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Citation for published version (APA):

Green, J. M., Hanckel, B. J., & Peacock, J. L. (2020). Developing a theory of change, outcome measures and evaluation design for an evaluation of the impact of the Daily Mile on obesity and health: project report. Unpublished.

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Final Project Report

Developing a theory of change, outcome measures and evaluation design for an evaluation of the impact of the Daily Mile on obesity and health

February 2020



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Project details

Funding

Medical Research Council Award: MR/RO14094/1 (Public Health Intervention Development Scheme)

Dates

1st Feb 2018 – 31st March 2019

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Acknowledgements

The project team are grateful to Gwenda Scott and Patricia Duffy from the London Borough of Lewisham for support on recruitment and for access to data; to Julia Fox-Rushby for advice on health economic evaluation scoping; and to Martin Gulliford, Peter Whincup, Derek Cook and Chris Bonell for discussion and input on a design protocol for an evaluation. We are indebted to the teachers, children and parents in participating schools who welcomed us into classrooms and playgrounds.

Please cite this report as:

Green J, Hanckel B and Peacock J. (2020) *Developing a theory of change, outcome measures and evaluation design for an evaluation of the impact of the Daily Mile on obesity and health: project report*. London: King's College London

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Abbreviations

BMI	Body Mass Index
DH	Department of Health
DHSC	Department of Health & Social Care
KCL	King's College London
LA	Local authority
MVPA	Moderate to vigorous physical activity
NHS	National Health Service
PA	Physical activity
QCA	Qualitative Comparative Analysis
TDM	The Daily Mile
TDMF	The Daily Mile Foundation
RCT	Randomised controlled trial
SATS	Statutory Assessment Tests (National Curriculum Tests)
TIDieR	Template for Intervention Description and Replication
TIDieR-PHP	Template for Intervention Description and Replication (Population Health and Policy)

Summary

Background The Daily Mile is a scheme in which children run/walk for 15 minutes a day, in curriculum time. It has been widely adopted in the UK, and encouraged in a number of policy initiatives. However, there is no robust evaluation to date of its effectiveness for increasing physical activity levels or contributing to reducing obesity rates. As for many complex interventions in complex systems, there are challenges in evaluating impact on the public health.

Aims This project was funded to understand The Daily Mile as a public health intervention, and to develop a study design and methods for an appropriate quasi-experimental evaluation.

Methods The design combined a rapid ethnographic assessment of the adoption and implementation of The Daily Mile in five schools in Lewisham; the development of a logic model for the impact of The Daily Mile on public health; and a scoping of designs and methods for a full evaluation, including mapping The Daily Mile as implemented against the Template for Intervention Description and Replication (TIDieR) framework. Data sources included routine local authority school records; participant observation in schools; interviews with children, teachers and local public health specialists.

Findings At school level, there was no evidence of differential uptake of The Daily Mile by school size or student population. In the schools implementing The Daily Mile, considerable variation was observed in how the scheme was adopted at class level. Teachers valued the scheme for the potential impact on students' physical activity rates, obesity rates and a range of other outcomes. Potential negative effects derived from the generation of stigmatising discourses around body size (of children and teachers) and lifestyles of local pupils. System complexity included the range of other initiatives schools were involved in (which could be alternatives, or additional), local authority support, and the changing role of the scheme funder (INEOS) in supporting the scheme.

A logic model was developed which mapped the important pathways for stakeholders and hypotheses about the impact of the scheme. Potential sources of secondary data for a full evaluation were identified. Although randomised controlled trials can provide information on how the scheme impacts on outcomes such as physical activity and body weight, they are unlikely to be informative on what the causal conditions are for successful implementation. One promising design for this is Qualitative Comparative Analysis, and a protocol was developed from findings from the rapid ethnography which hypothesised that leadership commitment, and teachers' perceptions of the importance of fostering physical capital would be necessary, along with the absence of infrastructure constraints such as lack of outdoor space.

Conclusion A useful evaluation of the impact of The Daily Mile on public health could incorporate a substantial qualitative component to better understand the conditions under which the scheme is successfully implemented, alongside a quasi-experimental study of the impact on body weight, using secondary data sources. However, key outcomes of importance (physical activity, fitness, wellbeing) will require primary data to assess change over time.

Developing a theory of change, outcome measures and evaluation design for an evaluation of the impact of the Daily Mile on obesity and health: final project report

1. Background

Increasing the amount of physical exercise undertaken by young people has become a key goal of public health policy in the UK, in the light of considerable evidence that children do not do enough to maintain and promote health (DH 2011, DHSC 2019). A number of initiatives aim to promote more physical activity (PA) in schools. One, which has now had considerable uptake across and beyond the UK, is The Daily Mile (TDM). This scheme is supported by the Daily Mile Foundation (funded by INEOS, a chemical and energy company) which encourages children to run outdoors for 15 minutes per day, every day, during school hours. In principle, it is simple, free and sustainable, and has been acceptable to schools, parents and children, and has considerable policy support (DH 2016). A small-scale evaluation of the scheme identified a positive impact on children who take part compared with those from other classes who do not (Chesham et al 2018); and an RCT is underway in Birmingham (Breheny et al 2018). However, there have been criticisms of the intervention (Fairhurst & Hotham 2017), as a structured activity which might displace other (more beneficial) physical activity (PA) within schools, which might take away valuable teaching time. In general, high quality UK studies have failed to identify significant effects from behavioural interventions on outcomes such as PA and measures of overweight such as body-mass index (BMI) (Adab et al 2018, Kipping et al 2014, Jago et al 2015).

Evaluating the impact of interventions such as TDM is challenging. Like many programmes aiming to increase physical activity in schools, it is being rolled out opportunistically in most areas, and with schools signing up, reducing ability to randomise initiation. The intervention already has strong policy support, and support from many local authority public health departments. As for most complex interventions, results from randomised controlled trials (RCTs) where there are efforts to address fidelity, and typically enthusiasm from initiators, are unlikely to be informative about real world implementation. This study therefore aimed to develop theory and methods to support a national level (in England) quasi-experimental study that would provide useful and credible evidence on the impacts of the scheme in real world settings.

Aims and objectives

This project aimed to understand an existing scheme, The Daily Mile, as a public health intervention and to identify a robust mixed-method design for evaluating its impact on public health, particularly child health. The main objectives were:

1. To develop a refined logic model for TDM as a public health intervention, to include a detailed description of the core elements of the intervention, the primary and secondary outcomes, and theoretical pathways to change in primary and secondary outcomes.
2. To use the TIDieR checklist (Hoffman et al 2014) to map the intervention.

3. To assess the feasibility of using National Child Measurement Programme (NCMP) measurements of BMI in 5 - 6 and 10 - 11 year old children, to compare change over time in exposed and non-exposed populations of children.
4. To identify other routine datasets that could be used to provide information on primary and secondary outcomes.
5. To identify the strongest feasible design that would enable a quasi-experimental evaluation of TDM.
6. To assess the feasibility of using rapid ethnographic methods to generate sufficient data for 'cases' in Qualitative Comparative Analysis (QCA) (Ragin 1999, Ragin et al 2003).
7. To assess the feasibility of using QCA in a future evaluation, and identify any causally important conditions that should be included.

What to bring in when.....Year 6

Monday	Tuesday	Wednesday	Thursday	Friday
Indoor PE kit Black trousers/ shorts White T-shirt ----- Reading Journal Reading book ----- Trainers for Mile-a-day	Reading Journal Reading book ----- Trainers for Mile-a-day	Completed homework to be brought in. ----- Reading Journal (to hand in) Reading book ----- Trainers for Mile-a-day ----- New homework will be handed out.	Reading Journal Reading book ----- Trainers for Mile-a-day	Outdoor PE kit Black trousers Plain white T-shirt Jumper or hoodie Trainers ----- Trainers for Mile-a-day ----- Reading Journal Reading book







2. Methods

We conducted an ethnographic study (fieldwork was undertaken by Benjamin Hanckel) of 12 classes across five schools within the London Borough of Lewisham using rapid ethnographic methods (Green et al 2015a), to study TDM in practice. Fieldwork was conducted between May and December 2018. This drew on observations (N = 49 Daily Miles as a participant observer, and general observation of the school context); interviews with teachers (N=11), public health stakeholders (N =3), parents (N = 3) and pupils (N = 45); photographs; documentary analysis of TDM Foundation materials and other guidance. Schools were sampled from volunteers to include a range of those who were implementing TDM and those about to start. Recruitment was aided by the London Borough of Lewisham public health team.

We used routine Local Authority data to create a database of school level characteristics of all schools in the borough, and whether or not they had adopted TDM, including date of adoption.

A draft logic model was developed in consultation with collaborators, participants and academic colleagues. Peer review comments from papers submitted for publication and external reviewer comments also informed the development of the logic model.

To identify potential datasets that could be used in an evaluation, we made an application to the Data Access Request Service for NCMP data; reviewed literature on similar interventions in schools; consulted local authorities on data sources; and consulted with academic colleagues.

Data analysis and management

Data from interview transcripts, observation fieldnotes and photographs were anonymised and managed using NVivo software. The qualitative data were analysed using deductive methods (for the mapping of the intervention to the Template for Intervention Description and Replication, adapted for population health and policy interventions (TIDierR-PHP framework) and more inductive methods were used to understand the intervention in practice.

For the quantitative dataset, summary statistics were calculated for the routine local authority data, and Mann-Whitney U tests used to compare distributions of key variables in adopting and non-adopting schools.

Permission was granted by participants for the re-use of qualitative data; once the anonymisation of transcripts has been checked and the meta-data completed, these will be offered for deposit in a suitable archive.

