

The *Active*CHILD study

**Understanding
behavioural pathways and interventions
for physical activity and health
in children with physical limitations**

Protocol v3.2017-11-15

BRIEF SUMMARY

We seek to find out how NHS professionals can support children (0-5 years) with and without physical limitations to participate in daily physical activity. The research is funded by NIHR from 2016 to 2021 and consists of three studies:

- 1: A longitudinal study where we follow children up for 3 years to find out about their participation in physical activity and factors influencing it.
- 2: A health economics study to estimate the costs and benefits of early life physical activity over the life course.
- 3: An intervention development study to design specific intervention techniques that can be repeated in practice, and to pilot these techniques.

The research will generate knowledge about children's physical activity, its costs and benefits, and pathways to increasing it. This will feed into the development of evidence-based training courses, guidelines, and policy to increase early life participation in physical activity. The specific interventions will be advanced to large-scale evaluation(s) through spin-off grant applications. The interventions, if effective, will directly improve children's participation, health, and functioning.

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PLAIN SUMMARY

Background

Young children (under-5s), including children with physical limitations, spend too little time being active. Children want to be active, and most parents, professionals, policy makers and researchers agree with this. But there is very little evidence to help them know what to do and how to change things.

Being active is how young children engage with the world and enjoy life. Being active is also important for children's health. It improves their bones, muscles, heart, blood vessels, mental health, physical skills, thinking, and learning. UK physical activity guidelines recommend that all children are active from birth. For example, under-5s who are walking should be active at least three hours a day. Only around 1 in every 10 children who are under 5 years meets these levels.

Children with physical limitations are particularly likely to be inactive. They often experience physical limitations which, together with environmental barriers, restrict their participation in physical activities. Increasing their participation would: i) Promote children's health both now and in the future (their bodies, their ability to complete tasks, and involvement in everyday life). ii) Prevent future health problems (e.g. diabetes, osteoporosis, obesity, and depression) and disability. iii) Prevent some of the personal, family, health, and social care costs associated with ill health and disability.

Methods

This research combines three related studies. The studies focus on children 0-5 years old, especially children with physical limitations (e.g. difficulties in mobility or co-ordination). The children may also have other limitations, such as in communication and learning. The main outcome will be the children's health and well-being.

Study 1: Investigation of physical activity in children with and without physical limitations, and factors that might affect their physical activity. Data will be collected over time using a small device that records movement ('an accelerometer') and parent questionnaires.

Study 2: Health economics study using existing information to estimate the costs and benefits of physical activity for children with and without physical limitations.

Study 3: Partnership working with parents of children 0-5 years old with physical limitations, NHS professionals, and other community providers (e.g., toddler groups) to develop and pilot a range of interventions to enable participation in physical activity.

Parents will steer the research, and partnering early-years groups will inform the data collection and analysis.

Key outputs

Knowledge and evidence about early life physical activity, its costs and benefits, and potentially effective pathways to increasing it. New interventions for increasing physical activity in young children, especially in children with physical limitations.

Potential impact

We will feed the new knowledge and evidence to guidelines and policy on early physical activity, and we will seek to translate it for training packages for professionals and parents, and for information to healthcare commissioners. The new interventions are likely to require further development and evaluation, and we will do this through follow-on proposals and potentially with industry partners. If the interventions are effective then the research will directly increase children's participation in physical activity and children's health. This will increase the well-being of the children and families, and bring cost-savings to the NHS.

TECHNICAL SUMMARY

The overall purpose of this research is to discover effective ways to promote active lifestyle and health in children with and without physical limitations.

Aims

- 1) To describe the levels and trajectories of physical activity participation in children with and without physical limitations.
- 2) To identify pathways to physical activity and health by investigating relationships between children's physical activity participation, physical limitations, modifiable behavioural factors, and health.
- 3) To estimate the potential benefits and costs of early life physical activity in children, from the perspective of the child, parents, NHS, and society.
- 4) To develop and model intervention techniques for physical activity in children with physical limitations, including to develop related theory and proof-of-concept evidence.

Methodology

Three concurrent studies in 3 UK regions involving children with and without physical limitations, parents, NHS clinicians, and community providers (e.g. toddler groups). Key outcomes: children's participation in physical activity behaviours and health.

Study 1: A longitudinal study to generate evidence about participation in physical activity and its relationship with physical limitations, social-behavioural factors, and health in children with and without physical limitations.

Study 2: Econometric modelling study to estimate the benefits and costs of physical activity.

Study 3: Intervention development and modelling study to design specific, replicable interventions and model them with actual children and a cohort of 100,000 hypothetical children in terms of processes, benefits, and costs.

Anticipated impact

This research programme will deliver new knowledge about children's physical activity, its costs and benefits, pathways to changing it, and interventions for increasing physical activity. This knowledge will, in turn, inform the development of applied interventions, training courses, guidelines, policy, and service provision—much of which will take place within the programme itself. The specific interventions that will be developed and piloted will, if effective, improve child and population health and NHS productivity, and provide cost-savings to the NHS and society.

1. IMPORTANCE OF THIS RESEARCH

This research investigates physical activity behaviours in young children (0-5yrs) as an intervention pathway to health. The research responds to the Public Health England's call to improve physical activity interventions in young children with and without health problems, and to the Chief Medical Officer's call¹ to improve interventions for disabled children.

Physical activity behaviour as a pathway to health

Regular participation in physical activity behaviours is one of the most effective ways to promote all children's health.² It is central to children's development, enjoyment, and quality of life.^{2,3} UK guidelines recommend all children be active from birth,² as active lifestyles develop early and track to later life.⁴ Participation in physical activity behaviours in typically developing children (0-5yrs) relates to bone, skeletal, cardiometabolic, adiposity, motor skill, cognitive, and psychosocial-emotional outcomes.⁵⁻⁷ Much of this also applies to children with physical limitations,⁸⁻¹¹ some with significantly larger effects.⁷

The UK has an estimated 952,700 disabled children (0-18yrs), and physical limitations are among the most common problems they experience.¹ Physical limitations place children at increased lifelong risk of secondary health problems, including obesity,¹² delayed cognitive and social development,¹ problems in learning,¹ and reduced health-related quality of life.^{13,14} Promoting positive health behaviours that prevent these secondary problems is therefore particularly important for children with physical limitations.

Despite the known benefits of physical activity, few UK children meet the recommended levels. The latest Health Survey England suggests only 9-10% of all 2-4-year-olds meet the recommended 3 hours per day of activity. International studies estimate pre-school children's participation in moderate-to-vigorous physical activity at median 47 minutes per day.¹⁵ Evidence about physical activity in under-5s with physical limitations is scarce, but evidence in older children indicates they are at especially high risk of inactivity.^{6,16} E.g., rates of physical activity in 5-18 year olds with cerebral palsy are 13-53% lower than in typically developing children.¹⁶

Increasing participation in physical activity, e.g. crawling, floor play, and community-based toddler groups, in children with physical limitations provides an opportunity to promote their health and to prevent secondary health problems and disability. Economic models with older children suggest participation in physical activity may provide substantial economic benefits to the NHS and society.¹

Interventions to increase participation in physical activity behaviours

There is a general lack of effective interventions to increase children's participation in physical activity.^{11,17,18} UK guidelines recommend children with physical limitations receive healthcare interventions to enable them to be active.² This is consistent with evidence that the best way to enable physical activity in clinical populations is to co-ordinate healthcare inputs with wider community activities. However, there is an absence of evidence about possible intervention techniques (i.e. 'active ingredients'), and pathways to changing participation in physical activity behaviours in children with physical limitations remain poorly understood. Improving physical activity interventions is the top international consensus priority for physical activity research in children in general,¹⁷ and an explicit priority of UK disabled children, NHS, and policy makers.^{1,6,19}

Development of better interventions is hindered by four key issues. Firstly, lack of evidence about objectively measured physical activity patterns and trajectories *across* child populations prevents effective specification and stratification of target populations for interventions. Secondly, while behavioural environment—i.e. the actions, beliefs, attitudes, and motivations of the people around the child—consistently explains physical activity in children with^{3,20} and without physical limitations,²¹ evidence about specific modifiable behavioural factors is limited. This lack of more granular knowledge hinders development of theory about pathways to change. Thirdly, it is unclear how much resource should be invested in promoting physical activity. Weighing up the potential lifetime benefits and costs is required to design interventions that have potential to be cost-effective. Fourthly, little is known about the relevance of current population-level physical activity interventions for children with physical limitations. Interdisciplinary approaches—especially, integration of population health,

behavioural science, and clinical approaches—are required to discover and advance intervention *techniques* ('active ingredients') and modes of *delivery* (i.e. how, where, when, by whom, to whom is it done) that enable population- and community-level behavioural interventions to include clinical populations.

2. THE PURPOSE AND AIMS

Overall purpose: To discover effective ways to promote active lifestyle and health in children with physical limitations. As per WHO definitions, health is understood broadly as physical, mental, and social well-being²² and functioning, including execution of tasks and involvement in life situations.²³

RQ: How to promote physical activity and health in children with physical limitations?

Aims:

- 1) To describe the levels and trajectories of physical activity participation in children with and without physical limitations.
- 2) To identify pathways to physical activity and health by investigating relationships between children's physical activity participation, physical limitations, modifiable behavioural factors and health.
- 3) To estimate the potential benefits and costs of early life physical activity in children, including children with physical limitations—from the perspective of the child, parents, NHS, and society.
- 4) To develop and model intervention techniques for physical activity in children with physical limitations, including to develop related theory and proof-of-concept evidence.

3. NATURE OF PHYSICAL ACTIVITY BEHAVIOUR IN UNDER5s

Authors: N Kolehmainen, E van Sluijs, O Verschuren

To change a behaviour requires one to understand that behaviour in terms of its multidimensional nature, including its physical, cognitive, psychosocial and cultural dimensions. One needs theory and hypotheses about these dimensions and relationships between them. Specifically, understanding the nature of under5s physical activity behaviour means having clear ideas about the key attributes that meaningfully describe the behaviour for the study purpose, and having evidence of the distributions of these attributes in the population in question. Specifying the nature of the behaviour is also the first step for planning its measurement.

Much of mainstream physical activity research has focused on physical activity as acceleration and/or as energy expenditure. There is now a recognised need to understand physical activity behaviour more broadly than that.²⁴ In the ActiveCHILD study, we will focus on conceptualising and understanding under5s' physical activity behaviour in terms of: 1) *the form of the behaviour*, 2) *the amount of the behaviour*; 3) *temporal patterns of the behaviour*; and 4) *the settings of the behaviour* (see Table 3.1; also later Figure 3.1). The following section briefly explains each of these dimensions, and summarises evidence about them in relation to under5s' physical activity.

Table 3.1 Dimensions of physical activity (PA) behaviour focused on in the ActiveCHILD study

Dimension of PA	Key questions
Form (i.e. 'the defining features')	▪ What does it look like? ▪ What are its 'built-in' rules and norms? ▪ Are there structures to the behaviour? If so, what are they? ▪ Are there necessary materials? If so what? ▪ What are the inherent (physical, cognitive, social) requirements for a person doing it? ▪ What is the 'meaning' of the behaviour (what does it symbolise, convey, or communicate)?
Amount	▪ How much of it is done? ▪ How often ('frequently') is it done? ▪ How intensively is it done?
Temporal pattern	▪ How is it spread over time? ▪ Are there patterns? If so, what are these?
Setting	▪ Where does it take place? ▪ What are the features of the wider setting? Do these matter?

The form of physical activity behaviour

The defining features of physical activity are commonly considered to be (i) bodily movements generated by skeletal muscles and (ii) energy expenditure above resting level.²⁵ There are several different ways to operationalise and measure these.

In under5s physical activity literature, bodily movements are increasingly operationalised as acceleration over the three planes of human movement, measured using e.g. accelerometers. The other common approach has been to categorise children's everyday behaviours considered to involve movement as 'modes' of physical activity, e.g. crawling, walking, running, ball games, riding a bike. The main limitation of this approach is that it relies on the use of self/parent-reports which are unlikely to capture activity effectively in under5s (see 'Temporal patterns', below). Also, the current categorisations are based on common perceptions about physical activity behaviours rather than on empirical evidence or explicit theory. It is not clear how the different modes of activity relate to bodily movements generated by skeletal muscles, to bodily acceleration, to energy expenditure, or to wider health outcomes usually attributable to physical activity.

From the perspective of the current study, classifying physical activity behaviour merely in terms of bodily movements and energy expenditure has a major limitation. That is that neither of these is likely to explain the full set of health and developmental outcomes attributed to physical activity in under5s. This is true in particular of cognitive and psychosocial benefits which are likely to accrue through a range of mechanisms, rather than through acceleration and energy expenditure alone.

In considering physical activity form in children, including under5s, much focus has also been placed on the physical and biomedical capacity that a child is thought to require to carry out specific modes of physical activity. It is commonly assumed that (i) the child's physical and biomedical capacity sets the limits to their performance of physical activity behaviours, and (ii) physical capacity is fixed to a set developmental trajectory. The most common example of these are the assumptions that walking capacity sets limits to a child's physical activity amount, intensity and diversity, and that walking capacity is part of a fixed developmental trajectory where the child will only acquire more sophisticated movement skills once they have acquired the capacity to walk. These assumptions have underpinned recent systematic reviews of physical activity and is embedded in most physical activity guidelines which differentiate expectations for physical activity based on the child's walking capacity. For example:

A background section to a recent review of physical activity:²⁶ *“Activity patterns and types of movements are also very different according to the developmental stages of infants and toddlers...” [...] “Around 1 year of age, children commence walking. With this increased opportunity for exploration and learning, toddlers develop locomotor skills such as running, jumping and hopping.”*

UK physical activity guidelines² for under5s: *“Children of pre-school age who are capable of walking unaided should be physically active daily for at least 180 minutes (3 hours), spread throughout the day.”*

The assumptions that physical capacity determines physical activity behaviour, and that physical capacity development is fixed to a specific trajectory, have been challenged by empirical evidence and evidence-based theory. Empirical evidence across studies has shown that there is only a weak association between physical capacity (measured as fundamental motor skills) and daily life physical activity behaviour in pre-schoolers.²⁷ Theory and evidence in fields such as sport sciences, and in rehabilitation intervention approaches such as repetitive practice, indicate that physical capacity is the outcome (as opposed to mere determinant) of performing a physical activity behaviour. Similarly, child development research has repeatedly shown that opportunities for active physical play are a means to developing physical capacity. In relation to walking specifically, there is no empirical evidence to support the assumption that one must be able to walk in order to perform physical activity behaviours, or that people can only acquire advanced physical capacity once they can walk. Anecdotally, watching non-walking Paralympians to perform physical activity behaviours provides a convincing counterfactual!

