A cluster randomised controlled trial to investigate the effectiveness and cost-effectiveness of the 'Girls Active' intervention

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2. PROTOCOL SIGNATURE PAGE

PROTOCOL: A cluster randomised controlled trial to investigate the effectiveness and cost-effectiveness of the 'Girls Active' intervention

VERSION: Version 4.0 (22/02/2016)

By my signature below, I confirm that I have read this protocol and its attachments, I understand it, and I will work according to this protocol. I will also work consistently with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with ICH Guidelines on good clinical practices and the applicable local laws and regulations. I will accept a monitor for the Sponsor overseeing the study.

Lead Principal Investigator: _____

[Title/Name]

Name of Facility: _____

[Study Site]

Signed: _____ **Date:** _____

3. SYNOPSIS

Study Title	A cluster randomised controlled trial to investigate the effectiveness and cost-effectiveness of the 'Girls Active' intervention
Trial Design	Cluster randomised controlled trial
Trial Participants	11-14 year old girls
Planned Sample Size	1600
Follow-up duration	At 7 and 14 months
Planned Trial Period	24 months
Primary Objective	To investigate whether 'Girls Active' leads to higher objectively measured moderate-to-vigorous physical activity (MVPA) in adolescent girls at 14 months after baseline assessment compared to the control group.
Secondary Objectives	To investigate whether 'Girls Active' results in changes to the following outcomes 7 and 14 months after baseline assessment: • Increases in objectively measured total volume of physical activity (accelerometer counts/days). • An increase in the proportion of girls meeting MVPA guidelines (measured objectively). • Increases in objectively measured MVPA (at 7 months). • Reductions in time spent sedentary (measured objectively and self-reported). • Reductions in measures of adiposity (body mass index percentile, percent body fat). • Improvements in psychological factors that may mediate physical activity participation (including health-related quality of life, self-efficacy, motivation, social support enjoyment and perceived importance of physical activity; and physical self-perceptions). To conduct: • A full cost-effectiveness and cost-consequence analysis of the 'Girls Active' programme; from a multi-agency public sector perspective, at 14 months follow up. • A process evaluation throughout the intervention implementation (qualitative and quantitative measures) with both the students and teachers to provide insight into the ways and extent in which the programme was implemented in each school and participant experiences of the intervention.

4. ABBREVIATIONS

AE	Adverse event
APHV	Age at peak height velocity
BME	Black and minority ethnicity
BMI	Body mass index
CI	Chief Investigator
CRF	Case report form
CTU	Clinical Trials Unit
EC	Ethics Committee (see REC)
GCP	Good Clinical Practice
ICF	Informed consent form
LDC	Leicester Diabetes Centre
MVPA	Moderate to vigorous physical activity
NHS	National Health Service
NIH	National Institute of Health Research
PE	Physical education
PI	Principal Investigator
PIL/S	Participant/ patient Information leaflet/sheet
PIN	Participant identification number
QMS	Quality management system
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard operating procedure
TMF	Trial master file
YST	Youth Sport Trust

5. BACKGROUND AND RATIONALE

5.1 Physical activity in adolescent girls

There is a growing concern around inactivity levels worldwide particularly in young people.[1] A large proportion of children and adolescents do not meet the UK physical activity guidelines of at least 60 minutes/day of moderate to vigorous physical activity (MVPA).[2] Adolescents are particularly at risk; in England only 18% of adolescents meet these guidelines.[3] The data also suggest that a sex and age inequality exists whereby boys are more active than girls and these differences become more profound with age.[3-5] For example, at age 5 to 7 the same proportion of boys and girls meet recommendations (~24%) but this declines to 14% in boys and 8% in girls by age 13 to 15.[3] These declines are compounded by increases in time spent sedentary.[4] Declines in MVPA are particularly evident during and following the transition to secondary school (age 11+) when a significant drop in the number of girls meeting MVPA guidelines is observed.[3,5] To stem this decline in MVPA and increase the number of adolescents meeting the recommended MVPA guidelines, there is a need to develop and implement evidence-based, innovative programmes that meet the need of the 21st century UK population. This need is greatest in girls where declines in MVPA are particularly marked during adolescence.

