's Booklet (weeks 1-6)
STAK street dance DVD (weeks 1-10)	STAK street dance DVD: No changes made (weeks 1-6)
STAK group activity sessions (circuit training) at school during the school day supervised by volunteers (weeks 4-8)	STAK-D group activity sessions (circuit training) at the weekend in a leisure room situated in the hospital supervised by volunteers trained in T1DM (weeks 1-6)
Pedometer (weeks 4-10)	Pedometer (weeks 1-6)
Motivational Interview with children in the 91st BMI centile at baseline (weeks 8-10)	Motivational Interview with every child (week 1-2)

7.3.1.8 Approval from healthcare professionals

Once developed, the STAK-D programme components were reviewed and approved by HCPs in the paediatric diabetes clinic from which children would be recruited. The resources were distributed to all members of the diabetes team and four HCPs provided feedback: one consultant; two dieticians specialising in paediatric diabetes; and one Clinical Support Worker. Minor adjustments were made to information in the STAK-D activity diary following this feedback.

7.4 Methods

This study followed the structured process evaluation framework proposed by Reelick and colleagues (2011). There is agreement that guidance is required for the conduct of process evaluations for complex interventions (Moore et al., 2015). Yet there is no one-size-fits-all method and numerous frameworks have been suggested (Moore et al., 2015). The framework proposed by Reelick et al. (2011) was chosen for the current study for its systematic and comprehensive guidance for process evaluations at the feasibility stage of development. The framework evaluates three main components of intervention and research processes: i) the success rate of recruitment and quality of the study population; ii) the process of data collection, and iii) the quality of implementation of the intervention (Table 25). These components appropriately addressed the current research aims to focus on the acceptability of the intervention and its evaluation by examining the quantity and quality of what is delivered, rather than reaching conclusions about effectiveness (Moore et al., 2015).

Data were collected through a mixed-methods approach at three time points over the course of the study: baseline (time point 1; T1), immediately post-intervention (time point 2; T2) and three months post-intervention (time point 3; T3) (Figure 14). The data collected at baseline (T1) is reported in Chapter 5 and Chapter 6.

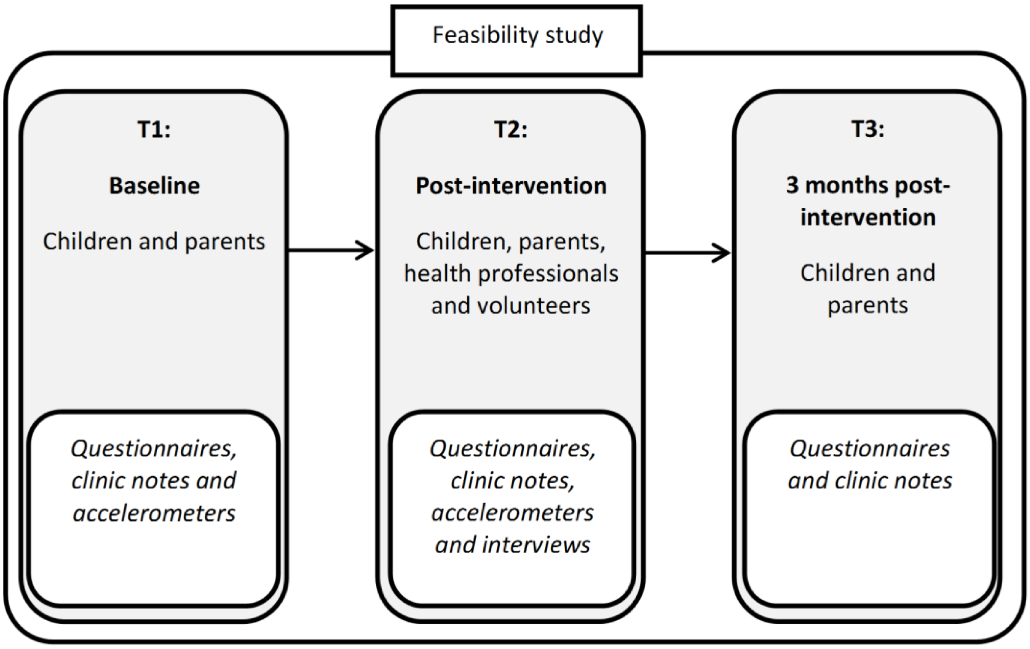

Figure 14 The feasibility study design

7.4.1 Ethical Approval

The study protocol and all prepared study documents were submitted to the Nottingham 1 Research Ethics Committee (REC). The REC meeting was attended by the researcher. Following the meeting, minor revisions were addressed and ethical approval was granted (REC ref 14/EM/0057) (Appendix 8). NHS Trust permissions (R&D approval) were sought from one site in the East Midlands (UK) and granted.

7.4.2 Recruitment of children

Details of the recruitment procedures can be found in Chapter 6, Section 6.3.4. In brief, children were recruited from one paediatric diabetes clinic in the UK. Children aged 9-11 years who had been diagnosed with T1DM for at least three months were eligible.

Those meeting the eligibility criteria were approached via letter and their parents were invited to express their interest in hearing more about the research. Feasibility studies often do not require formal sample size calculations (Thabane et al., 2010); instead a target sample size of 24 was set based on: i) the number of potentially eligible children on the clinic database, ii) estimates of uptake and attrition based on previous research (Faulkner et al., 2010 ; Karlson and Rapoff, 2009), iii) the number felt to be manageable by the researcher, and iv) within budgetary restrictions.

Informed assent and consent was received by 16 children and their parents (Table 21 and Table 22). Thirteen children and their parents completed the baseline questionnaires and 12 agreed to be randomised to a treatment group. One child who chose to complete baseline and follow-up questionnaires and not be randomised was allocated to the control group. All children and parents enrolled onto the study provided informed consent to being interviewed at the end of the intervention period.

Table 21 Children involved in the feasibility study and/or process evaluation (n=13)

Participant*	Group	Years diagnosed	Child's sex	Involved in process evaluation
P01 Amelia	Intervention	8.0	F	✓
P02 Ryan	Intervention	10.6	M	✓
P03 Jay	Control	4.8	M	✓
P04 Calum	Control	3.0	M	✓
P05 Ava	Intervention	2.1	F	
P06 Sophia	Intervention	3.3	F	✓
P07 Matthew	Intervention	5.8	M	✓
P08 Craig	Control	0.4	M	✓
P09 Natasha	Intervention	1.6	F	✓
P10 Daniel	Control	0.8	M	✓
P11 Lauren	Intervention	6.1	F	
P12 Andrew	Control	5.6	M	✓
P13 Rebecca	Intervention	3.4	F	

*All names are fictitious

Table 22 Parents involved in the feasibility study and/or process evaluation (n=13)

Participant*	Group	Sex	Involved in process evaluation
P01 Amelia's mother and father	Intervention	F	✓
P02 Ryan's mother	Intervention	M	✓
P03 Jay's mother	Control	M	
P04 Calum's mother	Control	M	✓
P05 Ava's mother	Intervention	F	
P06 Sophia's mother	Intervention	F	
P07 Matthew's mother	Intervention	M	✓
P08 Craig's mother	Control	M	✓
P09 Natasha's father	Intervention	F	✓
P10 Daniel's father	Control	M	✓
P11 Lauren's mother	Intervention	F	
P12 Andrew's mother	Control	M	✓
P13 Rebecca's mother	Intervention	F	

7.4.3 Recruitment of healthcare professionals

Four HCPs who worked in the clinic used for recruitment had supported the research and were aware of its implementation. They were contacted at the end of the intervention period with an information sheet and consent from and invitation for an interview with the researcher. Verbal consent was received from three HCPS willing to be interviewed (Table 23).

Table 23 Healthcare professionals involved in the process evaluation (n=3)

Participant	Role	Sex
HCP 01	Consultant Paediatrician	F
HCP 02	Diabetes Nurse	F
HCP 03	Diabetes Dietician	F

7.4.4 Recruitment of volunteers

STAK-D group activity session volunteers were targeted from populations of students studying Physiotherapy, Nursing and Medicine at the University of Nottingham. Eight volunteers attended at least one STAK-D group activity session and these volunteers were contacted at the end of the intervention with an information sheet and consent form and invited for an interview with the researcher. Verbal consent was received from seven volunteers willing to be interviewed. A clinical support worker who worked at the diabetes clinic and assisted with the recruitment of children onto this study was also interviewed (n=8; Table 24).

Table 24 Volunteers involved in the process evaluation (n=8)

Participant	Role	Sex
VOL 01	STAK-D volunteer	F
VOL 02	STAK-D volunteer	F
VOL 03	STAK-D volunteer	F
VOL 04	STAK-D volunteer	F
VOL 05	STAK-D volunteer	F
VOL 06	STAK-D volunteer	F
VOL 07	STAK-D volunteer	F
VOL 08	Clinical support worker/ Recruitment	M

7.4.5 Randomisation and blinding

Twelve children were randomised to the intervention or control group after baseline assessments had been completed (Figure 15). It was not possible for the researcher or participants to be blind to the group allocation, but the randomisation process was fully concealed using opaque sealed envelopes. A random sequence of numbers in blocks of four, six, and eight was generated using Microsoft Excel (2010) by an individual with no affiliation to the research study. Labels for each study group were placed into 30 consecutively numbered envelopes.

The first three participants were randomised on a 1:1 basis, after which the allocation ratio changed to 2:1 in favour of the intervention group. This was an attempt to increase rate of recruitment to the intervention group, as a minimum number of children were required to make delivery of the STAK-D group activity sessions viable and to evaluate the STAK-D programme. A new set of opaque envelopes in blocks of three were prepared to reflect the change in allocation ratio.

On completion and return of the baseline questionnaires, an envelope was labelled with the participant number and envelopes were opened by the researcher in groups of three. All participants were informed of their treatment group allocation immediately before the start of the intervention. Blinding of outcome assessors was also not possible; all outcome data were collected and analysed by the researcher, who also delivered the intervention. Whilst this heightened the risk of bias, it was an appropriate pragmatic decision given the research and resource restrictions.

7.4.6 Intervention implementation

The intervention used in this research was the STAK-D programme, adapted from an empirically tested physical activity programme targeted at school children aged 9-11 years with barriers to physical activity such as low exercise self-efficacy, overweight or asthma (Glazebrook et al., 2011 ; McWilliams, 2014). The adapted STAK-D programme has been described in (Section 7.3) of this chapter.

7.4.7 Process evaluation interviews

Semi-structured interviews were conducted by the researcher at T2 to explore children's, parents', HCPs' and volunteers' perceptions of the acceptability of the intervention. Interviews were chosen as a means of exploring perceptions of the research process and intervention acceptability and to provide participants an opportunity to confidentially share their views. The researcher conducted the interviews, which although gave potential for bias, was considered appropriate given that rapport had been established with the interviewees and resource limitations meant that an independent interviewer could not be used.

All children except one who had explicitly withdrawn from the study (n=12) and their parents (n=12) were invited for an interview. The researcher was unable to make contact with three parents, who were considered 'lost to follow-up'. Eight children were interviewed face-to-face either at the child's home (n=5) or at the clinic (n=3) and one child responded to the same questions via a survey due to being unable to commit to a verbal interview (intervention group n=5, control group n=4). Eight parents were interviewed on a separate occasion via telephone (intervention group n=4, control group n=4). Interviews with HCPs and volunteers were conducted over the telephone and the interview with the clinical support worker was conducted face-to-face.

All interviews were conducted within two months of the end of the intervention. Interviews followed an interview guide and separate schedules were used for each participant group. An extended interview guide was used with children and parents in the intervention group (Appendix 19 and Appendix 20). Interviews helped to address and add depth to the process evaluation criteria in Table 25. Specifically, they sought to evaluate the acceptability of research processes such as recruitment and data collection and participants' opinions of the STAK-D programme content and structure (if applicable), including how they perceived these processes could be improved.

Interviews with parents, HCPs and volunteers were recorded on an Olympus Dictaphone with permission from the interviewee. Children's answers were transcribed verbatim during the interview rather than being audio recorded. Although this led to inconsistency in methodology, it was deemed an appropriate pragmatic decision to facilitate the flow of conversation between the child and interviewer. As such, interview durations with children were not recorded. All interviews were transcribed verbatim and anonymised. The duration of interviews with parents ranged from 18 to 46 minutes (mean=29.5 minutes) among those in the intervention group and 6 to 18 minutes (mean=12 minutes) with those in the control group. The interview duration with HCPs ranged from 11 to 30 minutes (mean=27 minutes) and with volunteers 11 to 24 minutes (mean=15.7 minutes).

7.4.8 Outcome measures

This study explored a series of process evaluation measures. The process evaluation used mixed-methods to evaluate both the intervention and the research processes. The framework proposed by Reelick and colleagues (2011) was used to evaluate the study sample, data collection and intervention implementation components of the research. Each main evaluation component was assessed by several measures and variables. Table 25 shows each component and its related measures and variables assessed.

Table 25 Process evaluation components and related process measures of an intervention adapted from Reelick et al. (2011).

Evaluation component	Process measures	Process variables
Research processes: Study sample	Recruitment rate	• Number of potentially eligible participants in target population • Number of participants meeting the inclusion criteria • Number of participants recruited • Number of children who self-referred versus number recruited in the clinic
	Barriers and facilitators to recruitment process	• Motivation for participation • Reasons for non-participation • Experience of recruitment: time taken to recruit
	Follow-up rate	• Number of participants completing follow-up assessments versus number started
	Barriers and facilitators for follow-up	• Reasons for drop-out • Motivation for continued participation
Research processes: Data collection	Completeness of data collection	• Number and characteristics of missing data • Feasibility of outcome measures to detect change over time • Reasons for missing data
	Barriers and facilitators for data collection	• Burden of completing outcome measures • Rate of questionnaire completion • Geographical spread of where participants live • Time needed to collect and analyse data
Intervention processes: Intervention implementation	Delivery of intervention components	• Participant satisfaction • Volunteers' opinions
	Barriers and facilitators for delivery of intervention	• Reasons for diverging from protocol • Cost of resources and intervention materials • Experience of implementation: researcher reflections
	Adherence to intervention	• Number of children using the intervention materials • Number of children attending group activity sessions
	Barriers and facilitators for adherence to intervention	• Motivation for compliance and attendance • Reasons for lack of compliance and/or attendance
	Experience of the intervention	• Perceived benefit • Strong and weak aspects of the intervention • Adverse events

7.5 Research processes

7.5.1 Study sample

Evaluation of the study sample determined the success of the research participant selection process. It sought to give insight into the quality of the recruitment, characteristics of those included, presence of selection bias, and barriers and facilitators for recruitment.

7.5.1.1 Recruitment rate and barriers and facilitators to recruitment

Recruitment rate was defined as the number of eligible participants who enrolled on the research from those who self-referred via the expression of interest form or were recruited in clinics. Frequency counts of the number of participants recruited were conducted and the overall rate of recruitment was calculated. A recruitment rate of between 25-40% would be considered reasonable based on similar research (Faulkner et al., 2010 ; McWilliams, 2014). The feasibility of the randomisation procedure used was also explored via group characteristics and interviews with participants. Interviews also explore participants' motivations for and against involvement in the research. Researcher observations and reflections were used to evaluate the experience of the recruitment process, including the time taken to recruit a sufficient number of participants.

7.5.1.2 Retention rate and barriers and facilitators for follow-up

Retention was defined as the number of participants completing the STAK-D programme including all scheduled follow-up data collection (T1, T2 and T3) compared to the number who started. A retention rate of at least 70% at each time point would be considered feasible based on similar studies (Faulkner et al., 2010 ; Salem et al., 2010a). Interviews sought to explore participants' motivation for continued participation and wherever possible and appropriate, reasons for discontinuation.

7.5.2 Data collection

Evaluation of the data collection process aimed to explore the appropriateness of the outcome measures, the completeness of the data and characteristics of missing data.

7.5.2.1 Completeness of data collection and barriers and facilitators for data collection

For the questionnaire outcome measures, frequency counts of missing items were conducted at all data collection periods. The criterion for feasibility was met if less than

10% of items on each of the questionnaires were missing; the likely threshold for imputation in a definitive trial. Reasons for missing data were explored. Parents' perceived burden of completing the questionnaires was explored at T1 via a short five-item survey produced by the researcher. Perceived burden questions explored i) the time taken for questionnaire completion, ii) readability, iii) comprehensiveness of the questionnaires, iv) whether children required assistance, and v) other comments about the questionnaires. The rate of questionnaire completion (i.e., time taken to return questionnaires), time needed to collect and analyse data and geographical spread of participants were recorded.

Evaluation of data collection also explored the ability of the outcome measures to detect change in outcomes over time. The measures used in this study were: objective clinical data collected from clinic notes (height, weight, glycated haemoglobin (HbA1c)); accelerometer-measured moderate-to-vigorous physical activity (MVPA); a physical activity questionnaire (PAQ) (Appendix 10); the children's self-perceptions of adequacy in and predilection for physical activity scale (CSAPPA; Hay (1992), Appendix 13); and the parental hypoglycaemia fear survey (PHFS; Gonder-Frederick et al. (2006), Appendix 15). All outcome measures have been described in Chapter 5 (Section 5.6.5) and Chapter 6 (Section 6.3.6). The primary outcome measure was children's self-efficacy for physical activity, as measured by the CSAPPA scale.

7.6 Intervention processes

7.6.1 Intervention implementation

The evaluation of the intervention involved exploring whether the STAK-D programme could be delivered as per the research protocol and whether it was feasible and acceptable for participants involved.

7.6.1.1 Delivery of the intervention and barriers and facilitators for delivery

The evaluation of the delivery of the intervention sought to determine whether each component of the STAK-D programme was delivered as intended and explore reasons for diverging from the protocol. It sought to identify successful components of the intervention perceived by children and their parents and their recommendations for future implementation. The evaluation also explored HCPs' and volunteers' perceptions of the programme, including what helped and hindered its delivery. The intervention's cost effectiveness was evaluated by costing resources and intervention materials (e.g., equipment, STAK-D programme materials).

7.6.1.2 Adherence to the intervention and barriers and facilitators for adherence

Adherence was defined as engagement with one or more components of the STAK-D programme, including; reading the information provided in the STAK-D diary or parent's booklet, use of the street dance DVD, logging activities in the STAK-D diary, use of the pedometer and step-count log, and attendance at the STAK-D group activity sessions. Adherence was monitored via telephone calls, emails, text messages or face-to-face meetings. Attendance at group activity sessions was defined as the number of group based sessions attended and completed. Interviews with children and parents sought to explore participants' motivations for compliance and attendance and the reasons for non-adherence to the STAK-D programme components.

7.6.1.3 Experience of the intervention

Participants' experiences of the intervention were explored through interviews with children and parents. Interviews sought to elicit participants' satisfaction, perceived acceptability, perceived benefits, and recommendations for implementation of the STAK-D programme and its individual components. Adverse events experienced as a result of participation in the intervention were also evaluated. Serious adverse events were defined as any serious negative outcome resulting from the physical activity undertaken as part of the STAK-D programme. Light or mild episodes of hypo- or hyperglycaemia were not considered serious adverse events due to them being a common side-effect of insulin therapy.

7.7 Data Analysis

7.7.1 Quantitative data analysis strategy

Descriptive statistics were used to describe the sample characteristics, recruitment rates, retention rates, rates of completion, attendance and adherence rates (frequencies, percentages, means and standard deviations). Quantitative outcome data were analysed using IBM Statistical Package for the Social Sciences (SPSS) version 22 (SPSS Inc., Chicago, IL, USA). For the outcome measures, all data were checked for extreme values and boxplots were visually scanned for outliers. The mean and standard deviation (SD) were reported for normally distributed outcome measures and median and interquartile range (IQR) for non-normally distributed data.

To explore whether the primary outcome measure (self-efficacy) was sensitive to change over time, the difference in mean scores from T1 to T2 and from T1 to T3 were calculated (T2 minus T1, T3 minus T1). Adjusted effect size (ES) (Hedges g) was calculated to account for the small sample size. The magnitude of effects sizes were interpreted using Cohen's (1988) criteria of; .2 as small, .5 as moderate and .8 as large. For the non-normal data, differences in median values were reported.

Independent t-tests analysed the difference in mean scores between the intervention and control group at T2 and T3 for the primary outcome of self-efficacy. The data were not powered to detect statistically significant differences between groups; instead the focus was on estimates of effect size (Hedges g) and 95% confidence intervals (CI). P-values are reported for completeness ($p \leq .05$).

Participants who withdrew from the research were removed from post-intervention analysis, but retained for baseline assessment unless they had specifically requested that their data be withdrawn.

7.7.2 Qualitative data analysis strategy

Thematic analysis was used to analyse the data from the process evaluation interviews (Braun and Clarke, 2006). Thematic analysis has been explained in detail in Chapter 3. In brief, the researcher sought to code meaningful groups of data into themes that captured participants' experience of the research process and intervention, the acceptability of the intervention and suggestions for improvement. These evaluation aims generated initial ideas for themes (deductive), but these were refined during analysis as the data emerged (inductive). The qualitative software package NVivo version 10 (QSR International Pty Ltd., 2012) facilitated the organisation of interview data and the identification of relevant quotations to illustrate the main findings. Verbatim quotations are presented in the results to illustrate themes, with details of the respondent in parentheses.

7.8 Results

7.8.1 Study sample

The study sample has been described in detail in Chapter 6, Section 6.6.1. This section will describe the same sample, with particular attention to details relevant for the process evaluation.

7.8.1.1 Recruitment rate and barriers and facilitators to recruitment

Sixty-four children were identified as potentially eligible from the population of children in the clinic. A total of 50 children were eligible plus three more who became eligible during the recruitment period. Reasons for not meeting the eligibility criteria included being aged >11 years, 10 months (n=9), diagnosed <3 months (n=2), deemed unable to participate by their doctor (n=2) and not speaking English (n=1). Invitation packs were distributed to 53 children and 30 parents expressed an interest to hear more about the research (57% of those eligible), five of those via the expression of interest form (17%) and 25 via a meeting with the researcher at their routine clinic appointment (83%). Reasons for refusal were explored wherever possible and these included; i) the child already being very physically active, ii) the family having too many other commitments, iii) current or recent involvement in other research, and iv) the presence of other conditions that would make participation difficult (Figure 15).

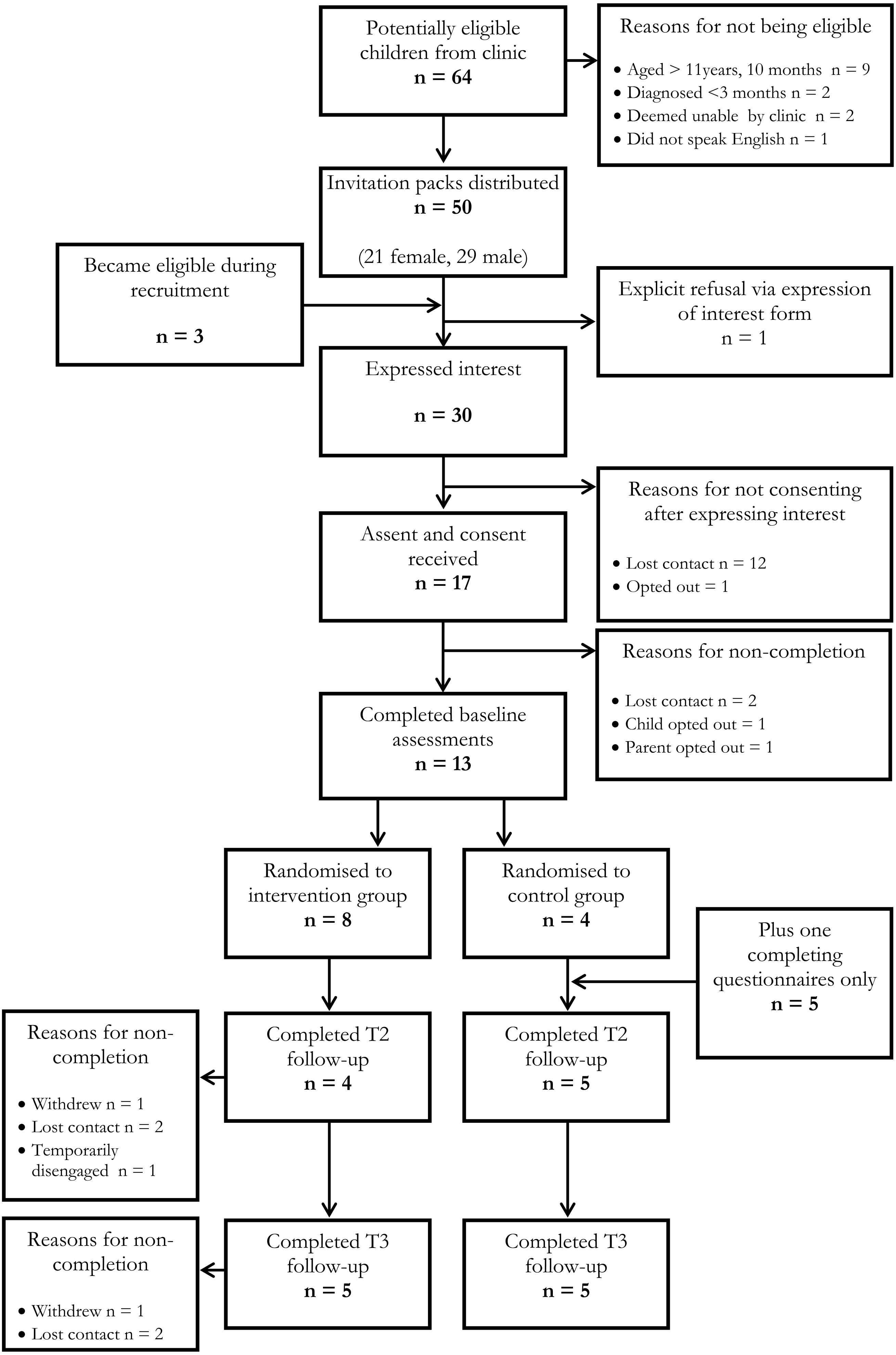

Figure 15 Feasibility study recruitment flowchart

Of the 30 interested children, 17 gave assent and consent to participate (57% of those interested). Assent and consent was not received from 13 interested children due to loss of contact (n=12) and one opted out. Contact was lost with a further two enrolled participants and two more opted out, leaving 13 participants in the final sample (76% of those recruited, 43% of those interested, 25% of those eligible). After four months of recruitment, a sufficient number of participants (n=13) had been recruited and randomised to enable commencement of the intervention and which point recruitment ceased.

Data were available for the population of children aged 9-11 years from the paediatric diabetes clinic from which children were recruited. The participants in this study were similar to the non-participating children with regards body mass index (BMI) and HbA1c (see Chapter 6, Section 6.6.1 for further discussion).

Recruitment involved a combination of direct (i.e., through clinics) and non-direct (i.e., through postal invite) methods. Parents were mixed in their perceptions of the recruitment methods. Four parents believed that the invitation letter allowed them to feel more informed when later approached by a researcher in the clinic. Four parents were happy to be approached by a researcher at their routine clinic appointment. One mother described her preference for this method:

> *I think if I'd have just received a letter in the post, not knowing much about it, I probably would've just left it to one side and not bothered. Whereas actually meeting you in clinic it sort of pushed us…more than just receiving a letter.*

P07 Matthew's mother, INT

The majority of children (78%) could remember discussing the research with their parents before deciding to take part, but children did not comment on the recruitment method.

Self-selected samples tend to be motivated to participate in research. One HCP described how, *"The [children] that we are really trying to get motivated, they're just on all levels harder to engage and involve in anything really" (*HCP 02, Nurse*).* Understanding what motivates people to be involved in research could help towards engaging those who are less likely to enrol onto research studies or intervention programmes. Interviews with children and their parents explored their motivation for participation. Generally, children were interested and excited by physical activity and the desire to *"know how active I am"* (P07, INT) and, *"see how much activity I am doing"* (P09, INT). Parents displayed more diverse motivations for participation which could be grouped into two subthemes; i) personal motivation and ii) advancing knowledge. The most common motivation, held by the majority of parents (75%) was personal motivation. Parents valued the chance to gain feedback into how active their child was and its effects on blood glucose levels, e.g., *"you can track how much exercise he is doing, so I think that's interesting to see how that affects him and blood sugar levels"* (P08 Craig's mother, CONT). Two parents were personally motivated to use the research to encourage their child to be active, e.g.:

> *I'm just always for anything which encourages Calum to be active and think about being active and just liked the idea that you were trying to see how kids responded to activity and to do some research into that area.*
>
> P04 Calum's mother, CONT

Four (50%) parents described being motivated by the opportunity to help towards advancing knowledge about T1DM. For example parents would refer to helping others, *"Anything that can help another child with diabetes live a normal life"* (P01 Amelia's father, INT).