Overall, cognitive and psychosocial aspects of physical activity have so far been largely overlooked in mainstream physical activity research.^{5,24} These aspects have, however, attracted attention in childhood disability research. This has mainly been through the consideration of the ‘participation’ aspects of physical activity as (subjectively or objectively measured) ‘involvement’ or ‘engagement’,²⁸⁻³² in line with the ICF definition.²³ A recent, systematic review of qualitative evidence found that participation in leisure activities, including and especially physical leisure behaviours, was defined by being: fun, enjoyable and pleasurable; free for choosing and free from constraints; psychologically and emotionally fulfilling (e.g. through opportunities for development and discovery of potential); and social connectedness and a sense of belonging.³ This provides a starting point for considering some of the cognitive and psychosocial dimensions of physical activity.

Another aspect that has been mentioned as potentially important is the structure of the behaviour, including its rules, competitiveness, playfulness, sensory stimulativeness, and controllability by children themselves.³³ These in turn influence the adaptability and inclusiveness of the activity for children with different capacities and interests. While many of these aspects have been implied in current literature there has been little explicit research to them.

In ActiveCHILD, we will focus on describing the forms of physical activity behaviour (Table 3.1), and developing theory and evidence about how the features of the form relate to health and development outcomes.

Amounts of physical activity behaviour

The UK guidelines recommend 180 minutes per day of any intensity physical activity for under5s who can walk unaided. There is no specific amount recommended for non-walkers.

The latest Health Survey England suggests that over 90% of 2-4-year-olds are active for less than 3 hours per day. However, these data are based on parental report and it has been shown that estimates of under5s physical activity frequency vary considerably depending on the data collection method used¹⁵—with accurate parental estimation identified as particularly challenging (see ‘temporal patterns’ below).

Estimates for time spent in light physical activity range from 4% to 33% depending on the data collection method used, and in moderate to vigorous physical activity from 2% to 41%;¹⁵ although one study in a south of England found higher rates of physical activity participation.³⁴ International studies estimate pre-school children’s participation in moderate-to-vigorous physical activity at median 47 minutes per day.¹⁵ These estimates are based largely on typically developing children, with little evidence that is specific to under5s with physical limitations.

In considering physical activity amounts, a key decision relates to whether to categorise physical activity to light, moderate and vigorous, or whether to use the total amount. So far it has not been possible to establish valid and reliable cut-points for categorising under5s physical activity, and there is no sufficient evidence to determine the specific intensities of physical activity needed to promote health and development in under5s.⁵

In the ActiveCHILD study, we will focus on generating evidence about the total amount of physical activity (any intensity) reported as minutes-per day (for details, see Study 1, below).

Temporal patterns of physical activity

A key feature of physical activity in under5s is that it tends to be sporadic and intermittent. For example, a longitudinal video observation of children combined with 1sec epoch accelerometer measures found that the children (n=6) spent 75% of their free play in one intensity level for less than 5 sec, and that the maximum amount of time spent in an activity prior to changing intensity was 98 sec.³⁵ This means under5s physical activity has been difficult to accurately capture with parent or other carer reports. The recent technological advancements that enable the measurement of human movement at much shorter time intervals has provided an opportunity for the field to begin to address this.

Evidence for other temporal patterns is inconsistent. For example, in terms of daily patterns, some studies have found that under5s physical activity is relatively consistent across weekdays,³⁶ while other studies have found variation e.g. based on attendance at childcare, the child’s gender and mother’s educational status.^{34,37}

In the ActiveCHILD study, we will seek to further understand and describe temporal patterns. The primary focus will be on patterns over months and years, specifically on understanding the development of physical activity behaviour from 6-9 months to 5 years. The secondary focus will be on generating further evidence about patterns within single days and over a period of few days, with a view to better understanding daily patterns and potential for change within these.

Settings of physical activity

There is currently limited research evidence about under5s physical activity environments, or ‘settings’, and no agreed framework for considering features of settings. To date, the mainstream physical activity research has primarily focused on built environment and physical resources (e.g.

access to a gross motor play area), and on parents' sociodemographic characteristics (e.g. educational level and income). None of the factors measured so far have been conclusively shown to explain physical activity.³⁶

Our recent qualitative systematic review of parents' views leisure participation in children with disabilities³⁸ identified six categories of potentially influential environmental factors, and several specific factors within them (Table 3.2). While some of these may be more common in children with disabilities (e.g. "others look and stare") many are likely to be relevant across children (e.g. having peers with similar characteristics and interests to do activities with).

The categories, and the factors within, provide a starting point for a broad yet granular investigation of modifiable environmental factors in the ActiveCHILD study. The focus will be on identifying factors that mediate physical activity behaviour and that could be targeted for change through interventions.

Table 3.2 Environmental factors proposed to influence physical activity in children (0-18 years)

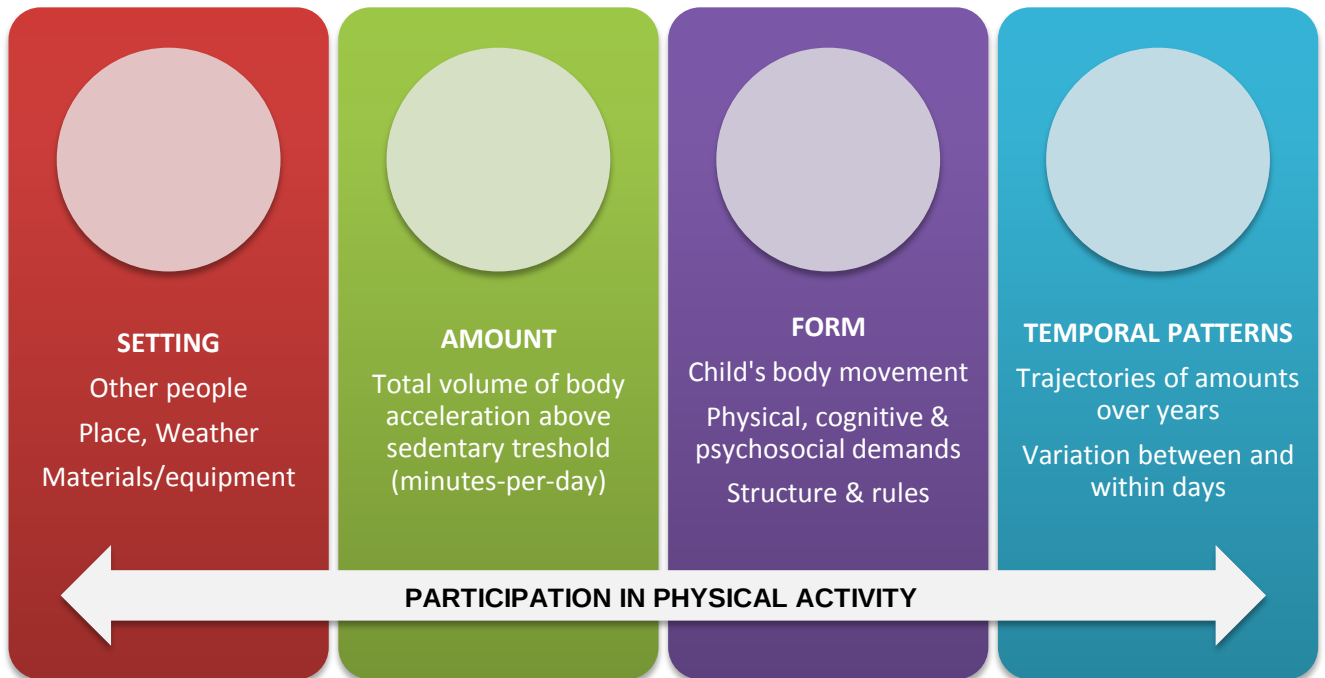
Environmental factor category	Examples of factors
Parent behaviours and cognitions	▪ Parent behaviours that facilitate/encourage child physical activity, e.g. coach/encourage the child verbally, orchestrate events, participate in play with the child, supervise play with friends, initiate activities, speak to coach ▪ Parent behaviours that limit/restrict child behaviour, e.g. avoid activities, cut back swimming, don't go out, limit bath play ▪ Parent behaviours that regulate child behaviour, e.g. make decisions on the child's behalf, register the child in activities, let the child have fun ▪ Parents' positive beliefs about their own and their child's capabilities, e.g. to take child to activities, solve challenges ▪ Parents' negative beliefs about their own and their child's capabilities, e.g. find activities difficult, can't do it, hard to know what's going on ▪ Parents' negative beliefs about consequences, e.g. risk of injury, have to nag, have to take the child there, feeling embarrassed, irritated ▪ Parents' positive beliefs about consequences, e.g. break for caring for the child, child develops, child is accepted/entertained, child's self-esteem, teach child social behaviour, enjoyable, reduce anxiety ▪ Parental negative emotions, e.g. fear, apprehension, don't look forward to it, awkward, worry, stress, frustration, sadness, tension, disappointment ▪ Parental positive emotions, e.g. exciting, grateful, pleased, feel made a right decision, restful, no anxiety ▪ Parental goals, including: – process goals (e.g. child's active involvement, engagement, child's cooperation, child to work hard) – goals related to social relationships, inclusion and emotional well-being (e.g. child be accepted, have friendships, play with peers, be happy, thrive) – goals related to development, independence and empowerment (e.g. child be independent, in control, do what she wants, develop competence) – goals related to the child 'doing stuff' (e.g. child to get out, use his strengths, relax, laugh with others, have good time) – avoiding negative end points, (e.g. the child's mind is off the illness, child not alone/lonely, protect from disempowerment) ▪ Parent knowledge about the child (e.g. child's motivation, the child wants), the child's condition (e.g. disease risk), opportunities, and how to join ▪ Parent motivation (e.g. for the child to obtain friends, play) ▪ Parent's perceptions about their role in the activity (e.g. an assistant, guide/teacher, facilitator, follower, helper, social catalyst)

	▪ Parent's perceptions about social influences, e.g. that the child needs help all the time, parent feeling obliged to withdraw from activity
Other people's behaviours and cognitions	▪ Peers with similar characteristics, similar ability vs gap/correspondence in capacity and skills with peers, rate of progress ▪ Compatible peers, friends with similar interests ▪ Behaviour, comments of peers, e.g. kids come to house, others make the child feel welcome, peers adapt activity, play PA vs peers bully, tease, whisper, point, shout, exclude, ostracize ▪ Knowledge, understanding, acceptance of other people, e.g. people view the child as naughty ▪ Behaviour, comments of others, e.g. others look and stare, other parents complain, others question the child's right to be there
Physical structures and resources	▪ Funding, cost ▪ "Gear", toys ▪ Access to back yard, facilities vs lack of suitable facilities ▪ Other children don't live near, not a lot of social things ▪ Time ▪ General planning/set up of the environment
Policies	▪ Activities are time limited ▪ Activities are restricted by biological age (as opposed to capacity) ▪ "Health safety" ▪ Expectations and formats of local programmes, and accommodation of varying skills, numbers of participants, age ranges
Social structures and rules	▪ Clubs choose children, control who can join, place children in groups ▪ The community provides social support for access, e.g. coach provides 1:1 input, encourages parents to go and register, tells parents not to worry, forms a relationship with the child, and is patient with the child ▪ The community recognises child's capabilities (vs instructors' expectations too low, programme not challenging enough or too difficult) ▪ People in the community treat children with respect, don't try to change the child, speak to child properly
Professionals (health, education)	▪ Professionals' understanding, knowledge, empathy (vs not these) ▪ Professionals' behaviours, e.g. teacher bans children vs teacher allows

In summary

The ActiveCHILD study seeks to advance theory and evidence about the nature of under5s physical activity participation by describing: the amounts of activity under5s do, the forms the activity takes, the settings where it occurs, and the temporal patterns of activity both over time and within/between days (Figure 3.1).

Figure 3.1 The dimensions of physical activity participation that will be measured and described



4. BIOPSYCHOSOCIAL FACTORS EXPLAINING PHYSICAL ACTIVITY

A key question for the ActiveCHILD research is: what factors should be targeted to increase children's total physical activity behaviour at 5 years of age? The focus will be on factors modifiable by NHS-delivered therapeutic and/or health promotion interventions (referred to as mediators – details below). Factors deemed unlikely to be modifiable by NHS-delivered interventions will be referred to as moderators, and will be considered as part of the intervention context.

Both mediators and moderators will be considered through the WHO International Classification of Functioning, Disability and Health (ICF).²³ The ICF is a biopsychosocial consensus framework for classifying health outcomes and understanding pathways to health. The ICF covers health outcomes related to body structures and functions, activity (i.e. capacity), and participation (i.e. performance, or 'involvement in life situations'). It proposes that any of these outcomes can act as a pathway to one of the other outcomes. For example, increased body function (e.g. fitness) can lead to increased activity (e.g. ability to run longer) and increased participation (e.g. playing football). Similarly, in reverse, increased participation (e.g. playing football) can lead to increased activity (e.g. ability to run longer) and increased body function (e.g. fitness). The ICF also proposes two further pathways to these health outcomes: the environment and personal factors. The ICF covers the biological, psychological, interpersonal, environmental, and policy dimensions later proposed in the ecological model of physical activity,^{39,40} and similarly covers the full life span.

The ICF is widely used in child health research and practice, and has been shown to be compatible with health behaviour research,⁴¹ including research into children's physical activity.²⁰ As a multidisciplinary consensus framework, the ICF enables communication of ideas and hypotheses to a range of health and NHS stakeholders using agreed terminology. However, the ICF is also mainly atheoretical (as opposed to based on evidence-based theory) and so it benefits from being supplemented with specific theory and evidence-based constructs from other fields, e.g. behaviour change and therapy. Methods for doing this have been previously published.^{41,42}

The key pathways, including the hypothesised mediators within them as extracted from current literature (October 2016), are summarised in a theoretical model of children's participation in physical activity in Figure 4.1. It is important to note that, so far, evidence of factors related to under5s physical activity is overall limited and of low quality;⁴³ and most of the evidence comes from mainstream studies, with very little evidence specific to under5s with disabilities. The different facets of the model will be further elaborated on in the two sections, below.