Qualitative Comparative Analysis (QCA)

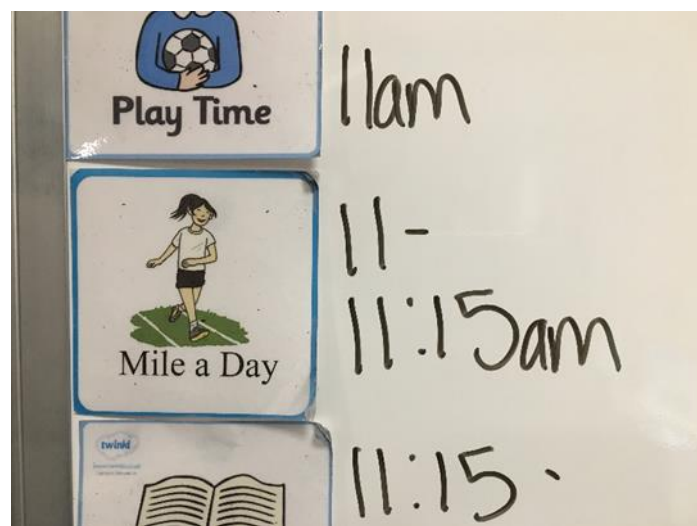
One aim of the study was to investigate the value of Qualitative Comparative Analysis (QCA) for developing methods appropriate for public health evaluation. There has been recent interest in developing alternative designs to RCTS, which have well-documented limitations for making valid and useful causal inferences about the impact of complex interventions in complex systems (Byrne 2013; Green et al 2015b). QCA has potential for addressing issues of complex causation (Blackman et al 2011). It differs from most methods for integrating data from diverse sources because it maintains the integrity of the 'case' as a whole, rather than disaggregating the case into component variables: characteristics of the case such as 'constellations, configurations and conjunctures' (Ragin, 2014: px) can be kept in the analysis. Essentially, the method involves comparing cases of a particular phenomenon of interest (i.e. implementing TDM) and an outcome (e.g. levels of obesity; successful implementation), and using 'truth tables' with all the possible combinations of present or

absent characteristics (e.g. stakeholder support; deprivation levels; local authority registration) about that case that are likely to be causally relevant, along with the number of cases identified with those combinations. The characteristics of the case are treated as members of 'sets': that is, a case is either a member or not a member. For further information on analysis methods, see Ragin (1999) and Ragin et al (2003). A protocol was developed for a QCA study (see Appendix 5).

Ethics

All participants, including children, provided consent to interviews and observations; we initially sought opt-in parental consent for children's participation, but this proved impossible to manage within school administrative arrangements and (following an ethics committee amendment) opt-out parental consent was approved. Photographs were edited to ensure individual children cannot be identified. Audio-recordings and transcripts were kept securely. All names and identifying details have been changed to ensure confidentiality.

The study was approved by the Biomedical & Health Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee (BDM RESC) at King's College London (approval number's LRS-17/18-5510 & LRS-17/18-6465).



3. Summary of findings

Key findings of the ethnographic study

Background context

TDM was being supported by the local Public Health team. The 2016 (London Borough of Lewisham, 2016) Annual Public Health Report had focused on obesity, and the need for a whole system approach to tackle ‘a truly global epidemic’ (p3). The report noted the high rate of excess weight in primary school children, with National Child Measurement Programme data suggesting that 39.3% of Year 6 children were overweight or obese. TDM was highlighted as a contributor to action on obesity in the borough, as one of three priority actions (the others were Sugar Smart and the use of local parks). TDM founder Elaine Wylie had been invited to speak to local heads, and the Annual Report showcased one early adopter school (which had started after having seen the scheme on a television report).

In practice, borough support included organising meetings for school heads and physical education leads to publicise the scheme, including one with the founder of TDM, Elaine Wylie, after which 5 schools had signed up. A survey (sent through the schools’ mailing list) out to all schools to garner interest identified a further eight, and subsequent visits over the school year generated further interest. The public health team surveyed schools to identify challenges.

Analysis of interview and observational data

The findings related to implementation are reported below, under the TIDieR framework. Inductive analysis identified a number of additional themes which would be potentially fruitful for further research.

The role of TDM for the school: Being a ‘healthy school’ is seen as symbolically important and aspirational, particularly in London. TDM is seen to contribute to this aim. However, there are a large number of other initiatives around both physical activity and food (e.g. healthy lunch programs, SugarSmart, 5-a-day); schools have limited capacity to engage with many at one time. TDM may be chosen from among alternatives, or may replace those already existing, or be added.

What TDM ‘does’, in addition to its intended benefits: TDM often has an effect of creating a new space for teachers and children to talk, an informal space of discussion during the walk/run, which is not afforded at any other time during the day. Teachers also discussed other benefits of TDM, such as providing a space to settle disputes between children after playtime.

Body pedagogics: Much of the talk about TDM involved explicit learning about how to manage and deport the body: for instance, in learning to run children experienced the need to be out of breath or puffing, and the need for the heartrate to rise.

He [the teacher] asks them “what happens when you do TDM...tell me how it affects your body?” Several hands go up in the air. They say I “lose weight” and “get fitter” – the teacher says “yes good, but those things happen more long term, what happens immediately to the body?”. One child says “I get tired”, another says “I get sweaty”, another says “I have energy”. He says “yes good, but I want to talk about what immediately happens to the body”. He goes on to talk about finding your pulse [showing them how to find their pulse,

either on their wrist or on their necks. He holds some of their fingers to their wrists or their necks to provide explanation]. (Fieldnotes, 111218, School04, Class08)

The teacher is talking to one student about TDM - she says to him "your heart beats fast that's how you know it's working". (Fieldnotes, 101218, School02, Class06)

So we've got a little girl who's really sweet, little autistic girl and I was talking to the whole school about it because obviously when I notice things I talk to the whole of them and I sort of said, you know, "What do you think we could do to help us to remember [to get our heartrate up]?" and one of the teachers had said, you know, [Jenny] always talks about...her heartbeat as the 'Jenny Beep', so it became...a code almost for children...you just go, "Oh, the Jenny Beep," and then they smile and they pick up the pace. (Gail, Teacher)

During observations, there was a clear role in using the intervention to teach children to undertake purposeful, disciplined exercise, rather than unstructured, more playful forms that were explicitly disallowed:

She (teacher) asks them to get in a line, but as she does this, she says 'you are not out there to play' and 'you are not out there to wind each other up'. (Fieldnotes, School02, Class04)

I notice some children playing on the play equipment - this teacher gets annoyed with them if they are not following the circuit and moving. (Fieldnotes, School 02, Class06)

The role of the digital in health: In schools digital devices get used in adoption/implementation of TDM, such as tracking devices (fitbits, garmin watches, iphones). They are used to initially map out a mile, and were then subsequently used to monitor movement (heartrate and steps taken) during the mile. Many children discuss using a parent's device at home. In one school the devices got used to map the route they take, which gets viewed when they come back into classroom on Google Maps. Absent in these discussions were any references to privacy or the potential uses of surveillance from the collection of data, particularly in relation to those tech /big data companies collecting this information. There were also few concerns about the accuracy of the data generated.

Devices are also conceptualised as useful in classroom settings, where they increase mobility; but problematised in the home (screen time etc.), where they are seen as a contributor to decreased mobility, and unhealthy behaviours. Children also, when talking about health, draw on narratives about the amount of time they spend on devices as problematic; and teachers talk about digital devices as both problematic/good for health dependent on context of use (classroom/home). Whilst these emerge in the context of TDM, they also speak to broader concerns related to discourses and narratives about young people, risk and new technologies, which must be considered in relation to how they influence and shape ideas and practices of those engaging in the intervention.

And I think what worries me is the time spent in front of a screen at home and I want to, you know, make sure that at least when they're with me at school they are active, all of them are active. (Esther, Teacher)

Last year [students] took turns to wear a watch, and a heartrate monitor, and we had a go in class to show how activity, increased activity and intense activity raises their own heart rates, they were amazed at how fast their hearts would beat, and it measured it for them, and they could see it online. We also did lots and lots of mapping work on Google, and street map, to see where we were going, and how far we'd gone, and how much ground we covered as the weeks progressed, and you can see that via the Garmin, so it maps the route, maps your pace, and maps your heart rate. So a different child might have a go at wearing

the watch and we could see how fast their heart beats and how it slowed down again and relaxed as we did our walking section. (Melissa, Teacher)

Narratives of ‘resisting’ teachers: TDM also entailed considerable surveillance of class teachers’ bodies, as they were encouraged to take part, and those not taking part were described as ‘lazy’ or ‘unsporty’: this is a theme that was developed in a paper now under review (abstract in appendix 1). Notably, teaching assistants and other school support staff rarely took part, and were typically not expected to, although highly praised when they did.

Mapping TDM as a public health intervention

A more deductive analysis mapped findings from the rapid ethnography against the TIDieR-PHP checklist (Campbell et al 2018), which was adapted to be appropriate for public health interventions. TDM was mapped in two ways: as described by TDMF in its promotion materials (that is, the intervention as intended) and as implemented in the case study schools in Lewisham. Items on fidelity were less relevant, as this study looked at ‘real world’ implementation, rather than roll out in the context of a trial, but our ‘as implemented’ column could be interpreted as a measure of ‘fidelity’, through identifying where differences occur. Table 1 summarises these findings.

Table 1: TIDieR-PHP items

(Originally published in: Hanckel B, Ruta D, Scott G, Peacock J and Green J. (2019) The Daily Mile as a public health intervention: A rapid ethnographic assessment of uptake and implementation in south London, UK. *BMC Public Health* 19 (1): 1167. <https://doi.org/10.1186/s12889-019-7511-9>)