The HCPs from the recruitment clinic had expected a higher recruitment rate, but acknowledged that, *"it's quite a difficult client group to target"* (HCP02, Nurse). The clinical support worker who helped with recruitment gave a possible reason for why children with T1DM might be difficult group to target:

> *[The clinic] take part in a lot of research, it's like some [families] felt like they'd done their bit, been bombarded over the years with research and had enough of filling forms in. So just sort of, didn't want to do it this time.*
>
> Volunteer (VOL08)

All three HCPs indicated that they '*could have done more to help support*' (HCP03, Dietician) the research. For example, when reflecting on the recruitment rates, the dietician stated;

> *[the research] had a good set-up, but the recruitment wasn't great, so it's whether as a clinic we could have done more to help support [the researcher] with that… As a team we didn't do enough to remind [the patients]…sending letters out about research, [families] don't respond, but when we mention it in clinic, they're quite excited and more than happy to do it.*

Dietician (HCP03)

The volunteer involved in recruitment echoed this, *"I think [the diabetes team] actively need to discuss the research more … if we're going to be actively involved in research we need to be more engaged with it"* (VOL08). The parents' perceptions were consistent with this; all parents said the research had never been discussed with their diabetes team. This implies that there is scope for clinic staff to endorse and promote the research which may stimulate interest among potential participants at the recruitment stage.

7.8.1.2 Feasibility of randomisation procedure

The groups did not differ significantly on any outcome variables at baseline and all participants reported satisfaction with the study group they were allocated to.

7.8.1.3 Retention rate and barriers and facilitators for follow-up

Retention referred to the number of participants completing follow-up assessments compared with the number started. The retention rate was 69% at T2 and was 77% at T3, meaning fewer (n=1) children completed the immediate post-intervention assessment (T2) compared with the longer-term follow-up (T3) (Table 26). Reasons for non-completion of outcome measures were recorded. One participant withdrew from the research, two participants disengaged and the researcher was unable to establish contact and one participant temporarily disengaged due to personal issues. At T3, the participant who had temporarily disengaged at T2 engaged, meaning the completion rate of 77% would be considered acceptable.

Interviews with children and parents explored motivation for continued participation in the research. For children in the control group, the primary motivator was seeing the results from the activity monitor. Three children in the intervention group were also interested *"to see how active"* (P07 Matthew, INT) they were and another child in the intervention group stated, *"because it's [the STAK-D programme] fun… I'm going to carry on"*

(P09 Natasha, INT). Parents' motivations for continued participation were similar to their children's as they felt motivated by the feedback they would receive about their child's level of physical activity. Additionally, two parents valued the low level of perceived burden and commitment involved in their participation in the research, as highlighted by, *"we've not had to put ourselves out to do it, you've come to us that's been nice, you coming to us, not asking us to come over here and do this and that…has made a big difference"* (P01 Amelia's mother, INT).

Table 26 Rates of recruitment, completion, drop-out, attendance and adverse events

	Whole group	Intervention group	Control group
Recruitment (% of those interested)	17 (57%)	-	-
Number of completers (retention)			
T1 (% of those recruited)	13 (76%)	8	5
T2 (% of the sample)	9 (69%)	4 (50%)	5 (100%)
T3 (% of the sample)	10 (77%)	5 (63%)	5 (100%)
Rate of questionnaire return (days)			
T1 (postal)	21.5	20.6	22.8
T2 (home-visits)	4	0	8
T3 (postal)	21.9	26.2	17.6
Number of drop-outs	3	3	0
Attendance at activity sessions			
Week 1	-	2 (25%)	-
Week 2	-	2 (25%)	-
Week 3	-	3 (38%)	-
Week 4	-	3 (38%)	-
Week 5	-	1 (13%)	-
Adverse events	0 (0%)	0 (0%)	0 (0%)

7.8.2 Data collection

7.8.2.1 Completeness of data collection

Questionnaires were checked for completeness and reasons for missing data were explored. If the researcher was present on completion of questionnaires, the missing data was completed immediately. Missing data was described in a logbook in an effort to determine whether it was missing at random. At T1, entire CSAPPA questionnaires were completed incorrectly by two children. Thereafter, additional instructions were always provided with the CSAPPA scale. At T2, one set of completed questionnaires were reported as 'missing in the post'.

During data processing, a visual scan of the data identified single items as missing. The missing items appeared at random and thus the most appropriate imputation strategy was considered to be a single imputation method. For the CSAPPA scale the mean of the subscale for that person (mean imputation) was used. For the PAQ a missing value was considered no activity. For missing data in the PHFS, only the questions answered were used in analyses.

7.8.2.2 *Burden of completing outcome measures*

Clinical data (height, weight, HbA1c) were retrieved by the researcher from clinic notes via the clinical support worker at each time point with ease. To help assess the level of burden for participants to complete the set of questionnaires, a short questionnaire was administered at T1. This perceived burden questionnaire revealed that it took six participants (46%) between 11-20 minutes to complete the set of questionnaires, for four participants it took less than 10 minutes and for three participants it took up to 30 minutes. Five (38%) of the parents reported that their child needed adult assistance to complete the questionnaires. Interviews with children and parents also explored the perceived burden of completing outcome measures. Parents suggested that the wording of questions was sometimes difficult to understand, but generally the questionnaires were received by children and parents with little burden. Participants' evaluation of the accelerometer has been described in Chapter 5, Section 5.7.

7.8.2.3 *Time needed to collect and analyse data*

Most participants preferred to take the questionnaires home for completion as the clinic setting was not always conducive (e.g., disruptions and lack of time). Based on the questionnaire return rates (Table 26), home-visits were considered the most timely way to distribute and collect outcome measures, but the benefits of doing so were offset by the time, commitment and resources needed by the researcher to travel to participants' homes.

7.8.2.4 *Feasibility of outcome measures to detect change*

Table 27 shows the change in mean scores from T1 to T2 and from T1 to T3 in outcome measures.

Self-efficacy for physical activity

From T1 to T2, the CSAPPA scale detected a two point increase in total CSAPPA score in the intervention group which equated to a small-to-moderate effect size of 0.3. Whereas over the same period the control group showed a five point decrease in total CSAPPA score which equated to an effect size of -0.4. However, the improvement for the intervention group was not maintained to T3. The adequacy subscale followed a similar pattern to the total CSAPPA scores, with the intervention group demonstrating an improvement from T1 to T2 (0.5 effect size) that was not maintained at T3. Predilection scores remained relatively stable across all time points in the intervention group, whereas the scale detected a reduction in the control group's predilection score over time (reduction of -3.75 between T1 and T2, ES= -0.6). The enjoyment subscale remained relatively stable over time, except for a detected decrease between T1 and T3 in the intervention group (-1.37, ES= -0.7).

Accelerometer-derived MVPA

Between T1 and T2, the accelerometers were able to detect a 15 minute, 17 minute and 14 minute decline in MVPA in the whole group, intervention group and control group, respectively. The ability for the accelerometer to detect change over time has been discussed in Chapter 5, Section 5.8.

Self-reported physical activity

The self-reported physical activity suggested that physical activity decreased between T1 and T2 in all groups, but the largest change was observed in the intervention group (-4.78, ES= -0.5). Change over time between T1 and T3 suggested that lower self-reported activity levels in the intervention group at T2 were not maintained (2.02, ES= 0.2). Self-reported sedentary behaviour scores remained relatively stable across time in both groups, with the exception of a three point increase in sedentary behaviour score in the intervention group between T1 and T3 (2.65, ES= 0.6).

Clinical outcomes

Changes in clinical outcomes (BMI and HbA1c) were modest in all participants across all time points.

Parental fear of hypoglycaemia

The median scores are presented for the PHFS due to the non-normal distribution of the data (presence of outliers in the data). The PHFS detected modest change in median score in the whole group between T1 and T2. Most change was detected in the intervention group. Between T1 and T2 the PHFS detected an increase in worry score (+7.90) and a decrease between T1 and T3 (-6.00).

Table 27 Change in mean scores from T1 to T2 and from T1 to T3 in outcome measures

Outcome	Group	T1		T2		T3		T1-T2		T1 –T3	
		Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Difference (ES†)	95% CI for difference	Difference (ES†)	95% CI for difference
Physical activity MVPA (minutes)	Whole	**84.82 (26.94)**	11	**69.46 (24.16)**	8	-	-	**-15.36 (-0.57)**	-40.68, 9.96	-	-
	INT	**83.59 (27.25)**	7	**66.15 (18.67)**	4	-	-	**-17.44 (-0.64)**	-52.49, 17.61	-	-
	CONT	86.98 (30.42)	4	72.78 (31.38)	4	-	-	-14.20 (-0.40)	-67.67, 39.27	-	-
Self-report activity Physical activity	Whole	**54.10 (8.47)**	13	**49.63 (5.01)**	8	54.30 (7.86)	10	**-4.47 (-0.58)**	-11.42, 2.48	0.20 (0.02)	-6.99, 7.39
	INT	**56.78 (9.10)**	8	**52.00 (5.42)**	4	58.80 (7.46)	5	**-4.78 (-0.54)**	-15.93, 6.37	2.02 (0.22)	-8.70, 12.74
	CONT	49.80 (5.72)	5	47.25 (3.77)	4	49.80 (5.72)	5	-2.55 (-0.45)	-10.45, 5.35	0.00 (0.00)	-8.34, 8.34
Sedentary behaviour	Whole	20.31 (4.33)	13	21.00 (4.14)	8	21.70 (4.08)	10	0.69 (0.16)	-3.32, 4.70	1.39 (0.32)	-2.31, 5.09
	INT	**21.75 (4.98)**	8	22.75 (2.99)	4	**24.40 (3.13)**	5	1.00 (0.21)	-5.11, 7.11	**2.65 (0.56)**	-2.87, 8.17
	CONT	18.00 (1.41)	5	19.25 (4.79)	4	19.00 (3.08)	5	1.25 (0.34)	-4.00, 6.50	1.00 (0.38)	-2.49, 4.49
Self-efficacy Total CSAPPA	Whole	60.82 (7.10)	11	58.88 (9.49)	8	58.80 (9.14)	10	-1.94 (-0.23)	-9.95, 6.07	-2.02 (-0.24)	-9.46, 5.42
	INT	61.71 (5.71)	7	63.50 (4.65)	4	58.60 (9.81)	5	1.79 (0.30)	-5.84, 9.42	-3.11 (-0.38)	-13.05, 6.83
	CONT	59.25 (9.88)	4	54.25 (11.47)	4	59.00 (9.57)	5	-5.00 (-0.41)	-23.52, 13.52	-0.25 (-0.02)	-15.64, 15.14
Adequacy	Whole	21.55 (3.11)	11	21.63 (3.78)	8	21.40 (3.44)	10	0.08 (0.02)	-3.83, 3.99	-0.15 (-0.04)	-3.64, 3.34
	INT	**22.43 (1.81)**	7	**23.50 (2.38)**	4	21.60 (3.97)	5	**1.07 (0.48)**	-1.79, 3.93	-0.83 (-0.27)	-4.58, 2.92
	CONT	20.00 (4.55)	4	19.75 (4.27)	4	21.20 (3.27)	5	-0.25 (-0.05)	-7.88, 7.38	1.20 (0.28)	-4.94, 7.34
Predilection	Whole	28.82 (4.12)	11	27.25 (4.80)	8	27.50 (5.28)	10	-1.57 (-0.34)	-5.90, 2.76	-1.32 (-0.39)	-4.31, 1.67
	INT	28.71 (3.99)	7	29.25 (2.75)	4	27.80 (5.36)	5	0.54 (0.14)	-4.60, 5.68	-0.91 (-0.18)	-6.89, 5.07
	CONT	**29.00 (4.97)**	4	**25.25 (5.97)**	4	27.20 (5.81)	5	**-3.75 (-0.59)**	-13.25, 5.75	-1.80 (-0.28)	-10.37, 6.97
Enjoyment	Whole	10.45 (1.57)	11	10.00 (2.07)	8	9.90 (1.91)	10	-0.45 (-0.24)	-2.21, 1.31	-0.55 (-0.30)	-2.14, 1.04
	INT	**10.57 (1.72)**	7	10.75 (1.50)	4	**9.20 (2.17)**	5	0.18 (0.10)	-2.16, 2.52	**-1.37 (-0.66)**	-3.87, 1.13
	CONT	10.25 (1.50)	4	9.25 (2.50)	4	10.60 (1.52)	5	-1.00 (-0.42)	-4.57, 2.57	0.35 (0.21)	-2.05, 2.75
Parent FOH * Total PHFS	Whole	40.00 (21.05)	13	39.50 (17.75)	8	36.00 (18.00)	10	-0.50	-19.21, 18.21	-4.00	-52.71, -6.79
	INT	40.95 (25.00)	8	47.06 (19.71)	4	33.00 (35.50)	5	6.11	-26.01, 38.23	-7.95	-44.66, 28.76
	CONT	36.00 (18.55)	5	39.50 (16.75)	4	39.00 (14.00)	5	3.50	-24.74, 31.74	3.00	-20.97, 26.97
Worry	Whole	15.00 (17.00)	13	17.50 (17.00)	8	14.00 (16.25)	10	2.50	-13.49, 18.49	-1.00	-15.59, 13.59
	INT	18.00 (17.50)	8	25.90 (18.96)	4	12.00 (29.50)	5	7.90	-16.59, 32.39	-6.00	-34.37, 22.37
	CONT	14.00 (17.00)	5	17.50 (9.75)	4	15.00 (11.00)	5	3.50	-19.26, 26.26	1.00	-19.88, 21.88
Behaviour	Whole	20.90 (7.50)	13	22.00 (2.50)	8	21.00 (7.50)	10	1.10	-4.68, 6.88	0.10	-6.46, 6.66
	INT	22.45 (12.00)	8	22.00 (0.75)	4	21.00 (9.00)	5	-0.45	-14.16, 13.26	-1.45	-15.26, 12.36
	CONT	20.90 (5.00)	5	22.50 (9.00)	4	24.00 (9.00)	5	1.60	-9.50, 12.70	3.10	-7.52, 13.72

* Median (IQR); † hedges g

Note: data in **bold** represent effect sizes of 0.50 and above

BMI = body mass index; CI = confidence interval; CONT = control group; CSAPPA = children's self-perceptions of adequacy in and predilection for physical activity scale; ES = effect size (Cohen's d, r); FOH = fear of hypoglycaemia; HbA1c = glycosylated haemoglobin; INT = intervention group; IQR = inter-quartile range; MVPA = moderate-to-vigorous physical activity; PHFS = parental hypoglycaemia fear survey; SD = standard deviation.

Table 28 shows the difference between the intervention and control group in the CSAPPA scale subscales. Large effect sizes in favour of the intervention group were found at T2 (total self-efficacy ES=0.9; adequacy ES=0.9; predilection ES=0.8; and enjoyment ES=0.6), but the differences were not maintained at T3.

Table 28 Difference in self-efficacy scores between intervention and control groups at T2 and T3

	INT			CONT					
T2	M	SD	n	M	SD	n	ES (g)	t (df) and 95% CI of the difference	P
Total self-efficacy	63.50	4.65	4	54.25	11.47	4	0.9	t = -1.49 (6), (-24.40 to 5.90)	.186
Adequacy	23.50	2.38	4	19.75	4.27	4	0.9	t = -1.53 (6), (-9.73 to 2.23)	.176
Predilection	29.25	2.75	4	25.25	5.97	4	0.8	t = -1.22 (6), (-12.04 to 4.04)	.269
Enjoyment	10.75	1.50	4	9.25	2.50	4	0.6	t = -1.03 (6), (-5.07 to 2.07)	.343
T3									
Total self-efficacy	58.60	9.81	5	59.00	9.57	5	-0.0	t = .065 (8), (-13.73 to 14.53)	.950
Adequacy	21.60	3.97	5	21.20	3.27	5	0.1	t = -.17 (8), (-5.71 to 4.91)	.866
Predilection	27.80	5.36	5	27.20	5.81	5	0.1	t = -.17 (8), (-8.75 to 7.55)	.869
Enjoyment	9.20	2.17	5	10.60	1.52	5	-0.7	t = 1.18 (8), (-1.33 to 4.13)	.271

NB: g = Hedges g

7.8.3 Intervention implementation

7.8.3.1 Delivery of the intervention

All eight children in the intervention group received the STAK-D programme resources as planned; i) children's activity diary, ii) street dance DVD, iii) pedometer, and iv) parent's booklet. In addition to the home-based resources, motivational interviews took place with six children (two children had disengaged from the research). The clinic waiting area was not deemed a suitable environment for the MI component due to time limitations at clinic appointments and noise levels. Therefore, successful implementation of MI was dependent on home-visits which limited the frequency of sessions to one in-depth session per child due to the significant investment of time. Nevertheless, the researcher (STAK-D programme deliverer) considered the MI component to be fundamental in eliciting the children's understanding of physical activity, including their perceptions of the perceived barriers and facilitators to participation, and their readiness to make changes to their current level of activity.

Six group activity sessions were planned and five were delivered due to children's lack of availability for the sixth session (see Section 7.8.3.5 for attendance). Group activity sessions were delivered by the researcher and volunteers. According to the volunteers interviewed, successful delivery of the activity session was determined by the organisation of the session and sufficient numbers of children.

7.8.3.2 The organisation of the group physical activity session

All volunteers gave a positive evaluation of the organisation of the activity sessions and activities within the session. The variety of activities was considered to be appealing for children. The scheduled breaks for water and blood glucose testing were perceived as beneficial to the successful delivery of the group activity sessions. Two volunteers suggested that the delivery of the activity session would benefit from more stringent rules for blood glucose testing as there appeared to be some inconsistency in children meeting the expectation of doing frequent blood glucose testing. For example; "*When measuring glucose levels, some of the children did it before, some during, it wasn't consistent, it didn't appear that way, so I didn't know if that could've been stricter*" (VOL04).

This point was also raised by one of the HCPs who agreed that future implementation of the group activity sessions would benefit from *"ground rules and expectations"* from the child's doctor about blood glucose testing:

> *A statement from the doctor to say I've discussed this with the [diabetes] team and these are some recommendations that they think it's important that we all do today…so it's not [the researcher/STAK-D deliverer] advising, but you passing on the information from us… you will test beginning, during and end, something just to make it more formal.*

Dietician (HCP03)

7.8.3.3 *Sufficient numbers of children*

Over half of the volunteers believed that having more children attend the group activity session would benefit its delivery and might encourage children to make friends. For example, *"if there were more children there, so a busier environment, children could've made friends through exercise"* (VOL04). Children and parents did not comment on the numbers of children attending group activity sessions.

7.8.3.4 *Estimated cost of delivery*

Implementation of the research processes (i.e., data collection) was estimated at £250-£300 per participant, based on the cost of one accelerometer (with the added cost of computer software). Future implementation of this research would also need to consider the cost of researchers, researcher training and travel for home-visits (if applicable). The cost of the STAK-D programme was estimated at £8.75 per participant for the home-based resources (STAK-D activity diary; pedometer, parent's booklet). The equipment for the STAK-D group activity sessions was estimated at a single cost of £500. Future implementation of this research would also need to consider the cost of hiring space for the group activity session and participant travel expenses, if applicable.

7.8.3.5 *Adherence to intervention*

Some components of the STAK-D programme were adhered to better than others. Children used the pedometer and step-count log and the STAK-D activity diary more than they used the street dance DVD and group activity sessions (Table 29).

Table 29 shows attendance at the STAK-D group activity sessions during the intervention. In total, four (50%) children in the intervention group attended at least two sessions. Barriers and facilitators for adherence to the STAK-D programme, including attendance at the group activity session were explored through interviews. The influences were grouped into three main themes: i) enjoyment, ii) bringing a friend or sibling, and iii) family engagement.

Table 29 Adherence to the STAK-D programme components by children in the intervention group

Intervention group participants*	STAK-D activity diary	Street dance DVD	Pedometer	Group sessions (number attended)	Motivational interview
P01 Amelia	✓	✓	✓	×	✓
P02 Ryan	✓	×	✓	×	✓
P06 Sophia	✓	×	✓	×	×
P07 Matthew	✓	✓	✓	✓ (2)	✓
P09 Natasha	✓	✓	✓	✓ (4)	✓
P05 Ava *	**?**	**?**	**?**	**✓ (3)**	**✓**
P11 Lauren †	**?**	**?**	**?**	**✓ (2)**	**✓**
P13 Rebecca †	**?**	**?**	**?**	**×**	**×**
Total children	5	3	5	4	6

*names have been changed
✓ = used, × = did not use, ? = unknown
Note: Participants in **bold** disengaged (†) or withdrew (*) from the research

Enjoyment

Children's motivation for compliance to the STAK-D programme was enjoyment of physical activity and interest in the STAK-D programme resources. Consistent with this, every volunteer perceived the group activity sessions to be fun and enjoyable for the children who attended.

Bringing a friend or sibling

Among the STAK-D group activity session attendees, all children except one attended the sessions with a friend or sibling. Whilst the opportunity to bring a friend or sibling was generally perceived as a facilitator for attendance and adherence by children, parents and volunteers, this may not always be the case. One volunteer suggested that it might have, *"created a bit of a division when some people didn't have anyone [to bring]… That kid, her friend couldn't come, she was really quite sad about it, especially as everyone else had a friend there"* (VOL02).

Family engagement

Three parents described family engagement with the STAK-D programme. For example, one mother described how different family members had worn the pedometer, another mother described how they had played on an active video game as a family instead of the STAK street dance DVD and a father described sibling involvement.

Reasons for lack of adherence to the STAK-D programme were explored. Sophia, who did not attend any group activity sessions, was deterred as the programme was targeted at children with T1DM rather than children in general. This echoes the concerns raised about stigma by participants in the PPI activities (Section 7.3 of the current chapter and Appendix 18).

The HCPs offered reasons for poor attendance at group activity sessions, and believed that children's attendance was dependent on parental 'engagement' and family 'commitment':

> *I suppose that the 9 to 11 age group, they're very dependent on parents actually taking them, they can't make their own way there. Which could be a plus, it could be a negative, it just really shows it's a parental engagement issue rather than a children's one.*

Consultant Paediatrician (HCP01)

> *With children because you need the commitment from the whole family, so you need more than just commitment from one person which you would do with adults.*

Nurse (HCP02)

The importance of parental commitment was supported by parents' own account of the barriers to intervention adherence. Parents perceived the main barrier to adherence to be their busy lifestyle e.g., *"our life is so busy… if we could've made it, we would've loved to have come"* (P01 Amelia's mother, INT). One father perceived time as a barrier despite his daughter and her sister attending the group activity sessions on four occasions; *"the timing…everybody is busy"* (P09 Natasha's father, INT). One mother implied that the commitment required to manage her child's diabetes made it difficult to dedicate more time to attending the STAK-D group activity session:

You've got to be incredibly dedicated and it just depends what kind of week you've had. And as much as you put 110% in to your kids [diabetes] management sometimes it's just like, I don't know if I can do this this weekend!

P02 Ryan's mother, INT

Related to parental time commitment, two parents mentioned the distance required to travel to the group activity session was a barrier to their child's attendance. This is a potential problem for clinic-based interventions when patients cover a wide catchment area. The average (mean) distance the participants lived from clinic was 10.3 miles (range 3.3 to 24.3 miles).

7.8.3.6 Experience of the intervention

Interviews explored participants' experiences with the STAK-D programme.

The STAK activity diary and parent's booklet

The activity diary received positive evaluation from children and their parents. All parents could appreciate the benefit of information about physical activity for children with T1DM. Some felt that the information reinforced what they already knew, which led one parent to suggest that the information would be more appropriate for less informed families, *"it was stuff I already knew, but I think for somebody that probably has not dealt with diabetes before it would be really helpful."* (P01 Amelia's father, INT). Support for this suggestion came from Natasha's father, whose daughter had been diagnosed with T1DM for less than two years; *"I found lots of things new for me, talking about why children need to be active"* (Natasha's father, INT).

The HCPs positively appraised the STAK-D programme, particularly the combination of home-based and group-based activities, because, *"Some families are completely against meeting other people with diabetes… and vice versa there are people that would really like social interaction"* (HCP03, Dietician). The dietician valued how attempt was made to engage parents. For example:

> *It was really good that there was a parents' information leaflet that they could fill in and feel involved in. So it was their responsibility to make sure that their child was active, rather than assuming their child would go away and do activity without being motivated or encouraged to do it.*

Dietician (HCP03)

Pedometer

The pedometer was a popular component of the STAK-D programme for children and families. All five children who completed the intervention adhered to wearing the pedometer, although compliance in wearing the pedometer was not measured by the researcher. Parents referred to the pedometer being used to help set physical activity targets, such as, *"trying to set more targets to get more steps on it so she was trying to find all different ways of doing it"* (P01 Amelia's mother, INT). One mother believed that pedometers for children with T1DM could be useful as an educational tool to help families understand the relationship between physical activity and blood glucose control. For example, she explained how they had used the pedometer to gauge activity levels on different days of the week:

> *I was just looking at Ryan's book of the weeks he wrote it down [steps]. And at school on average it was 7-8 thousand steps and I noticed on last Sunday he'd only done two and half thousand and it's like that's a huge difference, no wonder we have to up his basal [insulin dose] by 20%. So that to me, it supports your management of your child when you can see the evidence in front of you.*

P02 Ryan's mother, INT

The STAK street dance DVD

The STAK street dance DVD received mixed evaluation from children and their parents. Although two children did not adhere, three children engaged and found it enjoyable. The main reason cited for not engaging with the DVD was the child's dislike of dance.

STAK-D group activity sessions

Attendance at the STAK-D group activity sessions was lower than anticipated, yet children who attended the sessions and their parents evaluated it positively. Children enjoyed the activities, e.g., *"I tried things that I haven't tried before like the rowing and step-ups and the big ball against the wall to squat"* (P09 Natasha, INT). In agreement, her father valued his daughter and her siblings being able to continue to practice the activities after the end of the intervention. A boy valued having fun, especially with his friend, *"I had fun doing active stuff…and I could spend time with my friend Tim"* (P07 Matthew, INT). In line with this, Matthew's mother valued the insight it gave her son's friend into, *"what things are like for [children with diabetes]"* (P07 Matthew's mother, INT). Matthew's mother also appreciated being able to leave her son under the supervision of the staff and being able to talk to one of the volunteers:

> *One of the staff [volunteers] that you had there was diabetic herself … that was really good to chat with her because if I remember rightly she did a lot of dancing, yeh so it was great to chat to her as well.*
>
> P07 Matthew's mother, INT

One parent mentioned that having trained staff to supervise children during physical activity was an attractive feature of the STAK-D programme:

> *When you take her to street dance you've got to go through everything with them [the instructors], but when she's in a group of just Type 1s and trained people in Type 1, they can be a lot more active.*
>
> P01 Amelia's father, INT

Perceived benefits of the STAK-D programme

Interviews with children, their parents, volunteers and HCPs enabled potential benefits of the STAK-D programme not measured quantitatively to be identified. All parents indicated that they benefitted from being involved in the STAK-D programme or noticed benefits in their children. The perceived benefits were categorised into three themes: i) increased knowledge and understanding,, ii) increased awareness and iii) family-oriented physical activity promotion.

Increased knowledge and understanding referred to parents learning about the importance of physical activity and understanding how physical activity relates to blood glucose levels. For example:

> *It's made me think in more detail about activity … Even if it's the simple message of why is my child's blood sugar level so high at the weekend, because he's not doing anything, but at least you've got the proof [from the pedometer].*

P02 Ryan's mother, INT

Parents also described becoming more aware of their child's physical activity, which included recognising the factors that influence activity levels, e.g.:

> *I think sometimes you don't realise how inactive you are until you look at it from the outside and read stuff like this. You think well we think we're quite active but then you go hang on, or the other way, you think actually just doing that is activity, so it makes you look at it in a different way as well. Rather than just drop them off at school, drop them off 10 minute or an extra 10 more steps down makes them walk that bit more. And then how inactive she becomes in the winter as well.*

P01 Amelia's mother, INT

One parent also suggested that the STAK-D programme raised awareness of physical activity in the child's school by prompting discussion with teachers.

Parents of children in the intervention group described how their involvement in the STAK-D programme had prompted family-oriented physical activity, e.g., *"One thing we did do was get back on the Wii Fit and the Wii Sport which we hadn't done in a while"* (P02 Ryan's mother, INT) and, *"As a family you know my daughter, the other daughter as well does the exercise especially the STAK DVDs"* (P09 Natasha's father, INT).