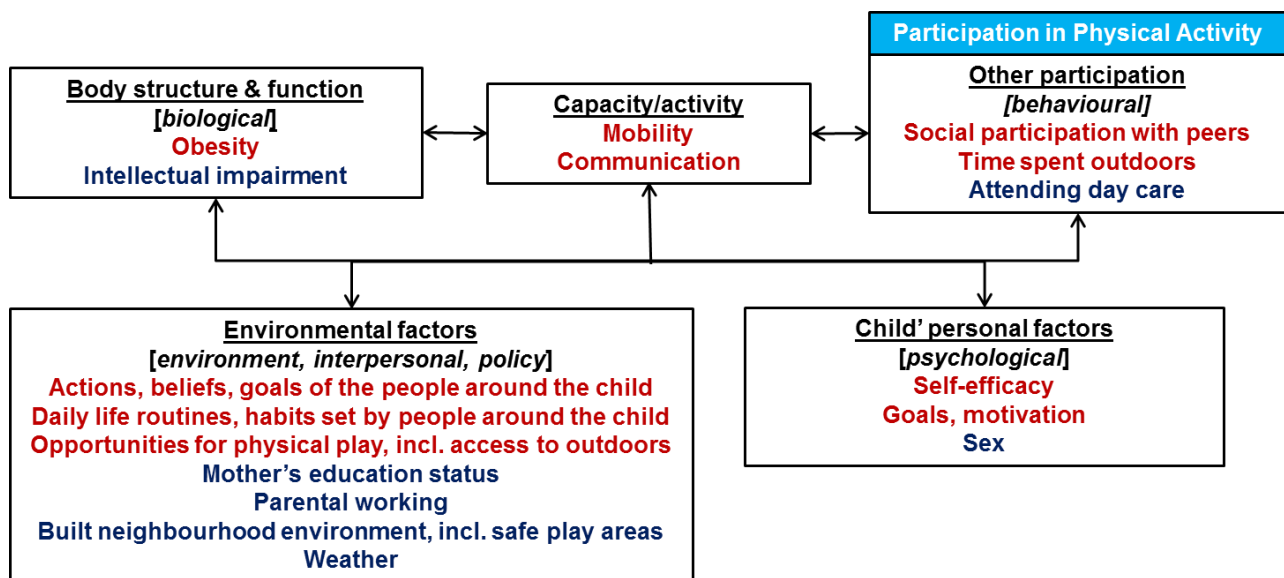
Mediators: factors modifiable by NHS interventions

Factors will be considered as mediators, i.e. as modifiable by the NHS interventions, if they are currently targeted by NHS staff or could plausibly be targeted with adjustments to staff role, service delivery, and organisation of care.

Current NHS-delivered therapy and/or public health interventions target all the proposed broad ICF pathways: body structures and functions, activity, participation (including participation in other than physical activity that can be a conduit to physical activity, e.g. wider leisure and social participation), environment, and personal factors. However, within these broad pathways, it is unclear if the current interventions target the best, specific factors. Evidence so far has shown that at least some of the factors currently targeted are unlikely to lead to changes in physical activity and that some of the factors that should be targeted are overlooked.⁴⁴

For *body structure and function pathway*, in mainstream children, obesity has been found to relate to less activity—however, the direction of this relationship is not clear. In children with disabilities, there is little evidence from under5s about any factors in this pathway. Evidence from older children with disabilities suggests that intellectual impairment is negatively related to physical activity participation,⁴⁵ while none of the other factors investigated so far (e.g. strength, aerobic capacity) do not.^{44,45}

Figure 4.1 A summary conceptual model of children's participation in physical activity for the present study



Black = biopsychosocial dimension [ecological category cross referenced]

Red = hypothesised mediator

Blue = hypothesised moderator

For the *child's capacity pathway*, the main factor investigated to date has been movement skills, which have been shown not to be a strong determinant of daily physical activity in pre-schoolers.²⁷ Evidence from older children with disabilities suggests that mobility⁴⁵ may explain participation in physical activities, while e.g. self-care²⁰ and manual/fine motor capacity^{20,45} do not. Communication capacity has been consistently found to explain participation in other domains, and might explain participation in physical activity also—especially in activities undertaken with others—but we were unable to identify much evidence on this.

For *participation in other domains pathway*, some studies have found that time spent outdoors and TV-viewing are associated with participation in physical activity; however, stronger designs have not found these relationships.⁴³ Systematic reviews of qualitative studies with children with disabilities³ and with parents³⁸ have both suggested that social participation, e.g. doing things with friends and attending clubs, may be an important pathway to physical activity; however, most of these studies have been with children over 5 years old.

For *social environmental pathways*, studies have consistently indicated that the actions, beliefs, and goals of the people around the child influence physical activity in children with^{3,20} and without physical limitations.²¹ However, evidence about the specific contribution of discrete factors remains limited. While some studies have found that parental physical activity and specific parental support for physical activity are associated with self-reported child physical activity, this association is not consistent across studies; and higher quality studies with objectively measured child physical activity do not tend to find a relationship.^{39,43} Based on our previous mixed methods study,^{20,46} we have hypothesised that the link between parent/family activity and child activity could be through *opportunities* that parents, and other people around the child, allow for the child to instigate to be active—that is instead of the previously proposed pathways of direct modelling of, or social support for, physical activity. Essentially, our findings suggested that children were prepared to initiate and do physical activity for most of the time, but the actualisation of this depended on the routines and habits that structured their days, and the windows of opportunities within these routines that allowed the children to drive their own behaviour (as opposed to undertaken behaviours expected of them). The routines and habits were set by parents, older siblings and other adults (e.g. education

professionals); and so where e.g. the parents had an active lifestyle this tended to translate to the children also having more opportunities to be active. This hypothesis is yet confirmed, but will be further investigated within the ActiveCHILD. For *physical environmental pathways*, evidence about access to the use of an outdoor space in explaining physical activity is inconsistent.^{43,47,48}

For *personal factors pathway*, there has been limited research into child psychological factors.⁴³ Of the factors that have been investigated, self-efficacy has been consistently found to positively explain physical activity in mainstream children.³⁹ Self-regulation has also been identified as a potential factor; the evidence so far is sparse but its plausibility is supported by the strong evidence for the role of self-regulation and executive function in health behaviours in general. In the absence of strong quantitative evidence, qualitative studies have consistently, and across children with and without disabilities, indicated that it may be important for physical activity to be linked with the child's wider goals, motivations and interests, e.g. having social contact, having fun, relaxing, exploring one's capabilities, and experiencing a sense of achievement and competence.^{3,46}

Moderators: factors outside NHS scope and influence

For *personal factors*, male sex is the only factor consistently found to explain physical activity in mainstream studies,^{39,43,47} with boys generally more active than girls and in particular girls being less active in the mornings.^{34,36} It is unclear if this pattern is also the case in under5s with disabilities – studies with older children with disabilities⁴⁵ have not found this to be the case. Other factors, e.g. socioeconomic status, ethnicity and family structure have been consistently found not to explain physical activity.^{43,48}

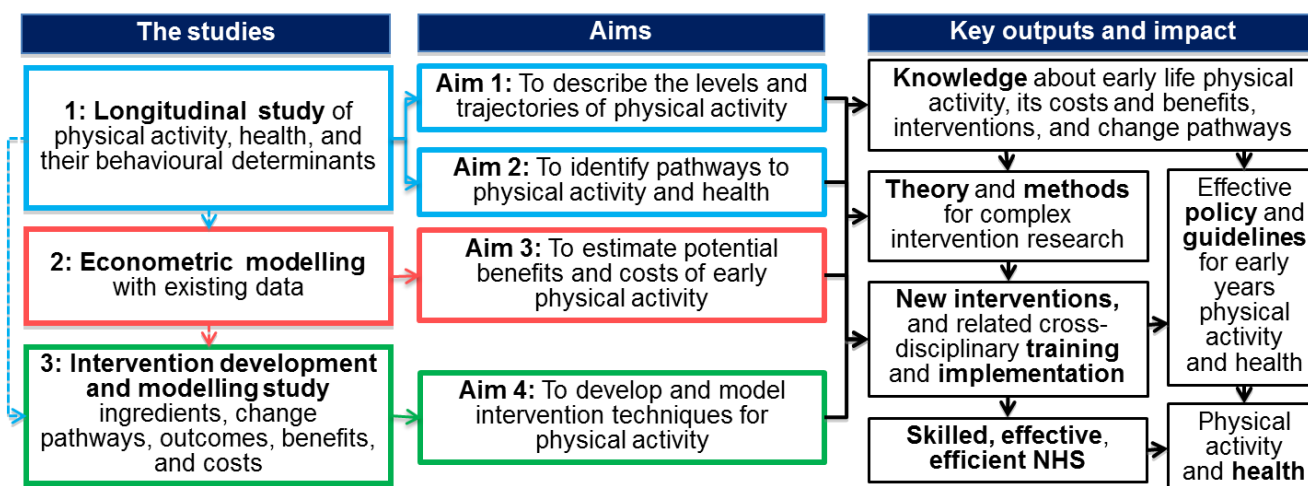
For *participation in other domains*, attendance at day-care has been found to be negatively related to physical activity on those days. This is hypothesised to be due to the increased structure in day-care that reduces opportunities for children to instigate active play (see above).

For *environmental factors*, mother's education has been found to negatively explain physical activity in the evenings.^{34,36} Parents' marital status³⁹ and most generic parent actions (e.g. providing encouragement, transporting the child, or paying participation fees)^{43,48} have been consistently found not to explain child physical activity. Weather, especially rain and temperature, has been found to explain physical activity.^{34,36} Evidence about parental working and built environment, including neighbourhood safety, is inconsistent.^{43,47}

5. RESEARCH PLAN

Design Three concurrent studies using epidemiology, health economics, and intervention development and modelling methods (Fig.5.1) as recommended by MRC guidance for development of complex interventions.⁴⁹⁻⁵¹ The WHO International Classification of Functioning, Disability and Health (ICF)²³ will provide a biopsychosocial synthesis framework, while behavioural theories will be used to build scientific causal models of physical activity and related interventions (see section 4).

Fig. 5.1 The three studies, their relationship to the aims, and key outputs and potential impact



Population Children 0-5 years who: have impairments in neuromusculoskeletal and movement-related functions (e.g. muscle strength/tone, joint functions, co-ordination)²³ or mobility limitations (e.g. rolling, sitting, walking);²³ have at least some independent movement through the use of skeletal muscles; and whose parents agree to participate. Diagnosis will be recorded but not used as a criterion—this approach reflects the realities of the children and their care and thus supports external validity. Many children will not have a diagnosis, especially at this early age, and many will obtain several diagnoses over the first 5-7 years of their lives. Most care pathways and interventions they access are not defined by diagnosis but e.g. by impairments and abilities.

For study 1, a parallel group of children 0-5 years where there are no concerns about development and no known impairments, and where parents agree to participation, will also be recruited (for details, see below).

Primary outcome

The primary outcome is defined as a behavioural target, according to the TACT (Target, Action, Context, Time) principle:⁵² children under5 (Target) to participate in physical activity (Action) in any social and physical setting (Context) during the 7-day measurement periods (Time). In this, participation in physical activity is understood to mean the child performing any behaviour(s) that involve bodily movements generated by skeletal muscles and energy expenditure above resting levels,²⁵ regardless of the form, amount and time patterns of these behaviours.

The primary outcome will be measured objectively as frequency of movement. Parent-reported data will be collected on the further nature of the behaviour (for details, please see Study 1, below).

Secondary outcomes, with the related measures:

- *Parent-reported health-related quality of life*, measured using Pediatric Quality of Life Inventory (PedsQL)
- *Adiposity*, measured using body mass index BMI for the 3 year-olds and BMI-for-age for the 1 year-olds
- *Executive function*, measured using Behavior Rating Inventory of Executive Function (BRIEF)
- *Learning*, measured using Early Years Foundation Stage Profile (EYFS) that collects English statutory data
- *mobility, self-care, and social performance*, measured using Pediatric Evaluation of Disability Inventory Computer Administered Testing (PEDI-CAT).

These outcomes and measured have been selected as: likely to change as a result of physical activity, relevant to healthcare practice, feasible to use within the design, and with published evidence of validity, reliability, and responsiveness in the population.

Exposures and process outcomes, including data on the change pathways/mechanisms, will be specific to each study. For details, please see below.

STUDY 1: Longitudinal study of participation in physical activity

N Kolehmainen, E van Sluijs, O Verschuren, K Mann, M Pearce

Rationale: Evidence about objectively measured physical activity in young children and its modifiable determinants is limited,³⁹ as is evidence about differences and similarities between children with different abilities. Emerging evidence indicates social environment could explain physical activity across child populations,^{20,21,53,54} but evidence about specific modifiable factors is limited.

Aims: 1) To describe the levels and trajectories of physical activity in children with and without physical limitations. 2) To investigate relationships between children's physical activity, physical limitations, modifiable behavioural factors, and health.

Specific questions:

- What are the levels and trajectories of physical activity in children 1-5 years old?
- Do these differ according to the child's physical limitation status, or demographics?
- What is the relative importance of behavioural factors in explaining physical activity levels and trajectories, including interactions with physical limitation status, at the different time points?
- Does early participation in physical activity influence later health outcomes; if so how?

Primary outcome: The primary outcome is as above: children under5 (Target) to participate in physical activity (Action) in any social and physical setting (Context) during the 7-day measurement periods (Time). The primary outcome will be measured objectively as frequency of movement (total minutes-per-day). Parent-reported data will be collected on the further nature of the behaviour (for details, please see, below).

Sampling and recruitment: Two cohorts of children, aged 1 and 3 years, sampled using **purposive** sampling with strata for family income and presence of physical limitation from **four** healthcare organisations (Newcastle, Sheffield, Cheshire, **Birmingham**) that cover a range of socioeconomic and ethnic populations. The children and their parents will be recruited through routine contacts with health visitors **and other child health professionals (e.g. therapists, paediatricians, paediatric neurologists)** at 9-12 months and 24-30 months of age.

Health visitors **and other professionals** linked to the study will identify eligible children, and the administrator for the service will send out pre-prepared recruitment packs to the parents of these children. Parents who are willing to be approached for physical activity data collection will be asked to return the baseline demographic questionnaire and a contact information slip to **their health professional or to post it directly to** the study team. The study team will then follow up the willing families to discuss the study and, where appropriate to take the informed consent and set up data collection (below).