TIDieR- PHP Item	As described by TDM Foundation*	How TDM was implemented in Lewisham (Items 9.2: Fidelity)
1. Name	The Daily Mile	The Daily Mile On occasion other terms used by schools, such as ‘The Daily Run’ or ‘The Daily Stroll and Chat’
2. Why: logic, mechanisms or goals of intervention	To increase children’s physical, mental, emotional and social health and wellbeing,	The public health team, teachers and heads focused on the potential to reduce childhood obesity. Teachers and heads also emphasised TDM as a potential ‘corrective’ to health disadvantage from deprivation.
3. What materials	Outdoor space, a ‘firm and mud free surface’ and a route that has been risk assessed. No special clothing or equipment needed ‘Transitions between class and route should be slick’.	Participating schools generally had this, either in playgrounds or nearby parks, but some had very restricted outdoor space, with physical barriers (such as several flights of stairs; lack of outdoor space). Classes must navigate with other classes undertaking TDM, or regular PE, and have

		to coordinate around these other activities as space is often limited.
4. What and how	<p>TDM aims to include whole classes in a daily run (or jog) (self-paced) for 15 minutes per day, outdoors, within the school day.</p> <p>'Social, non-competitive, fun'.</p> <p>'They can chat to their friends as they run along enjoying the experience together.'</p>	<p>Variations in who walked, ran, jogged.</p> <p>Variations in delivery – some classes developed games, which included a mixture of walking, running and sitting at different intervals.</p> <p>Reductions in TDM time if class curriculum runs overtime.</p> <p>Not all classes were running a mile (some walked, or engaged in class activities that required some physical movement), and it often did not conform to only 15mins per day.</p> <p>Many children (and some teachers) introduced elements of competition.n</p> <p>'Chatting' often perceived as a negative by staff and associated with walking: it is often not seen as an activity that is congruent with running and completing the mile and/or increasing fitness/stamina.</p>
5. Who provided the intervention	<p>Head teachers sign up school.</p> <p>TDM requires no particular training, but TDM Foundation web site provides information and resources such as promotional material for those signing up https://thedailymile.co.uk/</p> <p>Teachers go out with their class.</p>	<p>Lewisham public health department provided considerable input, including: organising initial meetings and a schools conference with the TDM founder; 2 surveys to generate interest from schools; regular promotional mailings to schools; ongoing phone calls and visits; providing case study materials; including information with the NCMP letter to schools and information in a school governor pack.</p> <p>Teachers did generally go out with their class; some ran, some stood and watched. In general, other class staff (e.g. teaching assistants) did not participate.</p>
6. Where	<p>Primary schools (ages 5-11).</p> <p>It can also be done in early years settings.</p> <p>Started in Scotland, now in operation across Europe and beyond.</p> <p>Outside in fresh air.</p>	<p>48% of primary schools in Lewisham had adopted the scheme, and at least one Year 7 class in a secondary school.</p> <p>Low air quality levels in some areas of Lewisham reduce access to fresh air</p>
7. When and how often	<p>Every day (in practice 'at least 3 times a week'), whatever weather, 15 minutes.</p>	<p>Not every day in most schools/classes.</p> <p>Seen as interchangeable with other physical health interventions adopted within the school; only undertaken on non-PE days in some schools; depends on busy periods. May take longer than 15 minutes; sometimes less time.</p> <p>Weather was an inhibitor at times, and TDM not undertaken when considered 'unsafe' or too wet.</p>

	During curricular time.	At times TDM is not implemented as the curriculum for the day is considered too full.
8. Planned and unplanned variation	Inclusive: all children. 'keep it simple'.	All children were included, but there were gender differences in how it was adopted by participating children. Girls observed and reported to be more likely to walk and 'chat'. Many teachers initiated games to keep it interesting.

*Quoted material from the TDM web site 'Core principles' and other pages

<https://thedailymile.co.uk/steps-to-success/>



School level factors influencing uptake of TDM

Data on number of pupils, proportion eligible for free school meals (an indicator of low income) and the proportion of the school in Black and Minority Ethnic (BAME) communities were also collated, with borough held details of which schools had adopted TDM by September 2018. Across the borough, there were 69 schools with primary years provision, with almost half (48%) adopting TDM. Five ‘early adopters’ had signed up in 2016, 17 had started in 2017, and six during 2018. There were no statistically significant differences between those who had and those who had not adopted TDM (Table 2), with considerable variability across both groups.

Table 2 Summary statistics of participating and non-participating schools in Lewisham

(Originally published in: Hanckel B, Ruta D, Scott G, Peacock J and Green J. (2019) The Daily Mile as a public health intervention: A rapid ethnographic assessment of uptake and implementation in south London, UK. *BMC Public Health* 19 (1): 1167. <https://doi.org/10.1186/s12889-019-7511-9>)

	Daily Mile implemented in School N=33	No Daily Mile in School N=36	P value (Mann-Whitney U test)
Number of pupils <i>Mean (Std Dev)</i> <i>Range</i>	377 (128) 204 to 645	397 (147) 192 to 665	0.70
Percent with Free School Meals <i>Mean (Std Dev)</i> <i>Range</i>	16.2% (8.5%) 4.1 to 41.6%	14.3% (6.7) 4.2 to 31.2%	0.39
Percent pupils Black or Ethnic Minority <i>Mean (Std Dev)</i> <i>Range</i>	76.3% (13.0) 53.1 to 99.7%	78.2% (15.1) 42.5 to 97.6%	0.41

The logic model

This was developed in collaboration with participants, scholars in public health, and key TDM stakeholders to represent the key pathways through which TDM is hypothesised to impact on public health, and the evidence that would be needed to evaluate this impact. As the ethnographic study found, the ways in which TDM is implemented are not just about ‘fidelity’ to the intervention: they shape the kinds of effects it is likely to have. Context is, therefore, crucial: some schools did not adopt TDM because they are already doing other physical activity interventions, others added it to existing ones. Some teachers focused on competitive elements and/or additional activities and

games to keep the daily run interesting: these are likely to be more appealing to some children than others. The ethnographic work identified that TDM intensified stigmatising discourses around obesity: these are likely to also have damaging effects that are difficult to capture quantitatively, or assess in terms of future impacts on (for instance) sustaining PA change, or willingness to do exercise.

In general, public health colleagues wanted to emphasise outcomes related to obesity, as this is a key priority for public health strategy locally and across the UK. Comments from public health specialists also included the need to take into account potential changes ‘other completely unrelated lifestyle [issues]’,– ‘spill over effects...beyond just the physical’ (such as developing confidence through engaging in TDM, which would (potentially) increase likelihood of changing diet, “whether they smoke or not or whether they engage in, you know, underage sex, you know, it makes them feel more in control of themselves”). These broad ranging effects would be extremely difficult to measure in an evaluation, as they are distal to implementation, but any future evaluation should aim to capture initial indicators of children’s changing health literacy.

For teachers, it was important to also include outcomes of more immediate relevance for classroom practice, including impact on behaviour in class and possible outcomes (e.g. better concentration, which might lead to better results in SATS and other tests, and potentially fewer exclusions). These of course do have longer term public health impacts, particularly through their potential to affect life chances, but evidence for such distal links would be difficult to evidence.

The final model (Figure 1) captures the simplified main outcomes and pathways of interest to those in the field. This represents a model for a future evaluation of the impact of TDM on public health.

Figure 1: The logic model for an evaluation of the impact of The Daily Mile on public health

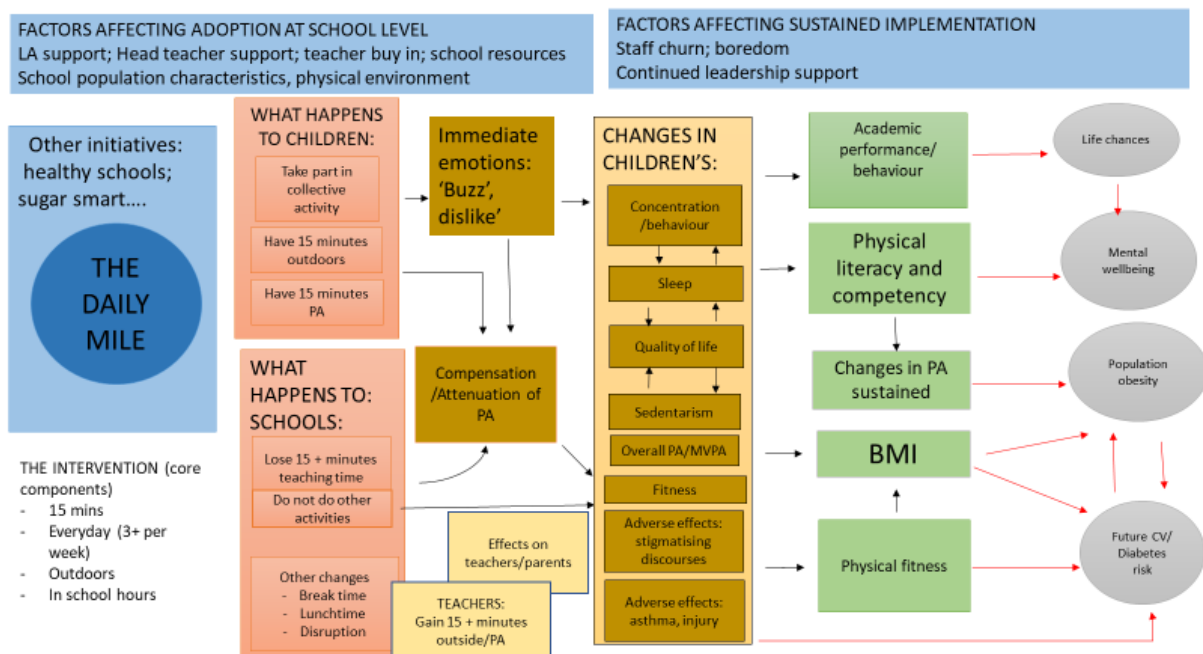
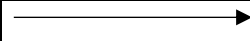








Figure 1 Key: PA (Physical activity); CV (cardio-vascular); LA (local authority)

	Hypothesised causal link to be evaluated in study
	Causal link for which there is likely to be existing evidence
	Contextual details
	Intermediate/longer term changes for children
	Longer term impacts on public health
	Initial changes associate with intervention
	Short term changes in health related outcomes in children

Assessing potential routine data sets and implications for outcome measures

BMI: National Child Measurement Programme

NCMP measurements of BMI in 5 - 6 and 10 - 11 year old children go back to 2005, potentially providing a useful national dataset for use in quasi-experimental designs, if changes over time in children or classes can be linked to interventions such as TDM. There are a number of challenges in using this dataset. First, variability over time is large. Second, data relate to schools and classes, not individuals. School and general population churn means that comparing schools or classes over time is not straightforward; measures of the same class at two time points are not measures of the same children. Third, this data set is particularly sensitive, and any linkage would have to be done by NHS Digital. Forth, schools often adopt a suite of interventions (TDM, 5-a-day, SugarSmart), making it difficult to link changes to the implementation of a single intervention. In principle, though, NCMP could be used to link school-level interventions with clustered individual level outcomes and examine the role of TDM on one measure of obesity. Possible designs for this kind of quasi-experimental design were considered (and are outlined in the protocol in Appendix 4). As part of the work for the study outlined in this report, applications to NHS Digital via the Data Access Request Service proved challenging and time consuming: by the end of the project, we had not secured access to anonymised, unlinked data, so were unable to assess these data before project end. Locally, NCMP data is held by the borough, but concerns about the large variability by year and class, and the ‘churn’ of children over time, precluded using these data.