All three HCPs valued the feedback they had received about the group activity sessions. They believed that important information had been revealed about the way children manage diabetes in 'real life'. In the comments below, the healthcare professionals are referring to feedback they had received from the researcher about some children failing to demonstrate adequate blood glucose management behaviours during the STAK-D group activity sessions:

> *What was really useful from your feedback was finding out what was really happening with young people despite the multiple pieces of advice we give them and what they say they do, in reality what was really going on and it in no way matched what they were advised to do in an shape or form. So that was really interesting and useful… perhaps we've unmasked what really goes on in the real life rather than when they come into clinic.*

Consultant Paediatrician (HCP01)

> *[The group activity sessions] You know that they do different things when you're not supervising them and they all live their own life and tell you something completely different in clinic… But even though you kind of know that, it's always surprising how far off the rails they go from what they're supposed to be doing and how dangerous that can be really, so I think that's been quite interesting.*

Nurse (HCP02)

Adverse events

No serious adverse event as a consequence of the child's involvement in the STAK-D programme was reported. The researcher documented one episode of light hypoglycaemia and one episode of mild hypoglycaemia during STAK-D group activity sessions.

7.9 Discussion

This is the first study to evaluate the feasibility of a physical activity intervention for children with T1DM in the UK. This study has used a standardised framework (Reelick et al., 2011) to evaluate both research and intervention processes, to increase our understanding about how to promote physical activity in this population and to inform the development of a definitive trial.

Issues around the research processes (e.g., study sample and data collection) and those around the intervention processes (e.g., intervention implementation) will be discussed separately. This will help reach a decision about i) the feasibility of the research conditions for a future trial and ii) feasibility of the STAK-D programme for this population.

7.9.1 Research processes

Research processes referred to components of the study design, methodological quality, and statistical precision. The processes relating to the study sample and data collection procedures will be discussed in turn.

7.9.1.1 Study sample

Results from the evaluation of the study population indicate that it is possible to recruit children and their parents onto the research study. Recruitment was slower than expected despite a combination of indirect (via expression of interest form) and direct (face-to-face) recruitment approaches and great investment of time by the researcher. The most interest was achieved through direct recruitment strategies. It is not uncommon for research among children with T1DM to demonstrate slow uptake. Faulkner et al. (2010) reported that it took 16 months to recruit 12 out of 35 eligible adolescents with T1DM for an exercise intervention study, although the authors of this study did not report the method of recruitment. Face-to-face approaches have previously been identified as a beneficial recruitment strategy in a parenting intervention aimed at increasing children's physical activity, particularly for parents who were initially reticent on receiving distributed study leaflets (Jago et al., 2013b).

As shown in the flowchart (Figure 15), expression of interest did not translate into consent in just under half of those who signed the expression of interest form (n=13). The main reason for loss at this stage was the researcher being unable to establish contact with the parents to follow-up their expression of interest in the time available. This suggests that there is a need for techniques to translate participants' initial interest into recruitment targets and encouragement from the healthcare team might facilitate this.

Taken together, these findings highlight the challenge of recruitment in this population, which has implications for a future definitive trial. Recruitment difficulties can result in studies lacking statistical power to produce significant results. Consequently, improving the recruitment process in a future definitive trial is important. These findings suggest using the diabetes team to endorse the research may facilitate recruitment and reduce the time invested by researchers.

Participants' motivations for enrolment onto the research study were explored. The interview findings demonstrated that children's main motivation for enrolling was an interest in physical activity, suggesting that the sample may have been biased towards children with an existing interest in being active. For parents, there were two main motivations for enrolling and these were personal motivation and advancing knowledge. Being motivated by the personal relevance of the intervention is consistent with results from a previous study, which found that parents were motivated to enrol onto a physical activity parenting course when the programme was perceived as a useful way to improve parenting skills and learn how to change their child's behaviour (Jago et al., 2013b). The ability to receive feedback into how physical activity influences their child's blood glucose levels was particularly attractive for some parents, which supports findings in Chapter 3 and 4, which suggested that there is a perceived need for educational resources around physical activity in children with T1DM (Quirk et al., 2014a ; Quirk et al., 2015). The findings indicate that the advertisement of future researchers would benefit from considering participant motivation for involvement.

The sample size was modest, although reasonable for a feasibility study and compared with similar research in this field (Faulkner et al., 2010 ; Heyman et al., 2007 ; Ramalho et al., 2006) and sufficient to address the study aims. Once recruited onto the research, no participants withdrew as a result of randomisation and the treatment groups were balanced. When interviewed, participants confirmed their willingness to be randomised. Overall retention in the control group was good, with a zero attrition rate. In the intervention group, retention rate would be considered acceptable based on the rates achieved in similar research (Faulkner et al., 2010 ; Salem et al., 2010a). The main motivation for continued participation among all children and parents was the desire for results about the child's physical activity. This suggests that emphasising the relevance of physical activity feedback to children and parents may encourage uptake and continued participation.

7.9.1.2 Data collection

The clinical data (height, weight, HbA1c) were successfully collected, but the date clinical outcomes were measured did not always match the research data collection period due to the scheduling of clinic appointments. The choice to collect clinical data from clinical notes, rather than take a direct measurement, was a pragmatic decision and future research should seek to take measurements at the time of data collection.

Evaluation of the data collection procedures showed that parents and children did not find the assessment procedures burdensome. The most successful completion of the CSAPPA scale was when the child was assisted by a parent or researcher. Home-visits were considered the most time efficient method of data collection, but this is unlikely to be feasible for a larger trial, especially given the wide geographical spread of participants. Future implementation of research must take into consideration the time taken for postal questionnaire distribution and collection.

The study suggests that the CSAPPA scale was able to detect a modest improvement in self-efficacy in the intervention group between T1 and T2. Over the same period, the control group demonstrated a decrease in self-efficacy. Although the results should be interpreted with caution, the study has highlighted the STAK-D programme may have counteracted the deterioration in self-efficacy demonstrated in the control group. Furthermore, given that the positive change in self-efficacy between T1 and T2 in the intervention group was not maintained at the T3 follow-up, additional strategies might be needed to maintain any benefits of the STAK-D programme. Future research would need to incorporate some post-intervention maintenance techniques and explore their efficacy in maintaining outcomes in the long-term.

The largest change over time was detected in MVPA by accelerometer. As discussed in Chapter 5, the decline in MVPA after the intervention in both study groups may equate to a seasonal effect on children's level of physical activity which has important implications for the timing of future research implementation (see Chapter 5, Section 5.8 for full discussion). Chapter 6 demonstrated correlation between the objective measure of physical activity and self-report measure of physical activity at baseline. An objective measure of physical activity was not assessed at T3, but the self-reported results suggest that decline in physical activity was not maintained in the longer term. At T3, self-reported activity scores returned to baseline level in the control group and increased slightly in the intervention group.

The clinical outcomes demonstrated little change over time which was to be expected given the short follow-up period and potential confounding effect of children's diet and insulin management. The review in Chapter 2 suggested that BMI and HbA1c are sensitive to change after a physical activity intervention, thus future research utilising a longer follow-up period (e.g., 12 months) might expect to see changes in these outcomes as demonstrated by previous research (Aouadi et al., 2011 ; Heyman et al., 2007 ; Michaliszyn and Faulkner, 2010 ; Tunar et al., 2012).

The parental hypoglycaemia fear scale produced a wide range of scores with extreme values as possible outliers. Previous research using the PHFS to measure fear of hypoglycaemia among parents of children with T1DM would imply that the PHFS is sensitive to change (Barnard et al., 2014). To the researcher's knowledge, no research has used the PHFS in the context of physical activity. The current findings imply that parents' involvement in the research did not have a detrimental effect on their concerns or behaviours around hypoglycaemia. Whilst fear of hypoglycaemia was the only parental construct measured in this feasibility study, the interviews revealed potential benefits for parents, such as increased awareness of their child's physical activity levels which warrant exploration in future research.

7.9.2 Intervention processes

7.9.2.1 Intervention implementation

Evaluation of intervention processes referred to whether the intervention was delivered as intended and was feasible. The processes evaluation included delivery of intervention components, barriers and facilitators for delivery of intervention, adherence to intervention components, barriers and facilitators for adherence to the intervention and experience of the intervention. All intervention components were delivered as intended and will now be discussed in turn.

7.9.2.2 Motivational Interview

The MI session during the STAK-D programme was delivered successfully, although required a home-visit by the researcher. The MI session enabled the researcher to elicit children's values, beliefs and outcome expectations around physical activity and gain insight into the children's perceived barriers and facilitators to goal attainment. Future implementation of the intervention would benefit from allocating more time for this component and scheduling regular sessions with children to monitor and reassess goals. Whilst being feasible in this small-scale study context, time and resource constraints in a large-scale RCT may limit the extent to which in-depth MI sessions are possible. Future implementation may therefore use motivational interviewing techniques in brief consultations with children. Studies using MI implemented by nurses in the diabetes team for the management of T1DM in adolescents have shown improved glycaemic control compared with adolescents receiving standard care (Channon et al., 2005 ; Channon et al., 2003 ; Channon et al., 2007). This suggests that the utilisation of MI techniques in the promotion of physical activity among children with T1DM warrants exploration.

7.9.2.3 Home-based STAK-D components

Compliance to the home-based STAK-D programme components (pedometer, STAK-D activity diary and street dance DVD) was reasonable. Children and parents indicated a great deal of interest and benefit from the pedometer due to the automatic feedback and source of motivation it provided. Parents also perceived it to be useful for self-monitoring and goal-setting, indicating that emphasis could be placed on activity tracking in future implementation of the intervention. Feedback about the pedometers suggested that they promoted family engagement and thus were useful for children to enlist social support. An unexpected finding from the process evaluation was feedback about how the pedometer gave parents an increased awareness of their child's activity levels and perceived competence for managing blood glucose levels in relation to physical activity.

The STAK-D activity diary was received well by children and parents. The most engagement and perceived benefit of the STAK-D activity diary was gained from the activity logs (5-a-day log and daily step-count log), which promoted self-monitoring of steps and activity behaviours. Children showed less interest in the educational elements of the activity diary and some parents felt the information contained within the diary was pitched at children and parents with less knowledge about T1DM. This suggests that information-giving should be tailored to existing level of knowledge to enhance its impact.

The street dance DVD appealed to those children who had an existing interest in dance and was not used by those with a negative attitude to dance. This suggests that an introductory session to the street dance DVDs may be beneficial to challenge pre-existing beliefs.

7.9.2.4 STAK-D group activity sessions

Attendance at the STAK-D group activity sessions was lower than anticipated. Establishing a date and time for the group activity sessions has been noted as extremely challenging in similar research exploring the feasibility of an education programme for children with T1DM (Sawtell et al., 2015). Similarly, late cancellation or non-attendance by participants has been reported as common in similar research (Sawtell et al., 2015).

In the current study, as a result of the difficulties with group activity session attendance, compromises were made to the intended group size. Groups often had small numbers and mirrors findings from an education programme targeted at children with T1DM (Sawtell et al., 2015). Together, these findings highlight the practical constraints to setting up and running group activity sessions for children in this population (Sawtell et al., 2015).

Although attendance at the STAK-D group activity sessions was modest, the sessions were evaluated positively by those who attended. Perceived benefits of the group activity session included the opportunity for children to practice and develop competency in new skills. Parents particularly valued having activity leaders trained in diabetes management and the opportunity for children have fun and be active with friends, which supports the findings from Chapter 3 (Quirk et al., 2014a). Reasons for non-attendance were logistical (i.e., session timing and location) rather than the appeal of the session.

The group activity sessions were a particularly valuable exercise for HCPs to gain an insight into how children manage their diabetes in a real life setting. The findings suggest that future implementation of the group activity sessions would benefit from firmly established blood glucose testing ground rules to promote optimal diabetes management behaviours among children and their families.

Results from the evaluation of the intervention implementation show that most parents perceived that they had benefitted from being involved in the intervention. Perceived benefits included increased knowledge and awareness of physical activity and family-oriented physical activity promotion. Even parents whose child was in the control group mentioned increased awareness of their child's activity level as a result of their child wearing the accelerometer and being involved in the research. This is worthy of consideration in a future trial as it suggests a potential Hawthorne effect in the control group (reactivity whereby participants in the control group modify behaviour in response to their awareness of being observed).

Overall, evaluation of the intervention implementation indicates that it is feasible to deliver the STAK-D programme as a home-based intervention with complementary group activity sessions, but the programme in its current form requires simple alteration to optimise its efficiency and potential efficacy.

7.9.3 Recommendations for a future trial

To address the issues raised in this study, and support the development of a future definitive trial, we make specific recommendations. These recommendations focus on strategies to enhance recruitment, implementation, retention and compliance and outcomes.

7.9.3.1 Recommendations: Recruitment

The difficulties experienced in this study provide limited support for the feasibility of a RCT at the individual level of recruitment. The recruitment of individual participants and face-to-face recruitment techniques placed burden on the researcher. During the process evaluation it became apparent that clinic staff did not fully engage with the recruitment process, yet, having the research promoted and endorsed by clinic staff could play a valuable role in future implementation of similar research. The need for greater 'buy-in' from the wider clinic team to facilitate recruitment has arisen from similar research implementing a group-based programme for children with T1DM (Sawtell et al., 2015).

A pragmatic cluster randomised controlled trial (cluster RCT) would allow strategies at clinic level to be implemented that support recruitment and retention such as encouragement from clinic staff to enrol onto the research. Researchers using a cluster RCT design require cooperation and commitment from the clusters and should allow for correlations between individuals in the same cluster. Another consideration is that cluster RCTs may require larger numbers of participants, but alternative methods to the traditional parallel group design are available (Hemming et al., 2015 ; Hooper and Bourke, 2015). A stepped wedge design, which the cluster of children allocated to the control group switch to become exposed to the intervention, can reduce the number of participants in the required sample size and could also be considered as an alternative research design in future studies.

7.9.3.2 *Recommendations: Implementation*

In the current study, there was no agreement among stakeholders or participants as regards the best time to schedule the group activity sessions. Organising the group activity sessions for a time when children and parents are already attending clinic might enhance accessibility and overcome the need for families to make additional hospital visits. This would require extensive administrative planning to reschedule clinic appointments. Implementing ground-rules for blood glucose testing during group activity sessions may give more structure to the session and promote high-standard management behaviours that meet clinic expectations. Providing family members with pedometers may encourage family involvement with the home-based intervention materials. Consideration should be given to the effect of season on children's level of physical activity, especially when scheduling data collection points. Winter months could be used as a target for intervention implementation to encourage physical activity despite dark evenings and bad weather.

7.9.3.3 *Recommendations: Retention and compliance*

Parents and children suggested that they would have liked to have seen the results from the accelerometer after the first time the children wore the device. Using the accelerometer data from T1 (baseline) as an incentive might encourage ongoing engagement with the research and adherence to the accelerometer wear-time protocol in subsequent measurement periods.

The findings suggest that strategies may be needed to maintain any beneficial effects of the intervention and participants' interest after cessation of the programme. Such post-programme maintenance strategies could include "top up" sessions (Fortier et al., 2012) or the provision of continuing, tailored support such as a telephone helpline (Rankin et al., 2012) and personalised letters (Horne et al., 2009).

7.9.3.4 *Recommendations: Outcomes*

Future research could consider using the accelerometer data as an intervention tool to educate children and parents about blood glucose control in relation to physical activity. This may also promote compliance to the accelerometer monitoring protocol at later data collection periods.

7.10 Evaluation

This study has provided an insight into the feasibility of research processes for a future trial and acceptability of the STAK-D programme for this population. The use of a standardised framework enhances the methodological rigour of this study. Combining quantitative and qualitative data gives insight into potential underlying working elements as well as the diverse perspectives of participants. The mixed-methods have been combined in a way which enables a gradual accumulation of knowledge (Moore et al., 2015). It is important that the preliminary findings are disseminated prior to the replication of similar interventions and implementation of larger trials (Jago and Sebire, 2012).

The findings should be considered in light of methodological considerations. The researcher collected the data, delivered the intervention and conducted the process evaluation interviews, thus findings should be considered with potential for bias in mind. The sample size was small and the poor uptake may have resulted in a sample that was more motivated to be physically active. Further efforts may be required to reach children and families who have low levels of physical activity and/or self-efficacy for physical activity. Statements about the effects of the intervention on outcome measures should be interpreted with caution as there was a lack of statistical power to infer effect or to generalise the findings. Replication of this research would require a longer-term follow-up to explore the maintenance of any intervention effects. Furthermore, in the current study, no specific criteria were in place to assess the fidelity of intervention delivery, which was also a weakness of existing interventions demonstrated in the systematic review in Chapter 2, 2.4.4 (Quirk et al., 2014b). Fidelity will be essential when evaluating the effectiveness of this intervention to capture the quality (fidelity) and quantity (dose) of implementation and to understand the mechanisms underlying any changes in outcomes.

7.11 Conclusions

The STAK-D programme is shown to be a promising intervention for children aged 9-11 years with T1DM. The intervention and research process were acceptable to children and their parents and evaluated favourably by HCPs and volunteers. The findings imply that a future definitive trial would be appropriate, and discussion of the findings has provided suggestions for changes to the research and intervention processes to optimise its potential acceptability and efficacy.

Chapter Eight

General Discussion

8.1 Introduction

This thesis aimed to expand our current understanding of how children with Type 1 Diabetes Mellitus (T1DM) experience physical activity and advance knowledge of how to promote active lifestyles in this population. An evidence-based physical activity intervention was adapted for delivery among children with T1DM and evaluated for feasibility and acceptability among this population.

This chapter summarises and synthesises the findings of the studies undertaken in this thesis. Within this collation of the thesis findings, the researcher seeks to elucidate how the findings correspond with existing theoretical understanding, how they advance our knowledge of physical activity for children with T1DM and discuss the implications of the findings for future research and practice. A detailed discussion of each individual study is provided in the associated chapter.

8.2 Overview of the thesis

The studies within this thesis follow Medical Research Council (MRC) guidelines for the development and evaluation of complex interventions (Craig et al., 2008). The research has formed the development and feasibility work which will inform and underpin the implementation of an evidence-based physical activity intervention for children with T1DM. Figure 16 shows the anticipated progress of the research beyond this thesis, in accordance with MRC guidelines to evaluate and implement the intervention (Craig et al., 2008).

The next section provides an overview of the findings from each thesis chapter, including concise summaries of the implications of the findings. The recommendations for a future definitive trial are then discussed, followed by discussion of how the findings contribute to existing knowledge and understanding of physical activity for children with T1DM. The implications of the findings for future research and clinical practice are then considered. Finally, the methodological considerations are examined before final conclusions are given.

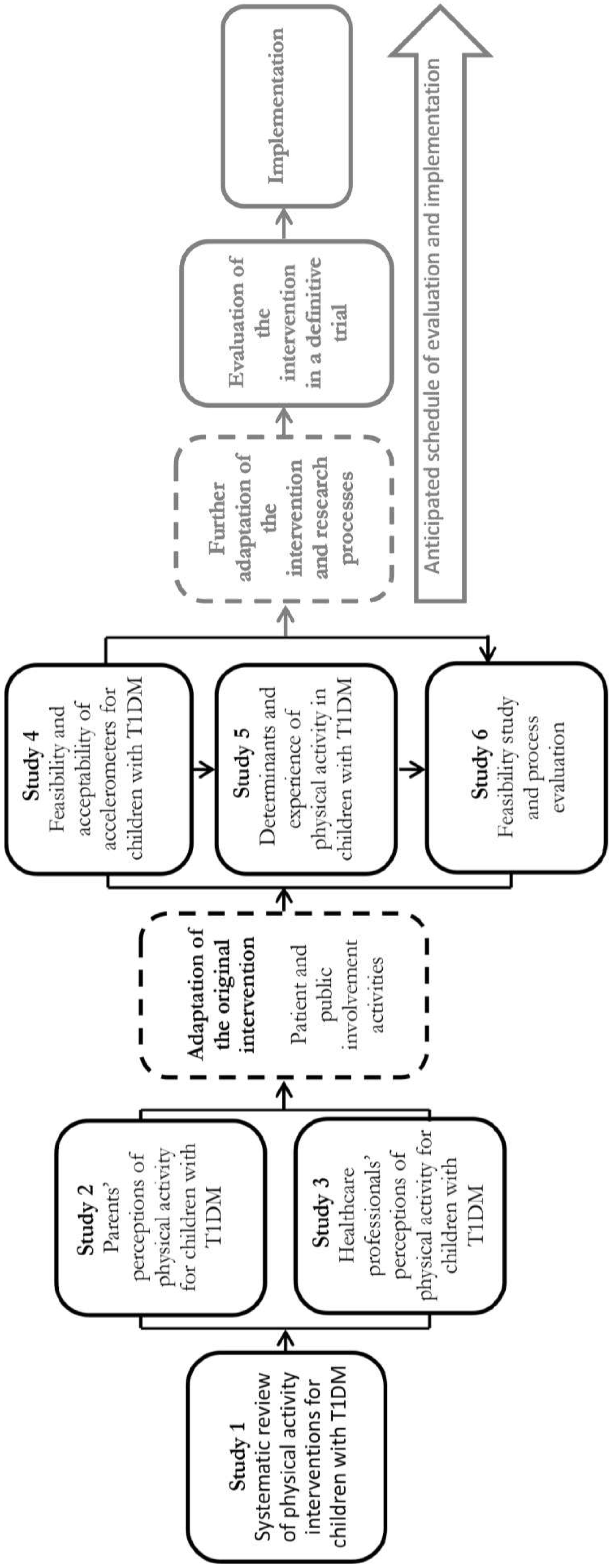

Figure 16 Thesis overview and anticipated schedule of evaluation and implementation in accordance with MRC guidelines

8.3 Summary and interpretation of the thesis findings

8.3.1 Chapter 2

Physical activity interventions in children with Type 1 Diabetes: A systematic review with meta-analysis

The systematic review aimed to establish the evidence base of physical activity and exercise interventions for children with T1DM. The MRC guidelines recommend that researchers conduct a systematic review of the existing literature to establish existing knowledge and identify where understanding of the phenomenon is lacking (Craig et al., 2008). The findings from this review demonstrated gaps in the literature to be addressed by future research.

The systematic review in Chapter 2 formed the building blocks upon which the subsequent studies within the thesis were built. This review indicated that it remains unclear which is the best mechanism for promoting physical activity among children with T1DM. It concluded that further research was needed to explore how to develop and implement efficacious strategies to promote active lifestyles in this population. The box below summarises the main findings from the systematic review and implications of the results for future research (Box 2).

Summary of the findings from Chapter 2

The findings from the systematic review suggested that:

- Physical activity interventions have the potential to improve glycaemic control, BMI, triglyceride level and total cholesterol among children with T1DM in the short-term. However not all studies reported physical activity or fitness outcomes.
- Heterogeneity in study design, methods and reporting of research studies remains a barrier to fully understanding the influence of physical activity on health outcomes in children with T1DM.
- There are limited studies; i) underpinned by psychological theory of behaviour change, ii) measuring the maintenance of physical activity in the long-term, and iii) exploring psychological outcomes.

Implications of the findings from Chapter 2

The findings from the systematic review suggest that future physical activity intervention research among children with T1DM may wish to:

- Report a measure of physical activity level or fitness level to demonstrate whether changes in clinical outcomes are related to changes in physical activity behaviour. If researchers wish to demonstrate that changes in outcomes are a result of the physical activity intervention, then diet and insulin dosages should be closely monitored and reported in research studies.
- Report the research in accordance with standardised guidelines such as those outlined in the CONSORT (Consolidated Standards of Reporting Trials) statement (Schulz et al., 2010). Such transparency in reporting would facilitate the review and replication of studies.
- Underpin physical activity interventions with psychological theory of behaviour change. This will help identify the active content of the intervention and aid replication of the intervention components.
- Explore physical activity maintenance techniques and the long-term maintenance of physical activity and health outcomes after cessation of the intervention. This will help identify the strategies needed to help support longer-term behaviour change.
- Consider the potential psychological outcomes of physical activity interventions. This could have important implications for the long term health and wellbeing of children with T1DM.

Box 2 Summary and implications of the findings from Chapter 2

8.3.2 Chapter 3

A qualitative study exploring parents' perceptions of physical activity in children with Type 1 Diabetes

Chapter 3 reported the first of two qualitative studies that sought the perceptions of key stakeholders in attempt to advance our understanding of physical activity for children with T1DM and inform the implementation of strategies to promote active lifestyles and practice of those working with this population.

Chapter 3 explored the perceptions of parents who have a child with T1DM. The parents interviewed identified themselves, diabetes healthcare professionals (HCPs) and personnel involved in the supervision of children (e.g., school teachers and activity leaders) as influential figures of support and encouragement for their child's participation in physical activity. Social cognitive theories of behaviour change can help to explain the importance of significant others in children's social environment. A supportive environment must be in place if a child is to succeed at becoming physically active (Bandura, 1986). Significant figures such as parents can influence children's self-efficacy, motivation and behaviour by providing role models, rewarding opportunities to participate in physical activity and through encouragement and reinforcement.

The parents interviewed perceived a number of challenges to their child's involvement in physical activities. Most parents experienced concern about exercise-induced hypoglycaemia and apprehension about leaving their child under the supervision of others. This reluctance stemmed from the belief that other people lack the competence to recognise and manage the needs of a child who has diabetes. Yet the parents demonstrated qualities such as vigilance, resilience and determination to overcome these potential barriers. The parents interviewed perceived challenges as '*hurdles to get over*' rather than barriers to stop their child participating in a 'normal' active lifestyle.

The current findings are consistent with previous qualitative research among parents of children with T1DM that demonstrated similar parental characteristics which facilitate resilience to potential barriers to their child's participation in physical activity (Fereday et al., 2009 ; MacMillan et al., 2014b). Whilst finding that parents can overcome barriers to physical activity is reassuring, the small samples in these qualitative studies may not be representative of the wider population of parents who have a child with T1DM. Many families may demonstrate less resilience characteristics (Koegelenberg, 2013) and it is these families who may benefit from supportive interventions to overcome barriers to regular physical activity participation. Further research in more diverse samples would develop our understanding of how families with a child who has T1DM cope with potential barriers to physical activity.

Given that parents identified HCPs as influential facilitators of children's physical activity, the next study sought to explore HCPs' perceptions of physical activity for children with T1DM.

8.3.3 Chapter 4

A qualitative study exploring healthcare professionals' perceptions of physical activity in children with Type 1 Diabetes

The diabetes healthcare team have an ongoing opportunity to promote active lifestyles among children with T1DM. They are also in the position to explore parental beliefs and concerns related to children's participation in physical activity. Chapter 4 investigated the perspective of paediatric T1DM HCPs and sought to explore their competency to promote regular physical activity and identify any support needs for communicating physical activity guidance to their patients.

The HCPs identified a number of facilitators to children's engagement in regular physical activity. Social support was perceived as the main facilitator of children's activity. Supportive figures were identified as parents, peers and personnel from formal organisations such as school teachers and the diabetes healthcare team. The child's personal motivation to be active was also identified as a key facilitator.

The HCPs believed that diabetes should not inhibit physical activity when appropriate support and management behaviours are in place. Nevertheless, they identified potential barriers to physical activity at the participation level (i.e., child factors) and at the promotion level (HCP factors). At the participation level, the potential inhibitors mirrored those mentioned by parents such as blood glucose control and hypoglycaemia. At the promotion level, HCPs perceived barriers to their ability to promote physical activity. HCPs experienced problems with the limited time available during clinic appointments to discuss physical activity, found it difficult to translate physical activity guidance into a digestible form for children and parents to understand and acknowledged having limited competence and/or confidence to promote physical activity to children.

The barriers to physical activity promotion identified by the HCPs in Chapter 4 correspond with those identified by the HCPs in other health domains (Douglas et al., 2006 ; McKenna et al., 1998 ; McPhail and Schippers, 2012). Thus, HCPs , including those specialising in paediatric diabetes, may benefit from training opportunities to foster competence in the implementation and promotion of physical activity guidelines. Alternatively, having a staff member who is specifically trained in physical activity advice and guidance and who has the confidence to champion physical activity promotion within the clinic might be beneficial. The effectiveness of these approaches could be explored in future research.

National Institute for Health and Care Excellence (NICE) guidelines for the treatment and management of T1DM among children recommend that HCPs encourage regular exercise among children with T1DM and warn about the effect of exercise on hypoglycaemia (NICE, 2015). The findings from this study suggest that HCPs may need more guidance to meet this recommendation. Specifically, HCPs may benefit from support around; i) *how* to promote regular exercise and physical activity to children with T1DM ii) *how* to explore and deal with concerns children and parents may have about hypoglycaemia, and iii) *how* to help and support those children and parents who have worries and concerns about physical activity.

The findings from Chapter 3 and Chapter 4 suggest that HCPs could collaborate with families to ensure understanding of how to manage physical activity. Collaboration between HCPs and their patients requires a mutual understanding of the barriers and facilitators to physical activity participation. It is therefore beneficial to compare the perspectives of the parents with those of the HCPs.

8.3.4 Comparison of parents' and healthcare professionals' perceptions

Parents and HCPs shared similar opinions about the difficulty of managing the spontaneous nature of children's activity. Parents preferred having a structured routine with management plans in place for scheduled physical activity (e.g., Physical Education in school). Similarly, HCPs acknowledged that spontaneous activities made it difficult to implement management plans because changes in blood glucose levels could not be anticipated in advance. Given that children's physical activity is typically unplanned and sporadic (Bailey et al., 1995), it is important that parents are equipped with the skills to manage fluctuations in blood glucose levels.