Data collection:

The primary outcome, total volume of physical activity, will be recorded using accelerometers set to record at 1 second epochs. Data will be collected for six waves, where a wave is the waking hours for seven consecutive days, at 6-month intervals, using the MRC guidelines for physical activity measurement. The chosen accelerometer, ActiGraph GT3X+, has been found to be acceptable and feasible to use in under5s,⁵⁵ have good clinical utility, and have been validated for typically developing and disabled children. A single monitor will be used as this has been shown to be sufficient for valid data and is considerably more practicable than multiple monitors. Parents will be asked to place the monitors on children's hip or lower back (the difference is likely to be non-significant), and wear them for seven days from waking up in the morning until going to bed at night, except water activities. The 1 second epochs will capture even short bursts of activity while ensuring the full data set size remains storable on the accelerometer memory.

To maximise good quality data returns, we will:

- Charge and check the accelerometers, and set them up to automatically start recording at 5am on the morning of the participant's first agreed wear date.
- Demonstrate to parents how to wear the accelerometers on the first wave, and provide clear, one-page instructions for them to keep at home.
- Provide incentives contingent on compliance. The incentives, designed together with the parent PPI group and informed by our previous research, will include e.g. brief, positive, general good parenting reinforcement and information to parents together with small, activity-neutral, age-appropriate toys for the child (e.g. sticker activities).
- Use daily logs to promote sufficient wear time, with a sticker for the child to put on a time log for every time the monitor is put on and taken off
- Encourage parents to avoid carrying the accelerometers around.
- Encourage parents to report any barriers to wearing the accelerometers, and address these.
- For children in nursery/day care, provide an information leaflet for the staff also.
- Provide self-addressed, padded, paid envelopes for returning the accelerometers to us, including a quick check list for items and logs to return at the back of the envelopes.
- Follow up parents for meter retrieval, including reminder calls/emails/texts tailored to parent preferences.

In addition to the objectively measured frequency, complementary parent-reported data on the nature of the physical activity participation will be recorded using a daily log of activities. This will capture information about the form and setting of the child's physical activity, and will be collected alongside the amount data.

For the secondary outcomes, for both cohorts, baseline data will be collected on *mobility, self-care and social performance* and *adiposity* using the measures listed above. For the 3 year-olds, data will also be collected on *parent-reported health related quality of life* and *executive function*; the measures for these are not suitable for 1 year-olds. The measures will be repeated at the final wave for both cohorts. Data on *learning* (EYFS) will be collected at the final wave from the older cohort.

For the exposures, data will be collected on the previously identified factors (see Section 4, mediators and moderators, including Figure 4.2).

Child's *adiposity, mobility* and *social performance* (for measures, see 'secondary outcomes' above), and *communication* (measured using the Communication Function Classification System) will be recorded at baseline through healthcare provider.²⁰ The baseline data will be considered as exposures, while the later data points will be considered as secondary outcomes, as above.

Child's *self-efficacy, motivation* and *goals* will be explored through brief questions to parents. For self-efficacy, standard items will be used. Motivation and goals will be explored using open ended questions previously successfully applied in similar studies of parents in this population.

Child's *social participation* and *time spent outdoors* as they relate to physical activity will be recorded through the parent-reported daily log of activities (see, above).

The *actions of the child's parents* will be assessed through a brief parent-completed behavioural questionnaire (Adult Actions Questionnaire) based on existing reviews of literature that identified specific parental actions potentially important for their child's participation in leisure, including physical activity. The questionnaire covers 19 specific actions across four actions type categories (facilitative, regulating, limiting, and encouraging actions). The parents report whether they have done any of these in the last week, and if so estimate the frequency at which they have done then, from nearly daily (5 times in the last week or more) to a few times (3-4 times in the last week) to once or twice. The questionnaires will be administered at each wave of data collection, and takes 5-10 minutes to complete.

The *beliefs and goals of parents* will be assessed through a brief, established behavioural questionnaire (the Adult Views Questionnaire—the adapted Theoretical Domains Framework Questionnaire). The specific constructs to be measured have been identified from an existing

systematic qualitative review of parents' views on important beliefs and goals influencing children's participation in leisure, including physical activity. For the selected constructs, standard item stems will be used as recommended in the literature, populated for the specific language from the systematic review to ensure appropriate terms and qualifiers to the population and behaviour under investigation. The questionnaire will be administered at baseline and at every other wave of data collection after that, and takes up to 5 minutes to complete.

Daily life routines and habits, and opportunities for children to initiate physical activity, will be assessed indirectly through the Adult Actions Questionnaire, and through a follow-up semi-structured, 1:1 interviews with a sub-sample of parents. Interviews with a sub-sample will be used because current evidence about specific routines is scarce, and assessment of habits through direct questionnaire items is in principle challenging as by definition habits are behaviours people are not actively conscious of (and thus plausibly not well placed to report on them). There is little conceptual or theoretical basis at this point for direct, quantitative measurement of routines and habits. The interviews will thus be used to explore, in an open-ended way, the routines and habits that set the daily context of the child's life, and the opportunities for self-directed activity, in broad terms. The interview schedule will be based on our previous interviews with older children, and will ask generally about the family's typical week and, in contrast, their previous, actual 7 days. From family narratives, habits and routines will be identified through careful listening of indicative statements (e.g. "if-then" statements such as "On Saturday's, if it's sunny then we go to the park but if it's wet then we usually stay in"), and further prompting around these. Particular attention will also be paid to descriptions of events or incidents that disrupt habits and provide opportunities for children to initiate physical activity. We anticipate that, through the interviews and the related increase in theoretical understanding and empirical evidence, we may be in position to explore the routines and habits quantitatively on subsequent waves.

Other environment data will be collected on *main carer's educational status* and *weekly hours worked*, *distance to an outdoor play area perceived by parents as safe and usable for the child* through a parent questionnaire at baseline and at the third wave. Rain fall (in mm) and temperature (in degrees of Celsius) in the child's area during each wave will be accessed through the UK Met Office.

In addition, *demographic data*, including child's age, sex, socioeconomic status and ethnicity will be collected at baseline, and medical diagnoses and impairments at baseline and at every second wave thereafter, in order to describe the sample. These data will be obtained through a combination of the parent and healthcare provider (at parents' consent).

Data analysis:

The acceleration data will be analysed using a pre-defined processing pipeline, consisting of five broad stages. First, the movement recorded by the accelerometer will be converted to counts per 1 second epochs, using the GT3X+ algorithm. These data will be stored (see also Section 6, Data management) for subsequent analysis where the 1 second epochs will be accumulated for reporting as minutes (below).

Second, the stored data will be cleaned and reduced manually, using established procedures and decision making rules from previous physical activity research in under5s. Any invalid data will be identified and removed. These are any data (i) greater than 16,000 counts per minute (assumed to be biologically implausible) or (ii) greater than zero but remain constant for 10 minutes (assumed to be accelerometer malfunction, may appear as 32767 counts per minute).^{#Masse et al MSSE 2005} Any non-wear times will be identified and removed. This will be (i) any string of consecutive zero counts for longer than 60 minutes⁵⁶ or (ii) where both accelerometry output and parent-completed log-sheets indicate non-wear (e.g. for bathing). The data will then be assessed for inclusion of individual children's waves. A child's wave will be included where the accelerometer has been worn for at least 360 minutes between waking and going to bed for at least 3 days over the wave.

Third, mean counts will be calculated for conversion to total physical activity (any intensity) using cut-points previously validated through video observation of young children.⁵⁷ The only cut point(s) that will be applied is that separating active from sedentary behaviour. No differentiation will be made

on activity intensity (i.e. low, moderate, vigorous) because the sporadic and intermittent nature of physical activity in under5s (see above) means that cut-points for activity intensity in this age group tend not to be valid,^{35,55} and because current physical activity guidelines in under5s² focus on the total amount of participation at any intensity. Specifically, for 1-2 year olds, 40 counts per 5 seconds will be used as this has been shown to maximise sensitivity [79-82%] and specificity [72-83%] for identifying minutes of non-sedentary activity,⁵⁸ and for 3-4 year olds, 1100 counts per minute will be used (sensitivity 83% and specificity 82%).⁵⁹ Using these cut points will require for the data to be adjusted to account for the specific ActiGraph model. The 1100 counts per minute cut-point was derived from studies of a previous model of the ActiGraph (model 7164), and a correction of 9% to the raw accelerometry data is required to account for the difference to the model used in the present study.

Fourth, data will be checked for normality, and medians and interquartile ranges for total minutes of physical activity per test day reported. Bouts of activity (any intensity) will also be explored to describe time patterns of physical activity over the course of a day. A bout will be considered to be sustained periods (at least 10 minutes) of activity with no longer than 5 minute intervals of epochs below 40 counts per 5 seconds (for 1-2 year olds) or below 1100 counts per minute (for 3-5 year olds). Data about the forms and settings of physical activity will be used to complement the analysis.

Fifth, longitudinal changes in physical activity and the exposures over the 3-year period will be incorporated into multiple linear regression models, which will be used to identify factors that explain variation in physical activity and health. Spearman rank correlations between baseline and follow-up measures will be used to assess the extent to which tracking occurs over the 3-year period for physical activity and behavioural factors.

IBM SPSS Statistics 21, Stata 14 by Stata Corp., and ActiLife by ActiGraph will be used for analysis. Significance will be set at $P < .05$.

The qualitative data on daily routines and habits will be analysed using content analysis by Krippendorff. In this, the data will be analysed in light of the research question (here, “what daily habits and routines are associated with participation in physical activity?”) and the context (here, children’s daily life) using analytical constructs (statements that guide the analysis, especially the categorisation of data to habits and routines, and to sub-categories within these) and abductive inferences. The focus will be on generating evidence that can be validated in principle, e.g. specific hypotheses about associations between certain habits and physical activity participation that are testable in a further study (e.g. a subsequent wave of data collection) using quantitative data methods.

Sample size: As is the case for most epidemiology studies, the key parameters for a sample size calculation will not be known until after the study. Therefore, instead of a formal sample size calculation, we have used an estimate for a number of children likely to be needed to capture important, significant relationships. In this, assuming that children without physical limitations are active for one hour a day (with standard deviation 14 minutes), then with a sample of 400, as an example of the likely statistical power available to this study, we would have around 80% power to detect a difference in physical activity levels between children with and without physical limitations of at least 4 minutes. While 4 minutes is unlikely to be biologically significant, this estimate provides confidence that a sample size of around 400 will be sufficient to detect significant differences even with heterogeneity in the population.

Retention of participants: Families’ engagement for the full duration of the study will be supported using established, evidence based strategies: incentives and feedback. Families will be incentivised to return data at each wave through small positive recognitions to both parents and children (see primary outcome data collection above). Families will also be provided a secure log-in to the study web site, through which they can view feedback specific to their data, can engage with their data, and provide comments and thoughts on the data. Previous research has shown that such feedback, when carefully constructed, does not alter the family or child physical activity, but improves retention.

Results and outputs: Evidence about physical activity, modifiable factors, and similarities and differences between children will directly inform intervention development research (study 3), commissioning, and practice about what factors to target and when, and tailoring required for children with physical limitations.

STUDY 2: Econometric model of benefits and costs of physical activity

N Kolehmainen, H Brown, L Vale

Rationale: Under5s' physical activity behaviours are assumed to influence their subsequent lifetime growth, health, development, and well-being; and through these to further influence resource utilisation across health, care, and education. However, the size of such effects remains unknown.

Aim: To estimate the potential benefits and costs of early life physical activity in children, including children with physical limitations, from the perspective of the child, parents, NHS, and society.

Methods: Existing data will be used to extrapolate lifetime benefits and costs of all children's (0-5yrs) participation in physical activity, with an adjusted model for children with physical limitations. The benefits and costs will be considered from different stakeholder perspectives (child, parent, NHS, and local authority). Incidence rates for the chosen indicators will be estimated from existing data on physical activity, various health outcomes, and long-term economic outcomes (for examples of available data, see Table S2.1).

The main explanatory data, under5s PA behaviour, will be taken from the Growing up in Scotland data set, and matched to existing longitudinal data on PA benefits on region and socioeconomic and health characteristics.

Lifetime benefits for the child will be extrapolated from existing longitudinal studies. The specific indicators, and data for each indicator, selected through two stakeholder groups (n=8-10 each). The main benefits to be considered will be health (conditions), and the use of health, social care and education support. Other benefits may include further indicators on growth, development and well-being.

The costs will include time to participate in physical activity, and the benefits child's health, prevented burden of disease (e.g. diabetes, obesity, depression), and education/employment.

The data will be used to construct an econometric model to estimate how changes in children's participation in physical activity impact on benefits and costs. First, a 'base model' consisting of PA behaviour and socioeconomic and demographic characteristics (gender, age, region, dummy variables for year of data collected) will be developed. Second, that model will be further built to a 'childhood PA' model by adding under5s' PA data—this is to explore how much additional variation in the outcomes is explained by under5s' PA compared to adulthood PA (already included in the base model) alone.

Results and impact: The resulting model will provide information about the estimated lifetime benefits and costs of children's participation in physical activity. Providing the information in monetary terms allows comparison of the potential benefits of physical activity with other ways of spending the available resources. The resulting model will also provide a starting point for economic modelling of different physical activity interventions (study 3, below).