Adoption of The Daily Mile

TDMF initially indicated willingness to share names of schools signing up to TDM from their records, and from a potential follow up email, which could have been linked (remotely) to NCMP data. However, not all participating schools do sign up formally with the organisation, and those who stop participating do not necessarily inform TDM Foundation. As TDMF has moved on to a more formal Expert Steering Committee structure, chaired by an academic funded by the Foundation to do evaluation of the scheme, it is unlikely that this data would now be provided to an independent research team.

Locally, the London Borough of Lewisham, which had been supporting TDM, had records of schools that had expressed interest in TDM, and the date participating schools had started. We could therefore identify both ‘exposed’ and ‘non-exposed’ populations at borough level, which (at scale, if

other boroughs also had these) could be used in an interrupted time series analysis if it was possible to link with NCMP.

Data on socio-demographic factors

Routine school-level data held by the local authority included school size, percentage of children in each ethnic group, gender, percentage receiving free school meals (an indicator of social disadvantage), school building characteristics. Surveys had also been conducted of schools participating in TDM, but these were designed for public health purposes and could not provide usable data for research.

Implications for future evaluation outcome measures

Routine data sets are limited for providing evidence of the impact of TDM on key intermediate outcomes (such as PA, physical fitness, quality of life). Any evaluation will therefore need to include primary data on these where possible. We considered measures for which there is reasonable evidence for validity, and for which both the instrument and any algorithms needed for scaling are publicly available. We favoured those used widely in similar studies, to aid future reviews and comparability. We also considered the burden on teachers (and parents) and favoured those that could be collected by child self-report or researcher measurement. Additional teacher-reported measures of educational attainment, class behaviour are possible to supplement routine data (for some school years) on SATS. Candidate measures considered for a full evaluation included the following.

BMI Measures of height and weight using standardised protocols, to calculate BMIs.

Physical activity. There are no valid self-report measures of PA, MVPA or sedentary time; these would need to be assessed by accelerometer (actigraphs were costed up for use in a study).

Physical fitness. The British Athletics Linear Track Test is a measure of endurance, commonly used in similar studies, with the distance participants can run within two minutes measured on a 50m linear track.

Wellbeing. The Child Health Utility Index (CHU9D) was developed originally to measure and value health related quality of life in children aged 7 - 11, for economic evaluations. It has 9 dimensions (worried, sad, annoyed, tired, pain, sleep, daily routine, school/homework, being able to join in activities) each with 5 levels and a preference-based scoring algorithm. It has been shown to have better validity than the EQ-5D-Y (a measure of Health Related Quality of Life) among school children participating in a diet and physical activity programme to reduce obesity (Canaway & Frew, 2013), and would be a good candidate measure.

Mental health. On mental health, the Me and My School self-report measure of emotional and behavioural difficulties is free to use, and has evidence for validity, and is suitable for children from age 8 (Patalay et al 2014).

4. Implications for evaluation design

Findings of this study reiterated the importance of context, and that good descriptions of context are vital for reporting public health interventions (Craig et al 2018) to understand better how and why they have their effects, and on whom. Any evaluation must therefore include a substantial qualitative component to do this, alongside quantitative methods for measuring changes over time. Methods for developing causal inference from evaluations in complex systems are underdeveloped (Green et al 2015), and alternatives to RCT designs are urgently needed. This study has identified the potential for Qualitative Comparative Analysis (QCA) (Hanckel et al 2019a). QCA methods can identify key conditions likely to be important to both adopting the intervention and to sustaining it over time in varied contexts.

Routine data sets are unlikely to provide good evidence for measuring the impact of TDM on the outcomes that are claimed for the intervention, and those important to key stakeholders. Any evaluation will therefore have to include primary measures for short term and intermediate outcomes.

The logic model (Figure 1) summarised the pathways through which TDM was hypothesised to impact on public health.

To summarise the hypotheses in this model:

If schools adopt TDM, and it is sustained such that most classes take out children most days (3-5 days per week), this will increase the amount of physical activity most children do.

If this is not offset by compensation (e.g. that classes do fewer PE lessons, or individual children no longer walk to school once TDM is started), this is likely to improve most children's physical fitness, instil healthier habits that will be sustained over time, improve concentration in the classroom, and lead to improved health and lower BMI in adulthood.

There are likely to be both positive impacts on attainment from increased concentration in schools, but negative consequences from reduced teaching time (around 20 minutes per day).

There may be co-benefits of TDM for teachers, who have an additional 15 minutes activity per day if they join in, and potentially for parents if their behaviours are affected.

The negative consequences may include an increase in stigmatising discourses around obesity and body shape, which appear to have implications for children and teachers.

To test this model, and assess the impact of TDM on key determinants of health, one approach would be to combine a study which looked at when it is adopted and how it is sustained in primary schools (given that it might not be sustained over time, particularly when not within a trial); use primary data to look at impact of the intervention in a 'real world' (not an RCT) setting on (individual, class level) PA, and to use QCA as a methodological tool to look and better understand the conditions which are causally related to outcomes such as increased PA. Obesity would not be a primary outcome, given the long causal pathways between 'school adopting TDM' and BMI. However, given the increased interest in TDM as contributor to the suite of measures to address obesity, and the reported evidence to date on individual level measures of overweight, it would be valuable to assess whether there is any evidence of an effect, as a secondary measure. Such an evaluation would have four aims:

- 1) Identify the conditions under which it is a sustainable intervention;
- 2) Identify whether it is an effective and cost-effective intervention for contributing to increasing physical activity levels and other important outcomes in primary schools in England;
- 3) Identify what the necessary conditions for successful implementation and sustainability are across contexts;
- 4) Identify whether there is any evidence of impact (at school level) of taking part in TDM on obesity rates.

A mixed-method evaluation of TDM could combine a series of qualitative case studies of schools about to take up the intervention, with a national level quasi-experimental evaluation of changes in BMI over time in exposed and non-exposed schools, as recorded in the NCMP.

If the pragmatic challenges of accessing NCMP and TDM adoption data could be overcome, a national-level assessment of whether taking up TDM affected BMI levels could be undertaken as above; this is described in Appendix 4.

The case studies will provide data on the intervention as an interruption in a complex system; mechanisms which cannot (feasibility) be directly measured; and to estimate cost variability.

Qualitative Comparative Analysis would be a feasible way to identify causal conditions for TDM to increase PA at class level and to look at the conditions for successful implementation (see Appendix 5 for a protocol for the latter study).

A final important context is the political context within which TDM is supported. The scheme is promoted and supported by The Daily Mile Foundation (TDMF), which is funded largely by INEOS, a large petrochemical company which now has a significant role in supporting (and directly funding) evaluations, and increasingly funding outreach workers to help schools establish the scheme. Independent evaluations may become more difficult, as TDMF seeks to protect its reputation.



5. Conclusion

A rapid ethnographic study was possible in the context of a borough that was supporting the scheme, and could offer contacts and introductions to head teachers. Sufficient schools volunteered to take part, so long as key parts of the schools year (SATS, run up to Christmas) were not affected. In one year, it was feasible to include 12 classes across 5 schools, which provided sufficient variation across school size, class teacher characteristics and other variables likely to influence take up. Recruiting schools who are not interested would be more difficult. Although locally (and elsewhere) the key driver for adopting the scheme was a contribution to addressing obesity, this may be the most difficult outcome to evaluate: few interventions to date have demonstrated impact on obesity at population level, and it is not likely that The Daily Mile will perform better. Indeed, a recently published trial (Breheny et al 2020) failed to find a significant impact on BMI overall at a 12 month follow up (though there was a positive effect for girls). However, if it is possible to overcome the pragmatic challenges to accessing both NCMP data and school level take up of TDM data, it would be worthwhile to identify whether there is any evidence of impact on this outcome at national level. A research question for this study would then be: is there any evidence that pupils in schools which have undertaken TDM have a lower risk of increasing BMI over time than those that did not?

Intermediate outcomes such as MVPA and wellbeing are more feasible to explore, and there are good grounds for supporting an evaluation of implementation that did examine TDM as a complex intervention in a complex system. Again, however, recent trial evidence failed to find a positive impact on physical fitness or wellbeing (Breheny et al 2020). A question that would have relevance for many stakeholders is that of what the conditions are which would lead to the scheme having a positive impact. We have identified the potential feasibility of QCA methods for doing this, utilising both rapid ethnography and primary collection of PA and measures of wellbeing and quality of life, to identify what combinations of factors might lead to a) sustained implementation, and, b) positive impact on important child health outcomes.

Any evaluation should also identify potential negative impacts. We identified the scheme to be associated with stigmatising discourses around both children and teachers' body size and weight, and health practices. These discourses are unlikely to have positive effects on the public health.

It is unlikely that an independent evaluation of TDM is now possible, given the importance of TDMF's main funder (INEOS) in shaping access to data, and the research field. This has wider implications for public health strategy and research. Whilst local authorities are keen to take up and support an intervention which costs them little, there are implications of how far they can act strategically, when implementation may be heavily reliant on interventions for which there is private- or voluntary-sector support.

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Appendix 1. Peer-reviewed publication outputs

1. Hanckel, B., Ruta, D., Scott, G., Peacock, J. L., & Green, J. (2019). The Daily Mile as a public health intervention: a rapid ethnographic assessment of uptake and implementation in South London, UK. *BMC public health*, 19(1), 1167.

Abstract

Background

Existing evidence identifies health benefits for children of additional daily physical activity (PA) on a range of cardiovascular and metabolic outcomes. The Daily Mile (TDM) is a popular scheme designed to increase children's PA within the school day. There is proof of concept that taking part in TDM can increase children's PA, reduce sedentarism and reduce skinfold measures. However, little is known about the potential effects of TDM as a public health intervention, and the benefits and disbenefits that might flow from wider implementation.

Methods

To develop an understanding of the potential impact of TDM on population health, we undertook a rapid ethnographic assessment of uptake and implementation in Lewisham, south London. Data included 62 in-depth interviews with stakeholders; observations of implementation in 12 primary school classes; and analysis of routine data sources to identify school level factors associated with uptake.