The clinical advice recommends meal planning, insulin adjustment and blood glucose monitoring in the management of exercise in children with T1DM (NICE, 2015). Both parents and HCPs acknowledged this as being arduous, disruptive and not applicable when the activity is unplanned. The current clinical guidelines for T1DM among children give little recommendation for the management of spontaneous physical activity (NICE, 2015). Previous studies support the perceived difficulty of managing spontaneous physical activity among children with T1DM (Fereday et al., 2009 ; MacMillan et al., 2014b). These findings suggest that HCPs could be trained in how to give advice around spontaneous physical activity to support children and parents with the management of blood glucose levels.

Parents and HCPs agreed that the paediatric diabetes team was an important influence on children's physical activity There was some disparity between parents' and HCPs' views of parental concerns about hypoglycaemia. Parents valued having their concerns about the physical and emotional effect of exercise-induced hypoglycaemia understood by HCPs. The HCPs interviewed acknowledged that parents can have concerns or worries about hypoglycaemia, but this was generally perceived as 'part and parcel' of being a parent of child with T1DM. Some parents suggested that worry about hypoglycaemia led to more vigilant blood glucose testing and maladaptive avoidance behaviours such as keeping their child's blood glucose level higher than recommended. The findings suggest that parental concerns around physical activity and its side-effects need addressing in more detail in routine clinic appointments. Research suggests that patient-centred communication may be advantageous to encourage patients and HCPs to build a collaborative relationship with focus on the patient or parents' beliefs and goals (Croom et al., 2011).

Summary of the findings from Chapter 3 and Chapter 4

Exploration of the perceptions of parents and HCPs suggested that:

- Parents perceived physical activity as a challenge for children with T1DM, but demonstrated characteristics such as parental determination to persevere in the face of barriers.
- HCPs acknowledged the challenge of physical activity for children with T1DM and appreciated parental concerns, but did not believe diabetes should stop children from being active.
- HCPs perceived barriers that pose challenges for the participation in and promotion of physical activity among children with T1DM. In particular, HCPs perceived barriers to their role in promoting physical activity to children with T1DM.
- Parents and HCPs shared opinions about the importance of social support from parents, HCPs and school teachers to facilitate children's participation in physical activity.
- Parents and HCPs shared similar opinions about the difficulty of managing children's spontaneous physical activity.
- Parents and HCPs shared similar opinions on the need for further guidance around managing physical activity and T1DM.

Implications of the findings from Chapter 3 and Chapter 4

The findings from Chapter 3 and Chapter 4 suggest that:

- HCPs could be trained to give advice around spontaneous lifestyle physical activity as well as structured exercise to support children and parents with the task of managing blood glucose level and preventing hypoglycaemia.
- Divergence in some opinions may exist between parents and HCPs and as such, HCPs should seek to establish a mutual understanding between themselves, children and parents.
- Policy makers should be sensitive to parental concerns and to the barriers preventing HCPs from actively promoting physical activity to children with T1DM.
- The influence parents and HCPs may have in shaping children's physical activity necessitates their engagement in attempts to promote active lifestyles in children with T1DM.

Box 3 Summary and implications of the findings from Chapter 3 and Chapter 4

8.3.5 Chapter 5

The feasibility of objectively measured physical activity in children with Type 1 Diabetes

Chapter 5 explored the feasibility and acceptability of using wrist-worn accelerometry to objectively measure physical activity among children aged 9-11 years with T1DM. This was in accordance with the feasibility phase of the MRC framework for developing and evaluating complex interventions, which recommends testing research procedures for their acceptability (Craig et al., 2008). To the researcher's knowledge, this was the first study of its kind to explore whether wrist-worn ActiGraph GT3X+ accelerometers are feasible and acceptable among children when worn twice; before and after an intervention. The results have important implications for future research using wrist-worn accelerometers in children of this age as well as informing the development and implementation of a future definitive trial.

In this small sample, wrist-worn ActiGraph GT3X+ accelerometers were feasible to implement, considered acceptable by children with T1DM and were sensitive to change in physical activity over time. Overall, compliance to the accelerometer monitoring protocol was good, which supports the suggestion that wrist-worn accelerometers may promote compliance (Esliger et al., 2011 ; Schaefer et al., 2014). Although compliance was lower at the second time-point, it still met the valid wear-time criteria. The findings implied that future implementation of accelerometers at multiple time-points may require strategies to maintain compliance, such as using the results as external motivation or incentive for continued compliance. Previous research has demonstrated the utility of waist-worn ActiGraph accelerometers among children with T1DM (MacMillan et al., 2014c), but the current study is the first to demonstrate the usefulness of wrist-worn accelerometers in this population.

When children and their parents were asked for their perceptions of the accelerometer, there was an overwhelming desire to 'know how active' the child was. For parents, this was related to the ability to compare activity levels with blood glucose levels whilst for children this was more out of curiosity. These findings suggest that children and parents derive satisfaction from monitoring behaviour and receiving external feedback about the child's activity level. Education and guidance around physical activity may benefit from monitoring children's physical activity levels and using this as a reference point for clinic discussion and tailored advice. As it may not be practical to use accelerometer devices in whole clinic populations, the findings from Chapter 6 and Chapter 7 of this thesis study suggest that pedometers and self-report questionnaires might be feasible and less expensive alternative measures of physical activity.

Summary of the findings from Chapter 5

Chapter 5 concluded that wrist-worn ActiGraph GT3X+ accelerometers:

- Were feasible to implement in this small sample of children with T1DM.
- Were considered acceptable by this small sample of children with T1DM and their parents.
- Were sensitive to change in physical activity over time.
- Were feasible to administer over two time-points; before and after an intervention.

Implications of the findings from Chapter 5

The findings from Chapter 5 suggest that:

- Future researchers may wish to consider using strategies to maintain compliance, such as using the accelerometer results as an incentive for ongoing engagement with the research protocol, although further research is needed to support this assumption.
- Accelerometers could be used in clinical practice to help educate patients and families about physical activity and to facilitate tailored guidance around physical activity participation. Again, further research is needed to explore this suggestion.
- The cut-points derived from Chandler et al. (2015) can be used to classify sedentary behaviour, light, moderate and moderate-to-vigorous physical activity in children aged 9-11 years with T1DM. Further research is required in large, representative samples of children with T1DM to establish the amount and intensity of their accumulated physical activity.

Box 4 Summary and implications of the findings from Chapter 5

8.3.6 Chapter 6

Correlates and experience of physical activity among children with Type 1 Diabetes

In Chapter 6, a cross-sectional mixed-methods study explored potential correlates of physical activity among children with T1DM alongside children's values, beliefs and outcome expectations related to their physical activity participation. The study sought to advance our existing understanding of physical activity among a sample of children with T1DM.

The study revealed generally high physical activity levels among participants and self-efficacy scores were considered normative. A positive correlation was found between children's self-efficacy for physical activity and their objectively-measured level of physical activity.

Interviews with children showed that they were positive about physical activity and understood the relationship between physical activity and health, although they appeared to have limited awareness of how active they should be. The main motivation for participation was the expectation of socialisation with friends. Social cognitive theories of behaviour change advocate the importance of supportive social environments and self-determined forms of motivation. Children were motivated by the expectation of social engagement with friends and having friends who model and encourage physical activity promotes further participation. The enjoyment and fun children associated with physical activity would suggest that the children in this sample were intrinsically motivated towards being active.

Previous researchers have suggested that children with T1DM may have a unique psychological experience of physical activity due to the connection of physical activity to disease management (Edmunds et al., 2007). The current findings suggest that children's perceptions of physical activity were similar to those found in the general population of children without diabetes (Mulvihill et al., 2000 ; Tannehill et al., 2015). There was little indication that the children interviewed in the current study had any anxiety or concern about participation in physical activity. There is a possibility that the small, single-centre sample used in this study had different perceptions to the wider population of children with T1DM, which warrants replication in a larger, more diverse sample.

The advantage of the current study over previous cross-sectional studies exploring physical activity in children with T1DM (Edmunds et al., 2007) was that it took into consideration parent variables such as fear of hypoglycaemia (FOH). The findings indicated a potential relationship between children's moderate-to-vigorous physical activity (MVPA) and parental worry about hypoglycaemia, which warrants further investigation. The importance of parents in children's T1DM management warrants their inclusion in future research exploring children's physical activity participation. Since the management of T1DM is largely a process of communication between children, their parents and HCPs, it is important to understand the similarities and differences in their perceptions of physical activity (Clark, 2005).

8.3.7 Comparison of children's, parents' and healthcare professionals' perceptions

Children, parents and HCPs shared the view that children's enjoyment of physical activity was of central importance to their participation. Enjoyment is discussed in more detail in Section 8.5.1.1 of this chapter.

All groups considered parents, teachers, HCPs and peers as influential social agents facilitating children's physical activity, supporting the importance of considering the influence of the social environment on children's physical activity. Children and HCPs valued friendships for providing socialisation opportunities and modelling active behaviour, whereas parents spoke relatively little about their child's peers and more about their own role and responsibilities.

There was congruency between groups in their perceptions of barriers to physical activity. All groups acknowledged that children can be distracted by screen-based activities. Research exploring sedentary behaviours in children with T1DM implies that future physical activity promotion might benefit from education around sedentary behaviour (MacMillan et al., 2014c). Research is suggestive of a positive relationship between daily media consumption time and poor blood glucose control among children with T1DM, reinforcing the need for further research on sedentary behaviour (Galler et al., 2011).

There was consensus among children, parents and HCPs about diabetes-related negative influences on children's physical activity such as hypoglycaemia and blood glucose testing. Children did not go into depth about the influence of diabetes on their physical activity participation; instead they preferred to talk about what they can do. In contrast, parents and HCPs spoke in detail about the potential for T1DM to impede children's physical activity participation. This finding supports the previous qualitative research that found children to demonstrate little concern about the participation in physical activity (Fereday et al., 2009 ; MacMillan et al., 2014b).

The findings from Chapter 6, together with the comparison of children's, parents and HCPs' perceptions, should help HCPs, activity providers and policy makers understand the factors influencing children's activity levels and the aspects of physical activity participation that children value.

Summary of the findings from Chapter 6

The findings from Chapter 6 suggest that:

- Social cognitive constructs such as self-efficacy, intrinsic motivation, outcome expectations, enjoyment, social support (relatedness) and perceived barriers and facilitators could be influential constructs to target for the success of interventions to promote physical activity among children with T1DM.
- Comparing the perceptions of children, parents and HCPs has been valuable to identify similarities and differences in their values and beliefs around physical activity.
- Children may differ from their parents and HCPs in their perceptions of hypoglycaemia as a barrier to physical activity.
- Whilst parents and HCPs value the importance of the diabetes healthcare team to promote physical activity, children may place more value on the support from peers and teachers.

Implications of the findings from Chapter 6

- Similarities and differences in children's, parents' and HCPs' beliefs should be considered when designing and implementing interventions to promote physical activity.
- Identifying the influential figures in children's social environment and involving them in the promotion of physical activity among children with T1DM is an important avenue for further research.
- The findings would suggest that children with T1DM would benefit from:
  - Environments that promote and maintain self-efficacy beliefs (including adequacy, predilection and enjoyment).
  - Fun opportunities to be active with their friends.
  - Support from their parents and opportunities to be active with family members.
  - A school environment in which teachers promote and support physical activity opportunities.
  - Environments that support physical activity practice and mastery.
  - Support for those children and families who have concerns about blood glucose control and hypoglycaemia in relation to physical activity.

Box 5 Summary and implications of the findings from Chapter 6

8.3.8 Chapter 7

An intervention to promote self-efficacy for physical activity among children aged 9-11 years with Type 1 Diabetes: A feasibility study

The final study in this thesis reported the first UK-based implementation of a physical activity programme for children with T1DM. The intervention was adapted from the original Steps To Active Kids (STAK) programme (Glazebrook et al., 2011). Adaptations to the original STAK programme sought to accommodate the unique needs of children with T1DM and included:

- Clinic-based recruitment (rather than school-based).
- Home-based and clinic-based implementation (rather than school-based).
- A parent's booklet to promote parental involvement.
- Inviting a friend or sibling to group activity sessions to promote peer support.
- A measure of parental fear of hypoglycaemia.
- Additional informational inserts in the diary educating children and parents about physical activity for children with T1DM.
- Implementation of the motivational interview at the beginning of the intervention to help establish children's perceived barriers and facilitators to physical activity and readiness to make changes to their level of participation.

Given the novelty of the newly adapted STAK-Diabetes (STAK-D) programme, it was evaluated in a single-centre randomised feasibility trial. The study was complemented with a qualitative process evaluation and sought to explore the feasibility of both intervention and research processes using a standardised framework of process evaluation criteria (Reelick et al., 2011).

It was the primary purpose of this study to evaluate the feasibility of the STAK-D programme and this purpose was satisfied using a range of feasibility outcomes. The findings from the feasibility study demonstrated that it is possible to recruit and retain children with T1DM to a physical activity intervention. Successful engagement and implementation of the programme was dependent on the child's enjoyment of physical activity and parental engagement, which supports the use of promoting children's self-efficacy, intrinsic motivation and utilising children's social environment, as suggested by social cognitive theories of behaviour change. The STAK-D programme was evaluated positively by those involved and the results implied that outcome measures could be used as intended and were sensitive to change. It was concluded that the STAK-D programme and research processes in their current form require simple adaptations to optimise their potential efficacy.

Qualitative interviews provided suggestions for the potential benefit of the STAK-D programme. Interviews with parents suggested that parents may benefit from their child's involvement in the programme. Possible mechanisms through which parents may benefit were through raised awareness of their child's activity levels, immediate feedback about their child's activity level (e.g., steps per day) and education around physical activity for children with T1DM.

8.4 Implications of the findings for a future definitive trial

The findings from the feasibility study indicate that the adapted STAK-D programme can be delivered in a formal evaluation across several clinics in a future definitive trial. Future researchers can use the effect sizes to guide sample size calculations. Likewise, recruitment data can be used to estimate the required time, resources and techniques needed to reach a desired sample size. The recommendations made for future implementation are summarised in the box below:

Summary of the findings from Chapter 7

The findings from the feasibility study showed:

- The combination of indirect and direct recruitment strategies achieved a low and slow recruitment rate (43% recruitment rate over a 4-month period).
- Children were motivated to participate to "see how active I am" and parents were motivated for personal benefit (to learn about their child's physical activity) and also for the benefit of others (advancing clinical knowledge about T1DM).
- The retention rate was acceptable (69% at T2 and 77% at T3). The motivation for continued participation was the chance to receive feedback about physical activity level.
- Home-visits were considered the best method for questionnaire distribution and completion. Questionnaires had low perceived burden for children and parents.
- Outcome measures were able to detect change in self-efficacy for physical activity and self-reported physical activity.
- The STAK-D programme components were implemented successfully and evaluated positively.
- There was low attendance at group activity sessions, but the sessions received positive evaluation. More stringent ground rules for blood glucose testing were required during the session.
- Adherence to the intervention was dependent on the i) the child's enjoyment of physical activities and the intervention content and ii) family engagement with the resources and commitment to the research.
- Potential benefits of the STAK-D programme perceived by parents were; i) increased awareness of child's physical activity, ii) increased knowledge and understanding of physical activity and iii) family-oriented physical activity promotion.
- No adverse events of the STAK programme were reported.

Box 6 Summary the findings from Chapter 7

Implications for a future definitive trial

The implications for a future definitive trial as discussed in Chapter 7 can be summarised as follows:

- A pragmatic cluster-randomised controlled trial may facilitate recruitment and engagement (see Chapter 7, Section 7.9.3 for explanation).
- Enlisting the support of HCPs from recruitment clinics may help promote and endorse the research at clinic level.
- Group activity sessions scheduled to coincide with clinic appointments may promote accessibility.
- Applying 'ground rules' during group activity sessions may promote diabetes management behaviours that meet clinic expectations.
- Identifying parental concerns about physical activity at the outset and encouraging parental involvement with the intervention may enhance its successful implementation.
- Providing family members with pedometers may encourage family involvement.
- Using physical activity data from the accelerometer as an intervention tool may facilitate education around blood glucose control in relation to physical activity.
- Accelerometer data may also provide feedback and incentive for ongoing engagement with the research.
- Implementing physical activity maintenance strategies may promote ongoing physical activity.

Box 6 *continued* Implications of the findings from Chapter 7

8.5 Wider implications of the thesis findings

This section discusses the practical implications of the thesis findings to; i) knowledge and understanding of physical activity for children with T1DM, ii) future research, and iii) clinical practice.

8.5.1 *Implications of the findings for knowledge and understanding*

This research is one of the first to explore psychological constructs in relation to physical activity among children with T1DM. The findings have been essential in developing a theoretical understanding of the behaviour and identifying the likely process of behaviour change (Craig et al., 2008). The findings support observations from other domains of T1DM research that suggest social cognitive constructs such as self-efficacy are a useful target for T1DM management interventions in children and adolescents (Iannotti et al., 2006 ; Murphy et al., 2006). The following section summarises the theoretical constructs that help inform and advance our understanding of physical activity among children with T1DM.

8.5.1.1 Enjoyment of physical activity

The findings from this thesis suggest that children's enjoyment of physical activity is crucial to their participation. The children interviewed in this research were encouraged by the belief that physical activity would be fun and enjoyable. Enjoyment is a well-founded psychological construct underpinning children's physical activity (DiLorenzo et al., 1998 ; Dishman et al., 2005 ; Pender et al., 2002 ; Robbins et al., 2004). Social cognitive theories can help explain the mechanisms behind the importance of enjoyment in children's physical activity. Theories such as SCT suggest that behaviour is more likely to occur if positive outcomes are expected (e.g., enjoyment) (Bandura, 2004). Enjoyment may reflect one's intrinsic motivation toward physical activity as it relates to positive feelings such as fun (Deci and Ryan, 2000). Intrinsic motivation is driven by an innate need for competence and autonomy (Deci and Ryan, 2000). When physical activity is motivated intrinsically, children are rewarded with feelings of enjoyment. Thus, interventions such as Jago et al.'s (2014a) Action 3:30 and the STAK programme which aim to foster children's feelings of self-efficacy (or competence), autonomy and relatedness are intrinsically rewarding and serve to maintain or increase children's intrinsic motivation for physical activity. In turn, self-efficacy and self-determined motivation for physical activity can promote subsequent participation (Dishman et al., 2005) and perseverance in the face of barriers (Bandura, 2004).

With a better theoretical understanding of the mechanisms underpinning children's behaviour, researchers and policy-makers are in a better position to implement strategies to help change behaviour. The findings from this thesis suggest that encouraging children with T1DM to choose physical activities they enjoy has the potential to promote physical activity via constructs such as intrinsic motivation and self-efficacy.

8.5.1.2 Overcoming potential barriers to physical activity

In the Introduction of this thesis, potential challenges associated with physical activity for children with T1DM were proposed. Thesis findings supported the suggestion that diabetes management is demanding around times of physical activity, especially activity that is sporadic or unplanned. Parents and HCPs described how children's participation in regular physical activity requires frequent blood glucose testing and the careful monitoring of diet and insulin and is often associated with ongoing worry about exercise-induced hypoglycaemia. In contrast, the children interviewed in this research did not demonstrate the same level of concern about diabetes-related barriers to physical activity, but they did believe that sedentary behaviours such as television can distract them from being physically active.

Interventions may help children overcome barriers to physical activity by targeting cognitions about physical activity. Bandura's health promotion model suggested that self-efficacy influences behaviour indirectly via perceived barriers (Bandura, 2004). Thus, promoting self-efficacy for physical activity among children with T1DM has the potential to encourage perseverance in the face of barriers (e.g., hypoglycaemia or sedentary alternatives) (Bandura, 2004). This research has outlined the STAK-D programme as one way of providing children with T1DM experience in successfully enacting physical activity which may help towards overcoming barriers.

8.5.1.3 Social support as a facilitator to physical activity

The findings from this thesis have demonstrated that children's physical activity depends on support from parents, friends, school teachers and the diabetes healthcare team. The social environment consistently emerged as the most significant factor around which children constructed the meaning of physical activity and was also perceived by parents and HCPs as essential to children's positive experience of physical activity. Thus, understanding physical activity among children with T1DM requires recognition of the dynamic interplay of socially supportive influences. This section focuses on the influence of social engagement with friends and the role of parents.

8.5.1.4 Social engagement with friends

Children's physical activity participation was motivated by friendships and social interaction. This mirrors findings from children without diabetes; e.g. friends can provide the support for children to initiate and maintain physical activity (Jago et al., 2009). Social cognitive theories of behaviour change can help us understand the importance of social engagement in children's physical activity. The importance of friends in children's experience of physical activity satisfies the psychological drive of relatedness, which refers to feeling connected with or supported by significant others in the environment (Deci and Ryan, 2000). Being active with friends is also likely to build a sense of autonomy to engage in independent physical activity (Jago et al., 2009). According to SCT, friends can be important role models of active behaviour and children learn from their friends via vicarious experience and social persuasion (Bandura, 1986). According to Bandura's health promotion model, if children expect physical activity to consist of social engagement and value this outcome, they are more likely to be physically active (Bandura, 2004).

The NICE guidelines for behaviour change interventions (NICE, 2007a) concluded that interventions were more effective at changing behaviour if they targeted variables at the individual and community level. The findings from the current research suggest that targeting existing social groups in the promotion of physical activity among children with T1DM may serve as a catalyst for increased activity and long-term health. Social support is multidimensional and a child's peers may exert a different form of social support to a child's parents.

8.5.1.5 The role of parents in the management and promotion of physical activity

The findings from this thesis highlight that parental support may be particularly relevant to children aged 9-11 years with T1DM. The findings suggest that parents are important role models and encouragers of their child's participation in physical activity, which supports previous research in children without diabetes (Edwardson and Gorely, 2010). Yet parents of children with T1DM require skill and competence to manage their child's blood glucose levels and must overcome barriers such as concerns about hypoglycaemia.

The findings from the feasibility study suggested that the STAK-D programme may be beneficial for parents through educating them about physical activity, reinforcing what they already know about physical activity, raising awareness of their child's physical activity and helping them recognise how physical activity effects blood glucose levels. According to SCT, parents who believe they can control their child's blood glucose level during and after physical activity, should be better able to persevere and succeed in the face of barriers (Bandura, 2001). Research has demonstrated that parental self-efficacy for diabetes management is associated with diabetes outcomes (Streisand et al., 2005). To the researcher's knowledge, no research in the T1DM literature has explored parental self-efficacy that is specific to their child's participation in physical activity. It is theoretically plausible that a relationship may exist between parental self-efficacy and children's physical activity and further research is required to explore this assumption.

Given the importance of parents in children's diabetes management, interventions to promote active lifestyles among children with T1DM should take into consideration parental involvement and influence. Targeting parents in interventions has helped diabetes-related family conflict and parental stress (Doherty et al., 2013) and has the potential to help promote children's physical activity (Bentley et al., 2012 ; Jago et al., 2013c).

Summary of implications to knowledge and understanding

The implications of findings from this thesis to our knowledge and understanding of physical activity among children with T1DM can be summarised as follows:

- Promoting self-efficacy for physical activity among children with T1DM has the potential to encourage perseverance in the face of barriers to a physically active lifestyle.
- Encouraging children with T1DM to choose physical activities that they enjoy has the potential to promote intrinsic motivation, autonomy, self-efficacy for physical activity and positive outcome expectations.
- Parents, teachers, peers and HCPs are key influential figures in children's social environment who can promote or hinder children's participation in physical activity.
- Parental support for physical activity might be particularly relevant to children aged 9-11 years with T1DM and may be dependent on parents having the self-efficacy to manage their child's diabetes in relation to the activity.

Box 7 Summary of implications to our knowledge and understanding of physical activity among children with T1DM

The implications of the thesis findings could be used to help plan and implement future research or physical activity promotion strategies for children with T1DM.

8.5.2 Implications of the findings for future research

The implications of the findings for future research have been discussed within each chapter of this thesis. The main implications are discussed below and relate to how further research might continue to explore the role of key influential figures in children's social environment.

8.5.2.1 How the influence of parents changes over time

The current research primarily explored the physical activity experience of pre-adolescent children. Parents of pre-adolescent children with T1DM are generally the primary caregiver and responsible for their child's diabetes management and behaviours.

Consistent with this, parents were identified as key influential figures in children's physical activity and important targets in attempts to promote physical activity in this population. The parental role in physical activity among children with T1DM is likely to change as children age and become more responsible for their diabetes management (Iannotti et al., 2006). Research is warranted in an older age group of children with T1DM to explore parental influence on physical activity. Longitudinal research may be useful to demonstrate change in parental influence over time and useful insights may be gleaned from exploring how children's perceptions of parental support change over time.

8.5.2.2 The role and influence of fathers

This study did not look at gender differences in parental influence on physical activity participation in detail and fathers were underrepresented in the research. Fathers may have a unique influence on children's diabetes management (Seiffge-Krenke, 2002) and participation in physical activity (e.g., father-son modelling of physical activity; Yao and Rhodes (2015)) and their role could be investigated further. Future research may wish give particular attention to the recruitment of fathers (Jago et al., 2014b ; Seiffge-Krenke, 2002) and uncover fathers' perceptions of physical activity for their children with T1DM.

8.5.2.3 The perceptions and role of the peer group

The findings in Chapters 3, 4 and 6 identified the peer group as influential in the physical activity of children with T1DM. This thesis did not explore peers' perceptions of physical activity for children with T1DM, yet peers may be an important group to target in attempts to promote physical activity among children with T1DM. Future research may wish to explore the role of peers to develop our understanding of how the peer group can be used to help encourage active lifestyles in this population.

8.5.2.4 The perceptions and role of physical activity supervisors

The current findings have suggested that personnel involved in the supervision of children's physical activity should have an understanding of T1DM, its complications and physical activity side-effects (e.g., hypoglycaemia). Further research could explore the perceptions of school teachers, physical education teachers, activity leaders and sports coaches. One recent study has explored the perceptions of school teachers with regards participation in physical education by children with T1DM in Scotland

(MacMillan et al., 2014a). This qualitative study by MacMillan and colleagues has been an important advance in our understanding of the support needs of children with T1DM when participating in physical activity in school. The findings highlighted the need for improved provision from schools and teachers to support children with T1DM to participate in school physical activity. Given that poor communication, limited diabetes knowledge and low teacher confidence to deal with diabetes were identified among school teachers in the schools studied (MacMillan et al., 2014a), further research is needed to explore whether these findings generalise to other areas and other roles such as activity leaders and sports coaches.

Summary of implications for future research

Future research may wish to explore:

- Change in parental influence on children's physical activity as children become older.
- Fathers' perceptions of physical activity and his role in children's physical activity.
- The perceptions and role of the peer group.
- The perceptions and role of physical activity supervisors.

Box 8 Summary of implications for future research

8.5.3 Implications of the findings for clinical practice

The findings from this thesis have also led to further consideration for education and practice in this area. The implications of the findings for clinical practice can be categorised into three areas; i) promoting physical activity as part of routine diabetes care, ii) promoting parental involvement and eliciting parental concerns, and iii) making diabetes education mandatory in the training physical activity supervisors.

8.5.3.1 Promoting physical activity as part of routine diabetes care

Healthcare professionals should be in a position to signpost parents and children to sources of information about physical activity participation. This would be especially relevant if barriers prevent HCPs from promoting physical activity during routine clinic appointments with their patients (e.g., lack of confidence, time constraints; Quirk et al. (2015)). Diabetes teams might benefit from having a staff member who is specifically trained in physical activity advice and guidance and who has the confidence to champion physical activity promotion within the clinic. This research has outlined one way of promoting physical activity among children with T1DM (e.g., the STAK-D programme).

8.5.3.2 Promoting parental involvement and eliciting parental concerns

For parents to feel efficacious to manage their child's blood glucose levels at times of physical activity, they will require skill, competence and confidence. Healthcare professionals should encourage parental involvement and provide relevant advice and guidance about managing diabetes around regular physical activity. This research has outlined one way of including parents in an intervention to promote physical activity among children with T1DM (e.g., via a parent's booklet). As children get older and assume more independent responsibility for diabetes management, it is reasonable to expect child self-efficacy and beliefs to increase in importance (Iannotti et al., 2006). Healthcare professionals might consider screening children and their parents for low self-efficacy to target those who may stand to benefit from interventions aimed at fostering higher levels of self-efficacy.

Children and parents may have different concerns around physical activity. HCPs should explore parental concerns as part of routine clinical practice because parental concerns have the potential to limit children's participation or encourage maladaptive behaviours. Uncovering these concerns could be beneficial for the collaborative relationship between child, parent and HCP, facilitating a mutual understanding and enabling individualised advice and guidance around physical activity participation to be delivered.