Table S2.1 Example of the type of data available for use to populate the econometric model

FACTORS IN THE MODEL From the conceptual model on page 7	DATA AVAILABLE
Contextual factors that will be used as the characteristics for matching (at birth to 5 years)	
Access to outdoor environment	BSC72: garden to play in? NCDS65 has info on garden but this is too late?
Child's health conditions	BSC72: developmental abilities, illnesses NCDS65: range of medical conditions (by medical exam) NCDS69: disabling conditions, physical handicap, alignment NCDS69: child special needs, conditions, illnesses

	NCDS74: disabling condition (general, physical, CNS, etc)
SES	NCDS58: husbands socioeconomic group, husband's social class, mum's paid job when starting the baby, mum's paid job during pregnancy, n of persons in room
Under5 PPA	
Amount of PPA	BSC72: garden to play in? BCS72: if no garden which play facilities used BSC75: visit to park or playground (no, with someone, etc)
Growth, health and well-being from 5yr to mid-childhood (~15yrs)	
Motor skills/development	NCDS65: awkward when walking (mum report) NCDS65: walking alone by 1,5yrs (mum report) NCDS65: clumsy (teacher report) NCDS69: co-ordination, balance NCDS69: child has poor co-ordination NCDS69: abnormality, clumsiness NCDS69: motor coordination (medical exam) NCDS74: aptitude sports and games NCDS74: motor coordination (medical exam)
Cognitive skills / development	NCDS65: a range of learning variables, need to choose NCDS69: child's number work NCDS69: reading, maths, copying test NCDS74: (N1923) concerns about progress at school
Social skills / development	NCDS65: mtg other kids outside household NCDS65: bullied by others NCDS65: fight other children NCDS65: irritable NCDS65: continually worried NCDS74: how often goes to friends' parties
Physical health	NCDS65: weight NCDS69: signs of cardiovascular disease [NCDS69: is there neuro/MSK disorder?] NCDS69: upper lower respiratory tract NCDS69: weight NCDS74: weight NCDS74: full details for a range of variables (medical exam) NCDS74: range of conditions also listed under disability (incl diabetes, asthma, etc)
Happiness / QoL	NCDS65: miserable/tearful NCDS69: questions on depression/anxiety but unclear NCDS69: attitude towards spare time (enjoys/bored) NCDS74: seen psychiatrist/psychologist NCDS74: a lot of parent report items on psychosocial health
Child PPA	NCDS69: child activities (swimming, use of parks, use of recreational garden) NCDS69: goes to clubs NCDS69: takes sports NCDS74: how often games, sports, swims
Health/care costs	BSC80: therapy input BSC80: special school / special education
From mid-childhood on: health	
Adiposity/BMI	**I think this is available in all of them (height and weight)
Cardiometabolic - Diabetes - Blood pressure - Cholesterol	NCDS81: health conditions NCDS00: illnesses, conditions NCDS02: any medicines taken for cardiovascular NCDS00: ever had diabetes NCDS04: ever had diabetes NCDS08: several items on diabetes NCDS00: whether ever had high blood pressure (and age) NCDS08: whether suffers high blood pressure

Respiratory	**not checked but seen this everywhere
Bones & skeletal	**not yet checked but seen this everywhere
Cancer	NCDS00: ever had cancer NCDS04: ever had cancer NCDS08: seen dr about cancer in the last 12 months
Motor function (at 20s), later mobility	
Cognitive	NCDS08: cognitive function (test results)
Psychosocial, emotional	NCDS08: several items on mental health, anxiety, etc
PPA	BSC80: PA NCDS02: PA+++ (in-depth questions) NCDS04: whether exercised regularly (yes/no) NCDS08: whether regularly does any of the listed exercises (yes/no) and how often NCDS08: whether exercises regularly BSC04: PA
From mid-childhood on: social & economic	
Educational/qualifications	NCDS78: school exam results NCDS04: educational attainment BSC04: educational qualifications
Employment	BSC96: economic activity NCDS5: economic activity
SES	**extract after discussion with Heather on which to use
Activity/participation	NCDS08: whether health limits everyday activities
QoL physical	NCDS08: SF-36 NCDS08: work health BSC04: health
QoL psychosocial	BSC00: mental health NCDS00: happiness all things considered NCDS08: look back on life with sense of happiness NCDS08: several items on friends
Disability	NCDS81: disabilities NCDS00: disabilities BSC00: disability NCDS5: disability?
Death	

NCDS58 = National Child Development Study 1958; BCS70 = British Cohort Study 1970

STUDY 3: Intervention development and modelling study

N Kolehmainen, L Vale, E van Sluijs, T Rapley

Rationale: There is a general lack of effective interventions to increase children's participation in physical activity,^{11,17,18} and an absence of evidence about possible intervention techniques (i.e. 'active ingredients'). Improving physical activity interventions is the top international consensus priority for physical activity research in children in general,¹⁷ and an explicit priority of UK disabled children, NHS, and policy makers.^{1,6,19}

Aim: To develop and model intervention techniques for physical activity behaviours in children with physical limitations, including developing theory and proof-of-concept evidence about outcomes, processes and efficiency.

Design: Four interrelated development and modelling tasks in line with MRC guidance: A) Identify critical situations where enabling/restricting physical activity occurs, and children's and parents' experiences of these. B) Describe the situations in terms of replicable intervention techniques, their delivery, outcomes, and change processes. C) Develop scientific theory about the techniques, their delivery, outcomes/benefits, and processes. D) Model the processes, benefits, and costs.

Tasks A+B: Identify and describe critical situations

Participants: A purposive diversity sample of 8-10 NHS clinicians (therapists, health visitors) across the three participating organisations (above). Through the clinicians, further purposive samples of 10-12 parents of children (0-5yrs) with high and low levels of physical activity participation; and 4-5 other community providers (e.g. toddler groups). Sample size is based on estimated number of clinicians and families required to cover a range of critical situations, and feasibility of data collection and analysis.

Data collection: Open-ended, semi-structured, retrospective interviews based on modified critical incident technique⁶⁰ will be used to encourage participants to describe and reflect on 'critical' physical activity situations across settings (clinical, home, community). Interviews will be followed up with direct observations of 8-10 selected situations to further identify intervention techniques, their delivery, and potential outcomes and processes. Interviews will be audio recorded verbatim; observations video and/or audio recorded where possible. All audio recordings will be transcribed.

Data analysis: Inductive thematic analysis will be used to identify intervention contexts and participants' experiences of them. Content analysis by Krippendorff will be used to identify discrete intervention techniques, ways to deliver them, outcomes, and change processes. Existing definitions will be used where possible, e.g. from a recent systematic review of interventions and outcomes in this population,⁶¹ the ICF,²³ and the Behaviour Change Taxonomy v1.

Output: The identified techniques and evidence about delivery, outcomes, processes, contexts, and participant experiences will be described using standards for complex interventions (TiDier), and entered in Rehabilitation Intervention Techniques (RITs)⁶¹ database for further development.

Task C: Developing scientific theory

Information from the RITs database will be presented to a scientific expert panel (incl. experts in population health, physical activity, clinical interventions, behaviour change, medical sociology).

The panel will appraise the RITs in relation to wider evidence and theories, and propose: (i) Refinements to the RIT descriptions, (ii) Areas for further investigation (Tasks A+B), (iii) RITs for modelling (Task D, below), (iv) RITs for formal evaluation through spin-off applications, and (v) RITs with already sufficient evidence for translation to practice.

Task D: Modelling processes, benefits, and costs

Design: Processes, outcomes, benefits, and costs of selected RITs (n=6-8) will be modelled through series of mixed methods single cases, and decision-analytical modelling.

Intervention: RITs identified from Task A+B, above. To be eligible for modelling, the RITs must be replicable and must have been proposed as ready for modelling by the scientific panel (Task C).

Mixed methods single cases: A purposive sample of 3-4 children with physical limitations per RIT, their parents, and treating clinicians. Qualitative and quantitative methods will be used to collect data on: intervention processes (uptake, mechanisms, context); and potential benefits, costs, and harms for the child, parents, and the NHS. A sample of delivery situations will be observed, as above. Data on perceived benefits, intervention costs (e.g. time, travel, materials), and harms will be recorded through parent and provider questionnaires. Potential effect sizes for physical activity will be estimated as in study 1. Data on children's physical limitations, demographics, and behavioural factors will be collected as in study 1.

Open-ended data (intervention uptake, mechanisms, interactions with context, provider experiences, perceived benefits, and harms) will be analysed using thematic and content analyses as above. Data on physical limitations, demographics, behavioural factors, and costs will be analysed using descriptive statistics; physical activity as in study 1. The results will be synthesised in relation to each intervention technique, entered in the RITs database, and presented back to the scientific panel for further development.

Decision-analytic modelling: A two-part decision-analytic model, incorporating the econometric model (study 2), will be developed using best-practice methods.⁶² Part 1 will estimate each RIT's costs and impact on physical activity. Results will be presented as incremental cost per minute of additional physical activity. Part 2 will use this incremental cost per minute data and the information from the econometric model (study 2) to predict the health effects and cost consequences related to each RIT. A microsimulation technique will be used, where the decision-analytic model will be run with a cohort of 100,000 hypothetical children, computer-generated using explicit assumptions (e.g. age at intervention, the cohort's age-related health prior to intervention). The results will be presented as the costs and consequences of each RIT, and entered in the RITs database to inform considerations about which RITs to advance for formal evaluation(s). All benefits and costs will be discounted at the recommended UK rate of 3.5%. Sensitivity analyses will be used to test the robustness of the estimates. Initially, a best case/worst case scenario analysis will be conducted. If the conclusions drawn from these analyses differ, then probabilistic and further deterministic sensitivity analysis will be considered to explore uncertainty more fully.

Outputs: A selection of replicable interventions specified to recommended standards, with evidence of potential outcomes, mechanisms, processes, and relative efficiency. The interventions, selected by the scientific panel, will be advanced to funding applications for formal evaluation(s).

6. STUDY MANAGEMENT

The project conduct will adhere to the NHS Research Governance Framework and the specific procedures agreed for the project in the REC approval. Please refer to the original REC application form for full details. All members of the team who will have access to the data are made aware of the Protecting Information Policy that sets out how data must be handled to ensure compliance with the Data Protection Act 1998.

Central project management (Newcastle)

The project will be led by Dr Kolehmainen from Newcastle University, with day-to-day research support from an RA. Dr Kolehmainen will also be supported by a project management group that will meet twice a year to review progress against the project and plan and key milestone (Figure 6.1), and provide steering on the science. The management group will consist of Prof Mark Pearce (epidemiology), Prof Luke Vale (health economics), Dr Tim Rapley (qualitative methods). In addition, the project will be reviewed and steered by the integrated PPI-clinical advisory group 4-5 times a year (see below).

Dr Kolehmainen and the RA will also work with wider Newcastle partners through both existing and developing multidisciplinary relationships. The key partnerships will be with the behaviour change and implementation science (the Newcastle Health Psychology Group, the FUSE Behaviour Change Group), epidemiology (the Applied Epidemiology Group), health economics (Newcastle Health Economics Group) and physical activity measurement (the Brain and Movement Group).

Within the wider Newcastle University context, the lead institute, the Institute of Health & Society, spans traditional disciplinary boundaries through three research themes highly relevant to the present research: unravelling the origins of disease, understanding health and disability across the life-course, and developing and evaluating interventions to improve health and well-being. The Institute is involved in multi-partner health research initiatives which provide us access to relevant further collaborations, including universities, the NHS, local government, and other public, private, and voluntary organisations.

The participating NHS sites (Newcastle, Sheffield, Cheshire)

The project will involve collaborations with three NHS Trusts (Newcastle, Sheffield, Cheshire), and a selection of wider local authority and other community provider organisations in their locations.

In terms of NHS collaborators, Newcastle upon Tyne NHS Hospitals Trust (NuTH) is one of the largest hospital Trusts in the UK, with a relatively small community healthcare provision for children with physical limitations. Working with the Trust will enable us to explore community provision in a context of larger hospital care setting. Sheffield Children's NHS Foundation Trust is one of only four specialist NHS children's Trusts in the UK and a collaboration with them will enable research with an organisation solely focused on children. Primary Care Cheshire is one of the first 29 NHS England Vanguard sites that leads on the development of the new Multispecialty Community Provider model, and the related Primary Care Cheshire partnership involves four organisations including the clinical commissioning group and community, hospital, and local authority providers working together to move specialist care out of the hospital in to the community. Primary Care Cheshire is developing a dedicated programme for children, and this collaboration will allow the research to work directly with commissioners, NHS and local authority decision-makers, as well as clinicians developing new approaches to community care.

Dr Kolehmainen will oversee the study at the local sites, with close links to the local site investigators and support from the study RA as appropriate. The oversight from Newcastle will involve:

- i. Spending time at each site, with the collaborating clinicians, at the start of each study
- ii. Spend time at the study sites at regular intervals throughout each study, and have at least fortnightly contact with the clinicians (via phone, email)

- iii. Ensuring the collaborating clinicians:
 - Understand the study and its requirements
 - Are competent in discussing the study with potential child and parent participants
 - Are competent in any data collection required of them (study 1) and in administering any study interventions (study 3)
 - Know the procedures related to answering any queries and alerting the research team to information, including any adverse events
- iv. Having direct contact with the families participating in the study
- v. Being available to the clinicians to make contact in order to easily check details and clarify any uncertainties.

In terms of local authority and other community provider collaborations, we will further develop links with under-5s community providers and charity groups through the recently established Change4Life Under-5s Group for Newcastle and through NAPI, the Newcastle Parent and Toddler Group Initiative. The under-5s group involves local authority, charity, and NHS partners in advancing healthy eating and physical activity in young children. NAPI is a charity supporting 120 toddler groups, run by volunteers (often parents) across Newcastle. These groups are keen to collaborate.

Integrated PPI-Clinical Advisory Group

The project has already benefitted substantially from advice from children, parents, therapists, and academic topic experts. The further work will build on this.

PPI and clinician involvement in developing the project

Families and clinicians prioritised the topic in a recent James Lind Alliance research priority-setting partnership: interventions to support participation in physical activity in children with disabilities, including children with physical limitations. [For the report, see Morris C et al., *BMJ Open* 2015;5:e006233. <http://dx.doi.org/10.1136/bmjopen-2014-006233>]. Dr Kolehmainen was involved in instigating the partnership through the Strategic Research Group of the British Academy of Childhood Disability.

Children and parents directly influenced the proposed outcomes and study design:

- a. Input from 9 child patient and public involvement ('PPI') partners, and 17 children contributing to previous work, informed the specification of health and participation outcomes. They advised me on what "health", "doing healthy things", and "being active" looks like in day-to-day life for young children.
- b. The focus on integration of health and wider community activities was discussed in three collaboration events involving 106 participants, including parents, clinicians, education and social work professionals, and leisure instructors. This focus attracted strong support across stakeholders, especially parents.
- c. The focus on social environment has been consistently and strongly advocated for by our parent and child advisors, and was raised in the James Lind Alliance partnership.
- d. Generating evidence for commissioning was specifically requested by parent PPI partners to address the research-to-practice gap.
- e. Local parents (n=5) and the proposed community partners (n=3) (see 'Collaborations') were further involved in preparing the application. The key points were:

- f. The interventions should focus on supporting families to make small changes within their day-to-day lives, and enabling all children to participate according to their ability. This introduced the idea about identifying 'critical' participation situations as the starting point.
- g. Economic considerations should focus on benefits to the child and family first, and costs second. Benefits should be considered broadly, not just as healthcare cost-savings. This prompted the plan to involve stakeholders in selecting the benefit and cost indicators in study 2.
- h. Incentives for involving parents could helpfully focus on supporting parents' knowledge, skills, and confidence in parenting: ideas that help them "be good parents – and feel we are good parents". This has steered the Dissemination Plans and the requested resources for incentives and dissemination.

PPI and clinician involvement steering the project

A collaborative, flexible approach to patient and public involvement ('PPI') will be adopted. This will involve (i) structured activities emerging from the needs of the research (e.g. developing participation information resources) and (ii) responsive activities proposed and led by the Advisory Group members (see below) in response to emerging ideas and requests/feedback from stakeholders. In addition, the integrated approach, where PPI, clinicians and other partners work together rather than in separate streams will be continued.