Results

Of the 69 primary schools, 33 (48%) had adopted TDM by September 2018. There were no significant differences between adopters and non-adopters in mean school size (means 377 vs 397, $P=0.70$), mean percentage of children eligible for free school meals (16.2 vs 14.3%, $P=0.39$), or mean percentage of children from BME populations (76.3 vs 78.2%, $P=0.41$). For public health professionals and school staff, addressing obesity was a key incentive for adoption, although a range of health and educational benefits were also hypothesised to accrue from participation. Mapping TDM to the TiDierR-PHP checklist to describe the intervention in practice identified considerable adaption happened at the level of borough, school, class and pupil. Population health effects are likely to be influenced by the interaction of intervention and context at each of these levels.

Conclusions

TDM has promise for many health outcomes, but evaluation of its impact in non-trial settings is needed to demonstrate its value as a public health intervention. Given variation in implementation, evaluations should identify the full range of benefits and disbenefits of adoption, and the necessary and sufficient conditions of success for programmes such as TDM. There is an urgent need for more appropriate methods for evaluating public health impact and implementation in complex contexts.

Keywords: children, physical activity, schools, implementation, rapid assessment, qualitative research, The Daily Mile

2. **Hanckel, B.,** Milton, S. & Green, J (Under Review) 'Unruly bodies: Resistance, (in)action and hysteresis in a public health intervention' *Social Theory and Health*

Abstract

Schools have long been sites of public health intervention on the bodies of children. Increasingly, these interventions also act on the bodies of educators. Our case study is an intervention focused on the future health of children's bodies ('The Daily Mile'), which, we argue, also resulted in the surveillance of educators' bodies. We draw on Bourdieu's concept of hysteresis to explore how those bodies can become 'unruly' during implementation, in both resisting and being positioned as reluctant. Hysteresis, an under-utilised Bourdieusian concept, proved useful for exploring embodiment at a point when there were mismatches between habitus and the changing field of primary education. We show how the non-participation of some actors (e.g. teachers) was positioned as part of a broader resistance to health as a dominant value, whereas non-participation of less privileged social actors (e.g. Teaching Assistants) was problematised in different ways. We argue that attending to moments of hysteresis, in which the changing symbolic values of physical capital become explicit, surfaces not just how dominant discourses (e.g. healthism) become reproduced in fields, but also how they change and are resisted, and with what effects.

Keywords: Bourdieu, Hysteresis, Education, Habitus, Field, Public Health

3. Hanckel, B., Petticrew, M., Thomas, J., & Green, J. (2019). Protocol for a systematic review of the use of qualitative comparative analysis for evaluative questions in public health research. *Systematic reviews*, 8(1), 252.

Abstract

Background

There is an increasing recognition that health intervention research requires methods and approaches that can engage with the complexity of systems, interventions, and the relations between systems and interventions. One approach which shows promise to this end is qualitative comparative analysis (QCA), which examines casual complexity across a medium to large number of cases (between 10 and 60+), whilst also being able to generalise across those cases. Increasingly, QCA is being adopted in public health intervention research. However, there is a limited understanding of how it is being adopted. This systematic review will address this gap, examining how it is being used to understand complex causation; for what settings, populations and interventions; and with which datasets to describe cases.

Methods

We will include published and peer-reviewed studies of any public health intervention where the effects on population health, health equity, or intervention uptake are being evaluated. Electronic searches of PubMed, Scopus, Web of Science (incorporating Social Sciences Citation Index and Arts & Humanities Citation Index), Microsoft Academic, and Google Scholar will be performed. This will be supplemented with reference citation tracking and personal contact with experts to identify any additional published studies. Search results will be single screened, with machine learning used to check these results, acting as a 'second screener'. Any disagreement will be resolved through discussion. Data will be extracted from full texts of eligible studies, which will be assessed against inclusion criteria, and synthesised narratively, using thematic synthesis methods.

Discussion

This systematic review will provide an important map of the increasing use of QCA in public health intervention literature. This review will identify the current scope of research in this area, as well as assessing claims about the utility of the method for addressing complex causation in public health research. We will identify implications for better reporting of QCA methods in public health research and for reporting of case studies such that they can be used in future QCA studies.

Systematic review registration

PROSPERO, [CRD42019131910](https://www.crd.york.ac.uk/PROSPERO/record/CRD42019131910)

Appendix 2. Conference presentation outputs

1. Benjamin Hanckel, Emma Garnett, Judith Green (2019)

Youth as sites of Intervention: Troubling care for uncertain public health futures

BSA Youth Study Group Symposium: Youth Intersections, Manchester Sept 2019

Abstract

This work-in-progress paper examines how young people are becoming sites of intervention in public health research. Drawing on two case studies - one on obesity and one on air pollution - we examine how young people are imagined as the 'future public health', and therefore targets for change through care, as a way to 'intervene' in uncertain futures. Health research and interventions with young people follow a behavioral change model that is underpinned by the idea that parental 'care' translates to youth experiencing improved health. Drawing on our empirical research we discuss the ways in which research interventions on obesity and air pollution complicate and vex care as a public health good. We argue public health interventions work in this way to entangle blame, agency, and care. Problem framing and solution making around obesity and air pollution become located 'in' youth, in ways that do not account for the structural, cultural and historical factors that shape these public health issues. We argue, the embodied nature of these interventions are also attempts to address and control uncertain futures.

2. Benjamin Hanckel, Judith Green (2019)

(Re)Configuring Healthy Bodies & Imagined Futures: A Case Study of a Physical Health Intervention in Schools

BSA Young Lives in Contemporary Times Symposium, Stirling April 2019

Abstract

Across the UK there has been an increasing interest in getting young people to be more physically active, with the intention of decreasing obesity and enhancing population health and wellbeing. In this work-in-progress paper we examine the implementation of one physical activity health intervention in 5 primary schools in South London. Drawing on interviews with teachers, parents, and children (n=62) as well as ethnographic data, we explore the body pedagogics at work in the structure and implementation of the intervention in classroom settings, and the role these play in young peoples imagined futures. Our initial findings point to how narratives of competition with others and the self, as well as particular felt bodily sensations, are (re)configured as part of the expected development of a healthy moving body. We examine how these young people talk about these experiences, make sense of them and how they come to be embedded into their imagined futures. We conclude by reflecting on the implications this has for youth transitions, and understandings of contemporary citizenship.

3. Benjamin Hanckel, Sarah Milton, Judith Green (2019)
Unruly Bodies: Examining resistant bodies and hysteresis in health interventions
BSA Medical Sociology Annual Conference, York Sept 2019

Abstract


In this paper we bring together two diverse case studies of complex health interventions in England to examine how resistant bodies are conceptualised and made through professional practices within those interventions. The first case study is of The Daily Mile, an intervention delivered by teachers aiming to increase physical activity in schools. The second is an intervention aiming to increase the accuracy of referral for developmental dysplasia of the hip in infants in primary care. Drawing on observations, field notes, and narratives from participants of the interventions, we focus on how resistance to the interventions surfaces and is conceptualised. Discursively evoked, these include: teachers who do not participate in implementation framed as having particular types of resistant, un-moving reluctant bodies; and, in the second case study, the GPs' imagination of the infant body as multifaceted and relational, versus the orthopaedic infant body (discrete, anatomical parts), framed as resistant to the intervention. We show how discourses of resistance are framed through the imagination of different, 'right' and/or 'wrong' bodies. Our findings show how boundaries of body possibilities are framed through the intervention, and the professional fields in which bodies are located. Using the Bourdieusian concept of hysteresis, we show how health interventions draw attention to and shape the changing nature of, and interaction between, professional fields and bodies. Health interventions are important spaces in which to explore the hysteresis effect, to better understand resistance and its productive potential, and to critically explore the role health interventions play in marginalising particular bodies.

4. Benjamin Hanckel, Judith Green (2018)
Running the Class: Examining the implementation of a physical health intervention in primary schools
BSA Medical Sociology Annual Conference, Glasgow Sept 2018

Abstract

Across the UK there has been an increasing interest in getting children to be more physically active, with the intention of decreasing obesity and enhancing population health and wellbeing. It is within this context that an intervention called The Daily Mile (TDM) has been developed, which requires children to walk, jog or run for 15 minutes each day in the schools in which it has been implemented. Whilst the program has been met with enthusiasm by many schools, and is a supported intervention in the UK Childhood Obesity plan, there remains a need for further sociological research into how the program gets implemented in the classroom setting, and how it impacts on the lifeworlds and bodies of children. In this work-in-progress paper we draw on Bourdieu's concepts of social field, habitus and capital to present initial findings from a rapid-ethnographic study conducted across several schools that have implemented the TDM with children (7-11 years old) in the south of England. Our study examines how the implementation of the intervention works to (re)produce forms of physical capital in specific locations. We examine the socially structured expectations placed on children's bodies, particularly in relation to gender, race and class, within the temporal and spatial constraints of each school. In doing so we reflect on how habitual action is extended and disrupted as physical activity interventions move children's bodies in particular ways, at particular times of the school day.

Appendix 3. Feedback report for participants

The Daily Mile in Lewisham Study

This study looked at how 'The Daily Mile' initiative gets implemented within schools in Lewisham. The study was done by researchers at King's College London, and supported by Lewisham Public Health.

What is The Daily Mile?

The Daily Mile is a health initiative designed to increase children's physical activity. It requires teachers to take children out of the classroom to run or jog for 15 mins per day, at least 3 times per week.

Why the study was needed

The Daily Mile has been adopted in over 4000 schools nationally. However, we do not know enough about how The Daily Mile gets implemented, or any challenges schools face. This study addresses this lack of knowledge.

How we did the study

We used different types of data to ensure we heard about a range of experiences:

- Interviews and focus groups with teachers, parents, and children from 9 schools. Schools included those who had school-wide adoption, and those where it had only been adopted in some classes
- Interviews with Public Health Professionals
- 12 class observations of The Daily Mile. Each conducted over a two-three week period.

What we found

Adoption of The Daily Mile

Important for the implementation of The Daily Mile was supportive school leadership, as well as staff input into the way it was rolled out within each school.

In all schools it was one of several healthy initiatives undertaken, as part of a focus on becoming a 'Healthy school':

... we were seeing an increase in children, with very worrying weight problems... although the school does have healthy lunch policies, we've a 'Healthy school'... it wasn't enough, so, we needed something else (Teacher)

Running the mile

In practice children were observed engaging in a mixture of activities each Daily Mile. This included running, hopping, skipping, and, at times, sitting.