8.5.3.3 Making diabetes education mandatory in the training of physical activity supervisors

Parents often supervise and oversee their children's physical activity due to an unwillingness to transfer the responsibility onto others. This creates a paradox between encouraging children's independence and children's dependence on parents. To manage this paradox, children and their parents must trust that personnel involved in the supervision of children's physical activity are skilled, competent and confident to recognise and treat hypo- or hyperglycaemia. This may involve making diabetes education mandatory in the training of staff such as school teachers, extracurricular activity leaders, recreational club leaders and sports coaches.

Summary of implications for clinical practice

The implications of findings from this thesis to clinical practice can be summarised as follows:

- HCPs could explore children's and parents' concerns around physical activity as part of routine care.
- HCPs could screen for those children and parents who have low self-efficacy for physical activity management and thus target those who may benefit from intervention.
- HCPs should be able to signpost children and their parents to sources of advice and guidance about participation in physical activity.
- Personnel involved in the supervision of children's physical activities should be skilled and competent to recognise and manage hypo- or hyperglycaemia.

Box 9 Summary of the implications for clinical practice

8.6 Methodological considerations

The methodological considerations of each study were considered separately within each chapter. This section will highlight the general methodological limitations that should be considered when interpreting the findings.

The sample sizes in Chapters 5, 6 and 7 were small, albeit comparable to similar literature (Faulkner et al., 2010 ; Heyman et al., 2007 ; Ramalho et al., 2006) and sufficient to address the research aims of each study. There is a possibility that the samples recruited across the studies were particularly engaged with diabetes management behaviours and interested in physical activity. This self-selection bias has implications for future physical activity promotion strategies because the group of people who chose to be participants in this research may differ from the wider population of children and families with T1DM.

The strength of Chapter 3 and Chapter 4 was that parents and HCPs were recruited from across the UK, giving some geographical disparity to the viewpoints captured. The samples in Chapters 5, 6 and 7 were recruited from a single diabetes centre, meaning the findings could be subject to recruitment bias. There was also a disproportionate recruitment of White-British participants, although this reflects wider demographic figures that show 86.4% of young people with T1DM in the East Midlands are of white ethnicity (The Royal College of Paediatrics and Child Health (RCPCH), 2015). Finally, as already discussed, the small number of fathers involved in this research meant that the perspective of fathers was largely unexamined.

These methodological considerations highlight challenges in recruitment. Recruitment strategies should be explored that achieve more diverse and representative samples. Further patient and public involvement (PPI) such as consultations with Young Person's Advisory Groups (YPAGs) might be advantageous to help broaden the appeal and frame the research message to be effective in recruiting a wide range of children and families. Representative samples are needed in the development of interventions to ensure that strategies are designed and tailored to meet the needs of the majority rather than a subset of the population represented in the research sample.

This thesis has demonstrated how careful consideration of factors known to promote behavioural change and adherence is important in the implementation of physical activity promotion strategies. A strength of the research is that it followed MRC guidelines for developing and evaluating complex interventions, however this framework does not specify *how* to select and apply theory to intervention development (Michie et al., 2005). The social cognitive approaches drawn upon in this thesis provided useful constructs to help further our understanding of physical activity for children with T1DM, and demonstrated how theories can be integrated to help explain and change behaviour. The Behavioural Change Wheel has been developed from a comprehensive synthesis of behavioural change frameworks and advocates the integration of theoretical constructs to help researchers and HCPs select and design interventions that more effectively target and change behaviours (Michie et al., 2011). Using an integrative tool such as this in the future may help our understanding and facilitate the translation of research into practice.

8.7 Final conclusions

The thesis has highlighted the need for physical activity guidance and promotion to be an integral part of the management of T1DM. It has identified that the promotion of physical activity among children with T1DM is complex and a range of factors are influential in changing and maintaining this behaviour. The thesis has contributed to the body of knowledge surrounding physical activity for children with T1DM. In particular, the studies have provided insight into the experience of physical activity for children with T1DM and have offered suggestions for future physical activity promotion strategies, further research and clinical practice. The thesis has demonstrated that the research processes and adapted STAK-D programme are feasible and acceptable among children and their families, and has offered recommendations to help optimise its delivery in a future definitive trial.

The findings from this thesis offer exciting avenues of future research, including a definitive trial to evaluate the efficacy and long-term effectiveness of the STAK-D programme for children with T1DM. The findings will continue to be disseminated among the research participants, academic and clinical audiences. Attempts to raise awareness of the importance of promoting physical activity among children with T1DM are ongoing. The findings from Chapter 3 and Chapter 4 have informed the development of an exercise booklet for patients in Nottingham Children's Hospital Paediatric Diabetes clinic. If the STAK-D programme is found to be effective in promoting self-efficacy for physical activity, it could be used in clinical practice to promote physical activity among children with T1DM.

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Appendices

Appendix 1: The STAK programme group activity session stations

The STAK group activity stations and areas of skill development

	Station	**Activity**	**Skill development**
1	Trampoline (trampette)	Continuous jumping on two legs or on leg	Balance, coordination
2	Ball catch	Throwing a ball against a wall and catching it on return at a distance from which the child feels able	Hand-eye coordination
3	Skipping	Skipping continuously with or without a rope	Balance, coordination
4	Xbox Kinect (Reflex Ridge)	The player stands on a moving platform and is required to dodge left and right, duck and jump over hazards approaching them on the screen	Balance, coordination, reaction time, agility
5	Hopscotch	Hopping up and down a hopscotch mat as fast as the child feels able	Balance, power, speed
6	Wii Fit (Hula Hoop)	Rotating hips on a balance board as if using a hula hoop	Balance, coordination, agility
7	Step-ups	Stepping up and down on a box or bench as quick as the child feels able	Balance, coordination,
8	Swing ball	Batting the ball back to a volunteer	Hand-eye coordination, power, reaction
9	Rowing machine	Rowing on an exercise machine using distance as measurement	Coordination, power
10	Bridges/ crunches	Holding hips off the floor from lying position for as long as the child feels able or lifting shoulders off the floor repeatedly as many times as the child	Core strength
11	Exercise ball wall squats	Lowering and raising knees using exercise ball against a wall	Balance, power

Appendix 2: Systematic review included study details (Chapter 2)

General Information			Participants	Intervention Characteristics	Outcomes
Author (date) Country	**Type of Intervention**	**Study Design**	**Age/Sex/Number**	**Time/Activity/Frequency/Intensity**	**Outcome measures and key findings [a]**
Aouadi et al. (2011) Tunisia	Non-home based supervised aerobic activity	**Design:** NON-RCT: Controlled before and after study **Duration:** 24 weeks **Design/delivery:** Delivered by physical trainer	**Age:** mean (± SD) = 12.4 (± 1.5) **Sex:** M **Number:** 33(all T1DM) Int 1 (n=11)Int 2 (n=11)Cont (n=11)	**Intervention:** 10-15min warm-up, 45-50min aerobic activity (30-40min running/walking 10-min sports games in teams), 10-15min cool down. Progressive intensity – trained at 50-55% max HR during weeks 1-2, 55-60% in weeks 3-4, and 60-65% in weeks 5-24. Int 1: 2d/wk Int 2: 4d/wk Control: No training.	**Measures:** HbA1c, lipid profile (TG, HDL-c, LDL-c, TC). **Findings:** Within groups: 3months: Int 1 = ↓ TG Int 2 = ↑HDL-c, ↓ TG. Cont = not reported. 6months: Int 1 = ↑HDL-C, ↓ TG Int 2 = ↓LDL-c, ↑HDL-C, ↓ TG, ↓HbA1c. Between groups (Int 1 and Int 2): 3months: NS 6months: ↓LDL-c in Int 2Cont = not reported
Baevre et al. (1985) Norway	Non-home based supervised aerobic activity	**Design:** NON-RCT: Prospective cohort study **Duration:** 6 month (26 weeks) training period and 2wk intensive training programme **Design/delivery:** Delivered by physiotherapy students and supervised by physiotherapist and physician	**Age:** 16 ± 11/12 **Sex:** F (n = 5), M (n = 5) **Number:** 10	**Intervention:** Part 1 and 2 (1) 6 month training: 30-min various intermittent and continuous workloads. 2d/wk at intensity of 130bpm. (2) 2 week intensive physical training: 3 hour per day for 2 weeks. Running, swimming, ball games and gymnastics.	**Measures:** (1) GL, HbA1, TC, TG, aerobic work capacity, weight, DID. (2) GL, HbA1, ketone bodies, FFA, lactate, alanine, glucagon, growth hormone, cortisol, aerobic work capacity. Findings: (1) ↑weight, ↑aerobic work capacity (2) ↓GL, ↓ketone bodies

Campaigne et al., (1984) USA	Non-home based supervised aerobic activity	**Design:** RCT **Duration:** 12 weeks **Design/delivery:** Delivered by activity instructor.	**Age:** mean (± SD) = *Int:* 9 ± 0.47 *Cont:* 8.5 ± 0.57 **Sex:** M (n=12), F (n=7) **Number:** 19(all T1DM) Int (n=9)Cont (n=10)	**Intervention:** 30-min vigorous PA (e.g., running, games and movement to music). 3d/wk at intensity of = 160bpm. **Control:** No training.	**Measures:** peak VO_2, peak VE, peak HR, FBG, HbA1, calorie intake. **Findings:** Within groups: Int = ↑peak VO_2, ↓FBG, ↓HbA1 Cont = NS Between groups: ↓HbA1 and ↓FBG in Int
Dahl-Jorgensen et al. (1980) Norway	Combined supervised and home-based exercise (type unknown)	**Design:** NON-RCT: controlled before and after study **Duration:** 22 weeks **Design/delivery:** No details provided.	**Age:** *Int:* range 9-15 (mean 11) *Cont*: range 9-13 (mean 11) **Sex:** M F **Number:** 22 (all T1DM) Int (n=14) Cont (n=8)	**Intervention:** 60-min exercise 2d/wk and 'weekly home exercise experience'. **Control:** No training	**Measures:** HbA1, GL, urinary glucose, VO_2 max, DID. **Findings:** Within groups: Int = ↓HbA1 Cont = NS Between groups: NS
D'hooge et al. (2011) Belgium	Non-home based supervised aerobic & weight training	**Design**: RCT: double-blind **Duration**: 20 weeks **Design/delivery:** Delivered by physiotherapist	**Age:** range: 10-18 *Int:* mean 14.1 *Cont:* mean 13.2 **Sex:** M (n=7), F (n=9) **Number**: 16(all T1DM) Int (n= 8)Cont (n=8)	**Intervention:** 70-min exercise 2d/wk. 5-min warm-up. 30-min strength training. 30-min aerobic activity (e.g., cycling, running, swimming). 5-min cool down. Progressive intensity 60-75% max HR. Stationary equipment used for strength training, intensity calculated from 1rep max values. Individually prescribed. **Control**: Normal daily activity.	**Measures:** Body composition (e.g., WC, FM, FFM, BMI), peak VO_2, peak power, peak HR, physical fitness (PWC-170, 6min walk test, strength tests) HbA1c, GL, QOL, DID. **Findings:** Within groups: Int = ↓PWC-170, ↑upper and lower limb strength, ↑muscle fatigue score, ↑sit-to-stand score, ↑6min walk distance, ↓DID. Cont = NS Between groups: ↓ PWC-170 and ↓DID in Int. ↑ upper and lower limb strength, ↑ muscle fatigue score, ↑ sit-to-stand score and ↑ 6min walk distance score in Int

Faulkner, Michaliszyn & Hepworth (2010) [34]USA	Home-based unsupervised aerobic activity	**Design**: NON-RCT: prospective cohort study **Duration**: 16 weeks **Design/delivery:** Study personnel	**Age**: mean (± SD) = 14.2 (± 1.4) **Sex**: M (n=9), F (n=3) **Number**: 12	**Intervention:** Personalised exercise - aerobic activities (e.g., biking, dance revolution and walking), 60-min. Exercise 5d/wk at an intensity of 60-75% predicted HR. Split into smaller sessions of at least 10-min. Accelerometers worn during waking hours.Parent/guardian role model exercising 30-min/day, 5d/wk.	**Measures:** CV fitness, intervention adherence, exercise perceptions (perceived self-efficacy, perceived benefits of action, perceived barriers to action), PA, social support, diabetes QOL. **Findings:** ↑perception of family support following intervention, ↑ MVPA 60-min MVPA 45.5% of the time. More days of at least 60-min MVPA = ↑ in CV fitness
Heyman et al. (2007) France	Combined supervised/ unsupervised aerobic and resistance training	**Design:** RCT **Duration:** 26 weeks **Design/delivery:** No details provided.	**Age:** mean (± SD) = *Int:* 15.9 ± 1.5 *Cont:* 16.3 ± 1.2 **Sex:** F **Number:** 16(all T1DM) Int (n=9)Cont (n=7)	**Intervention:** One 2-hour supervised session and one 1-hour unsupervised session per week. Combined aerobic and strength exercises in approx. ratio 2:1 (incl. running, aerobic dance, step, football, basketball, volleyball, rock climbing, gymnastics, etc.). Progressive HR increase 80-90% HR reserve. **Control:** No training.	**Measures:** Body composition (e.g., height, weight, FM, FFM, BMI, WC), physical fitness (PWC-170), HbA1c, lipid profile (HDL-c, LDL-c, TC, TG, serum apolipoprotein), QOL, PA. **Findings:** Within groups**:** Int = ↑PA, ↑height, ↑weight, ↑FFM, ↓apolipoprotein B:apolipoprotein A ratio, ↑QOL ("satisfaction with diabetes" subscale). Cont = ↑height, ↑weight , ↑FM Between groups: ↑PA and ↑ FFM in Int
Huttunen et al. (1989) Finland	Non-home based supervised aerobic activity	**Design:** RCT: matched pairs **Duration:** 13 weeks **Design/delivery:** Delivered by physiotherapy students	**Age:** mean = 11.9 **Sex:** M (n=20), F (n=14) **Number:** 32(all T1DM) Int (n=16)Cont (n=16)	**Intervention:** 60-min aerobic activities 1d/wk (jogging, running, gymnastics and active games). HR at 150bpm for 45-min. Encouraged to engage in physical activities outside the sessions. **Control:** 60-min non-PA 1d/wk.	**Measures:** Peak VO_2, pedalling time, HbA1c, GL, urinary glucose. **Findings:** Within groups: Int = ↑VO_2, ↑pedalling time, ↑HbA1c Cont = NS Frequent pts = ↓age, ↓urinary glucose, ↓HbA1cBetween groups: NS

Landt et al. (1985) USA	Non-home based supervised aerobic activity	**Design:** RCT **Duration:** 12 weeks **Design/delivery:** No details provided	**Age:** mean (± SD) = *Int:* 16.1 ± 0.8 *Cont:* 15.9 ± 0.3 **Sex:** M F **Number:** 15(all T1DM) Int (n=9)Cont (n=6)	**Intervention:** 45-min aerobic exercise 3d/wk.10-min warm-up, 25-min movement to music, HR at =160bpm (80-85% max HR). 10-min cool down. **Control:** Normal daily activity.	**Measures:** HbA1, glucose utilisation rate, calorie intake, VO_2max, LBM. **Findings:** Within groups: Int = ↑glucose utilisation rate, ↑VO_2max.Between groups:Confirmed by analysis of covariance but not reported
Larsson et al. (1964a) Sweden	Non-home based supervised aerobic activity	**Design:** NON-RCT: Controlled before and after study with non-T1DM comparison group **Duration:** 22 weeks **Design/delivery:** Physical Education teacher	**Age:** T1DM mean = 16.3, non-T1DM mean = 16.5 **Sex:** M **Number:** 12Int (n = 6) Comp (n = 6)	**Intervention:** 60-mins 1d/wk; gymnastics, skiing, swimming, running. Stepwise increasing intensity. **Comparison: Non-T1DM** comparison group also completed training session.	**Measures:** Sub max HR, max HR, VO_2Max, PWC-170, heart volume, caloric intake, height, weight, glycosuria. **Findings:** Within groups: Int = ↑weight, ↓submaxHR, ↓maxHR, ↑VO_2max, ↑PWC-170, ↑heart volume Comp = ↓submaxHR, ↓maxHR, ↑VO_2max, ↑PWC-170, ↑heart volumeBetween groups: NS
Larsson et al. (1964b) Sweden	Non-home based supervised aerobic activity	**Design:** NON-RCT: Controlled before and after study with non-T1DM comparison group **Duration:** 22 weeks **Design/delivery:** Physical Education teacher	**Age:** T1DM mean = 16.3, non-T1DM mean = 16.5 **Sex:** M **Number:** 12Int (n = 6) Comp (n = 6)	**Intervention:** 60-mins 1d/wk; gymnastics, skiing, swimming, running. Stepwise increasing intensity. **Comparison: Non-T1DM** comparison group also completed training session.	**Measures:** TC, phospholipids, TG, FFA **Findings:** Within groups: Int = ↓TCComp = NSBetween groups: Not reported

Maggio et al. (2012) Switzerland	Non-home based supervised aerobic and weight-bearing activity	**Design**: RCT **Duration:** 39 weeks **Design/delivery:** Sessions supervised by 2 physical education teachers anda paediatrician	**Age:** mean (± SD) = 10.5 (± 2.5) **Sex:** M and F (1:1) **Number:** 59 (T1DM =27) (non-T1DM =32) PA T1DM (n=15) PA nonT1DM (n=15) Cont T1DM (n=12) Cont nonT1DM (n=17)	**Intervention:** 90-mins 2d/wk. 10-min warm-up; 10-min drop jump (height increasing from 20cm in first 3 months to 40cm in last 6 months); 60-min weight bearing exercises (e.g. rope skipping, jumping, ball games, gymnastics); 10-min cool down. First 8 weeks HR at least $140min^{-1}$. **Control:** No training.	**Measures:** Body composition (weight, height, BMI, LBM), BMD measures (total body, lumbar spine (LS2-LS4), right femoral neck and greater trochanter) and bone biochemical markers (OC, PINP, CTX, 25-OH-D). **Findings:** Within groups: PA T1DM and PA nonT1DM= ↑total body BMD, ↑ LS2-LS4 (lumbar spine) BMD Con T1DM = NS Con nonT1DM = NS Between groups: ↓25-OH-D and ↓CTX in PA groups ↑LS2-LS4 (lumbar spine) BMD, ↑ total body BMD and ↑ LBM in PA groups
Marrero, Fremion & Golden (1988) USA	Home-based unsupervised aerobic activity	**Design:** NON-RCT: Prospective cohort study **Duration:** 12 weeks **Design/delivery:** Developed by physical therapist. Delivered via videocassette.	**Age:** mean = 13.3 **Sex:** M (n=6), F (n=4) **Number:** 10Retrospective comparison group, matched by age, sex, insulin regimen, sedentary habits, HbA1 values (n=10)	**Intervention:** At least 3d/wk. 5-min warm-up; 30-min movement to music routine designed to keep HR above 160bpm; 10-min cool down. Specific exercise determined by participants' physical abilities and personal preferences.	**Measures: VO_2max, HbA1.** Findings: ↑VO_2max, ↓ HbA1 NS between Int and matched comparison group in pre-intervention HbA1 level. ↓ HbA1 in Int post-intervention but no change in HbA1 in matched comparison group during same time period
Michaliszyn & Faulkner (2010) USA	Home-based unsupervised aerobic activity	**Design**: NON-RCT: Prospective cohort study **Duration**: 16 weeks **Design/delivery:** Study personnel	**Age**: mean (± SD) = 14.4 (± 1.6) **Sex**: M (n=10), F (n=6) **Number**: 16	**Intervention:** Personalised aerobic activities (e.g., kickboxing, dance, walking), 60-min. 5 d/wk at intensity of 60-70% peak HR. Split into smaller sessions of at least 10-min. Accelerometers worn during waking hours. Parent/guardian role model exercising 30-min/day, 5d/wk.	**Measures:** Lipid profile (TC, HDL-c, LDL-c, TG), A1c, VO_2 peak, body composition (FM, FFM), PA (MVPA). **Findings:** Time spent in MVPA associated with; ↑FFM, ↑VO_2peak, ↓TC, ↓LDL-c, ↓TG, ↓HDL-c, ↓A1c Time spent sedentary associated with; ↓FFM, ↑TC, ↑LDL-c, ↑HDL-c, ↑TG

Mosher et al. (1998) USA	Non-home based supervised aerobic and strength activity	**Design:** NON-RCT: Controlled before and after study with non-T1DM comparison group **Duration:** 12 weeks **Design/delivery:** Study personnel	**Age:** mean (± SD) = T1DM - 17.2 (± 1.2) Non-T1DM Comp – 19.4 (± 1.3) **Sex:** M **Number:** 21Int (n = 10)Comp (n = 11)	**Intervention:** 3-min aerobic warm-up, 45-min circuit session: 5 x 3-min aerobic stations (running, rowing, cycling, stair climbing, arm and leg ergometer) at 75-85% maxHR, 1-min aerobic recovery period, 5 strength & callisthenic exercises (upper and lower body, abdominal, combo upper & lower body weight training) at least 40% of 1RM (upper body) and 50% of 1 RM (lower body), 5-min cool down, 3 d/wk. **Comparison:** Non-T1DM comparison group also participated in training sessions.	**Measures:** VO_2 max, upper and lower body strength, body composition (weight, skinfolds, % FM, LBM), plasma glucose, HbA1c, lipid profile (TC, LDL-c, HDL-c, TG). **Findings**: Within groups: Int = ↑VO_2 max, ↓FM, ↑LBM, ↑HDL-c, ↓LDL-c, ↑strength (bench press, leg extension, leg flexion, leg press, tricep extension, latissimus pull down, military press). Comp = ↑VO_2 max, ↓FM, ↑HDL-c, ↓LDL-c, ↑strength (leg press only) Between groups: ↓HbA1c, ↑latissimus pull down strength in Int ↑military press strength in Comp
Newton et al. (2009) New Zealand	Home-based unsupervised (unspecified) activity	**Design:** RCT **Duration**: 12 weeks **Design/Delivery**: study personnel	**Age:** mean (± SD) = 14.4 (± 2.37) **Sex** = M (n = 36), F (n = 42) **Number** = 78(all T1DM)Int (n= 40) (M = 20, F = 20)Cont = (n= 38) (M = 16, F = 22)	**Intervention:** Pedometer intervention with goal of 10,000 steps/day. Motivational text message 1 d/wk. **Control**: Standard care	**Measures:** PA (4-day step count and self-reported 7-day recall), HbA1c, BMI, BP, QOL, DID. **Findings**:Within groups:Int = NSCont = NSBetween groups: NS
Rowland et al. (1985) USA	Non-home based supervised aerobic activity	**Design:** NON-RCT: Prospective cohort study **Duration**: 12 weeks **Design/delivery:** No details provided.	**Age:** range= 9-14 **Sex**: M (n=7), F (n=7) **Number**: 14	**Intervention:** 60-min; 10-min stretching and calisthenics followed by run or walk on a track. First 2 weeks 20-min alternating 5-min walk/run, with progression to 30-min continuous running. 3d/wk at intensity of 60% HR reserve (160bpm) plus a post-exercise 15-min recreational swim 2d/wk. Control period: 12 weeks pre-training control period.	**Measures:** weight, VO_2 max, max respiratory quotient, maxHR, HbA1, FBG, urinary glucose. **Findings:** ↑VO_2max

Ruzic, Sporis & Matkovic, (2008) USA	Non-home based supervised aerobic activity	**Design:** NON-RCT: Prospective cohort study **Duration:** 2 weeks **Design/delivery:** Exercise physiologist and a kinesiology specialist	**Age:** mean (± SD) = 12.81 (± 2.14) **Sex:** M F **Number:** 20	**Intervention:** 3 d/wk (1.morning, 2.midday, 3.evening): 1) 60-min low intensity aerobic – up to 60% max HR 2) 120-min swimming or ball games 3) 60-min walk, skate or cycle Maintenance follow-up: 10 days and 2months post-camp	**Measures:** HbA1c, GL. **Findings:** 10days: ↓HbA1c 2months: ↑HbA1c ↓GL from day 1 to day 14 of camp Boys ↑HbA1c than girls at all time-points
Salem et al. (2010) Egypt	Non-home based supervised aerobic, flexibility and strength activities	**Design:** RCT **Duration:** 26 weeks **Design/delivery:** Designed by diabetologist, delivered by physiatrist	**Age:** mean (± SD) = 14.78 (± 2.31) **Sex:** M (n=75) and F (n=121) **Number:** 196 (all T1DM) Int 1 = 1d/wk (n=75)Int 2 = 3d/wk (n=73)Cont (n=48)148 completed	**Intervention:** 1) Aerobic cycling/treadmill 5 -min warm-up; 20-min aerobic training (target HR 65-85%); 5-min cool down. 2) Anaerobic, 1-2min interval training on treadmill at 85-95% HR. 3) 10-min leg strength using weight machines. 4) 10-min free strength & endurance. 5) 5-min flexibility. 6) 5-min co-ordination. 7) 10-min balance. Int 1: exercise 1d/wk Int 2: exercise 3d/wk **Control:** no training.	**Measures:** HbA1c, Body composition (e.g., BMI, WC, weight percentile, height), BP, lipid profile (HDL-c, TG, LDL-c, TC), DID. **Findings:** Within groups: Int 1 (1d/wk) = ↓weight percentile, ↓BMI, ↓WC, ↓DID, ↓HbA1c, ↓LDL-c, ↓TG, ↓TC, ↑HDL-c. Int 2 (3d/wk) = ↓weight percentile, ↓BMI, ↓WC, ↓diastolic BP, ↓DID, ↓HbA1c, ↓LDL-c, ↓TG, ↓TC, ↑HDL-c. Cont = ↑weight percentile Between groups: ↓BMI and ↓ HbA1c in Int 2
Seeger et al. (2011) Netherlands	Combined supervised/ unsupervised combination aerobic and anaerobic activity	**Design:** NON-RCT: Prospective cohort study **Duration:** 18 weeks **Design/delivery:** Athletic coach	**Age:** mean (± SD) = 10.9 (± 1.5) **Sex:** M (n=4), F (n=5) **Number:** 9 (2 dropouts)	**Intervention:** 1 of each session per week: Supervised session: 30-min interval running; 30-min group-based activities (e.g., ball games, sprint relay races, jumping, throwing, and stretching). Unsupervised session: 10-min warm-up; 30-min interval running; 10-min cool down.	**Measures:** Body composition (height, weight, BMI, WC), VO_2 max, time to exhaustion, maxHR, FMD, carotid artery wall thickness. **Findings:** ↑VO_2 max, ↑FMD

Sideravičiūtė et al. (2006a) Lithuania	Non-home based supervised aerobic activity	**Design:** NON-RCT: Controlled before and after study with non-T1DM comparison group **Duration:** 14 weeks **Design/delivery:** No details provided.	**Age:** range = 14-19 Mean±SD Non-T1DM = 16.9±0.24 T1DM = 17.0±0.36 **Sex:** F **Number:** 47Int (n= 19)Comp (n= 28)	**Intervention:** 45-min swimming session. 2d/wk. Intensity adjusted to keep pulse at 144-156bpm. **Comparison:** Non-T1DM comparison group also completed training session.	**Measures:** HbA1c, DID, HR, GL. **Findings:** Within groups: Int = ↓HbA1c, ↓short-acting insulin dose (but not total DID), ↓GL Comp = ↓GL Between groups: ↓GL in Int (at all time points)
Sideravičiūtė et al. (2006b) Lithuania	Non-home based supervised aerobic activity	**Design:** NON-RCT: Controlled before and after study with non-T1DM comparison group **Duration:** 14 weeks **Design/delivery:** No details provided	**Age:** range = 14-19 Mean±SD Non-T1DM = 16.9±0.24 T1DM = 17.0±0.36 **Sex:** F **Number:** 47Int (n= 19)Comp (n= 28)	**Intervention:** 45-min swimming. 2d/wk. Intensity adjusted to keep pulse at 144-156bpm. **Comparison:** Non-T1DM comparison group also completed training session.	**Measures:** Body composition (e.g., height, weight, FM, BMI), lipid profile (TC, LDL-c, HDL-c, TG), aerobic capacity. **Findings:** Within groups: (T1DM compared to Comp before and after training) Int = after training: ↑height, ↑weight, ↓FM, ↑BMI, ↑aerobic capacity Comp = after training: ↑height, ↑weight, ↓FM, ↑aerobic capacity, ↑HDL-c Between groups: Before training: ↑BMI, ↑FM, ↓LDL-c and ↓TC in Int After training: ↑BMI, ↑FM, ↑TG and ↓LDL-c in Int