The project will have an Integrated Advisory Group that will consist of parents (n=5), clinicians (n=3), an under-5s community provider (n=1), and a commissioner. The Group will steer the research to ensure high service-user and clinical relevance, and will provide co-leadership of engagement and dissemination activities. The Advisory Group will also have an important role in steering any spin-off funding applications related to the interventions designed. Examples of potential PPI roles and activities are provided below; exact activities will be agreed with the Advisory Group.

- Developing participant information resources:
 - Design participant information materials for studies 1 and 3
 - Designing sections of the study web site and newsletters. See also 'Dissemination'.
- Undertaking/analysing the research:
 - Develop recruitment strategies for studies 1 and 3.
 - Design the interview topic guide for study 3
 - Contribute to the development of the detailed outcome measurement protocol for studies 1 and 3.
 - Critique themes and codes emerging from study 3 and propose further themes.
 - Interpret the quantitative results across studies 1-3, and reflect on their implications.
- Contributing to reporting and dissemination:
 - Direct and co-lead all dissemination and implementation
 - Contribute to reporting, including peer-reviewed publications and media.

Dr Kolehmainen has a track record over ten years of enabling PPI in research. The Advisory Group will be encouraged to work together, and the members will be invited and supported to take leadership roles across a range of tasks. The members will have access to a range of PPI support, training, and activities via Newcastle University's Patient and Public Engagement/Involvement Group.

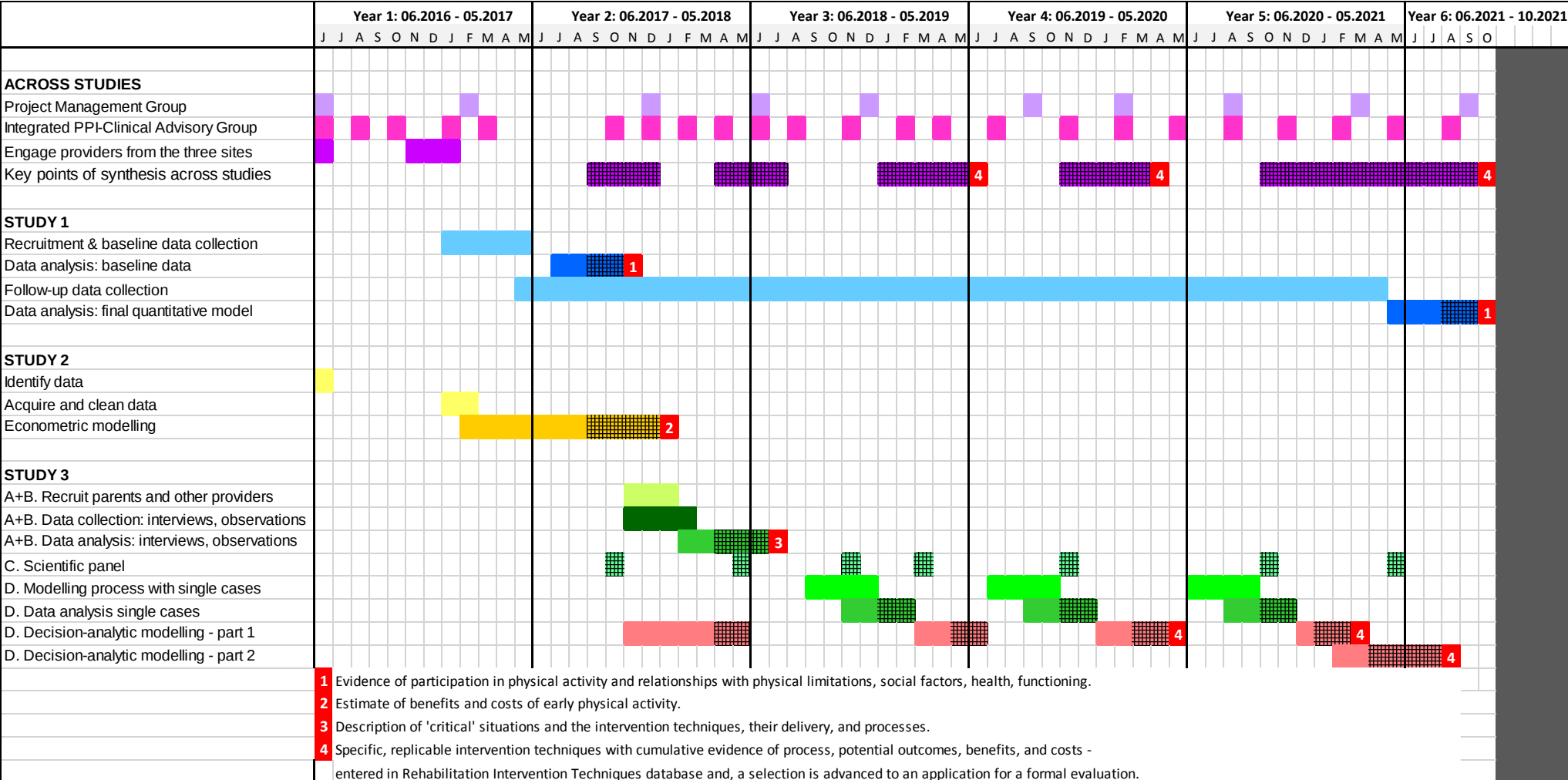
Academic collaborations

The project will also benefit from wider academic collaborations. A collaboration with Dr Olaf Verschuren at University Medical Center Utrecht will focus on physical activity measurement in research with children with physical limitations. Dr Verschuren has recognised, international experience in this from work with 18 rehabilitation centres/schools in the Netherlands, Canada, and Australia.

A collaboration with Dr Esther van Sluijs at the Behavioural Epidemiology Group in the MRC Epidemiology Unit, University of Cambridge, will inform the development and evaluation of physical activity interventions for children and young people. Dr van Sluijs' research considers psychological, socio-cultural, and other environmental influences on physical activity behaviour, and her Group is part of the Centre for Diet and Activity Research (CEDAR), an internationally recognised centre of excellence that develops health behaviour interventions and shapes public health policy and practice.

The project will also benefit from Dr Kolehmainen's other, existing international collaborations in childhood disability (e.g. Dr Nora Fayed, an expert in use of WHO definitions for outcome measurement, and Dr Briano Di Rezze, an expert in fidelity measures for allied health intervention techniques) and behaviour change (e.g. Dr Justin Presseau, an expert in multiple behaviour change in relation to physical activity, and in implementation science).

Figure 6.1 Project plan timetable with key milestones



7. ETHICS

The present research is aimed to be of benefit to children. Good research with children and young people is essential for finding out how to improve their healthcare and health.⁶³ Children and young people also repeatedly articulate that they believe research is important, and that children should be provided the option to take part in research and to help to improve their healthcare.⁶³

In research with children it is essential to gain knowledge of the children, their actions, and their views and perceptions. If we did not involve data from the children themselves, there is a risk that the research will not be relevant to them; will result in interventions that are not acceptable to them; or will not address the right issues. In the other words, there is a risk that the relevance, acceptability and effectiveness of the resulting model and interventions will be compromised.

To gain children's views, we will need to speak to and interact with them. We will collect as much information through routine observations as possible; however, some of the information needs to be collected directly from the children.

In doing research with children, it is important to appreciate that children both actively generate their own worlds⁶⁴ and are influenced by their environment⁶⁵ (e.g. other people, physical and institutional structures, and media), and that different children experience the world differently.⁶⁶ Children are their own entities, and as such they have rights. Two of the rights are of specific importance when considering research with children: (1) a right to make a contribution, and (2) a right to be safe from harm. Under5s, and especially under5s with physical limitations, have had little opportunity to use their right to make a contribution to research—studies with these children have been so few. By inviting the children themselves to take part, the present research will change that.

To keep the children safe from harm while they are making a contribution, special considerations need to be given to ethical (and related scientific) issues in the present project. These are in addition to the usual ethical and scientific considerations required. These are outlined below.

Specific actions to ensure the two key rights are respected

We have agreed some key principles and actions that will be followed to guide our research in order to protect the children's rights to both contribute and be safe from harm. These are based on the current recommendations⁶³ on ethical research with children, where the recommendations themselves have had input from children and parents.

To enable children to make a contribution:

- Children will be respected and appreciated as important contributors without whom the project would have limited meaning.
- The procedures for recruitment, consent/assent, and data collection will be designed to be sensitive for children's views about whether they wish to contribute, and how they may wish to contribute.
- Active steps will be taken to design and conduct the research so that children will be empowered to participate on their own terms and within their developmental abilities. This includes the use of 'child-friendly' research methods that are in-tune with children's ways of experiencing the world.
- Information about the outcomes of the research will be fed back to children and parents in ways that are accessible to them (see also 'PPI').

To ensure children are safe from harm:

It is a common concern that children may be vulnerable in research. A recent report by the Nuffield Council on Bioethics⁶³ recommended that the best way of ensuring that children do not become vulnerable in research is to involve children and/or their parents in designing the studies and to

ensure that they are enabled to make informed decisions throughout the research process. The report also recommended that the nature of child and parent involvement and enablement depends on the population of children (e.g. their capabilities and interests) and the nature of the research.

The proposed research focuses on young children who are unlikely to be able to make fully informed choices about their participation in research, and who are likely to have limited attention span and understanding for contributing directly to the research design. The Nuffield report recommends that in these circumstances the children's parents are usually best placed to inform the research and make decisions on their children's behalf. However, the children should also have opportunities to be involved in ways that suit them. The following actions will be taken:

- Good relationships and trust will be proactively built with both children and parents to facilitate open communication and reduce any worry about the research.
- Parents will be provided with clear information about the study before they are asked to take part to enable them to make the best choice for their children. The parent information leaflets will be designed with parents (see 'PPI').
- The information to parents will include fair representation of the likely risks, burdens, and benefits of the study, weighed up from the perspective of potential participants as advised by the Parent Advisors (see 'PPI').
- Potential participants will be offered opportunities to discuss the studies appropriately and sensitively so that they are able to make free and informed choices about whether to take part.
- Children will be given as much control over their participation as possible, and will be encouraged to take part in ways that they prefer. Sensitivity will be shown to their preferences not to participate (ongoing 'assent'). For example, in study 1, parents will be encouraged to allow their children to choose whether or not to wear the accelerometers, and in study 3, the children will be enabled to control engagement with intervention materials.
- The context of any data collection with children will be carefully considered.
- Any clinicians involved in the studies will be overseen by Dr Kolehmainen for their research involvement, and Dr Kolehmainen will ensure all clinicians have received the appropriate training.

Experience underpinning the management of the ethics

Dr Kolehmainen has extensive experience of interacting with children of all ages through her clinical, research, and voluntary sector experiences. She has advanced skills in building good relationships with children and their parents, including in building a high level of trust and confidence, listening to both the child and their parents, and dealing with sensitive issues in a manner that is respectful and empowering of all parties involved, including the child. Dr Kolehmainen has received specific training about discussing research with children and families for the purpose of consent/assent. As a practising clinician, Dr Kolehmainen is trained in appropriate safeguarding procedures. The study protocols will explicitly include procedures for discussing and raising any concerns related to safeguarding.

8. DATA MANAGEMENT

The following plan has been developed using the Medical Research Council guidance and template for data management in research.

0. Proposal name
Understanding behavioural pathways and interventions for physical activity and health in children with physical limitations: the ActiveCHILD study
1. Description of the data
1.1 Type of study, 1.2 Types of data, and 1.3 Format and scale of the data The research will consist of three studies involving children (0-5yrs) and their parents: 1. Longitudinal study with n=400 children resulting in quantitative data (numeric data on e.g. physical activity, health outcomes, body composition, behavioural determinants, and demographics) and qualitative data (brief, textual descriptions of variables and daily activities). These data will be identifiable with participant IDs, but anonymised for data storage. 2. Econometric modelling study primarily using existing, publicly available data, e.g. from existing systematic reviews and cohort studies. 3. Complex intervention development and modelling study involving clinicians (n=8-10), children (n=10-12) and their parents, and other community providers (n=4-5). Quantitative data will be collected as above in study 1, and additional direct observations of the children across life situations. Open-ended qualitative data will be collected through interviews, direct observations of life situations, and expert panel. Econometric data will be as above, and additional numeric and brief textual data on costs, benefits, and harms. A further stage will involve in-depth case study data from n=18-32 children and their parents; data is qualitative and quantitative as above. Quantitative data will be managed and analysed using ActiLife, SPSS and PEDI-CAT software. Qualitative data will be managed using NVivo. The University guidelines will inform selection of data formats for long-term preservation: http://www.ncl.ac.uk/res/research/rdm/organise/index.htm
2. Data collection / generation
To my knowledge there are no existing data that include children 0-5 years with and without physical limitations alongside data on their physical activity and behavioural determinants (study 1) – to meet the aims these data therefore need to be collected. Study 2 uses existing data. Study 3 explores new interventions for which data do not yet exist. 2.1 Methodologies for data collection / generation, and 2.2 Data quality and standards Please see case for support on methods for each study. The physical activity data collection will follow MRC guidelines for physical activity measurement; behavioural determinants data collection will follow established practice in behavioural sciences; and all data collection will adhere to NHS Research Ethics guidance as well as other best practice guidance (e.g. Nuffield Bioethics recommendations for research with children). Of the data that is manually entered, a proportion will be independently checked for quality assurance.
3. Data management, documentation and curation
3.1 Managing, storing and curating data Project data will be stored on the University of Newcastle file store which comprises enterprise level file servers in physically secure data centres with appropriate fire detection / suppression equipment. Snapshots are taken daily. An incremental copy to backup tape is taken every night and a full copy is taken every month; backups are kept for three months. Inactive tapes are stored in on-campus fireproof safes and are located behind the University's institutional firewall to protect against external attacks. http://www.ncl.ac.uk/res/research/rdm/storage/storage.htm Storage on laptops will be for short-term only, with automated transfer of data onto the University server. No identifiable data will be stored on portable devices.

3.2 Metadata standards and data documentation

Metadata for discovery will include title, publisher, data description, keywords, and date and method of collection. Data documentation will be used to provide contextual information for secondary users to understand the data. University guidance for data preservation will be followed: <http://www.ncl.ac.uk/res/research/rdm/preserve/index.htm>

3.3 Data preservation strategy and standards

The University policy on data preservation is for a 10-year storage period, which is the same as the MRC. Data to be stored will include all the longitudinal data (study 1), and data from studies 2 and 3 that underpin publications and/or with long-term value.