UK adolescent girls cite a number of personal factors (body image, embarrassment, skill), perceptions about physical activity (too competitive, not fun) and a perceived lack of support (limited opportunities and provision designed for girls, boys getting more support) as barriers to being active.[6] Challenges also emerge specific to black and minority ethnicity (BME) girls, such as family attitudes and perceptions of sport, deeply engrained socio-cultural norms pertaining to 'acceptable' feminine behaviour and appropriate dress code when engaging in activity (in South Asians in particular).[6] These issues tend to be exacerbated as girls move through adolescence,[6] a time when physical maturation has psychological and social impact that could contribute to girls disengagement from physical activity.[7] Due to the pronounced sex differences in physical activity levels, developing physical activity interventions and strategies that are sensitive to girls' needs and interests is a challenging priority.[8]

5.2 Previous physical activity intervention for young people

Systematic reviews have identified the key settings, methods, strengths and weaknesses of previous physical activity interventions for young people from around the world. A variety of settings and methods have been used to encourage physical activity including alterations to the school cultural or physical environment, modifying the school curriculum, adding extra physical activity within the school day, or interventions with a community or family component.[9-12] Reviews to date have struggled to draw general conclusions on the effectiveness of physical activity interventions among girls due to inconsistent findings, but some do indicate that interventions appeared to be most effective when they were school-based, included enjoyable physical education (PE) as a main component (i.e, making PE more enjoyable for girls by increasing choice and non-competitive and innovative activities) and promoted positive peer relationships through peer tutoring or peer modelling and social support of friendships groups in physical activity settings.[9,12] Research has also suggested that as children move into adolescence, peers become a strong influence on physical activity.[13,14] One review identified only two peer based interventions aimed at young girls; suggesting that future research is needed to evaluate these types of programmes especially when implemented with older girls.[9] Reviews identified limitations in the methodological quality of studies such as lack of high quality randomised controlled trials, lack of precision of the physical activity outcome measures and small sample sizes.[9,12] Furthermore, the majority of school-based evidence comes from North America[10,11,15-22] and differences in infrastructure, school systems and culture make it inappropriate to translate these directly to the UK.[9,12,21,23] There is a small evidence base for school based interventions in the UK but this is limited and focuses mainly on primary schools,[24-31] or increasing activity solely during PE classes.[32,33]

5.3 The 'Girls Active' Intervention

It is evident that the successes and limitations of past physical activity interventions need to be learned from, adapted for the UK and evaluated robustly through a formal randomised controlled trial to test effectiveness and cost-effectiveness.

In response to this need, and to the low and declining physical activity levels seen in adolescent girls, the Youth Sport Trust (YST), an independent charity, has developed a novel intervention called 'Girls Active'. 'Girls Active' is focused on providing a support framework to schools to review their physical activity, sport and PE provision, culture and practices to ensure they are relevant and attractive to all adolescent girls but with a particular focus on 11-14 year old girls. Furthermore, 'Girls Active' uses peer leadership and marketing to empower girls to influence decision making in their school, develop as role models and 'sell' physical activity to other girls. This process is underpinned by teachers and

girls working together to understand the preferences and motivations of girls to take part in physical activity, sport and PE. 'Girls Active' is designed to be a flexible process for delivery but there are several key elements that underpin the programme. The elements are listed below.

1. **Self-evaluation and mission analysis -** 'Girls Active' draws on the highly effective Mission 2012 review, planning and evaluation framework used by UK Sport to generate sporting success at the London Olympic and Paralympic Games. Using an adaptation of this Mission Analysis framework and a combination of marketing principles and youth leadership in the form of a peer leadership and marketing group, it helps schools to review their existing culture and practice and to deliver an action plan tailored to their girls' needs. This is an exercise that is carried out as a 'pre-intervention and training' task and allows schools to reflect on their practice that currently exists within their school. Following the peer review day school leads are invited to reassess their mission analysis and make adjustments for any new or changes of plan.
2. **Training for school leads –** Schools are invited to a one day orientation and training day to introduce schools leads to the resources and action planning This training covers the impact on school development plans and how using interventions such as 'Girls Active' can have a successful impact on attainment and achievement and on certain student groups that schools are trying to engage. The teachers also share challenges, successes and ideas with each other.
3. **Package of resources –** At the training day schools receive a package of resources from the YST aimed at the teachers and the peer leadership and marketing group. This package contains resources including marketing plans, an action planning guide, case studies, still and video images to stimulate discussion, and a 'Making it Yours' branding toolkit for peer leaders including a CD with logos, graphics and designs that peer leaders and teachers can use in their marketing campaign.
4. **Peer leadership and marketing group –** School leads can encourage, invite or ask for expressions of interest from Key Stage 3 girls to volunteer to be part of this group. They are commonly girls who are not necessarily engaged in sporting and physical activities or particularly enthusiastic about participation, but are often girls who would be seen as leaders for non-sporting reasons and thus could have a positive influence on their peers. This group will influence decision making in their school, develop as role models, 'sell' physical activity to other girls and run peer led physical activity sessions and events. From the pilot study, an average of 28% of all girls per school were involved in the peer leadership and marketing groups. It is important to note the impact that the intervention has on these girls themselves, as well as the impact on the broader female pupil population that are not currently active either through PE and sport or through recreational physical activity. Those involved in the peer