Stratton et al. (1987) USA	Non-home based supervised aerobic activity – *compared with unsupervised*	**Design:** RCT **Duration:** 8 weeks **Design/delivery:** No details provided	**Age:** mean (± SD) = *Int:* 15.1 (± 1.2) *Cont:* 15.5 (± 0.9) **Sex:** M (n=8), F (n=8) **Number:** 16(all T1DM) Int (n=8)Cont (n=8)	**Intervention:** 30-45min exercise 3d/wk. 2 days aerobic activities such as jogging on treadmill. 1 day activity such as basketball, swimming or resistance machines. **Control:** Unsupervised control group given a recommended exercise programme (20-60min, 3-6 d/wk) and asked to exercise regularly.	**Measures:** Glycaemic control (FBG, HbA1c, glycosylated serum albumin, plasma albuin) body composition (skinfolds, height, weight), fitness (Bruce treadmill time, submaximal HR), DID, lipid profile (TC, TG, HDL-c). **Findings:** Within groups: Int = ↑ Bruce treadmill time, ↓submaximal HR, ↓glycosylated serum albumin Cont = NS Between groups: ↓Submaximal HR, ↓ glycosylated serum and ↓ DID in Int
Tunar et al. (2012) Turkey	Non-home based supervised flexibility activity	**Design:** RCT **Duration:** 12 weeks **Design/delivery:** Pilates instructor	**Age:** mean (± SD) = 14.2 (± 2.2) **Sex:** M F **Number:** 40 (9 dropped out)31(all T1DM)Int (n=17)Cont (n=14)	**Intervention:** 45-min Pilates classes, 3d/wk. **Control: Normal daily activity.**	**Measures:** HbA1c, lipid profile (TC, HDL-c, LDL-c, TG), DID, body composition (height, weight, BMI), sit and reach flexibility, vertical jump, Wingate anaerobic test **Findings:** Within groups: Int = ↑peak power, ↑mean power, ↑flexibility, ↑vertical jump height Cont = ↑HDL-c (unexplained) Between groups: Not analysed

Wong et al. (2011) Taiwan	Home-based unsupervised aerobic activity	**Design**: NON-RCT: Controlled before and after study **Duration**: 12 weeks **Design/delivery:** delivered via video compact disc	**Age:** mean (± SD) = 12.40 (± 2.07) **Sex:** M F **Number:** 32(all T1DM) Int (n=18)Cont (n=18)	**Intervention**: 5-min warm-up; 20-min aerobic exercises – movement to music (target = 40-60% of max HR); 5-min cool-down at least 3d/wk. Frequency and duration individualised. **Self-directed exercise group (SDXG)**: (n=5) **Control**: No training. **Maintenance follow-up:** 6, 9, 12 months	**Measures:** HbA1c, peak VO_2, perceived exertion. **Findings:** Within groups: NS Between groups: 9months: ↑ HbA1c in SDXG
Woo et al. (2010) Korea	Non-home based supervised aerobic activity	**Design**: NON-RCT: Controlled before and after study with non-T1DM comparison group **Duration**: 12 weeks **Design/delivery:** No details provided	**Age:** mean (± SD) Int: 11.21 (± 0.97) Comp: 11.90 (± 1.85) **Sex:** M **Number:** 20 Int (n=10)Comp (n=10)	**Intervention**: 5-min warm-up; treadmill aerobic activity i) 1-3 weeks at 45% of HRR per session ii) 4-12 weeks at 55% of HRR per session; 5-min cool down, 3d/wk. **Comparison:** Non-T1DM comparison group also completed training session.	**Measures:** Body composition (height, weight, BMI, body fat %, waist-hip ratio), BP (systolic and diastolic), HR, DID, Lipid profile (TC, HDL-c), HbA1c, VO_2 Max, ox-LDL, 8-hydroxy-2-deoxyguanosine (DNA damage), SOD, GPx. **Findings:** Within groups: Int = ↑ GPx, ↑ -hydroxy-2-deoxyguanosine, ↑ SOD Comp = ↑ GPx Between groups: ↑ HbA1c pre and post in Int ↑ DBP pre and post in Comp
TOTAL			**Participants = 756** **T1DM = 661** **Non-T1DM = 95**	**Received exercise intervention = 535**	

NOTES: [a]key findings are significant unless specified as non-significant (NS)

↑ = increased or improved; ↓ = decreased or deteriorated; A1c = Glycated haemoglobin; BMD = bone mass density; BMI = body mass index; BP = blood pressure; bpm = beats per minute; Cont = control group; Comp = comparison group; CV = cardiovascular; d/wk = days per week; DID = daily insulin dose; F = female; FBG = fasting blood glucose; FFA = Free fatty acids; FFM = fat-free mass; FM = fat mass; FMD = brachial artery flow-mediated dilation; GL = blood glucose; GPx = glutathione peroxidase; HbA1 = Glycated haemoglobin; HbA1c = Glycated haemoglobin; HDL-c = high density lipoprotein cholesterol; HR = heart rate; Int = Intervention group;

LBM = lean body mass; LDL-c = low density lipoprotein cholesterol; M = male; Max = maximum; min = minutes; MVPA = moderate-to-vigorous physical activity; n = number of participants; non-RCT = non-randomised controlled trial; NS = non-significant change; Ox-LDL = oxidised low density lipoprotein; PA = physical activity; Pts = participants; PWC = physical work capacity; PWC-170 = physical work capacity at heart rate of 170 beats/min; QOL = quality of life; RCT = randomised controlled trial; SOD = superoxide dismutase; T1DM = Type 1 diabetes mellitus; TC = total cholesterol; TG = triglycerides; VE = minute ventilation; VO_2 = oxygen uptake; VO_2 max/peak = maximal/peak oxygen uptake; WC = waist circumference.

Appendix 3: Research ethics committee approval form (Chapter 3 and 4)

30th January 2013

Medical School Research Ethics Committee
Division of Therapeutics & Molecular Medicine
D Floor, South Block
Queen's Medical Centre Nottingham
NG7 2UH

Tel: +44 (0) 115 8231063
Fax: +44 (0) 115 8231059

Dear Helen

Ethics Reference No: B10012013 SNMP
Study Title: Exploring physical activity participation in children with type 1 diabetes: perceptions of parents and healthcare professionals.
Lead Investigator: Dr Helen Quirk, PhD Student, School of Nursing, Midwifery and Physiotherapy.
Chief Investigators/Supervisors: Professor Cris Glazebrook, Professor of Health Psychology, Institute of Mental Health and Dr Holly Blake, Lecturer in Behavioural Sciences, School of Nursing Midwifery & Physiotherapy.
Duration of Study: 1/02/2013-31/01/2014 1yr **No of Subjects:** min of 20

Thank you for your letter dated 29th January 2013 responding to the issues raised by the committee and enclosing the following revised documents and notification of amendment no 1 dated 29/01/2013:

- Physical Activity Children TIDM: Ethics Committee Application Form version 2.0: 29/01/2013
- Physical Activity Children TIDM: Experiment protocol, Version 1.0: 29/01/2013
- Physical Activity Children TIDM: Participant Consent Form, Version 1.0: 29/01/2013
- Physical Activity Children TIDM: Participant Information Sheet– Parents, Version 2: 29/01/13
- Physical Activity Children TIDM: Participant Information Sheet – Professionals, Version 1:29/01/13
- Physical Activity Children TIDM: Telephone Interview Schedule-Parents, Version 1.0: 29/01/2013
- Physical Activity Children TIDM: Telephone Interview Schedule-Professionals, Version 1.0: 29/01/2013
- Physical Activity Children TIDM: In-person Interview Schedule- Parents, Version 1.0: 29/01/2013
- Physical Activity Children TIDM: In-person Interview Schedule – Professionals, Version 1.0: 29/01/2013
- Physical Activity Children TIDM: Poster, Version 1.0: 29/01/2013
- Amendment no 1: Parents participants will receive a thank you £20 Amazon voucher dated 29/01/013

These have been reviewed and are satisfactory and the study is approved.

Approval is given on the understanding that the Conditions of Approval set out below are followed.

Conditions of Approval

You must follow the protocol agreed and any changes to the protocol will require prior Ethics' Committee approval.This study is approved for the period of active recruitment requested. The Committee also provides a further 5 year approval for any necessary work to be performed on the study which may arise in the process of publication and peer review.

You promptly inform the Chairman of the Research Ethics Committee of

(i) Deviations from or changes to the protocol which are made to eliminate immediate hazards to the research subjects.

(ii) Any changes that increase the risk to subjects and/or affect significantly the conduct of the research.

(iii) All adverse drug reactions that are both serious and unexpected.

(iv) New information that may affect adversely the safety of the subjects or the conduct of the study.

(v) The attached End of Project Progress Report is completed and returned when the study has finished.

Yours sincerely

Dr Clodagh Dugdale
Chair, Nottingham University Medical School Research Ethics Committee

Appendix 4: Participant information sheet for parents (Chapter 3)

University of Nottingham, School of Nursing, Midwifery and Physiotherapy

Exploring physical activity participation in children with type 1 diabetes: perceptions of parents

Investigators:
Miss Helen Quirk, PhD researcher
Prof Cris Glazebrook, Professor of Health Psychology
Dr Holly Blake, Lecturer in Behavioural Sciences

Participant Information Sheet

You have been invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish to. Please ask the investigator, Helen Quirk, if there is anything that is not clear or if you would like more information. Take your time to decide whether you wish to take part or not. Thank you for your interest in this study.

Background

Physical activity can play an important role in the management of type 1 diabetes mellitus. The purpose of this research is to explore physical activity in children and adolescents with type 1 diabetes by inviting parents to talk about their perceptions of physical activity for the child with type 1 diabetes. Interviewees will be encouraged to talk about what helps their child to be physically active and what prevents it. We are also interested in parents' opinions on ways to increase activity. Findings from interviews will provide an understanding of the specific issues faced by children and families with type 1 diabetes and will generate ideas for developing an intervention to help children with type 1 diabetes keep active.

What does the study involve?

This research involves interviews with parents of children living with type 1 diabetes. Eligible participants will be invited to take part in an interview either in person or on the telephone with the lead investigator (Helen Quirk) at a mutually convenient time. The interview will last approximately 30-45minutes and the conversation will be recorded and then typed up for analysis. All identifiable data (e.g., your name) will be removed from the transcript. Data from these interviews will inform the modification and implementation of a physical activity intervention for children with type 1 diabetes.

Why have you been chosen?

Parents or carers of children with type 1 diabetes have been contacted for interview because we would like to learn more about physical activity in children living with type 1 diabetes. You have been chosen because you are a parent or carer of a child aged 7-13years who has lived with type 1 diabetes for at least 12months.

Do you have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part:

- Please keep this information sheet (you will also be sent an electronic version to save).
- Please sign the consent form.
- If you would like any further information please do not hesitate to contact Helen Quirk on ntxhq1@nottingham.ac.uk

If you decide to take part you are still free to withdraw at any time and without giving a reason.

What do I have to do?

All you have to do is arrange a convenient time and/or place to do the interview. Arrangements can be made with Helen Quirk by contacting ntxhq1@nottingham.ac.uk.

After the interview, you will be given a £20 voucher to thank you for your time.

What if something goes wrong?

If you have reason to complain about this study, complaints should be addressed in the first instance to: Prof. Cris Glazebrook, Professor of Health Psychology, Institute of Mental Health, Jubilee Campus, Triumph Road, Nottingham, NG8 1BB. Telephone 0115 823 0420. E-mail cris.glazebrook@nottingham.ac.uk. If this achieves no satisfactory outcome, you should contact the University of Nottingham Medical School Ethics Committee Secretary: Louise Sabir, Division of Therapeutics and Molecular Medicine, D Floor South Block, Queen's Medical Centre Campus, Nottingham University Hospitals, Queen's Medical Centre, Nottingham, NG7 2UH. Telephone 0115 8231063. E-mail louise.sabir@nottingham.ac.uk.

Will my taking part in this study be kept confidential?

In accordance with the current Data protection Act all information collected about you will be stored on a database which is password protected and strictly confidential. Any information about you will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research study?

Data from the interviews will be used to inform the modification and implementation of an existing physical activity intervention to children with type 1 diabetes. Data will also be written up and submitted to a peer review journal and presented as part of a PhD thesis.

Who is organising and funding the research?

The research is organised by the University of Nottingham and funded by the School of Nursing, Midwifery and Physiotherapy and the National Institute for Health Research (NIHR).

Who has reviewed the study?

This study has been reviewed and approved by the University of Nottingham Medical School Ethics Committee.

Contact for Further Information

If you would like to find out more about the study, please contact:
Helen Quirk, PhD student.
E-Mail: ntxhq1@nottingham.ac.uk

Thank you for your time.

Appendix 5: Interview guide for parents (Chapter 3)

Interview Guide: Parents

- General introduction
- Personal introduction
- Recap purpose of the study
- If it's ok with you I will turn the recorder on now and everything we talk about from now on will be recorded.

Start recording

Obtain verbal consent to participate on tape

1. **Background information**

I'll start by asking you about you some general questions about home-life and diabetes.

- Who is in the family home at the moment?
  - Prompt brothers/sisters
- How old is X ?
- When did X get diagnosed with diabetes?
- How is x managing the diabetes now?
  - Any recent problems?
- How does X get on in school?

2. **Physical activity in children with Type 1 Diabetes**

Next I am going to ask you about your child's participation in physical activity.

- What sorts of physical activities does X take part in?
  - Prompt in school
  - Prompt out of school
- How do you feel about the amount of physical activity you child has?
  - Prompt (if appropriate) why do feel your child should be more active?
- How does X feel about taking part in physical activities?
  - Prompt Is there anything he/she particularly enjoys?

    - Prompt Is there anything that he/she finds difficult?

- What helps your child to be physically active?
- What would help your child to be more active?

- If not already mentioned: how does diabetes influence his/her participation?
    - Prompt What about strenuous activities such as team sports or running?

3. Physical activity interventions

Have you had chance to look at any of the materials I sent you?

- Have you and your family ever done anything like this?
- What were your initial thoughts about the STAK programme?
- Can you imagine your child enjoying something like this?
- What specific parts did you like?
- What specific parts didn't you like?
- What problems can you imagine facing?
- How could this be made better for use in the home?
    - Prompt Ideas: photo-blogging, social media.

4. Demographic information

- What area of the country do you live?

5. Closing questions

- Is there anything you would like to add about your child's level of physical activity?
- When we have developed the intervention, would you be willing to look over the materials and provide some feedback?

6. Remuneration

We would like to offer you a £20 Amazon voucher to thank you for your time.

Thank you for your time.

Is there anything you would like to ask me before we finish?

END OF INTERVIEW

Appendix 6: Participant information sheet for healthcare professionals (Chapter 4)

University of Nottingham, School of Nursing, Midwifery and Physiotherapy

Exploring physical activity participation in children with type 1 diabetes: perceptions healthcare professionals

Investigators:
Miss Helen Quirk, PhD researcher
Prof Cris Glazebrook, Professor of Health Psychology
Dr Holly Blake, Lecturer in Behavioural Sciences

Participant Information Sheet

You have been invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish to. Please ask the investigator, Helen Quirk, if there is anything that is not clear or if you would like more information. Take your time to decide whether you wish to take part or not. Thank you for your interest in this study.

Background

Physical activity can play an important role in the management of type 1 diabetes mellitus. The purpose of this research is to explore physical activity in children and adolescents with type 1 diabetes by inviting healthcare professionals who specialise in paediatric type 1 diabetes to talk about their perceptions of physical activity for the child with type 1 diabetes. Interviewees will be encouraged to talk about what helps children and young people with diabetes to be physically active and what prevents it. We are also interested in professionals' opinions on ways to increase activity. Findings from interviews will provide an understanding of the specific issues faced by children and families with type 1 diabetes and will generate ideas for developing an intervention to help children with type 1 diabetes keep active.

What does the study involve?

This research involves interviews with healthcare professionals who specialise in type 1 diabetes. Eligible participants will be invited to take part in an interview either in person or on the telephone with an investigator (Helen Quirk) or a third year medical student from the University of Nottingham (Beatrice Dee) at a mutually convenient time. The interview will last approximately 30-45minutes and the conversation will be recorded and then typed up for analysis. All identifiable data (e.g., your name) will be removed from the transcript. Data from these interviews will inform the modification and implementation of a physical activity intervention for children with type 1 diabetes.

Why have you been chosen?

Healthcare professionals who specialise in type 1 diabetes have been contacted for interview because we would like to learn more about physical activity in children living with type 1 diabetes. You have been chosen because you currently or have previously specialised in paediatric type 1 diabetes.

Do you have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part:

- Please keep this information sheet (you will also be sent an electronic version to save).
- Please sign the consent form.
- If you would like any further information please do not hesitate to contact Helen Quirk on ntxhq1@nottingham.ac.uk

If you decide to take part you are still free to withdraw at any time and without giving a reason.

What do I have to do?

All you have to do is arrange a convenient time and/or place to do the interview. Arrangements can be made with Helen Quirk by contacting ntxhq1@nottingham.ac.uk.

What if something goes wrong?

If you have reason to complain about this study, complaints should be addressed in the first instance to: Prof. Cris Glazebrook, Professor of Health Psychology, Institute of Mental Health, Jubilee Campus, Triumph Road, Nottingham, NG8 1BB. Telephone 0115 823 0420. E-mail cris.glazebrook@nottingham.ac.uk. If this achieves no satisfactory outcome, you should contact the University of Nottingham Medical School Ethics Committee Secretary: Louise Sabir, Division of Therapeutics and Molecular Medicine, D Floor South Block, Queen's Medical Centre Campus, Nottingham University Hospitals, Queen's Medical Centre, Nottingham, NG7 2UH. Telephone 0115 8231063. E-mail louise.sabir@nottingham.ac.uk.

Will my taking part in this study be kept confidential?

In accordance with the current Data protection Act all information collected about you will be stored on a database which is password protected and strictly confidential. Any information about you will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research study?

Data from the interviews will be used to inform the modification and implementation of an existing physical activity intervention to children with type 1 diabetes. Data will also be written up and submitted to a peer review journal and presented as part of a PhD thesis.

Who is organising and funding the research?

The research is organised by the University of Nottingham and funded by the School of Nursing, Midwifery and Physiotherapy and the National Institute for Health Research (NIHR).

Who has reviewed the study?

This study has been reviewed and approved by the University of Nottingham Medical School Ethics Committee.

Contact for Further Information

If you would like to find out more about the study, please contact:
Helen Quirk, PhD student.
E-Mail: ntxhq1@nottingham.ac.uk

Thank you for your time.

Appendix 7: Interview guide for healthcare professionals (Chapter 4)

Exploring physical activity participation in children with type 1 diabetes; perceptions of healthcare professionals

Telephone Interview Schedule: Healthcare Professionals

1. **Introduction**

- General introduction
- Personal introduction
- Recap purpose of the study
- If it's ok with you I will turn the recorder on now and everything we talk about from now on will be recorded.

Start recording

Obtain verbal consent to participate on tape

2. **Demographic information**

- Would you mind if I asked you some questions about yourself first?
  - What is your professional role/job title?
  - What area of the country do you work?
  - How long have you been working with children who have type 1 diabetes?
  - What would a typical appointment with a child (and their family) look like?

3. **Physical activity in children with type 1 diabetes**

Next I am going to ask you about physical activity participation in children with type 1 diabetes.

- What sorts of physical activities do children with type 1 diabetes take part in?
  - Prompt in school
  - Prompt out of school
  - How do they feel about taking part in physical activities?
  - Prompt Is there anything they particularly enjoy?
  - Prompt Is there anything they find difficult?
- How much physical activity might a typical child with type 1 diabetes participate in?
  - Prompt How does this compare to children without diabetes?
  - Prompt How does age influence participation?
- What helps children with Type 1 Diabetes to be physically active?

    - How do you feel about the amount of physical activity they have?
    - Prompt (if appropriate) why do feel they should be more active?

- What would help them to be more active?
-
- How do you think diabetes affects participation in physical activities for children with type 1 diabetes?
    - Prompt What about strenuous activities such as team sports or running?

- How do families manage physical activity with the diabetes?

4. Physical activity interventions

Have you had chance to look at any of the materials I sent you?

- Have you ever seen or been involved in anything like this?
- What were your initial thoughts about the STAK programme?
- Can you imagine children enjoying something like this?
    - Prompt How about if we engaged siblings and peers too?
- What specific parts did you like?
- What specific parts didn't you like?
- What problems can you imagine a typical family with a diabetic child facing?
- How could this be made better for use in the home?
    - Prompt examples: web-site, photo-blogging, social media (if age-appropriate).

5. Closing questions

- Is there anything you would like to add about physical activity in children with type 1 diabetes?

- When we have developed the intervention, would you be willing to look over the materials and provide some feedback?

6. Thank you for your time.

Is there anything you would like to ask me before we finish?

END OF INTERVIEW

Appendix 8: NHS research ethics committee approval form (Chapters 5, 6 and 7)

NHS
Health Research Authority

NRES Committee East Midlands - Nottingham 1
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 8839695

17 March 2014

Dr Holly Blake
Lecturer
University of Nottingham
Division of Nursing
University of Nottingham,
Queen's Medical Centre, Nottingham
NG7 2HA

Dear Dr Blake

Study title:	**The feasibility of a physical activity intervention for children with Type 1 Diabetes Mellitus: Steps To Active Kids (STAK)**
REC reference:	**14/EM/0057**
Protocol number:	**14005**
IRAS project ID:	**132229**

Thank you for your letter of 28 February 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager, Miss Helen Wakefield, at nrescommittee.eastmidlands-nottingham1@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or athttp://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host

*organisations*Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter		17 January 2014
Evidence of insurance or indemnity	Henderson Corporate	31 July 2013
Investigator CV	Dr Holly Blake	
Letter from Sponsor	University of Nottingham	20 January 2014
Other: Investigator's CV (Student)	Helen Quirk	09 January 2014
Other: Expression of Interest Form	1.0	13 January 2014
Other: Reminder	1.0	13 January 2014
Other: Childrens' Interview/Focus Group Guide	1.0	13 January 2014
Other: Parents' Interview/Focus Group Guide	1.0	13 January 2014
Other: HCP/Volunteer Interview Guide	1.0	13 January 2014
Other: Poster	1.0	13 January 2014
Other: Parent Pack	1.1	26 February 2014
Other: STAK Diary	1.1	26 February 2014
Participant Consent Form: Participant Consent Form	1.0	13 January 2014
Participant Consent Form: Child Assent	1.1	26 February 2014
Participant Consent Form: Parents Consent Form	1.1	26 February 2014
Participant Information Sheet: HCP Volunteer Information Sheet	1.0	13 January 2014
Participant Information Sheet: Child Info Sheet	1.1	26 February 2014
Participant Information Sheet: Parent Info Sheet	1.1	26 February 2014
Protocol	1.0	13 January 2014
Questionnaire: CSAPPA Scale	1.0	13 January 2014
Questionnaire: Demographic Questionnaire	1.0	13 January 2014
Questionnaire: University of Virginia - Parent Low Blood Sugar Survey	Validated	
REC application	132229/553372/1/324	23 January 2014
Response to Request for Further Information	Letter	28 February 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research

Ethics Committees in the

UK.**After ethical review**

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

14/EM/0057 Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members'training days – see details athttp://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

pp 

Mr Robert Johnson
Chair

Email:nrescommittee.eastmidlands-nottingham1@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: Mr Paul Cartledge
Charlotte Davies, Nottingham University Hospitals NHS Trust

Appendix 9: Accelerometer instruction sheet for children (Chapter 5)

STAK
★ STEPS ★ TO ★ ACTIVE ★ KIDS ★

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Your Activity Monitor

The activity monitor is a small red box worn on your wrist and is used to monitor measure all the movements you do. We are asking you to wear the activity **all day every day for 7 days.**

You should not need to take it off, unless:

- You are getting **wet** (swimming, showering, etc).
- You are playing **very rough** contact sport (e.g. rugby, karate etc).

The activity monitor should be worn when you are sitting down (e.g. eating meals, doing homework, reading), as well as when you are moving around.

Don't forget to put the monitor back on whenever you take it off! Leave it somewhere you will see it. Maybe stick post-it notes up to help you remember!

How to wear it

You can wear the activity monitor **underneath or outside** your clothes.

The wristband should be worn like a watch.
It should be worn on the wrist you do **not** write with.

Activity log

Please write down whenever you remove the monitor and why.
The activity monitor does not properly measure activities such as cycling, skating and scootering. If you do activities like these whilst wearing the activity monitor, write down what activity you were doing, at what time and for how long.

Please look after the monitor

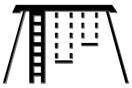
It is really important that you look after the activity monitor for us! If you leave it somewhere by accident, (e.g. at a friend's house) then please try to find it so that other children can use it after you. Don't worry if it gets lost or damaged, we won't tell you off, please just tell Helen what happened.

Appendix 10: Self-reported physical activity questionnaire (PAQ)

Physical Activity Questionnaire

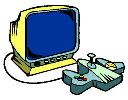
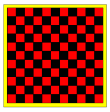
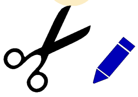
Section A. What did you do today before school?

Please circle to show whether you did the activity not at all **or** a little **or** a lot.

1. Bicycling		1 None	2 A little	3 A lot
2. Exercise: push-ups, sit-ups, weight training		1 None	2 A little	3 A lot
3. Climbing on playground equipment		1 None	2 A little	3 A lot
4. Team sports: football, netball		1 None	2 A little	3 A lot
5. Racket Sports: badminton, tennis		1 None	2 A little	3 A lot
6. Ball games: dodge ball, frisbee		1 None	2 A little	3 A lot
7. Games: chase, hopscotch		1 None	2 A little	3 A lot
8. Outdoor Play: climbing trees, hide & seek		1 None	2 A little	3 A lot
9. Swimming		1 None	2 A little	3 A lot
10. Skipping		1 None	2 A little	3 A lot

Please turn over

Before school

11. Dancing		1 None	2 A little	3 A lot
12. Walking		1 None	2 A little	3 A lot
13. Running		1 None	2 A little	3 A lot
14. Skateboarding / Skating		1 None	2 A little	3 A lot
15. Watch TV / DVDs		1 None	2 A little	3 A lot
16. Play Video Games		1 None	2 A little	3 A lot
17. Homework/Reading		1 None	2 A little	3 A lot
18. Play Board Games		1 None	2 A little	3 A lot
19. Housework		1 None	2 A little	3 A lot
20. Using phone		1 None	2 A little	3 A lot
21. On computer		1 None	2 A little	3 A lot
22. Arts and crafts		1 None	2 A little	3 A lot

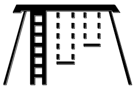
Before school

23. Other activity before school	?	1 None	2 A little	3 A lot

Activity: ______________________

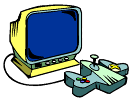
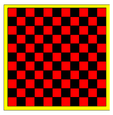
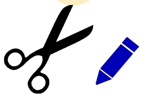
Please turn over

Section B. What activities did you do yesterday <u>after school</u> or the last day you were at school?

1. Bicycling		1 None	2 A little	3 A lot
2. Exercise: push-ups, sit-ups, weight training		1 None	2 A little	3 A lot
3. Climbing on playground equipment		1 None	2 A little	3 A lot
4. Team sports: football, netball		1 None	2 A little	3 A lot
5. Racket Sports: badminton, tennis		1 None	2 A little	3 A lot
6. Ball games: dodge ball, Frisbee		1 None	2 A little	3 A lot
7. Games: chase, hopscotch		1 None	2 A little	3 A lot
8. Outdoor Play: climbing trees, hide & seek		1 None	2 A little	3 A lot
9. Swimming:		1 None	2 A little	3 A lot
10. Skipping		1 None	2 A little	3 A lot
11. Dance		1 None	2 A little	3 A lot
12. Walking		1 None	2 A little	3 A lot

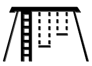
Please turn over

After school

13. Running		1 None	2 A little	3 A lot
14. Skateboarding / Skating		1 None	2 A little	3 A lot
15. Watch TV / DVDs		1 None	2 A little	3 A lot
16. Play Video Games		1 None	2 A little	3 A lot
17. Homework/Reading		1 None	2 A little	3 A lot
18. Play Board Games		1 None	2 A little	3 A lot
19. Housework		1 None	2 A little	3 A lot
20. Using phone		1 None	2 A little	3 A lot
21. On computer		1 None	2 A little	3 A lot
22. Arts and crafts		1 None	2 A little	3 A lot
23. Other activity after school Activity: ______________________	?	1 None	2 A little	3 A lot

Please turn over

Section C. What activities did you do <u>during school</u> yesterday or the last day you were at school?