4. Data security and confidentiality of potentially disclosive information

Both the quantitative and qualitative data collected will be anonymised in line with the UK Data Archive guidelines: <http://www.data-archive.ac.uk/create-manage/consent-ethics/anonymisation>
The anonymisation will be carried out as part of the initial data cleaning, before the analyses.

4.1 Formal information/data security standards

Newcastle University IT has a dedicated Security Team, which includes a member who is trained in ISO/IEC 27001:2005 and ISO/IEC 27001:2013 auditing, and is also a certified PCI-SSC Internal Security Assessor. An internal information security risk assessment is completed every three months. The findings of this risk assessment are subject to review by the University's IT Information Security Forum and form the basis of a risk treatment plan. This risk treatment plan is a key part of an on-going quality assurance process to ensure that information security risks are mitigated through improvement of the managed information security controls.
<http://www.ncl.ac.uk/res/assets/documents/InformationSecuritySummary-v1.5-July2014.pdf>

4.2 Main risks to data security

Potential risks include data loss, and breaches of anonymity, confidentiality, and invasions of privacy. For mitigating these, please see above. In addition, access to data will be carefully controlled, and restricted to the research team until made formally available. Further steps can be taken to encrypt the data as required: <http://www.ncl.ac.uk/itservice/security/encryption/>
MRC guidance on the confidentiality and data security will be followed, together with the University Good Research Practice policies, and NHS Research Ethics Governance requirements.

5. Data sharing and access

5.1 Suitability for sharing

Data from study 1 will be suitable for sharing as it will be a large cohort of children and the data collected will be feasible to anonymise. Data from study 2 will already be in public domain; further sharing will be considered if considered possible (given existing IP) and beneficial. Data from study 3 will be less likely suitable for open sharing. Any analysis will rely on contextual expertise on the data and how they were collected, and it will be difficult to anonymise the data sufficiently while still enabling the degree of triangulation required to maintain rigour.

5.2 Discovery by potential users of the research data

A metadata record will be created in Newcastle University's externally facing data catalogue: <https://rdm.ncl.ac.uk/landing/pages/10.17634/>

A link to this will be included in publications that use data from the project, and on the study web page. Meta-data will also be made available through MRC gateway for population and patient research data.

5.3 Governance of access

The PI, together with the three sponsors and with input from the study Advisory Group, will develop an access policy, and based on this a data access statement to accompany the links to the data (above). The policy will consider how best to ensure independent oversight of data access and sharing, in compliance with the MRC policy on data sharing.

5.4 The study team's exclusive use of the data

The research team will maintain 12 months exclusive use of the data from the end of the study (the common standard in the field), OR until acceptance of the key results for publication, whichever is sooner.

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

Permission to share anonymised data will be included in study 1 consent forms. PI will discuss with the IPR team in the Research and Enterprise Service before any data is made public.

5.6 Regulation of responsibilities of users

No data will be shared externally until it has been anonymised and prepared for external sharing (as above). Data sharing agreement will be developed as part of the policy on data sharing (above), and this will be informed by the views of the Advisory Group as well as the research team.

6. Responsibilities

PI will have the overall responsibility for quality of the data and data management. Other members of the research team will be further responsible within their agreed tasks; e.g. Ms Mann for managing the epidemiology data (study 1) and preparing it for archiving; and Dr Brown, together with the PI, for managing and preparing for archiving the econometric data (study 2). from the Research Data Service (<http://www.ncl.ac.uk/res/research/rdm/index.htm>) will assist with data storage, documentation, and sharing. The University Information Security Officer can provide guidance and training on data protection (<http://www.ncl.ac.uk/itservice/about/people/profile/peter.dinsdale>).

7. Relevant institutional, departmental or study policies on data sharing and data security

Policy	URL or Reference
Data Management Policy & Procedures	http://www.ncl.ac.uk/res/resources/Polices%20Forms%20and%20Guidance/Polices.htm
Information Security Policy; and Summary of Technical Information Security for Information Systems and Services Managed by Newcastle University IT	http://www.ncl.ac.uk/itservice/policies/information-security-policy.pdf http://www.ncl.ac.uk/res/assets/documents/InformationSecuritySummary-v1.5-July2014.pdf
Data Sharing Policy	http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/policy/
Institutional Information Policy	http://www.ncl.ac.uk/itservice/policies/
University Code of Good Research Practice	http://www.ncl.ac.uk/research/ethics/goodpractice.htm
NHS HRA Guidance for Information Governance	http://www.hra.nhs.uk/resources/data-legislation-and-information-governance/

8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their telephone & email contact details

Dr Niina Kolehmainen

9. ANTICIPATED IMPACT, AND PATHWAYS TO IT

The beneficiaries and the nature of impact

The research will benefit *policy makers* by providing much-needed evidence about early years participation in physical activity. Current policies and guidelines for early years physical activity, e.g. by Public Health England, Chief Medical Officer, and National Institute for Health and Social Care Excellence (NICE), explicitly state that due to a general lack of research on physical activity in children under 5-years-old, and especially due to a lack of UK-based evidence, policies and guidelines for under 5s are based on weak evidence. The NICE guidelines also highlight the lack of research into interventions for clinical childhood populations. The proposed research will inform future versions of these policies and guidelines, improving their effectiveness.

The research will directly benefit the *NHS and health commissioners* by enabling them to plan investments and interventions for early years physical activity. Allied health services deliver much of these preventative, health promotion interventions. Evidence from the research will help the interventions to be more precisely targeted in terms of what to provide, to whom, and when. This improves service planning, effectiveness, efficiency, and productivity.

The ultimate positive impact of the proposed research is on the health, well-being, and quality of life of *children*. Interventions to promote healthy lifestyles and health from early on have the potential to prevent chronic diseases and disability over the whole life course. Enabling all children's involvement in day-to-day physical activities and play is also as a key pathway to long-term psychological, social and emotional well-being.

Improving children's health and well-being will also benefit those around them, especially *parents*. Children's day-to-day participation, health, and functioning have been shown to directly affect parental physical, psychological, and social health, and has been proposed to relate to parental economic productivity.

The improvements in child and parental health and well-being will further benefit the *NHS, other public sector organisations* (including local authorities), and *wider society* by contributing to economic productivity and accruing cost-savings in health and other care costs.

The knowledge and interventions from the research provide opportunities for building *industry partnerships*. Current non-drug, complex interventions used with children (including allied health interventions) have little evidence of effectiveness, and there are few high-quality training courses in evidence-based interventions. I will seek opportunities to translate the generated knowledge and interventions to commercially available intervention materials and training courses; and I will work with the University's Business Development experts on this.

The improvements in policies, guidelines, organisational changes to service provision, and access to better training courses will benefit *clinical and other practitioners in children's health*. These changes, as well as direct dissemination of knowledge and evidence to clinicians and practitioners, will improve their knowledge and skills related to physical activity in children, including children with physical limitations, and pathways and interventions for promoting it.

The scientific and methodological developments (see Academic Beneficiaries) will increase UK *researchers'* capacity to provide research leadership in children's complex interventions research. The scientific and methodological developments from the proposed research significantly advance theories about interventions, and methods to specify and evaluate interventions. This will improve UK researchers' competitiveness to lead large-scale intervention studies, e.g. through European Union-funded international research partnerships.

Pathways to impact

Dr Kolehmainen will lead the identification of exploitable outputs with expertise from the Advisory Group, the Project Management Group, and Newcastle University Research Enterprise Services. We will translate outputs to impact within the broad Communication Plan (see below), which is founded on active engagement within the stakeholder communities. Stakeholder views and priorities have already informed the proposal. Activities planned for the duration of the research are described below.

We will engage **policy makers** early on to maximise opportunities to inform **policy** and **guidelines**. Dr Kolehmainen will update the key contacts at Public Health England (e.g. the Lead Allied Health Professional) and NHS England (e.g. the Chief Allied Health Professions Officer) of the research and anticipated policy-relevant outputs. We will do this by a brief email, with a follow-up on social media (which they use actively) and in person when an opportunity arises (usually 1-2x/year). We will similarly alert our contacts in the key advocacy groups, e.g. British Academy of Childhood Disability, Royal College of Paediatrics and Child Health, and UK Society of Behavioural Medicine, and express our interest to contribute to consultations and working groups. We will also seek to have a presence at events attended by policy makers, e.g. NHS Confederation conference. We will publish summary briefings on key results, e.g. on the project web page and through the University press office, and highlight these through the above contacts and social media to maximise visibility. **Key milestones:** Submit evidence to NICE review of physical activity guidelines in 2017-18. Showcase the key policy messages at an event such as NHS Confederation conference in 2021. Send Executive summary of the research and key policy-relevant findings to the key stakeholders in 2021. Contribute evidence and expertise to the next public health strategies for early years physical activity and allied health public health interventions (estimated in 2018-2021). **Indicators of success:** Stakeholder engagement on social media; requests for information/expertise; and citations in policy/guidelines. **Resources:** Dr Kolehmainen's time; support by RA and pooled admin to prepare materials and collate data on the success indicators; travel to meetings; and fees to attend/exhibit at events.

A combination of **NHS senior managers** and **health commissioners** from the partnering regions (Newcastle, Sheffield, Cheshire) will join the Advisory Group, and through that steer translation of the outputs to useful and engaging materials to their peers nationally. These are likely to include, e.g. explicit intervention description templates for managers and commissioners, to support planning for what interventions to provide to whom and at what time points. The stakeholders have indicated they wish to focus on specific, easy-to-use materials and the focus will be on co-producing these. It is likely that the materials will require further implementation support; this will be an opportunity for commercialisation (see below). **Key milestones:** Annual Executive summaries of the key outcomes for the 12-month period, supplemented by easy-to-use practical materials and templates where possible; disseminated directly to the partners, through their wider networks, and through social media (see also linkage to policy, above). Two regional, targeted dissemination events in years 2 and 5 (2018, 2021) to engage organisations and people beyond the immediate partners. **Indicators of success:** The co-created materials and templates are used across the UK, and providers and commissioners are aware of the results (a survey of providers and commissioners in 2021). A list of organisations who want further implementation support by 2021. Key effectiveness, efficiency and productivity markers for services to promote physical activity agreed, and baseline data for these collected by 2021 (ahead of future evaluations of impact about the interventions to be developed). **Resources:** Dr Kolehmainen's time; project RA; admin as above; travel, catering and compensation for time in relation to the Advisory Groups; costs for dissemination materials; and costs for dissemination events in years 2 and 5.

We will engage **clinicians** and **other practitioners** (e.g. toddler group leaders, activity co-ordinators), who will also join the Advisory Group and steer translation of outputs to their peers nationally and internationally. Based on Dr Kolehmainen's extensive experience of practice, our previous research into changing professionals' practice, and wider published evidence, we are confident that translation activities to clinicians and practitioners will be best focused on a combination of: (i) awareness raising through opinion leader networks (e.g. CountMein!, CanChild) and (ii) formal training that targets skills, confidence, goals, and action plans (not merely knowledge).

Targeting the determinants of practice enables clinicians and practitioners to move from “knowing what to do” to “actually doing it”. The translational activities with clinicians and practitioners will link to the activities with managers and commissioners, with an additional focus on changing practice; this will also be an opportunity for commercialisation (below). **Key milestones:** A presentation to multidisciplinary practitioner audience (n=150+) on the research and results to date in 2017. Clinicians and practitioners join the two regional, targeted dissemination events on years 2 and 5 (2018, 2021) above. **Indicators of success:** Clinicians and other practitioners have access to evidence-based training in early childhood physical activity by 2021, and in physical activity intervention techniques by ~2025. Clinicians and practitioners are using the intervention techniques in day-to-day practice from ~2025 onwards (a follow-up survey). **Resources:** As for managers and commissioners, above.

The ultimate health impact is aimed at **children and families**. Beyond the research itself, and the above pathways, there will also be opportunities to directly benefit children and families. Parents will join the Advisory Group; will identify outputs that can be translated to children and families; and will steer the translation. Suggestions made by parents include e.g. practical, easy-to-action tips for parents on how to help their children to play and develop. Parents will also take an active role in dissemination across sectors, including an active contribution to the social media dissemination plan and co-production for events. **Key milestones:** Parents join Advisory Group and, with support, develop a strategy for identifying and translating outputs directly to families (in 2016). These translated outputs are launched annually 2016-2021. Parents present research outputs at the regional events (years 2 and 5) and at other events. **Indicators of success:** Parents and parent organisations beyond the research group engage with the parent-translated outputs (by 2017, evidenced e.g. by examples shared on social media and/or with the team directly). The interventions have potential benefits for children (by 2021). The interventions are effective at promoting child health, and parental health and well-being (~2025).

As indicated above, the research outputs are likely to benefit from further commercialisation with **industry/business partners**. We will work with the University’s Research Enterprise Services to seek opportunities to translate the generated interventions to commercially available intervention materials, and to further develop training courses and implementation packages to match these. Based on our expertise of the field, it is possible that advancing this will require a new business to be set up, and Dr Kolehmainen will lead the exploration of this. **Key milestones and indicators of success:** As above, for training courses and implementation packages for managers, commissioners, clinicians and practitioners. **Resources:** As above, with additional time from me to explore the options, and small costs for travel and meetings to engage with potential industry/business partners.

We will target **UK allied health and behavioural sciences researchers** to build capacity in children’s complex interventions research through training workshops, to improve the UK’s competitiveness to lead international intervention studies. Some of these workshops may offer commercial opportunities, either with industry/business partners (above) or the University. **Key milestone:** Organise targeted methods workshops to UK researchers in children’s complex interventions (2020-2021). **Success indicator:** Improved quality of interventions studies (assessed e.g. from systematic reviews), with interventions clearly described and interventions exposures measured. **Resources:** Dr Kolehmainen’s, RA and administrator time to organise the workshops.

Dr Kolehmainen has a track record in leading engagement and co-production activities with service users and providers, including co-producing interventions, workshops, presentations, and printed materials, and in raising awareness through social media. She is well connected to the policy and advocacy bodies above, and increasingly recognised as an expert for consultations and working groups. She is frequently complimented as an engaging communicator across audiences, and is regularly invited to contribute to national and international events (1-2/year). She has recently organised three national multi-stakeholder events (100-300 people each).