leadership and marketing group will be provided with the branding toolkit and marketing ideas and will develop the campaign with support from the school lead.

5. **Using the student 'voice' to develop and market ideas for change –** The 'voice' of the adolescent girl is key in decisions about physical activity, PE and sport in the school including the provision of changing facilities, kit, activity content, programming, inclusion and imagery. This process is underpinned by teachers and girls working together to come up with innovative and alternative physical activity and sports that they would like to participate in and can be incorporated in PE and extra-curricular activities. Most importantly this is a 'different type' of student voice, one that probably hasn't been used before as it calls on the base of students who would not traditionally be involved in this type of provision.
6. **On-going support and mentorship from the Health and Wellbeing School and the YST –** Crown Hills Community College in Leicester have been a YST Health and Wellbeing School and a 'Girls Active' Centre for a number of years so are ideally placed to offer support and mentorship in the form of a mentorship hub. This on-going support throughout the intervention phase can involve phone or email support and one to one visit support as is required. Their experience of developing and implementing similar programmes in schools that have little experience will be crucial to the on-going success of the 'Girls Active' programme. This mentor hub will also work alongside the programme manager responsible for 'Girls Active' within the YST. A representative will also be part of the trial steering group for the cluster RCT.
7. **Peer review day -** All schools will be invited to a peer review day to identify learning and practice; this will be led by the YST and Crown Hills with the aim of teachers and peer leadership and marketing groups coming together to share ideas and solutions. This will tie in with the schools' 'mission analysis' self-review and allow schools to progress those areas of development that have been highlighted through their involvement in 'Girls Active'.
8. **Funding for capacity building within the school -** There will be capacity payments made available to the mentor hub (i.e. Health and Wellbeing School) and the 10 schools involved in the 'Girls Active' intervention. This funding will not be made available until after the recruitment process has been complete and not made public until after the randomised selection of the 10 schools to be involved. Each of the 10 intervention schools will be given capacity funding of £1000 in instalments and the Health and Wellbeing School will be paid £6,000 in three instalments of £2000. This funding will be provided by YST as an intervention cost.

6. OBJECTIVES

6.1 Primary Objective

To investigate whether 'Girls Active' leads to higher objectively measured moderate-to-vigorous physical activity (MVPA) in adolescent girls at 14 months after baseline assessment compared to the control group.

6.2 Secondary Objectives

To investigate whether 'Girls Active' results in changes to the following outcomes 7 and 14 months after baseline assessment:

- Increases in objectively measured total volume of physical activity (accelerometer counts/days).
- An increase in the proportion of girls meeting MVPA guidelines (measured objectively)
- Increases in objectively measured MVPA (at 7 months).
- Reductions in time spent sedentary (measured objectively and self-reported).
- Reductions in measures of adiposity (body mass index percentile, percent body fat).
- Improvements in psychological factors that may mediate physical activity participation (health-related quality of life; self-efficacy, motivation, social support enjoyment and perceived importance of physical activity; and physical self-perceptions).

We will also conduct the following:

- A full cost-effectiveness and cost-consequence analysis of the 'Girls Active' programme; from a multi-agency public sector perspective, at 14 months follow up.
- A process evaluation throughout the intervention implementation (qualitative and quantitative measures) with both the students and teachers to provide insight into the ways and extent in which the programme was implemented in each school and participant experiences of the intervention.