1. Exercise: push-ups, sit-ups, weights		1 None	2 A little	3 A lot
2. Gymnastics: bars, beams, trampoline		1 None	2 A little	3 A lot
3. Team sports: football, netball		1 None	2 A little	3 A lot
4. Racket Sports: badminton, tennis		1 None	2 A little	3 A lot
5. Ball playing: frisbee, catch		1 None	2 A little	3 A lot
6. Games: chase, tag, hopscotch		1 None	2 A little	3 A lot
7. Climbing on playground equipment		1 None	2 A little	3 A lot
8. Skipping		1 None	2 A little	3 A lot
9. Dancing		1 None	2 A little	3 A lot
10. Walking		1 None	2 A little	3 A lot
11. Running		1 None	2 A little	3 A lot

Please turn over

During school

12. Other activity during school Activity: ______________________	?	1 None	2 A little	3 A lot

END OF QUESTIONS

Thank you for completing the Physical Activity Questionnaire!

Appendix 11: Participant information sheet for children (Chapters 5, 6 and 7)

The University of Nottingham

Nottingham University Hospitals NHS NHS Trust

Physical activity in children with Type 1 Diabetes study

Steps To Active Kids (STAK)

You have been invited to take part in a research study. Before you decide whether to take part, you need to understand why the research is being done and what it will involve. We will explain it all here.

Please read this information carefully and talk about it with your friends and family. Your parent/carer also has a copy of this information, so you can talk about it together.

Ask me (Helen) if there is anything you do not understand or if you would like to know anything else about the research study. Even if you say you want to take part now, you can change your mind at any time, and you don't have to give a reason.

What is research?

Research is used to find the answer to an important question. We try to answer the question by doing a research study.

What is this Steps to Active Kids (STAK) study about?

Sometimes children do not get enough physical activity and prefer to sit down and watch TV or play on computer games. Physical activity is about moving around and doing things that makes your heart beat faster and makes you out of breath, like riding your bike or doing PE in school. It is important for children to be active so that they grow up to be healthy adults.

In this study, we want to see whether a programme of physical activity called the Steps To Active Kids (STAK) programme can be used by children with Type 1

Diabetes. We also want to see whether children with Type 1 Diabetes enjoy the STAK programme.

The STAK programme is a 6 week physical activity programme for children aged 9, 10 and 11 years old. It involves weekly group activity sessions with other children and daily activities for you to do at home.

Why have you been chosen?

You have been chosen because you are aged between 9 and 11 and have had Type 1 Diabetes for at least 3 months.

We have also asked other children from your diabetes clinic, who are aged 9-11 to take part. You might get the chance to meet some of them if you decide to take part.

Do you have to take part?

No. It is up to you and your parent/carer to decide whether or not to take part. This leaflet tells you what happens if you do take part, but if you decide to say "no", nobody will be upset or unhappy with you.

If you do decide to take part:

- Talk about it with your parent/carer. They will have to agree that you can take part.
- Keep this information leaflet.
- You will be asked to sign a form which says you are happy to take part.
- Even if you say "yes" now, you can change your mind at any time, and you don't have to give a reason.

What do you have to do?

This study will last 6 months in total, from the very first time we meet you, to the very last time we see you.

If you agree to take part, we will look at some information that your clinic has about you, such as your height, weight, and HbA1c.

If you agree to take part, you will be in one of two groups, the group that takes part in the STAK programme or the group that carry on with their normal daily activities.

You will not be told which group you are in before agreeing to take part in this study. Whether you are in the STAK programme or the normal daily activity group will be decided at random (a bit like picking names out of a hat). You will be given an envelope that will tell you which group you are in, nobody knows which group you are in until you open your envelope.

If your envelope shows that you are not in the group that takes part in the STAK programme, we will ask you to carry on your daily activities as normal and meet you again in 6 months when you will be given an Activity Pack full of ideas to help you stay active.

If your envelope shows that you are in the group that takes part in the STAK programme then it is up to you and your parent/carer to decide whether you want to take part. If you decide that you do not want to take part, that’s OK, you can carry on with your daily activities as normal and we will contact you again in 6 months.

What happens in the STAK group?

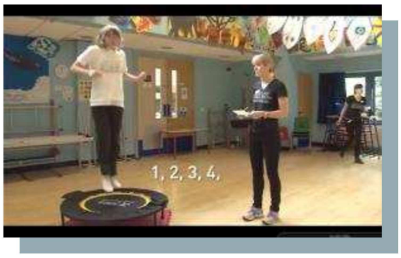
If you decide you do want to take part you will be invited to a group introduction session. At this session, you will meet other children and we will tell you more about the STAK programme.

We will give you a small activity monitor to wear for 1 week, it looks like this:

It can be worn on your wrist, like a watch or around your waist, and its job is to measure all the movement you make during the day. When you bring it back to us, we can see how active you have been over the week. After you have worn the activity monitor for one week, we will ask you to come to a group activity session.

Group activity sessions

These group activity sessions will be after school once every 1 or 2 weeks for 6 weeks. Each group session will last around 1 hour. Your parent/carer can stay, or they can drop you off and pick you up when you have finished.



At these sessions we will make sure everyone knows how to check and monitor their blood glucose levels. The activity leaders will be trained in how to manage Type 1 Diabetes and will make sure everything goes well.




At the group activity sessions you will be with at least 5 other children from your clinic. You might like to bring along a friend or brother/sister/cousin to this group activity session. But it's fine if you come along on your own because you may already know some of the other children, or you could make some new friends.

At these sessions you will take part in lots of different activities to music, such as swing ball, rowing machine, Wii Fit and Xbox Kinect.

STAK diary and Dance DVD for at home

We will give you a STAK Activity Diary to use when you are at home, in this you will be able to tell us about the activities you do each day. We will give you lots of ideas about how to keep active at home. We will also spend some time with you on your own to talk about physical activity and how you can set some of your own goals and targets for keeping active.

To help you keep active, we will also give you a dance DVD and videos of different types of exercises you can do with your family.

We will also give you a Step Counter, which counts the number of steps you take when you move about during the day.

The Step Counter will look a bit like this. It is yours to keep and you can

At the end of the 6 week STAK programme, we will measure your physical activity again with the activity monitor.

Focus groups

After the last group activity session, we will also invite you and the other children who took part to talk about what you liked and didn't like about STAK. This will be a group chat and you can talk as much or as little as you want. If you are happy with it, we will audio record this group discussion (on a Dictaphone) so that Helen can use the things we talk about in her research project.

What happens next?

We have asked your parent/carer to fill in the reply slip that came with this information pack. There is an envelope in the pack for you to send the reply slip back in. Sending back this reply slip does not mean you agree to take part in the study, it just means we can meet you to tell you more about it.

Reply slip and envelope

Nottingham University Hospitals NHS

Physical activity in children with Type 1 Diabetes study:
Steps To Active Kids (STAK)

Expression of Interest Form

Please tick the option that best describes you, fill in your details, and return the slip in the pre-paid envelope provided (no need for a stamp).

☐ We **are happy** to talk to Helen Quirk about the STAK programme.
Our next clinic appointment is on ……………
at this time: ……………

… are **not interested** in the STAK programme, but we are happy to fill in some questionnaires for Helen at our next clinic appointment.
Our next clinic appointment is on ……………
at this time: ……………

Parent's name …………… Child's name ……………
Address ……………
…………… Postcode ……………
Contact number HOME …………… MOBILE ……………
Email address ……………

☐ We are **not interested** in the STAK programme or questionnaires.
[Reason optional]

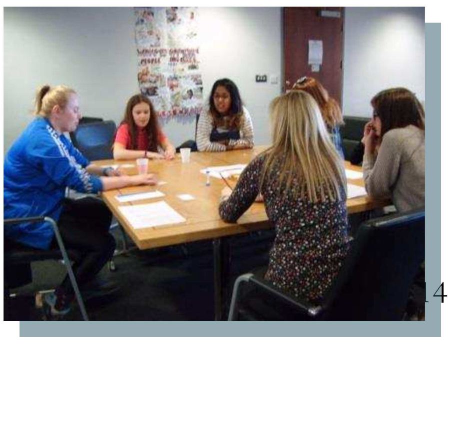
This reply slip will tell us when your next clinic appointment is, and we will arrange to meet you and your parent/carer there. If we can't see you in the clinic, then we can arrange to come and visit you at home.

When we meet you, we will ask you and your parent/carer to fill in a form which says you are both happy for you to take part in this study (called a Consent Form). We will then ask you to fill in some questionnaires about the activities you get up to and how you feel about being physically active. Your parent/carer will have some forms to fill in too. You can fill these in whilst you wait for your appointment. The forms will take around half an hour to complete, and there will be someone there to help you fill them in.

What happens at the end of the study?

Whether you are in the STAK programme group or not, we will meet you in 6 months and ask you to fill in some questionnaires again.

If you have not been in the STAK programme group, in 6 months' time we will give you the Activity Pack and a STAK Activity Diary, a dance DVD, a pedometer and a pack for your parent or carer too.



What if something goes wrong?

When you take part in physical activity, there is a chance that your blood glucose levels might go too low or too high. You should talk to your diabetes team about how to plan ahead and ask them how your body will respond to activity, because this can help stop anything going wrong. There will be lots of time to talk to your diabetes team if you want to find out more about being active before starting the STAK programme.

In the Activity Diary, there will be information about ways to help prevent blood glucose from going too high or too low, and what you can do if it happens. And at the group activity sessions there will be someone from your diabetes clinic there to help you.

It is unlikely that anything will go wrong during this study. But if you are unsure about anything, then please tell your parent/carer and Helen straight away.

Will it be fun?

Lots of children enjoy finding ways to keep active and we hope you will too!

Can you change your mind about taking part?

Yes. Taking part in this study is your choice and you can ask to leave the study at any time, and nobody will be unhappy with you. The treatment you get from your diabetes team will not be affected in any way.

Will your participation in the study be kept secret?

All information collected about you will be kept secret. But we might have to break this rule if we think that there is something important that puts you or someone else in danger.
You can discuss the study with friends and family, but when we speak to you and the other children at the end of the study (in the focus group), please do not discuss the conversation with others.

What will happen to the results of the research study?

The results from this study will tell us whether the STAK programme is helpful and enjoyable for children with Type 1 Diabetes. We hope the results will be very useful to help children with diabetes keep active.

Helen will also write about the results in her university research project and share her project with lots of different people who work at universities and hospitals. You and your family will be sent a leaflet explaining the results.

Contact for Further Information

If you would like to talk to me about the research, then please contact me:
Helen Quirk ntxhq1@nottingham.ac.uk

Thank you!

Appendix 12: Expression of interest form (Chapter 5, 6 and 7)

Physical activity in children with Type 1 Diabetes study:
Steps To Active Kids (STAK)

Expression of Interest Form

Please tick the option that best describes you and return the slip in the envelope provided.

☐ I **am** happy to talk to Helen Quirk about the STAK programme

My next clinic appointment is on ……………………………………………………

at this time: ……………………………………

☐ I am **not** interested in the STAK programme, but I am happy to fill in some questionnaires at my next clinic appointment.

My next clinic appointment is on ……………………………………………………

at this time: ……………………………………

Parent's name ……………………………………………… Child's name ……………………………………………

Address ………

……

…………………………………………………………………… Postcode ……………………………………………

Contact number HOME ………………………………………… MOBILE ……………………………………………

Email address ………………………………………………………………………………………………………

☐ I am **not** interested in the STAK programme.

[Optional]

……………………………………………………………………………………………………

……………………………………………………………………………………………………

Appendix 13: Children's self-perceptions of adequacy in and predilection for physical activity scale (CSAPPA)

REALLY TRUE for me	SORT OF TRUE for me				SORT OF TRUE for me	REALLY TRUE for me
☐	☐	Some kids can't wait to play active games after school.	BUT	Other kids would rather do something else.	☐	☐
☐	☐	Some kids really enjoy physical education class.	BUT	Other kids don't like physical education class.	☐	☐
☐	☐	Some kids don't like playing active games.	BUT	Other kids really like playing active games.	☐	☐
☐	☐	Some kids don't have much fun playing sports.	BUT	Other kids have a good time playing sports.	☐	☐
☐	☐	Some kids think physical education is the best class.	BUT	Other kids think physical education isn't much fun.	☐	☐
☐	☐	Some kids are good at active games.	BUT	Other kids find active games hard to play.	☐	☐
☐	☐	Some kids don't like playing sports.	BUT	Other kids really enjoy playing sports.	☐	☐
☐	☐	Some kids always hurt themselves when they play sports.	BUT	Other kids never hurt themselves playing sports.	☐	☐
☐	☐	Some kids like to play active games outside.	BUT	Other kids would rather read or play video games.	☐	☐

REALLY TRUE for me	SORT OF TRUE for me				SORT OF TRUE for me	REALLY TRUE for me
☐	☐	Some kids do well in most sports.	BUT	Other kids feel they aren’t good at sports.	☐	☐
☐	☐	Some kids learn to play active games easily.	BUT	Other kids find it hard learning to play active games.	☐	☐
☐	☐	Some kids think they are the best at sports.	BUT	Other kids think they aren’t good at sports.	☐	☐
☐	☐	Some kids find games in physical education hard to play.	BUT	Other kids are good at games in physical education.	☐	☐
☐	☐	Some kids like to watch games being played outside.	BUT	Other kids would rather play active games outside.	☐	☐
☐	☐	Some kids are among the last to be chosen for active games.	BUT	Other kids are usually picked to play first.	☐	☐
☐	☐	Some kids like to take it easy during recess.	BUT	Others kids would rather play active games.	☐	☐
☐	☐	Some kids have fun in physical education class.	BUT	Other kids would rather miss physical education class.	☐	☐
☐	☐	Some kids aren’t good enough for sports teams	BUT	Other kids do well on sports teams.	☐	☐
☐	☐	Some kids like to read or play quiet games.	BUT	Other kids like to play active games.	☐	☐
☐	☐	Some kids like to play active games outside on weekends.	BUT	Other kids like to relax and watch TV on weekends.	☐	☐

Appendix 14: Parents' demographic questionnaire

STAK
★STEPS★TO★ACTIVE★KIDS★

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Participant ID:

Date:

Physical activity in children with Type 1 Diabetes study

Demographic Questionnaire

About your child

Please complete the following information about your child by ticking the box or writing in the space.

- Date of birth ______________________ Age___________

Sex: Boy ☐ Girl ☐

- Ethnic background - please tick one:

White ☐ Black Caribbean ☐ Black African ☐

Black British ☐ Asian ☐ Mixed Race ☐

Other (please state)___________________________________

- Child's aged when diagnosed with Type 1 diabetes:

  ____

Please turn over

- Insulin delivery method:

Multiple daily insulin injections ☐ Twice daily insulin injections ☐

Insulin pump ☐ Insulin pen ☐

Other____

- Method of glucose monitoring:

Self-monitoring ☐ Continuous glucose monitoring system ☐

Other____

- Child lives with – please tick each that applies:

Mother ☐ Father ☐ Brother(s)/sister(s) How many? ☐ Other adult ☐

Please turn over

- Mother's occupation ______________________________

Brief description of role ______________________________

____

____

Not applicable ☐

Unemployed (homemaker, student) ☐ last main job ____________________

Retired ☐ last main job ____________________

Unpaid full-time carer ☐ last main job ____________________

Is/was the job employed ☐ or self-employed ☐

Is/was there formal responsibility for supervising the work of other employees?

Yes ☐ No ☐

- Mother's education level obtained:

  Left school before GCSE's/O-Levels ☐

  GCSE's/O-Levels or equivalent ☐

  A-Levels or equivalent ☐

  Degree ☐

  Postgraduate Qualification ☐

Please turn over

STAK ★ STEPS ★ TO ★ ACTIVE ★ KIDS ★

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

- Father's occupation ______________________________

Brief description of role ______________________________

____

____

Not applicable ☐

Unemployed (homemaker, student) ☐ last main job ______________

Retired ☐ last main job ______________

Unpaid full-time carer ☐ last main job ______________

Is/was the job employed ☐ or self-employed ☐

Is/was there formal responsibility for supervising the work of other employees?

Yes ☐ No ☐

- Father's education level obtained:

  Left school before GCSE's/O-Levels ☐

  GCSE's/O-Levels or equivalent ☐

  A-Levels or equivalent ☐

  Degree ☐

  Postgraduate Qualification ☐

END OF QUESTIONS

Appendix 15: Parental hypoglycaemia fear survey

Today's Date: __________________ Study ID #______

University of Virginia
Parent Low Blood Sugar Survey

This survey is intended to find out more about how low blood sugar makes people feel and behave. Please answer the following questions as frankly as possible.

I. Below is a list of things parents of children with diabetes sometimes DO IN ORDER TO AVOID LOW BLOOD SUGAR and related problems in their children. Read each item carefully. Circle one of the numbers that best describes YOU.

0 = NEVER 1 = RARELY 2 = SOMETIMES 3 = OFTEN 4 = ALMOST ALWAYS

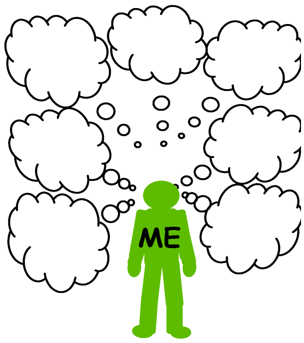
1.	Have my child eat large snacks at bedtime.	0	1	2	3	4
2.	Avoid having my child being alone when his/her sugar is likely to be low.	0	1	2	3	4
3.	Allow my child's blood sugar to be a little high to be on the safe side.	0	1	2	3	4
4.	Keep my child's sugar higher when he/she will be alone for awhile.	0	1	2	3	4
5.	Have my child eat something as soon as he/she feels the first sign of low blood sugar.	0	1	2	3	4
6.	Reduce my child's insulin when I think his/her sugar is too low.	0	1	2	3	4
7.	Keep my child's blood sugar higher when he/she plans to be away from me for awhile.	0	1	2	3	4
8.	Have my child carry fast-acting sugar.	0	1	2	3	4
9.	Have my child avoid a lot of exercise when I think his/her sugar is low.	0	1	2	3	4
10.	Check my child's sugar often when he/she plans to go on an outing.	0	1	2	3	4
11.	Get up in the middle of the night to check on my child or check my child's blood sugar levels.	0	1	2	3	4

II Worry: Below is a list of concerns parents of children with diabetes sometimes have. Read each item carefully. Circle one of the numbers that best describes HOW OFTEN YOU WORRY ABOUT EACH ITEM.

0 = NEVER 1 = RARELY 2 = SOMETIMES 3 = OFTEN 4 = ALMOST ALWAYS

12.	Child not recognizing/realizing that he/she is having a low.	0	1	2	3	4
13.	Child not having food, fruit, or juice with him/her.	0	1	2	3	4
14.	Child feeling dizzy or passing out in public.	0	1	2	3	4
15.	Child having a low while asleep.	0	1	2	3	4
16.	Child embarrassing self or friends/family in a social situation.	0	1	2	3	4
17.	Child having a low while alone.	0	1	2	3	4
18.	Child appearing to be "stupid" or clumsy.	0	1	2	3	4
19.	Child losing control of behavior due to low blood sugar.	0	1	2	3	4
20.	No one being around to help my child during a low.	0	1	2	3	4
21.	Child making a mistake or having an accident at school.	0	1	2	3	4
22.	Child getting a bad evaluation at school because of something that happens when his/her sugar is low.	0	1	2	3	4
23.	Child having seizures or convulsions.	0	1	2	3	4
24.	Child developing long term complications from frequent low blood sugar.	0	1	2	3	4
25.	Child feeling light-headed or faint.	0	1	2	3	4
26.	Child having a low.	0	1	2	3	4

Appendix 16: Interview guide for children (Chapter 6)



1 What does **being active** mean to you?

2 What **activities** do you do?

2.1 Prompt: sports/clubs/after school clubs

2.2 Prompt: in school/ out of school / in the holidays

2.3 Prompt: what do you do with friends/family.

3 What do you **like** about them?

3.1 Prompt: how do they make you feel?

3.1.1.1.1 Who are you active with?

3.1.1.1.2 What are you good at?

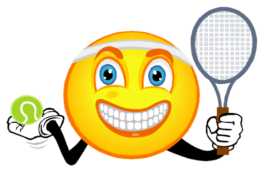
4 What do you **not like** about them?

4.1 Prompt: is anything difficult?

5 If you could do **ANYTHING**, what activities would you like to do?

5.1 Why?

5.2 Prompt: if appropriate, what stops you doing them now?



6 What **helps** you be active?

6.1 Prompt: do parents/teachers/siblings help?

6.1.1 Prompt: Facilities/equipment?

7 What makes it **harder** to be active?

7.1 Prompt: Can you think of anything that sometimes gets in the way of you being active?

7.2 Prompt: Does anything distract you?

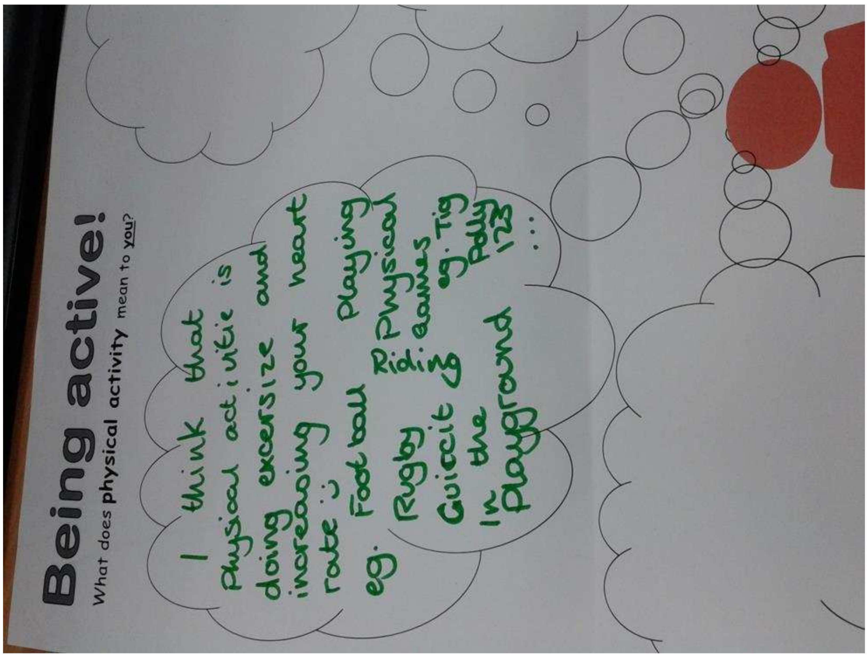
8 What does your **family think** about you doing physical activity?

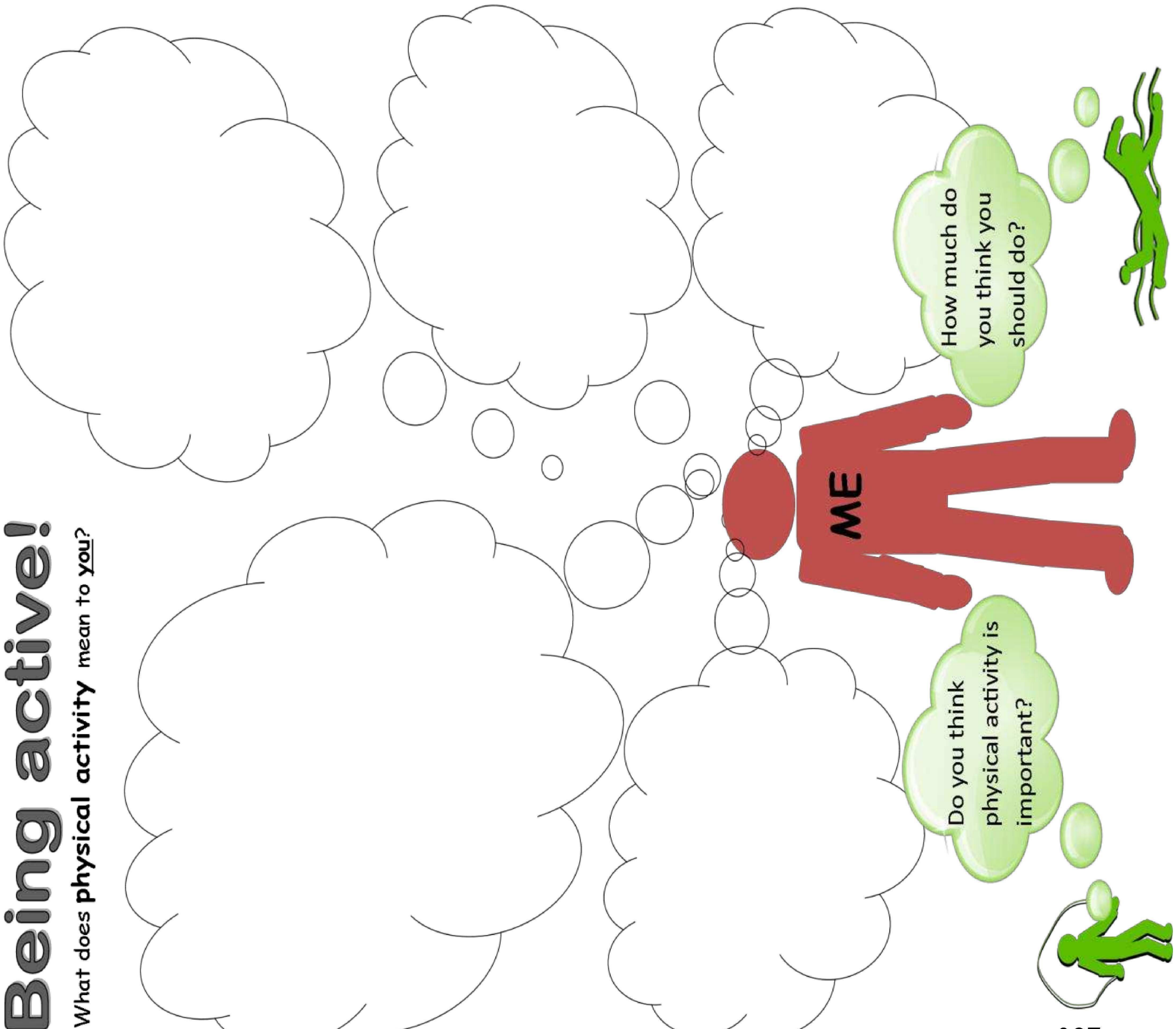
What's it like being active in **School?**

How do you your **teachers** help you to be active?

Is there **anything else** you'd like to say?

Appendix 17: Thought bubble sheet used in children's interviews (Chapter 6)





Appendix 18.1: Patient and Public Involvement activity

Formative research was carried out by the researcher in the early stages of the PhD process which informed the adaptations of the Steps To Active Kids (STAK) programme.

Adaptation of the original STAK programme

Formative research is exploratory and involves collecting evidence to help plan, design and implement the main body of research. This preliminary research can help inform recruitment and retention of study participants and determine measurement procedures and acceptability.

The original STAK programme has demonstrated effectiveness in promoting physical activity and improving self-efficacy in children aged 9-11 years (Glazebrook et al., 2011). Nevertheless, it cannot be assumed the same benefits will be observed among children with Type 1 Diabetes (T1DM).

Adaptations to the original STAK programme were informed by Patient and Public Involvement (PPI) research with a Young Person Advisory Group (YPAG), a child aged 9 years with T1DM, parents of children with T1DM, and healthcare professionals (HCPs) who specialise in paediatric diabetes.

Young Person's Advisory Group

Research in the early stages of the current PhD explored the perceptions of parents (Chapter 3) and HCPs (Chapter 4) and valuable insights were gained. It was important to hear the voices of children, which led the researcher to schedule a session with a Young Person's Advisory Group (YPAG). It was believed that would allow the researcher to take into account children's experiences, priorities and perspectives when making the adaptations to the STAK programme.

The National Institute for Health Research (NIHR) Medicines for Children Research Network (MCRN) Young Person's Advisory Group (YPAG) provides a forum for young people to learn about, and comment on, various aspects of research and clinical trials on medicines for children and young people. Membership of YPAG is open to any young person between the ages of 8-18 years who has some knowledge of taking medication, may be involved in a clinical trial, or has experience of using hospital services. Some young members, however, may not fit these inclusion criteria but may, e.g., have a personal ambition to study medicine. Sessions are held every 6-8 weeks to discuss research projects that involve children and young people. A meeting was arranged between the researcher and the MCRN YPAG East, based in Nottingham (UK). The researcher planned and was present at the YPAG meeting.

YPAG discussions

YPAG sharing group discussion points

STAK PowerPoint presentation given to the YPAG

Twelve young people (11 female, 1 male) aged 9 years (n=3), 10 years (n=1), 11 years (n=1), 12 years (n=2), 13 years (n=1), 15 years (n=2), 17 years (n=1) and 18 years (n=1) were present. The session was facilitated by three adults; two YPAG coordinators and the researcher. The session began with an introduction to T1DM. Children read the

Participant Information Sheet (PIS) and assent form and discussed the strengths and limitations, providing comments on content and format.

A PowerPoint Presentation delivered by the researcher described the STAK programme and research processes in more detail. After the presentation, the researcher had the opportunity to ask the group for their thoughts and opinions about the STAK-D programme for children with T1DM.