Communication plan

We have a three-pronged communication strategy:

- 1) We will *build and maintain strong, ongoing cross-sector partnerships* which enable timely two-way dialogue between research and application, developing skills, confidence, and passion for our research area (rather than merely imparting knowledge about results). These include e.g. proposed partnerships with Dr van Sluijs and Dr Verschuren, CountMeIn!, CanChild, and the NHS.
- 2) We will *work with existing multidisciplinary, cross-sector networks*—e.g. British Academy of Childhood Disability, CanChild, FUSE, UK Society of Behavioural Medicine—in order to have wide cross-disciplinary influence. These communications range from awareness raising and information sharing to skill development; events are commonly attended by researchers, clinicians and other professionals, and policy leaders—and also increasingly by service users.
- 3) We will take an active, focused role on *cross-sector social media* to build further interest in the research, to communicate key messages, and to extend reach beyond our current networks.

We will further use the three strategies above to:

Disseminate knowledge to advance science: We will disseminate new knowledge, theory, and methods to researchers and scientists in physical activity, behaviour change, and complex interventions. This will be primarily through multidisciplinary peer-reviewed publications and presentations at methodology conferences (e.g. International Society of Behavioural Nutrition and Physical Activity, MRC Hubs' International Clinical Trials Methodology Conference, and UK Society of Behavioural Medicine Scientific Meeting). We will also disseminate selected methods to applied health researchers through childhood disability and allied health conferences and partnerships (see above), and will use relevant social media networks (e.g. Twitter, ResearchGate) to promote wider cross-sector awareness and uptake.

Translate knowledge for practical application: We will translate new knowledge for use in physical activity policy and guidelines, childhood disability practice and training, and allied health interventions by targeting relevant clinical researchers, clinicians, provider organisations, commissioners, policy makers, and service users. We will use shared communications because of substantial overlap between these groups and their strong preference for integrated knowledge, rather than information silos. These communications will include, e.g. brief, engaging summaries to increase awareness, disseminated through existing networks (above). The shared communications will be supplemented by tailored activities, e.g. contributing evidence to policy and guideline consultations; and delivering interactive workshops at key events attended by target audiences (e.g. NHS Confederation Conference, Council for Disabled Children Conference, European Academy of Childhood Disability Conference). These will be designed and co-ordinated by an Advisory Group of professionals, healthcare leaders, policy makers, service users, and clinical researchers, using evidence about effective dissemination and implementation strategies.

Opportunities to translate specific knowledge into commercial training and implementation packages will also be explored with support from the University's Business Development team.

Management of intellectual property (IP)

Subject to the terms and conditions of the Secretary of State for Health, any arising IP will be protected using the Research Enterprise Services' procedures for the identification, management, and exploitation of IP. Newcastle University and the lead NHS organisation (Newcastle upon Tyne Hospitals NHS Foundation Trust) have an existing partnership managed through the Joint Research Executive and a Joint Business Office (JBO). This is responsible for overseeing the identification, management and exploitation of University- and Trust-generated IP. Establishment of the JBO reflects the extensive collaboration between the Trust and the University who, via a Memorandum of Understanding, have an overarching framework for joint activities. The JBO will facilitate further agreements with the other partners.

Anticipated areas for IP development include:

- a. The longitudinal study (Study 1, years 1-5) of physical activity and its relationships with wider health and social variables will generate a new dataset. Existing data from young children, and data comparing typically developing and clinical populations, are scarce.
- b. The econometric model (Study 2, year 1) of the benefits and costs of physical activity will be novel; a search did not find existing estimates of the benefits and costs of physical activity in young children, or in children with physical limitations.
- c. The detailed descriptions of clearly specified, replicable interventions (Study 3, years 2-5) will support cumulative advancement of participation interventions. This will be in addition to existing interventions in the database established and held by Dr Kolehmainen, and complementary taxonomies held by others. Allied health interventions in general remain under-specified and poorly theorised.
- d. Enhanced intervention delivery materials. E.g. guidance to clinicians; hand out to families.
- e. Evidence-based summaries for families and professionals on enabling children with physical limitations to participate in physical activities (Year 5). Existing guidance is limited.
- f. Publications in peer-reviewed journals, and publications at conferences and to key stakeholders (e.g. families, NHS professionals, NHS policy makers).

Immediate benefits for NHS service users will be realised as described in the 'Pathways to impact', above. This includes, but is not limited to: regional workshops involving key stakeholders; national and international conferences; publications in peer-reviewed academic journals; and use of existing networks of service users, healthcare professionals, and policy-makers.

Publication of the results of the study will follow NIHR guidance on communicating research outcomes. Results will also be publicised in national and social media, with the aid of press releases from Newcastle University.

There are no current regulatory barriers to using the potential IP for dissemination, clinical, or research purposes. For any new interventions designed, attention will be paid to the general regulatory frameworks, e.g. Medicines & Healthcare products Regulatory Agency guidance.

The key barriers in implementing new NHS interventions to enable participation in physical activity are likely to be:

- Lack of evidence that enables a clear case to be made to commissioners and decision makers that the innovation is worth adopting, including evidence about the effectiveness and cost-effectiveness of the innovation.
- Lack of evidence about how the innovation is likely to work with individual patients and what contextual factors may influence its adoption and effects.

The proposed research seeks to address some of these issues, as will the proposed spin-off applications. In addition, we will continue to engage with key stakeholders in implementation (i.e., commissioners, service providers, and families) to better understand the barriers to long-term adoption and implementation. This will involve identifying strategies to overcome the barriers to inform future implementation plans.

Authorship policy

We will use the guidance by International Committee of Medical Journal Editors to inform authorship decisions (<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>).

The following criteria will be used to identify those who deserve credit in a form of an authorship. The person has:

- Made a substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafted the work or revising it critically for important intellectual content; AND
- Given their final approval of the version to be published; AND
- Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work s/he has done, an author needs to be able to identify which co-authors are responsible for specific other parts of the work; AND have confidence in the integrity of the contributions of their co-authors.

All those designated as authors need to meet all four criteria for authorship, and all who meet the four criteria will be identified as authors. Those who do not meet all four criteria will be acknowledged.

To ensure all the above authorship criteria are systematically applied to all publications emerging from this programme of research, all papers are to be discussed with the lead investigator who, jointly with the author proposing the particular publication, will be responsible for identifying all individuals who meet the first criterion. The lead author and the proposing author will then approach all those individuals, and provide them the opportunity to participate in the review, drafting, and final approval of the manuscript.

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11. FURTHER STUDIES

Piloting for study 3 A+B

The piloting seeks to: 1) try out and enhance the materials and methods for study 3A+B; and 2) provide rich, descriptive information as to what physical activity behaviour 'looks like' in children aged 0-5 with physical limitations—where this second aim directly contributes to the broader ActiveCHILD aim of generating evidence about the nature of physical activity behaviour in this population (see Protocol p.8).

Within this, the SPECIFIC QUESTIONS for to the piloting are:

- a. What enhancements can be made to the materials and methods for study 3A+B?
- b. What form does physical activity behaviour take in under5s with physical limitations?
 - What does it look like?
 - Are there in-built rules and norms pertaining to the behaviour?
 - Are there structures to the behaviour?
 - Are there necessary materials? If so, what?
 - What are the inherent (physical , cognitive, social) requirements for a child doing it?
- c. What are the features of the setting of physical activity in under5s with physical limitations?
 - Where does it take place?
 - What are the key features of the setting?
- d. Are there other dimensions or ways to think about PA behaviour that should be considered and if so what are these?

The piloting will take place within one of the ActiveCHILD sites, the Sheffield Children's NHS Foundation Trust, where the MSc student is an employer and a clinical collaborator on the ActiveCHILD study. It will adhere to the methodological, ethical, and scientific principles outlined in the ActiveCHILD protocol. The MSc student will operate under the supervision of the ActiveCHILD team and the clinical local site collaborator, alongside her named academic supervisor.

The piloting will use the same POPULATION CRITERIA as for the main study, with three exceptions. The exceptions are that the pilot sample will be limited to children: 1) who are not able to walk independently (with or without an assistive device); 2) who's parent(s) have a conversational level of English (as this research is part of a Masters qualification, funding for interpretation services is not available); and 3) who do not have a progressive medical condition and are not waiting for a surgical procedure or significant medical changes during the piloting period. Three to five child participants (the 'index' children) and their parent(s) will be purposefully sampled. The sample will include children of a range of ages and limitations to allow for maximum variation. The sampling, screening, and recruitment processes will be those outlined in the ActiveCHILD protocol.

The processes for CONSENT (parents) and ASSENT (children) will adhere to those in the ActiveCHILD protocol. However, the piloting will also further explore possible issues around feasibility of consent and assent for study 3A+B. Specifically, the potential presence of other people than the index child and their parent in the observation situation. It is not possible to predict at this stage what exact settings the children and parents may wish to choose for the observations. Based on previous research with older children (6-8 year olds), we anticipate that the most likely settings will be the child's home (indoors or outdoors), nearby parks and beaches and the homes of close

relatives (for example the homes of grandparents). In keeping with the ActiveCHILD principle of enabling child (and family) led methods, it is important that the children and parents can freely choose the observation context, as this is likely to form an important part of their narrative and presentation of the child's physical activity behaviour. Thus it is important that they are given the option to extend the settings beyond the family home.

Observing the child in settings other than the home will bring additional challenges related to consent. These challenges will further depend on the nature of the out-of-home setting. In the case of open public spaces such as parks, if observations are of people not directly involved in research who form the wider setting for the focus of observations, negotiating access from everyone is impractical and not needed.¹ However, to ensure the anonymity of any people external to the research, the researcher will not be actively recording identifiable information relating to anyone other than the index child and their family.

In the case of more closed environments such as playgroups or activity clubs, it is more important to be sensitive to the needs of other parents and children. This is particularly the case for closed environments where there are only a handful of other children and parents present, who may attend the setting regularly and who are likely to be known to one another. All these factors make the people within the setting less likely to remain anonymous and may make them more likely to respond to the presence of the researcher by behaving differently than they would usually do.² Therefore in these more closed settings, the following strategies will be piloted:

- The researcher will ask the parent in advance if any other family members (e.g. siblings, relatives) or friends may be present during the observations, and if so the nature and purpose of the research will also be discussed with these further people (using the participant information sheets where appropriate), and an assent for including them in the data collection taken. If the other people are children from outside the original participating family (e.g. friends of the participating child) a written consent from their parents will also be sought—where this is not possible it will be ensured the other child(ren) are not included in the data collection.
- The parent and/or researcher will have a prior discussion with the person responsible for running any formal group or activity, and if possible, other parents who attend the group will be informed ahead of time that the researcher will be accompanying the child to the group and will be video recording the child and their parent(s).
- Parents will be advised that the researcher will be focusing on the index child and their parent(s) and whilst they may comment on contextual factors such as the presence of other children, they will not be recording any detail relating to those individual children and will not be identifying the other children individually.
- Should the researcher, through their role as participant-observer, find themselves in a situation whereby there are interacting with both the index child and another child, they will remain open and responsive to the specific needs of that particular situation. For example they may recognise the need to have an informal chat with the other child's parent or potentially to remove themselves from that situation.
- If at any point the researcher is concerned that their presence is causing distress or harm, they will again remove themselves from the situation.

The DATA COLLECTION will focus on the key construct of 'nature of physical activity behaviour'. Direct observations will be used as in the ActiveCHILD protocol v1-2016-12-12, as well as two additional methods that specifically support the piloting: child and parent led photography, and a reflective discussions within a feedback visit. The piloting will not cover the interviews (ActiveCHILD protocol v1-2016-12-12 and related materials) as we have already previously successfully used this interview method in a similar context.

For each of the 3-5 index children, two episodes of observation each lasting around 2 hours will take place. When and where an observation takes place and for how long it take will be agreed upon between the parent and the student researcher (see also the section on consent, above). As per the ActiveCHILD protocol v1-2016-12-12, the guiding principle will be for the preferences and voice of the child and family to be the priority, alongside methodological considerations. The observations will be video recorded as per the ActiveCHILD protocol v1-2016-12-12. The researcher will also make brief field notes on 'critical incidents' (see the ActiveCHILD protocol v1-2016-12-12). The field notes will comprise of aid memoirs such as verbatim quotes and key words or phrases that will be used to support analysis of the video recordings.

As an additional method for the piloting, to enable reflection of the validity and transferability of the data from the observation method, following the second observation the child and their parent(s) will be asked to also take photographs of 'critical incidents' (described to family as 'important moments') related to the child's participation in physical activity behaviours. The child and parent(s) are encouraged to use their device of preference (e.g. their own smart phone or digital camera), and the images will be held by them to support end-of-piloting feedback discussions. The images taken will not be passed to the research team at any stage.

A feedback visit with a reflective discussion about the observations—involving the student researcher, child, and parent—will take place approximately a week after the second observation at the parent's chosen location. The visit will last approximately 45-60 minutes and will largely be targeted at the parent(s), with the child's involvement where possible in age-appropriate ways. The photographs taken by the child and parent will be used as to facilitate the discussion. Also to facilitate the discussion, the student researcher will use the following broad and open-ended prompts:

- Please can you tell me about this photo? What's happening, what was the situation, and who was involved?
- Why did you select this photo? What was particularly special about this moment?
- Is there anything else you would like to tell me about this photo?

The researcher will then feedback to the child and their parent(s) about the observations via a brief descriptive summary of the critical incidents observed. This will be followed up by similarly broad and open-ended prompts:

- What are your thoughts on the interpretation of the events? Have I missed things?
- Is there anything you would like to pick out that you think is important or that I have got wrong?
- What's your view on what happened in the observation – is it typical or unusual?
- Thinking about everything we have covered today, is there anything else you would like to add?

The feedback visit will be audio recorded and transcribed as per the ActiveCHILD protocol. The resulting data will be stored, managed and shared as per the ActiveCHILD protocol 'DATA MANAGEMENT'.

The DATA ANALYSIS of the observations and the reflective discussion will use framework analysis as per the ActiveCHILD protocol, as will the quality assurance procedures.

The materials that are specific to the piloting and that differ from those of the main ActiveCHILD study are: the participant invitation letter (the only change is that the contact details are those of the Masters student instead of the CI Kolehmainen); and the participant information sheet. The other

materials that will be used in the piloting will be those previously submitted and approved as part of the initial ActiveCHILD IRAS application.

References:

- 1] O'Reilly, K. 2012. Ethnographic methods. Oxon: Routledge.
- 2] British Sociological Association. 2002. Statement of Ethical Practice for the British Sociological Association [Online]. [Accessed 7th February 2017]. Available from: https://www.britsoc.co.uk/equality-diversity/statement-of-ethical-practice/#_rel