Methods to move children

Several methods were used to encourage children to move, this included:

- Turning the daily mile into a game, where children would pretend to be animals
- Encouraging movements during the run, such as star jumps, or spinning on the spot
- Making it a competitive activity: encouraging students to run each other, or compete against the teacher
- Displaying the number of miles completed each week in a visible place in the classroom

In one school the miles are calculated at the end of each day by the teacher or TA. A weekly total is recorded in a logbook. The weekly total of each class is collected by Year 6 students. During the weekly assembly the head teacher calculates the miles for the week, and the cumulative number of miles for the term. The distance is calculated and visually shown on a map, displaying how far, cumulatively, they have gone. As they pass each marker on the map they discuss the language and culture, and if any students have family from that region of the world.

Are there other benefits?

Cross-curricular benefits: Interviews and observations show teachers linking the mile to, for instance, topics about the climate and weather (geography), and number of miles undertaken (maths).

Resolution of play-time tensions: Interviews with teachers indicate where The Daily Mile is implemented after playtime, it had the effect of addressing tensions, and important conflict resolution

Transitions from classroom to playground and back again, were recorded in follow-ups as relatively seamless, with children engaging with work quickly upon re-entering classrooms. Interviews with teachers indicates this is more difficult at the start of term, when The Daily Mile must become part of their routine.

For some classes The Daily Mile was shortened to 10 minutes, instead of the recommended 15 minutes, to account for the time from classroom to playground. Consensus about the time it took led to several adaptations: **One school referred to the initiative as 'The Daily Run' to emphasise that one mile did not need to be completed.**

Observations indicated teachers participated, but often TA's did not participate.

Inner London playgrounds

In all but two cases, The Daily Mile involved taking children outside the classroom to run around a defined circuit. In one case children were taken to a local park, but in all other observed cases children undertook The Daily Mile on concrete and/or asphalt playgrounds.

Children ran around a small playground the size of a basketball court, or across several smaller playgrounds. Classes would often run with other classes: teachers would cite the benefits of having multiple teachers engaged in student supervision, however we also observed how this created congestion and crowding, which impacted on children's opportunities for movement.

Teachers implemented infrastructure changes and/or adapted the mile to respond to these concerns:

In one school there were arrows that went across three playgrounds for the children to follow and participate in the run.

In one school we observed The Daily Mile as a circuit of activities (skipping, hula hoop, and kicking a football), which was a response to 'run off any problems'. Teachers indicate that this contributes to increased concentration in the classroom.

Observations and interviews indicate that the initiative is **very positive for teacher-student relationships**.

...it's also quite nice to get to know some of the children... they just talk to you about stuff, and you would never really have that opportunity in any other time (Teacher)

Peer relationships between children: Discussions with children indicate the importance of being able to run and 'chat' with friends. We observed children engage with peers within their class, as well as across classes and year-groups, such as Year 3 and Year 6. Teachers explained how the differing year groups would race each other also.

What happens next?

We will share our findings with public health practitioners, schools and teachers, as well as with The Daily Mile Foundation.

If you would like more information or have any comments, please get in touch with:

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We'd like to thank everyone who took part in the study.

The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the funder (DHU), funder: MR/R019932/1 and/or The Daily Mile Foundation.

the reported boredom expressed by students of running around a basketball court for 15 minutes.

In The Daily Mile undertaken daily?

In practice The Daily Mile is often undertaken between 3 - 5 times a week. During the study we observed 16 cancellations (18% of all planned daily miles). There were several factors that impeded implementation:

- Concerns about fitting around timetables and curricula that are 'too full'
- The Daily Mile is dependent on other school-based activities: assembly, exercises
- In several schools it is an activity for non-PE days only
- It was often substituted with other classroom-based activities (such as the '30-day initiative')
- Sometimes teachers opted not to disrupt a 'hotter' class by taking them outside
- Weather issues: when it was too wet The Daily Mile was not undertaken that day

Learning on the move

Children would be asked to check their pulse or feel their chests for their heartbeat, before, after and/or during the run. Teachers link physical body changes, to general fitness, and then overall long-term health. Interviews with children indicated this information was clear: they made connections between running, as part of a suite of healthy activities, to improve their overall fitness, which was often connected to their own future health concerns.

When your heart beats it means you've been doing very well, you've been running a lot, and you've been doing very well

1

2

3

4

5

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7

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Appendix 4. Protocol for a mixed-method evaluation of the impact of The Daily Mile on children's health

Aims and objectives

The overall research question is: What impact does the adoption and implementation of The Daily Mile have on the determinants of health? To answer this, we will identify the conditions under which it is a sustainable intervention; assess whether it is an effective and cost-effective intervention for contributing to increasing PA levels and other important outcomes in primary schools in England; identify the necessary conditions for successful implementation and sustainability; assess whether there is any evidence of impact on national obesity rates.

The hypothesis and logic model are derived from a preliminary study of the implementation of TDM in Lewisham (above).

Case studies (N=12) of schools about to implement TDM will combine quantitative measures of activity and QoL in one Y5 and one Y6 class per school, with a rapid ethnography [14] building on pilot work from the MRC PHIND study. This will provide data on: changes associated with TDM; context of wider programmes implemented in school/borough; barriers and facilitators of implementation; short term and one year impacts for children, parents and teachers; costs and benefits

Case study series

A purposive sample of schools will be selected from those identified by TDMF as interested in implementing TDM in the short term. This is a largely opportunistic sample, driven by schools' willingness to schedule a start one week post-baseline measures, and of relatively 'late adopters'. However, our study suggests the feasibility of identifying 12 schools that will provide a maximum variation sample, in terms of factors identified to date as salient (e.g. school-level 'champions'; school resources; local demographics). Late adopters are pragmatically of interest in terms of realistic roll out of interventions. In each school will be: baseline pre-intervention measures (T1); a one month post-implementation visit (T2); and one year follow up (T3) as below, with a focus on one Y5 and one Y6 class per school (~27 pupils each) to provide comparative year-to-year measures of change before and after intervention.

Case studies of schools taking up the intervention would enable baseline (T1) and post (one year) changes over time to be compared in primary schools. Rates of PA in general decline and sedentary time increases per annum for children at these ages (Cooper et al 2015); analysis will be directed at comparing the change over time between Y5 and Y6 after implementation (follow up) with the change between Y5 and Y6 before implementation (baseline), with the hypothesis that taking part in TDM mitigates these effects. Analysis will be of difference in difference of physical fitness, PA/MVPA, sedentary time between Y5 and Y6 at baseline/1 year.

T1 and T3: Quantitative measures at baseline (pre-TDM) and 12months post, in one Y5 and one Y6 class at pupil level:

- PA/MVPA/sedentary time measured by accelerometer (actigraph) for one week.
- Physical fitness test (The British Athletics Linear Track Test)
- Child Health Utility 9D. (Developed to measure and value health related quality of life in children aged 7-11, for economic evaluations. Has 9 dimensions (worried, sad, annoyed, tired, pain, sleep, daily routine, school/homework, being able to join in activities) each

with 5 levels and a preference-based scoring algorithm. It has been shown better validity than the EQ-5D-Y among school children participating in a diet and physical activity programme to reduce obesity.

•
T1 Qualitative interviews: with key school staff (heads, class teachers) and other stakeholders (parents, children, local public health practitioners) to identify implementation context factors.

T2/T3: Rapid ethnography at 1 and 12 months post-implementation will include observation of TDM (how has scheme been adapted, who is running, what else is happening, what effect it has on the class); semi-structured interviews with heads, Y5 and Y6 class teachers, parents; small group and individual interviews with children; document review (injury records, costs data). Interview topic guides (developed in the MRC PHIND study) include prompts for: (for teachers) when not done, alternatives, experiences, children’s behaviour, fit with curriculum; (for heads) broader context, history, instigation, motivation, barriers; (for children) best/worst thing, who does/doesn’t like TDM.

Quantitative analysis Rates of PA in general decline and sedentary time increases per annum for children at these ages; analysis will be directed at comparing the change over time between Y5 and Y6 after implementation (follow up) with the change between Y5 and Y6 before implementation (baseline), with the hypothesis that taking part in TDM mitigates these effects. Analysis will be of difference in difference of physical fitness, PA/MVPA, sedentary time between Y5 and Y6 at baseline/1 year.

Qualitative analysis: Data from interviews and rapid ethnographic will be analysed deductively and inductively to provide:

- Descriptive evidence for those elements on the logic model for which we are not collecting quantitative primary data (wider context; children’s experiences of TDM, parents’ views; impact on teachers; impact on injury rates, asthma incidence).
- Data on what facilitates and inhibits implementation, fidelity, adherence and sustainability (we will draw here on Normalisation Process Theory in analysis).
- Estimates of variability of costs and benefits
- Data to populate the QCA analysis in WP4.

Impact of adopting TDM on obesity

Design: A change on change analysis of NCMP data, comparing differences between years across time when there was no intervention (control) with differences between years before and after TDM (intervention) to analyse impact of taking part. A dataset of all primary schools in England which have notified TDM Foundation that they are taking part in TDM as of ‘Current Year’: i.e. a sample of schools which were taking part at and before the last set of available NCMP data or are planning to, but not currently. Including only TDMF-registered schools would ensure that the ‘controls’ years do not inadvertently include those doing TDM but unregistered. If TDMF identify intervention start date, exposed and non-exposed can be identified. For each school (N~1,000), NCMP data from NHS Digital on Y6 children between 2012 and Current Year could be linked, pseudo-anonymously, for analysis. There are limits to how many indicators can be added before anonymity would be breached; we could envisage adding one indicator of deprivation (% receiving free school meals) and one indicator of academic output (‘value added’ SATS scores). For each year 2012-8, each school will therefore be either ‘pre’ or ‘post’ intervention, as per Figure 1.

Figure 1 : using NCMP data in a quasi-experimental design

	SATS/FSM %	2012	2013	2014	2015	2016	2017	2018	2019 (registered)
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School 1	V	0	0	0	0	1	1	1	1
School 2	V	0	0	1	1	1	1	1	1
School 3	V	0	0	0	0	0	0	1	1
School N	V	0	0	0	0	0	0	0	1

A regression analysis of the annual changes in mean BMI z-score at school level would compare these changes in periods where the school has/has not implemented TDM. Using an estimate that these are in the ratio 3:1, and a conservative estimate ignoring the presence of repeated values: including these would increase the precision of the estimated difference. Assuming that power is 0.95, that the SD of individual BMIs z-score is 1 and correlation between pairs is 0.7, 2-sided significance 0.05, and ratio of samples with and without daily mile, with 1000 schools overall there is high power to detect a small difference in means (0.20 z-scores). This analysis, we suggest, could take account of repeated measures and adjust for important covariates. Thus, samples of 258 and 774 i.e. 1032 overall provide power 95% to detect a difference in mean z-score of 0.2 with 2-sided significance 0.05.