Positive evaluation of the STAK programme

When asked, 'What do you think about the STAK programme?', eight young people thought the study was "good" and said they would participate if given the opportunity. One 9-year-old explained that it was attractive because she likes, "*keeping fit and making new friends*". Six young people appraised it positively for its potential to help children; gain confidence, make friends, be more active, discover new activities, and experience independence from their parents.

Suggestions for implementation

The group liked the idea of children bringing a friend to the STAK-D group activity session. This was considered potentially beneficial if any children were feeling nervous at their first visit; *"I think it's a good idea yeh. Because otherwise it might be a bit daunting going to a session and doing sport and stuff that you might not be confident about with people you've never met"*[3]. A 17-year-old mentioned it could be parents who would worry more than the children:

> *I think you'd have more trouble getting the parents to agree because if they know their child has diabetes and they know the effects that exercise can have, then they might be more wary of it. But if you let them take other siblings who don't have diabetes I think they'd feel better about because then there would be someone they trust there.*

17-year-old

[3] All quotes and photographs were taken with child and parental consent.

One 12-year-old expressed that they would prefer to see boys and girls attending separate physical activity sessions, *"they might be embarrassed if they had to do it like boys and girls together. So maybe if you did like two different [groups]".* An 18-year-old said that finding a time of day for the STAK group activity session would be problematic, because children have homework to do after school during the week.

There was no consensus over the best location for the group activity session. When asked how young people would feel about attending the group activity sessions at the hospital, one 15-year-old said, "*it would be a bit tedious to come back to the place if you're here all the time [for clinic appointments]".* In contrast, another child said:

> *If you're coming to the clinic anyway, just coming back for classes wouldn't be too much of a problem and I think parents would encourage you to go because you can make friends and it would be good for your health as well.*

17-year-old

There was discussion around what music should be played at the group activity sessions. Some YPAG members suggested that children could pick the songs. Some suggested rhythmical music with no lyrics to keep everyone motivated. Current 'pop' music was favoured.

The YPAG shared opinions on the 5-a-day physical activity recommendation provided within the STAK diary. One 17-year-old believed that it would be "*a bit of a chore to do five. At first it would ok, you'd just think oh I'll just do a bit of the dance DVD, but then you get bored after a while*". Whereas a 15-year-old felt that a goal of 5-a-day was realistic, because you get some of your points in school, by running at playtime and walking home. The YPAG group valued children being given a choice of activities such as being able to choose an alternative option to the street dance DVD. Giving children the opportunity to choose activities they enjoy was considered potentially useful to help maintain children's engagement with the programme.

Implications from the YPAG session to the adaptation of the STAK programme

The YPAG decided that children should be invited to bring a friend or sibling to the STAK group activity sessions. The group believed that this would be beneficial because children and parents might be nervous or worried about the group activity session.

There was no consensus over the best timing and location of the group activity session. The group did not reach consensus about whether children with T1DM would find it convenient or tedious to attend group activity sessions in a hospital setting.

Suggestions were made for how to make the children's PIS and assent form more user-friendly to young people. Suggested changes involved making the information sheet into a booklet, adding more pictures, enlarging existing pictures, using more colours and using tick boxes on the assent form to enhance clarity.

Conclusion

This session with the YPAG was important for hearing children's perceptions of the STAK-D programme. Children's opinions and suggestions were considered when making changes to the STAK programme and when implementing the STAK-D programme among children with T1DM. Changes were made to the PIS and assent form to meet the suggestions from the YPAG.

Whilst the children in the YPAG were well-informed about chronic conditions and research processes, the views of children with T1DM would be more appropriate to obtain detailed information about the population for whom the intervention is developed for.

The researcher was unable to formally interview a sample of children with T1DM prior to the implementation of the intervention. As such, one child with T1DM was consulted in an informal discussion and pilot of the interview guide used in Chapter 6 of this thesis (Appendix 18.2).

Appendix 18.2 Patient and Public Involvement activity

The perceptions of a 9-year-old boy with Type 1 Diabetes

Prior to making adaptations to the original STAK programme, the researcher spoke to Charlie[4], a 9-year-old boy who had been diagnosed with T1DM for four years. The aim of this informal interview was to begin to explore the perceptions of physical activity from the perspective of the child. The purpose of this discussion was to uncover the potential facilitators and barriers the implementation of the STAK programme in this population.

Charlie described himself as an active child, describing his participation in a wide range of regular daily activities, such as; i) scootering to school, ii) running in the playground at school, iii) sports such as swimming and, iv) hobbies such as singing, dancing and acting. Charlie described his favourite activity as a dancing, singing and acting group that he attended for three hours every Saturday. When prompted (see Appendix 16 for interview guide), Charlie described enjoyment and making friends as his main motivations for participating in physical activity.

It was also apparent some underlying factors facilitated Charlie's participation in physical activity. These included; i) financial support from parents, ii) parental support and encouragement, iii) parental involvement and engagement, iv) parents (mother) training the dance instructors to recognise and treat hypoglycaemia, v) having a garden, vi) having equipment to play with or on, vii) active friends, and viii) friends who were supportive of his diabetes.

When Charlie described what made it difficult to be active, he explained that finding the activity difficult (i.e., competency, or lack of) had a negative influence on his enjoyment of the activity. Charlie also described it being more difficult to be physically active in the winter months, or when the weather was "terrible". Bad weather meant Charlies was more likely to spend time doing sedentary activities indoors such as watching television and reading.

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[4] Pseudonym

It was apparent that Charlie's participation in physical activity was dependent on his mother or father being present during the activity. And Charlie's mother, who contributed to the discussion, described how she found it difficult to trust that personnel involved in the supervision of Charlie's physical activities would adequately informed to recognise and treat hypoglycaemia should it occur. When describing an upcoming weekend away with his diabetes clinic, Charlie explained how he felt "nervous" about being away from his parents, concerned about his insulin pod falling off during outdoor activities and who/when it would get changed if his mother was not present.

Charlie's thoughts and opinions about the STAK programme

Charlie was shown the STAK resources and prompted to share his thoughts and opinions. Charlie was positive about the STAK programme. The specific elements of the STAK programme Charlie evaluated positively were:

- The pedometer: because he liked setting himself targets and trying to beat them.
- The activity diary and log: because he enjoyed reading, writing and learning about physical activity, e.g.; "*It would be good to know more. I would like to know more stuff about diabetes and stuff*" (Charlie).
- The activities: because it was important that the STAK programme involved activities Charlie already enjoyed, such as dancing.
- Other children: because making friends with other children and being active with them was important.
- Being active with other children with T1DM: because that "*might make me feel quite a lot better because they've got Type 1 diabetes and I'm not the only one there with Type 1 diabetes […] they've got the same problem as me*" (Charlie).
- Targeting children who are less active: "*probably more important for them that me […] because I'm active*".

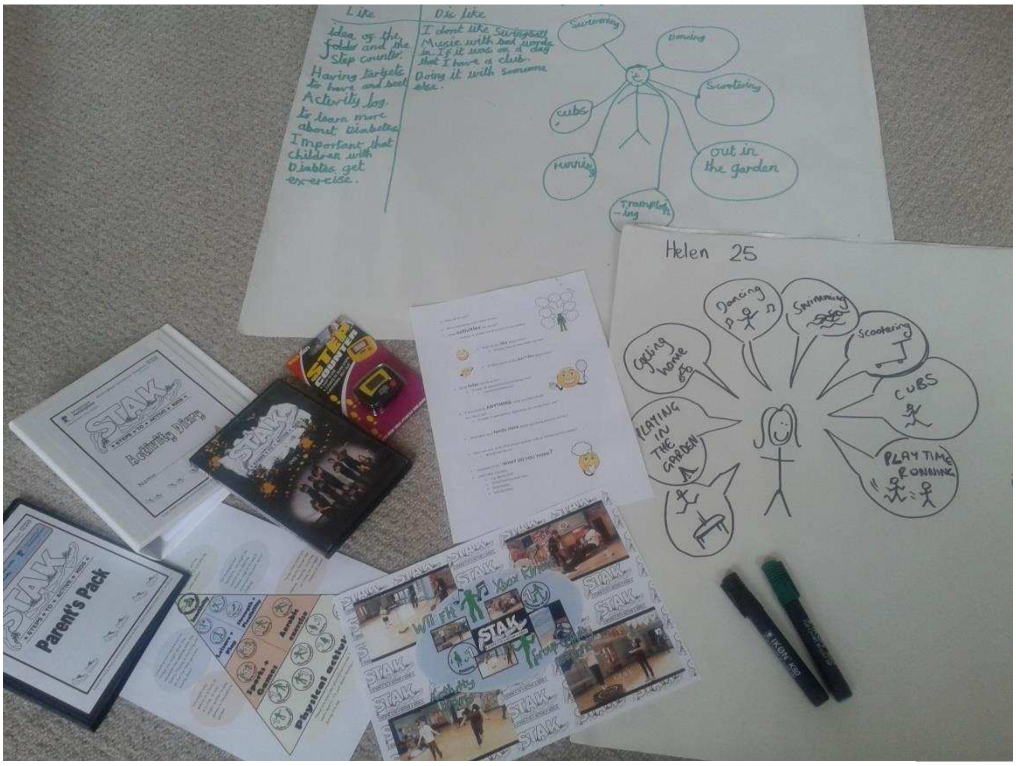
- Trained instructors: because it is important that activity instructors know about T1DM.

Charlie identified three main problems with the STAK programme:

- Finding a convenient time for the group physical activity session; a time when he was not already preoccupied with existing extra-curricular activities and hobbies.

- Undesirable activities: Charlie admitted that he did not like Swingball and he would only want to take part if it was activities he enjoyed.

- Activities alone: Although Charlie was positive about the group physical activity sessions, he was less enthusiastic about participating in the activity stations alone, suggesting that it would be more desirable to skip and trampoline with other children.



STAK materials and resources for discussion with Charlie

Conclusion

The discussion with Charlie was valuable to gain insight into the needs, values and desires of a child who has T1DM. It was apparent that Charlie was intrinsically motivated towards physical activity (e.g., fun and enjoyment) and dependent on his parents for physical activity opportunities. Charlie's thoughts and opinions about the STAK programme suggest that it is important; i) for children to find activities they enjoy, ii) that children want to be active with other children, iii) that children with T1DM might benefit from meeting other children with T1DM and iv) that finding a suitable time for the group activity session would be difficult.

Appendix 18.3 Patient and Public Involvement activity

Interviews with parents of children with Type 1 Diabetes

In Chapter 3, 20 parents of children with T1DM were interviewed. At the end of the interview, parents were invited to share their ideas and suggestions about physical activity programmes for children with T1DM and the STAK programme.

The majority (19/20) of the parents interviewed acknowledged the potential benefits of a physical activity promotion programme for children with T1DM. One parent stated that, "*anything that encourages children to be more active and not sit on, you know, on computer games and not in front of the TV etcetera, has got to be good*" *(Father of 7-year-old boy with 2 year diagnosis of T1DM*). When asked what they would like to see in a physical activity promotion programme, parents' desires could be organised into three main categories: i) peer and family support, ii) content of the programme and, iii) diabetes-specific factors.

Peer and family support

Fourteen parents described how social support, from peers and family, would be beneficial for children with T1DM. Social support consisted of; family involvement, existing friends, and meeting other children with T1DM. Seven parents wanted the programme to involve the whole family, and five parents said that involving a sibling would be beneficial. Four parents suggested involving the child's existing friends for reasons such as confidence-building and role models, but often, parents believed making new friends with children who have T1DM would be more beneficial. For example:

> *It's nice to have other children with the same problem as yourself maybe so you can see how they deal with it. And you know, to see that you're not on your own, you're not the only one who has to test their blood sugars before you set off […] gives you a bit of confidence.*

Mother of 9-year-old boy with 3 year diagnosis of T1DM

Content of the programme

Fifteen parents described features that they would like to see in a physical activity programme. For seven of the parents, fun and enjoyment were desirable. Seven parents described the need for a variety of activities, and two parents explained how giving the child choice over the activity would be important (i.e., autonomy-supportive). Parents also described how the programme should be "trendy", making use of modern technology such as iPod or mobile phone Apps, gadgets, internet and the latest crazes, such as Zumba.

Diabetes-specific factors: "for kids with diabetes, it does need some tailoring"

There was general agreement amongst parents that the STAK programme would need some adaptations to make it suitable for children with T1DM. The recommendations included; i) emphasis on the importance of monitoring, forming habits and developing routines (10/19), ii) personnel who were trained in T1DM (6/19), and iii) diabetes-specific information and educational elements of the programme (2/19).

Parents' thoughts about the STAK programme

Nineteen parents were positive about the STAK programme. Despite positive opinions, seven parents believed their child was already sufficient active, but could appreciate the potential benefits of the STAK programme for other less active children with T1DM. One parent believed that her daughter (aged 13) would like to supervise younger children with T1DM in an activity programme.

Reasons provided for the perceived usefulness of the STAK programme were its potential to:

- Promote physical activity in children who need more encouragement to be active.
- Facilitate the formation of physical activity habits and routines.
- Encourage a variety of activities in which there is no pressure to be skilled in sport or partake in long duration, high intensity exercise.

- Give children the chance to meet others with T1DM and for parents to meet other parents.

- Increase awareness of T1DM and educate children and families about physical activity.

Five parents expressed some concerns about the STAK programme. One mother believed that she might feel judged when questioned about her child's level of physical activity. One parent was concerned about the distance to travel to an activity session and finding the time in the family's busy schedule. Three parents were concerned about grouping children with T1DM together and "*labelling*" them.

Conclusions

Exploring the perceptions of parents was useful to help inform the adaptations to the STAK programme. It was concluded that parents perceived a need for physical activity support and promotion and the STAK programme was perceived as being potentially useful to implement among children in this population. It was anticipated that successful implementation of the STAK programme would be dependent on children's enjoyment of the activities, families having the time to dedicate to being involved, and social support networks facilitating their engagement with the activities, e.g. family and peer support.

Appendix 18.4 Patient and Public Involvement activity

Interviews with healthcare professionals

The eleven HCPs interviewed in Chapter 4 of this thesis were invited to share their views about the implementation of the STAK programme.

The need for a physical activity intervention

- Seven HCPs expressed the need for comprehensible resources to facilitate the promotion of regular physical activity in children with T1DM.
- Eight HCPs perceived a structured programme of physical activity to be a promising prospect for the promotion of physical activity in children with T1DM.
- All HCPs interviews spoke positively about the STAK programme's potential to be implemented in children with T1DM.

The potential benefits of the STAK programme

- The HCPs perceived the STAK programme to:
- Include fun and engaging activities; having a variety of activities was important.
- Be incorporated into daily routine without too much disruption to blood glucose control.
- Have the potential to promote physical activity routines and habits among children with T1DM.
- Have the potential to create social support networks for children with T1DM and their families.
- Encourage children to meet and interact with other children and feel a sense of belonging in a group.

- Be a potentially useful way to introduce the concept of physical activity to children and families with T1DM, particularly those who are insufficiently active, or for children who are newly diagnosed with T1DM, to build confidence to be physically active.

- Be a useful educational tool to inform families about physical activity, and the body's response to different physical activities.

- Have the potential to reassure parents that physical activity can be beneficial for diabetes control.

The table below shows quotes from the HCPs and their perceptions of the potential benefits of the STAK programme for children with T1DM

Quote	Potential benefit of the STAK programme
"this is brilliant because I think it will help with their diabetes control and motivation and just their general outlook on life" (*P11, Dietitian*).	Diabetes control General wellbeing
"I think something that is structured, something that is educational, motivational and practical is extremely good, erm for children as well as adults, so I think that could be definitely beneficial" (*P32, Dietitian*).	Educational Motivational
"most of them [activities] aren't high intensity activities, it won't have much effect on blood sugars anyway, so that might help to increase their confidence with exercise and about having problems with hypos" (*P09, Dietitian*)	Increase confidence Mastery experience
"opportunity to bond with other children" (*P09, Dietitian*)	Socialisation Meet others with T1DM
"What it might do is introduce the concept of exercise and being a bit more active ad then maybe they can look at their lifestyle and see how they can incorporate exercise into their	Education Promotion of physical activity

routine" (*P11, Consultant*)	
"My understanding of the STAK programme is targeting those children sort of end of primary school, just starting secondary school age, getting into the habit of exercise and particularly those children who wouldn't naturally be active, to break down the barriers and overcome their perceptions that activity is not for them" (*P16, Consultant*).	Promotion of physical activity habits Overcome barriers to physical activity
"it's about reassuring [the parents] that exercise is not going to be dangerous for their child erm it probably will be beneficial in terms of helping them to improve their diabetes control […] and potentially including the message that if you can get your children into the habit of exercising now, improving their diabetes control, you're setting them up for life" (*P16, Consultant*)	Reassure parents Diabetes control Promotion of physical activity habits
"I think it's good in giving them the message that you don't have to be a world class athlete to benefit from exercise […] just look at activity rather than exercise and start in small steps, so yeah, I'm hopeful that it'll work" (*P17, Specialist nurse*)	Education- benefit of exercise
"give people those skills to manage that activity and manage the blood glucose doing that" (*P30, Dietitian*)	Skill development Diabetes control
"good for socialisation and also feeling of belonging is important" (*P32, Dietitian*)	Socialisation Relatedness
"actually having a goal to do five different bits of exercise a day does sound like a new approach to doing it" (*P35, Dietitian*)	Goal-setting

"it does make a lot of sense for children who have T1DM to be involved in an exercise programme where the person running it knows how to manage their activity and can help them with knowing how to monitor and how to give extra glucose as and when needed and can really focus on perhaps giving more information about what's going on in their bodies during that exercise session, it sounds like a very positive thing" (*P35, Dietitian*).	Education Skill development

Perceived facilitators and barriers to the successful implementation of the STAK-D programme

HCPs discussed the factors believed to facilitate the implementation of the STAK programme and those they anticipated would be problematic in its implementation. These are summarised in the table below.

Facilitators	Barriers
Involving low cost home/indoor-based activities	Reluctant parents who will not engage with the programme
Having motivated and engaged parents and families	Lack of motivation in children and maintaining motivation in the long-term
Focusing on the family environment, including parents	Parents' concerns about safety
Introducing the programme close to diagnosis when families are most receptive to information	Sustaining engagement in physical activity in the long-term
The ability to reconceptualise what physical activity means to children and families	Participation in physical activity in the winter months
Bringing a friend to the group activity sessions for social support	Other family commitments
Having a component of the programme that is individualised to each child	Finding a suitable time to implement the STAK programme, especially in children with established diabetes
Having someone supervising physical activity sessions who can support and advise children and parents	It being perceived as a medical intervention
Continuity in delivery of the programme	Logistics – where the group activity

(i.e., same person delivering the whole programme)	sessions should take place, the time of day, the cost of activities for families
Variance in the activities delivered	Lack of support to keep children on track
Involving low cost home/indoor-based activities	Tediousness of filling in forms and diaries

Conclusion

Exploring the perceptions of HCPs was useful to help inform the adaptations to the STAK programme. It was concluded that HCPs valued the importance of promoting physical activity and perceived a structured programme to have a number of potential benefits for children with T1DM. There was a need for resources to help HCPs promote physical activity among children with T1DM and the STAK programme was perceived as being potentially useful to implement among children in this population. It was anticipated that successful implementation of the STAK programme would be dependent on children's social support networks facilitating their engagement with the activities, e.g. family support.

Overall conclusions from the formative research

In conclusion, the findings from the formative PPI work demonstrated:

- Support for the STAK programme and strong belief that it had the potential to benefit children with T1DM and their families. For example, the programme's potential to promote the importance of blood glucose monitoring, forming physical activity habits and developing routines.

- Adaptations would be needed to make the STAK programme suitable and safe for children with T1DM. For example, intervention deliverers who are trained in T1DM.

- Parents play and important part in children's diabetes and physical activity management and can have worries and concerns about their child's participation. Thus, carefully considered attempts should be made to engage parents with the STAK-D programme.

- Social support networks are key, therefore early attempt should be made to establish who the key supportive figures are for the child.

- There was agreement between groups that children should be allowed to bring a friend or sibling to the group activity session.

- Children value enjoyment and fun, therefore early attempt should made to establish what children like (or not) about physical activity and what motivates them to be active.

- There was no consensus over when the best time for the group activity session would be, with concern about whether families have the time to attend sessions.

- There was also a lack of agreement about whether children would be encouraged or discouraged from a diabetes-only group, with some concerns around stigma.

- There were doubts about whether activities would engage children in the long-term.

Adaptations to the STAK programme

Based on the conclusion drawn from this preliminary PPI work, the following adaptations were made to the STAK programme:

- Clinic-based recruitment (rather than school-based).

- Home-based and clinic-based implementation (rather than school-based).

- A parent's booklet to encourage parental involvement.

- Inviting a friend or sibling to group activity sessions to promote peer support.

- A measure of parental fear of hypoglycaemia.

- Additional information inserts in the STAK activity diary to educate children and parents about physical activity for children with T1DM.

- Implementation of the motivational interview at the beginning of the intervention to help establish children's motivations and values around physical activity, their perceived barriers and facilitators to physical activity and readiness to make changes to their level of participation.

Appendix 19: Post-intervention interview with children: interview guide

Steps To Active Kids (STAK) Programme: Feasibility Study
Qualitative Script: Acceptability, Desirability and Feasibility
Children

CONTROL AND INTERVENTION GROUP

- At the beginning we sent out an information pack about the study to your parents, do you remember whether they talked to you about it and did they ask you whether you wanted to participate?
- What did you think about the sound of the research/project?
- Do you remember completing the questionnaires?
    - Was there anything that was not so good about completing them?
- Do you remember wearing the activity monitor?
    - What did you think about it?
    - Why did you like / not like wearing it?
    - What do you think about having to wear it again?
    - *If appropriate*: Probe **why** participants are interested in finding out the results?
- Would you recommend this research to other children?
- Do you have any questions?

- **INTERVENTION GROUP ONLY**
- How much did you use the STAK programme?
- Did not use it / Used it a bit / Used it once a week / Used it every day

- What do you think about the STAK programme and the things included in it?
    - STAK diary
        - Did you read it / use it?
        - What was it telling you?
    - Dance DVDs
        - Did you look at the DVD?
    - Pedometer

        - Did you wear it?

    - Group sessions
        - Did you attend?
        - Probe why they did/did not attend (e.g. location, time)
        - What did you like about the group sessions (or idea of a group if they could not attend)?
            - Probe: other children – with diabetes/without diabetes
        - What did you not like about the group session?

- What did you think was particularly good about the STAK programme?
    - Content
    - Format

- How did it make you feel?
    - Probe perceived benefits

- What would you change about the STAK programme to make it better?
    - Content
    - Format (e.g. paper diary)

- Would you recommend this intervention to other children?
        - Yes No
        - Probe why? / how come?

Anything else you would like to say about this project or the STAK programme?

- Any questions?

- END OF INTERVIEW

Appendix 20: Post-intervention interview with parents: Interview guide

Steps To Active Kids (STAK) Programme: Feasibility Study
Qualitative Script: Acceptability, Desirability and Feasibility
<u>Parents</u>

**** RECEIVE (ongoing) CONSENT BEFORE STARTING THE INTERVIEW ****

- Do you understand why we want your feedback?
- Have you had the chance to ask any questions?
- Are you happy to go ahead with the interview?

CONTROL <u>AND</u> INTERVENTION GROUP

- What attracted you to taking part in this particular research study?
- What did you think about the recruitment process?
  - Receiving a letter at home
  - Meeting Helen in clinic/speaking to Helen about it
- Did you ever discuss the research with the diabetes team at the hospital?
  - If appropriate: Probe what/when it got discussed
- What did you think about us randomly putting your child into the group that got the STAK programme or the group that didn't (random allocation)
  - Were you happy with the group your child got put into?
- What did you think about filling in the questionnaires?
- What did ***you*** think about the accelerometer/activity monitor?
  - What did ***your child*** think about the accelerometer?
  - Why do you think they liked/did not like wearing it?

- *If appropriate*: Probe **why** participants are interested in finding out the results?

- Would you have liked to have been offered this STAK programme as part of your child's usual care? (advice and guidance around physical activity).

    - Yes No
    - Probe further: (if appropriate) At what stage after diagnosis would this have been useful?

- Do you think that this intervention that promotes and supports children's physical activity should be routinely offered to children when they are diagnosed with Type 1 Diabetes?

    - Yes No
    - Why?

- Is there anything else you would like to say about this research or the STAK programme?

- Do you have any questions?

- **INTERVENTION GROUP ONLY**

- How much did you and your child use the STAK programme?
    - How much of the information about physical activity did you already know?
    - Was there anything that prevented you engaging with the STAK programme or engaging in it as much as you would have liked?

- What is your opinion of the STAK programme and the things included in it?
    - STAK diary
        - Was it pitched right?
        - Did your child use it?

        - What about it did **you** like/not like?
        - What about it did **your child** like/not like?
    - Parents booklet
        - What messages do you think we were trying to give to children and their parents?
        - What about it did **you** like/not like?
        - What about it did **your child** like/not like?

    - Dance DVDs
        - Did you child look at the DVD?
        - What about it did **you** like/not like?
        - What about it did **your child** like/not like?
    - Pedometer
        - Did your child wear it?
        - What about it did **you** like/not like?
        - What about it did **your child** like/not like?
    - Group sessions
        - Did your child attend?
        - Probe why they did/did not attend (e.g. location, time)
        - What did you like about the group sessions (or idea of a group if they could not attend)?
        - What did you not like about the group session?
        - What about it did **your child** like/not like?
        - What, if any, changes could we make to the group sessions to make them more appealing to your child?

    - Your child will set some physical activity goals with Helen. What do you think about this?

- What did you think was particularly good about the STAK programme?
    - Content
    - Format

- What difficulties, if any, did you have with the STAK programme?
- What would you change about the STAK programme to improve it?
    - What additional information, if any, should be included?
    - Content
    - Format (e.g. paper diary)

- Can you suggest other ways that could be used to provide information about physical activity for children with Type 1 diabetes and their parents?

- What influence or effect, if any, did the STAK programme have on your child or family life?

- Would you recommend this intervention to other families who have a child with Type 1 Diabetes?
        - Yes No
        - Probe further: why? / how come?

- Is there anything else you would like to say about this research or the STAK programme?

- Do you have any questions?

END OF INTERVIEW

Appendix 21: Post-intervention interview with healthcare professionals: Interview guide

Steps To Active Kids (STAK) Programme: Feasibility Study
Qualitative Script: Acceptability, Desirability and Feasibility

Healthcare professionals

**** RECEIVE CONSENT BEFORE STARTING THE INTERVIEW ****

- Have you read the information sheet?
- Have you had the chance to ask any questions?
- Are you happy to go ahead with the interview?

- Overall, what do you think about this research?

- What do you think about the STAK programme and the things included in it?
    - STAK diary
    - Dance DVDs
    - Pedometer
    - Parents resource
    - Group sessions

- Why do you think children/parents may not have engaged with the research?
    - Explain the recruitment process.
    - How we can minimise this in future work?
    - Could we have done anything differently?

- Do you think there were any negative effects of the STAK programme?
    - Could we have done anything differently?

- What did you think was good about the STAK programme?
    - Content
    - Format
    - Effects on children/parents
    - Its potential influence/effects

- What would you change about the STAK programme to make it better?
    - What additional information, if any, should be included?
    - Content
    - Format (e.g. paper diary, delivery/location)

- What, if anything, have you/your clinic learnt from being involved in this research?

- Can you suggest other ways that could be used to provide information about physical activity for children with Type 1 diabetes and their parents?
    - What role do you think health professionals have in this kind of intervention?

- Would you recommend this intervention to children?
        - Yes No
        - Why?
        - (if appropriate) What stage of diagnosis / age of child?

- Is there anything else we could we have done differently?
- Anything else you would like to say about this project or the STAK programme?
- Do you have any questions?

END OF INTERVIEW

Appendix 22: Post-intervention interview with volunteers: Interview guide

Steps To Active Kids (STAK) Programme: Feasibility Study
Qualitative Script: Acceptability, Desirability and Feasibility

Volunteers

**** RECEIVE CONSENT BEFORE STARTING THE INTERVIEW ****

- Have you read the information sheet?
- Have you had the chance to ask any questions?
- Are you happy to go ahead with the interview?

- What are you studying – what year?
- Overall, what do you think about this research?
  - What attracted you to being involved?
- What did you think about the training?
  - Did you find it beneficial?
- What do you think about the STAK group sessions?
- How do you think the group sessions could have been done differently?
- Attendance – suggestions for how to boost attendance rate?
  - Could we have done anything differently?
- What would you change about the group session to make it better?
  - Activities
  - Logistics – location/timing
- Have you learnt anything from being involved in this project?

- Would you recommend this intervention?
    - Yes No
    - Why?
    - What stage of diagnosis / age of child?
- Anything else you would like to say about this research or the STAK programme?
- Do you have any questions?

END OF INTERVIEW