Cost consequence analysis

Although TDM is in principle free to implement, with no costs for schools, in practice, we identified that there were some costs for many, including improving playground facilities. An economic analysis, taking a public sector perspective, will compare the additional costs and benefits arising from adopting TDM versus not doing so. The identification of who, did what, to whom, where, and how often for TDM will be based on interviews and records from the 12 case study schools. Data on resource use and for apportionment will be measured for set up and delivery of TDM over 12 months in each school, using: data from rapid ethnography (see above) with additional interviews of estates staff and class observations (for time taken and resources used); targeted reviews of records (e.g. invoices, expense claims, computerised diaries, injury records); and parent questionnaires (for any participant costs).

Resources would be valued using national tariffs to increase generalisability, and local costs when unavailable. Each school will be invited to critically review their summary of resource use and costs. The distribution of total costs by type will be presented alongside the differences in all outcomes as a cost-consequence analysis. Incremental cost-effectiveness ratios, cost-effectiveness acceptability curves and net benefit analysis will be presented for BMI, MVPA, minutes of any PA and QALYs. Sensitivity analyses will examine the impact of perspective, alternative utility values, missing data and assumptions. Each primary outcome (from WPs1 & 2, suggested above) demonstrating a statistically significant difference will become a driving parameter estimate for a life-time model of cost-effectiveness (if there are no differences, this will not be done), with individual models presented as alternative rather additional futures. These models to be based on Harris et al (2018) for MVPA and the UK National Heart Forum model (Brown et al 2013) for BMI reduction. A critical review, accounting for good practice guidance (Caro et al 2012, van Halen et al 2014) will confirm whether these are the most appropriate models given outcome data, with better alternatives used if available. Models will be updated where appropriate, using systematic searches for parameter estimates.

Qualitative Comparative Analysis of case studies

The rapid ethnographic data from the 12 case study schools will populate a Qualitative Comparative Analysis. QCA has considerable potential for addressing issues of complex causation, yet has to date only been used in a few public health evaluations. The method involves comparing cases of a particular phenomenon of interest (i.e. 'implementing TDM') and an outcome (e.g. sustained implementation after 1 year; increases in PA), and using 'truth tables' with all the possible

combinations of present or absent characteristics (these will include: fidelity to intervention at 1 month follow up; champions for the initial implementation; policy context, such as embedded in broader programmes addressing healthy schools/obesity). The characteristics of the case are treated as members of 'sets': that is, a case is either a member or not a member. Our initial pilot work has suggested we can gather sufficiently rich qualitative data in a relatively short time span to enable this test of the QCA approach.

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Appendix 5. Protocol for a QCA Study

Qualitative Comparative Analysis (QCA) as a method for exploring complexity: Protocol for a case study of QCA used to examine implementation of a physical activity intervention in Primary Schools

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Abstract

Background

Recently there has been interest in developing methods for exploring complex causation in public health research. One potential approach is Qualitative Comparative Analysis (QCA), which seeks to bridge quantitative and qualitative research. This paper presents a protocol for a QCA study to explore the conditions for successful implementation within schools which have adopted one physical activity intervention: The Daily Mile.

Methods

Cases are classes within schools in the London Borough of Lewisham. Data about cases are being generated from a rapid ethnographic study, drawing on in-depth interviews, participant observation, and routine datasets collated by the local authority. A fuzzy set QCA is proposed.

Results

The proposed analysis hypothesises that the intervention will be both adopted and successfully implemented when there is teacher and leadership acceptance, perceived benefits to students and a commitment to physical capital resources, and an absence of physical infrastructure limitations.

Conclusions

The QCA analysis will test this hypothesis, and assess the usefulness of using QCA to address questions of complex causation in public health intervention research.

Keywords: complexity, sociology, public health, qualitative comparative analysis, physical activity, obesity, schools

Introduction

There is an increasing recognition that health service research and health intervention research requires methods and approaches that can engage with complex systems [1], and can account for diversity of adoption and implementation in 'real world' settings. Recent work has called for research methods that can better account for casual complexity across diverse contexts. The British Medical Council released new guidance in 2015 for 'Developing and Evaluating Complex Interventions' [2]. This guidance emphasised the need to take into account interactions between a given intervention and a system, as well as how best to study complexity, emphasising a systems perspective that accounts for non-linear causality and "gives appropriate weight to real-world case studies" [1]. These guidelines locate complexity within the interrelated interactions between intervention(s) and context(s) [2]. One implication is the variation of adaption likely across contexts, leading to a call for methods and approaches that can account for the effects of health interventions in complex systems [1–3], and "the inevitable adaptations that emerge from their implementation in local contexts" [3].

As previous work has shown [4–6], in randomised controlled trials (RCTs) there is often increased input to achieve fidelity, with participants often more committed to achieve the intervention. When interventions are rolled out in non-trial contexts, 'real world settings', measures of fidelity are more challenging, given the inevitable adaptations that occur and 'moderating factors' that exist, which can create difficulties for the transferability of RCTs to practice settings [6].

In this paper we examine the possibilities for using Qualitative Comparative Analysis (QCA), and its capacity to explore complexity, in the 'real world' settings of primary schools adopting and implementing a physical activity intervention. The case study is one intervention in south London: The Daily Mile.

Qualitative Comparative Analysis: An intervention towards understanding complexity

A novel way forward that is beginning to emerge to examine complex causality in public health research is Qualitative Comparative Analysis (QCA). QCA, a set-theoretic method, has been increasingly adopted across disciplines to examine casual complexity. Considered a 'third way' or a bridge between quantitative techniques (large-n statistical analyses) and qualitative approaches (small-n case study research), it can be used to examine complex causality across a medium to large number of cases (between 10 – 60+), whilst also being able to generalise across those cases [7]. QCA is often described as being suitable for 'small-n' scenarios and is less frequently used in large datasets, though some have used it with some success [8].

Causal complexity in set theoretic methods is defined by three features, which makes it appealing for questions about causal inference in complex systems [9]. The first feature is *equifinality*, meaning that more than one casual pathway can lead to the same outcome. Second is *conjunctural causation*, meaning that single conditions may not display the effects on their own, but can play a casual role in the presence of other factors. And third, *casual asymmetry*, meaning that casual pathways for achieving an outcome differ from casual pathways for not achieving the outcome.

Importantly QCA as a method asks what conditions (alone or in combination with other conditions) are 'necessary' or 'sufficient' to produce some outcome. Necessary conditions are those conditions shared by cases with the same outcome. Sufficiency, on the other hand, examines cases with the same casual conditions to see if they also share the same outcome. If we are focused on a health intervention, what is necessary might be what needs to be in place for an intervention to be effective. Whilst sufficiency would indicate what components are sufficient to produce the outcome. However, as Legewie [10] argues, the presence of a condition, or a combination of conditions, are, in actual datasets, likely to be "quasi-necessary' or 'quasi-sufficient' in that the causal relation holds in a great majority of cases, but some cases deviate from this pattern" (p. 11).

Case Study

In the United Kingdom there are increasing health concerns related to childhood obesity [11]. Whilst there have been several government-led initiatives adopted by schools, one initiative, recommended by the Childhood Obesity Strategy [11], is a health intervention called 'The Daily Mile' (TDM). Originating in Stirling, Scotland, in 2012, the TDM initiative requires school teachers to take their class out of the classroom and engage in a running or walking activity for 15 minutes a day, which equates to approximately one mile in length. The program, as outlined on The Daily Mile website [12], is framed as "simple and free" to run, where there is "no set up, tidy up, or equipment required". Teachers are supposed to be able to implement it at any time of the day, and in varied weather conditions, with the intention that it does not replace break times or scheduled physical education lesson time. Whilst there remains limited research on effectiveness, claims about the TDM initiative are that it could lead to improved student concentration, fitness and health, as well as increased student health literacy (The Daily Mile, 2018). To date the initiative has been implemented in schools across Scotland, and has currently been introduced into over 4000 schools across the UK. Whilst emerging work is starting to examine the effectiveness of the program for reducing negative health outcomes for children [13–15], research exploring the success of the implementation of the intervention remains nascent.

Recent work on adoption and implementation of the intervention indicates how this is a complex health intervention, as it gets implemented in varied ways [16, 17] with several schools opting out and/or having difficulties with implementation due to concerns about time, weather and resourcing constraints [16].

Overall then there remains limited knowledge about the implementation of The Daily Mile: what are the conditions that are required for the intervention to be successfully implemented in schools, and, in particular, what works for certain schools and classes, and in what contexts. These questions are particularly pertinent for schools and policy makers who are interested to know whether, and how The Daily Mile will work in their local areas, what the necessary or sufficient conditions for success are, as well as how best to implement the scheme to get the most benefit. Sociologically we are interested in how the stakeholders of the project, and their differing levels of access to resources, what Pierre Bourdieu [18, 19] calls 'capital' and 'symbolic power', impact the adoption and implementation of the intervention. The study protocol proposes a QCA approach to

explore the above concerns, and, more specifically the configuration of conditions that lead to the implementation of the initiative.

Research Aim and Research Questions

This study examines ‘cases’ of a health intervention (The Daily Mile) that has been adopted by around half of the schools in one London Borough [16]. Adoption refers to the school agreeing to participate. The question of interest here is whether those agreeing to adopt successfully implement the intervention. Successful implementation refers to a measure of meaningful participation after adoption. The data collection for cases in this study involves data collected from local health strategists, teachers, school leaders, children, and parents/carers of children [16]. We are interested in the following question:

- RQ1. Under what conditions is The Daily Mile successfully implemented by school classes in schools that have adopted the intervention?

Defining the Outcome

Although adoption is at school level, the delivery of the intervention (its presence/absence) often occurs at the classroom level. Thus, individual classes are used as ‘cases’ in this study on successful implementation, rather than schools. As we are assessing successful implementation, we will examine degree of implementation as an outcome among the subset of adopters.

The study thus includes classes that implement the intervention within 6 months (positive cases) through to those that do not within 6 months (negative cases) within one borough in London. To express the successful implementation of the intervention we are using a six-value fuzzy set, which allows for both full and partial implementation of the intervention. Membership in the outcome ‘implementation success’ requires the implementation of The Daily Mile in a classroom, on average, at least 3 times a week. As the intervention is designed to be undertaken daily we use 3 times as the threshold as it represents a majority of the week. The expression in the fuzzy set is outlined in Table 1.0:

Table 1.0: Outcome

Outcome:	Intervention is Successfully Implemented (‘Implementation Success’)
Membership in the Outcome	5 times or more per week = fully in 4 times per week = mostly but not fully in 3 times = more or less in 2 times = more or less out 1 time = mostly but not fully out 0 times = fully out

Data to determine presence/absence of the outcome is from data collected by the school, where each school measures the number of ‘daily miles’ taken by individual classrooms each day. Data will be verified against teacher self-reporting during interviews and focus groups, as well as observation data recorded in ethnographic field notes.

Research Methods

The methods used in this study include: In-depth interviews and focus groups with local health strategists, headteachers, teachers, parents and students (aged 7 – 11) from each site; Ethnographic observation in classrooms, to observe the implementation of the intervention; Document analysis: Documents include formative data collected by schools (‘daily miles’ run); health strategist data about the intervention (including formative survey data; and local adoption); TDM intervention documents produced in schools and by health strategists; as well as school mission statements/charter of values.

The ‘Conditions’

The table below (Table 2.0) provides a list of the anticipated casually relevant conditions, which are likely to have an impact on the successful implementation in schools which have adopted The Daily Mile. This includes 13 conditions in total, though these are subject to change based on data collection, as well as later within-case and cross-case analysis.

The conditions include the perceptions and experiences of the program by differing stakeholders during the initial adoption of the program (e.g. TeachAccept; StuAccept; ParAccept), which have been identified as important in health interventions [20, 21]. We are also interested in teacher authority and perception of acceptability of TDM by 'leaders' (e.g. LeaderAccept; TeacherAuthor), those with symbolic power within the school, to determine if this is casually relevant to the outcome.

In addition, we want to test the anecdotal information that suggests challenges related to resource constraints (physical space; time) impacts on adoption and successful implementation. Therefore, we are also interested in the perception of physical resource acceptability in the school (ResourceConstraint) and time-related concerns (TimeConstraint), and whether either of these are necessary or sufficient conditions for the outcome.

We are also interested in the role of the initiative within a broader public health context of 'healthy schools', which encourage adoption and implementation of varied initiatives, such as SugarSmart and 5-a-day, by schools across the borough. We are measuring whether the presence/absence of these other health initiatives adopted by the school impacts acceptability (InitiativesPresent), and whether the reputation of being a healthy school, that is, the degree of commitment to enhancing health resources ('physical capital'[22]) by school stakeholders (PhysCapValue) is important for the adoption and successful implementation of TDM.

In addition to these measures we are also measuring if student socioeconomic status (SESStatus) plays a role or not in the adoption of the intervention, as it has been shown to impact the adoption of health initiatives in schools in prior research [23].

To measure membership in each condition fuzzy sets are used in twelve of the thirteen conditions (see Table 2.0). This is to account for variability in the conditions examined in this analysis. Membership in several conditions is also timebound ('at initiation' or 'within 3 months'), which is being used to determine if membership in the condition at the beginning of the initiative and early implementation impacts the absence/presence of the outcome at 6 months.

Table 2.0: Conditions

Condition	Data	Fuzzy vs. Crisp Set	Calibration
1 TeachAccept: Overall Teacher Acceptability of TDM within the school, within first 3 months	Classroom teacher interviews Classroom Observation Data	Fuzzy set	1 = Total Acceptance .75 = Majority acceptance .25 = Teacher majority reluctance 0 = Reluctance
2 LeaderAccept: School Leadership Acceptability (Head teacher or PE Teacher Acceptability) within the first 3 months	All Interview Data	Fuzzy Set	1 = Complete school-wide commitment .75 = Some school-wide display of commitment .25 = Limited school-wide displays of commitment 0 = No display of commitment
3 StuAccept: Student Acceptability within classroom within the first 3 months	Student Focus Group Data All Interview Data Classroom Observation Data	Fuzzy Set	1 = Students actively ask for it .75 = Majority view it positively .25 = Majority Levels of disinterest/resistance 0 = Disinterest by all students
4 ParAccep: Parental Acceptability at point of initiation of program	Parental Interview Data Teacher Interview Data	Fuzzy Set	1 = Parents accept .75 =Majority of parents accept .25 =Majority of parents resist 0 = No parents accept
5 ResourceConstraint: Perception of physical infrastructure limitations within first 3 months	All Interview Data Observations	Fuzzy Set	1 =Physical infrastructure perceived as a problem .75 = Majority indicate infrastructure issues .25 =Majority no concern about infrastructure 0 =Physical infrastructure not a concern
6 TimeConstraint: TDM perceived by classroom teacher as taking up class time in first 3 months	Interview Data with teachers Observations	Fuzzy Set	1 = Time a problem .75 = Majority indicate time issues .25 =Majority no concern about time 0 =Time not a concern
7 Contact: Frequency of contact with health strategists	Health strategist interviews; document analysis	Fuzzy Set	1 = Frequent contact (More than fortnightly) .75 = Frequent contact (More than Monthly) .25 = Infrequent contact (Less than quarterly) 0 = No contact
8 StuChange: Perceptions of effectiveness of program at creating changes in children	Classroom teacher interviews	Fuzzy Set	1 = Perceived change for all students .75 = Perceived change for majority students

	behaviours/practices within the first 3 months			.25 = Perceived change for minority of students 0 = No change perceived
9	InitiativesPresent: Other initiatives present in the school (eg: SugarSmart; 5-a-day)	All Interview Data Observations	Fuzzy Set	1 = Intervention is part of 5 or more other health initiatives .75 = Intervention is part of 3 or more other health initiatives .25 = Intervention is part of 2 or less other health initiatives 0 = Intervention is not part of suite of other health initiatives
10	SESStatus: Lower SES Classroom	School Data: # of students on free school meals (Year 3 or greater)	Fuzzy Set	1 = More than 5 students in a classroom .75 = 3 or more students .25 = 2 or less students 0 = No students
11	TeacherAuthor: Level of 'authority' teacher has in the school	School Data: # length of time teachers at the school & position of teacher	Fuzzy Set	1 = Teacher at school > 3 years and holds a department role .75 = Teacher at school for > 3 years .25 = Teacher at school for < 3 years 0 = Teacher at school for less than a year
12	PhysCapValue: Physical Health Resources valued by school	All Interview Data Observations School Data: Values of school/Mission statement	Fuzzy Set	1 = Physical Capital embedded in cultural values of school .75 = Substantial commitment to improving physical capital in school .25 = Limited commitment to physical capital resource development 0 = No display of commitment
13	Injury: Adverse health impact (injury/asthma) within the first 3 months	All Interview Data Observations	Crisp Set	1 = Injury Occurs 0 = Absence of Injury

Hypothesis

In this study we hypothesise that the presence of teacher (TeachAccept) and leadership (LeaderAccept) acceptability, perceived changes of the intervention as effective for students (StuChange), as well as a commitment to physical capital resources (PhysCapValue), and an absence of constraining resources (~ResourceConstraint) will be 'quasi-necessary' or 'quasi-sufficient' conditions (see below) for the intervention to be successfully implemented (IntAdopt).

Or put another way, where the outcome condition is IntAdopt (Intervention is successfully implemented):

$$\text{IntAdopt} = \text{TeacAccept} * \text{LeaderAccept} * \text{PhysCapValue} * \text{StuChange} * \sim \text{Resourcelimit}$$

Planned QCA Analysis

In analysing this dataset using a QCA approach we are interested in both the conditions of best fit for the presence of the outcome (successful implementation), as well as those cases which do not conform to the general patterns. As Legewie [10] argues, the presence of a condition, or a combination of conditions, are, in actual datasets, likely to be "quasi-necessary' or 'quasi-sufficient' in that the causal relation holds in a great majority of cases, but some cases deviate from this pattern". Recognising that this will likely be the case the XY plot functions on *fsQCA* will be used to visualise the relation between the combination of conditions and outcome to examine how the cases cluster, as well as the inconsistent cases, as suggested by Schneider and Wagemann [7].

For the cases where the condition, or combination of conditions are present a within-case analysis will be conducted, and how the 'recipe' emerges and occurs in each case will be examined. Legewie [10] argues it is useful to examine both the temporal aspects of the recipes emergence as well as explore if the recipe works in the same way across all cases where it is present, which can illuminate whether or not two separate mechanisms are at work, and thus assist in the revision of the conditions and analysis. Analysis will follow Legewie's [10] suggestion, and use the descriptive statistics function on *fsQCA*, to explore the membership levels in differing conditions to examine if the coding/definitions of the

crisp/fuzzy sets is correct (i.e. too narrow / too broad), and/or if they require further calibration.

Concluding Comments

QCA in this project is being used to establish what combination of conditions exist when the intervention, TDM, is successfully implemented. Our goal is to contribute to better understanding TDM and health-based interventions in classroom settings, and better understand how QCA might assist in better understanding complexity of public health interventions in the contexts in which they are situated.

Ethics approval and consent to participate

The study was approved by the Biomedical & Health Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee (BDM RESC) at King's College London (approval numbers LRS-17/18–5510 & LRS-17/18–6465). Participants provided informed consent to participate in the study.

Consent for publication

Participants provided consent for data to be used in publications, subject to measures to ensure confidentiality.

Availability of data and material

Participants provided permission for data to be used in future research. Datasets of qualitative material are held by the authors, with the intention of deposit after project outputs are finalised.

Competing interests

The authors have no competing interests to declare.

Funding

The study was funded by the MRC's Public Health Intervention Development Award, MR/RO14094/1

Authors' contributions

BH designed the QCA study, generated the data and drafted this report. JG was PI on the MRC grant, contributed to design, and edited the report for significant content.

Acknowledgements

We thank Professor Charles Ragin, who provided feedback on an early draft of this paper.

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