7. STUDY DESIGN

7.1 Summary of Trial Design

This study is a cluster randomised controlled trial. Clusters will be randomised at the school level (stratified by school size and proportion of BME pupils) to receive either 'Girls Active' or usual care conditions (1:1). Randomisation will be done by an independent statistician within the Leicester Clinical Trials Unit (CTU).

As Girls Active is a flexible intervention that can be delivered in schools by teachers and girls themselves in whatever way this wish, all girls within the school will potentially be exposed to the Girls Active programme. However, only a random sample of ~80 Key Stage 3 girls (aged 11-14 years) at each school will be participating in the evaluation component. Follow up assessments will take place at 7 and 14 months from baseline measures. All the time points and dates were chosen to fit in with the school timetable and the school summer holidays.

7.2 Primary and Secondary Outcome Measures

Primary outcome:

A significant difference in mean minutes of MVPA between the intervention and control group measured by accelerometer at 14 months after baseline assessment will be the primary outcome. This has been chosen as the primary outcome because MVPA is the primary aim of the intervention and is negatively related to adiposity[34] and positively related to cardiorespiratory fitness and cardiometabolic health [35] in young people and can thus be considered a global marker of health status in this age group. Furthermore, government guidelines[2] focus on achievement of MVPA recommendations so this will allow us to directly assess whether 'Girls Active' increases the number of girls meeting recommended levels. The importance of other types of physical activity, such as increased light-activity movement or decreased sedentary behaviour have a weaker evidence base in children and are therefore inappropriate for the primary outcomes.[35,36] Furthermore, preserving and increasing MVPA levels in adolescence is important as it is a behaviour that tracks into adulthood.[37]

An accelerometer was chosen as the objective measurement tool for physical activity. An accelerometer is superior to self-report questionnaires due to the limitations of self-report (recall bias, inability to remember activity, for example) and objective measures are considered a basic requirement and necessary when physical activity is the primary endpoint.[38] Participants will be asked to wear the wrist worn GENEActiv accelerometer continuously for 7 days. This lightweight device,

resembling a sports watch, can be worn 24 hours/day as it is waterproof and has been found to be valid and reliable[39] objective measure of physical activity. The GENEActiv was selected for these advantages and based on our previous experience, these factors help maximise compliance and reduce missing data in this age group. Wrist worn accelerometry, as opposed to waist worn, is now being used in national surveys including the national health survey in the US (NHANES) and in the UK Biobank (https://www.ukbiobank.ac.uk/).

Secondary outcomes:

A number of secondary outcomes will be assessed at all measurement time points unless stated. A number of variables will be collected for use in a mediation and moderation analysis and also to assess any unintended consequences.

- *Objective activity variables*: Proportion of girls meeting the MVPA guidelines of 60 minutes per day, total volume of physical activity regardless of intensity (measured by mean total counts) and average time spent in sedentary and light physical activity will be assessed. The accelerometer provides time stamped data so activity at specific times of the day (e.g., lunchtimes, during school, after school) will also be extracted to investigate when activity change occurs and whether any displacement occurs (e.g. an increase in MVPA during school hours may lead to a decrease in MVPA outside of school).

- *Self-reported lifestyle behaviours*: As the objective physical activity measurement described above does not give a context to physical activity, we will also collect self-reported data using validated questionnaires on a number of key behaviours that have proven health related relationships namely active commuting (using an adapted version of the questionnaire employed in the ENERGY project)[40], sports and PE participation (using the Physical Activity Questionnaire for Adolescents (PAQ-A))[41]., and sedentary behaviours (using the Adolescent Sedentary Activity Questionnaire (ASAQ)[42]; To test the reliability of the adapted version of the ASAQ we will ask a small sub-sample of participants to complete the same ASAQ 1 week after the 14 month measurement visit. To test the validity of the adapted version of the ASAQ we have included the original full ASAQ as a supplementary question that the participant can answer only if they have time. We will also query screen use using items from the Screen based Media Use Scale)[43], whether they are a 'morning' or 'evening' person)[44] and some specific nutrition behaviours (fruit and vegetable, sugar sweetened beverages and snacking).[45,46] We are interested in active commuting as it is a behaviour that is relatively stable across school years and can make a viable and valuable form of overall physical activity.[47] PE and sports participation can improve social skills and behaviours, self-esteem and physical literacy while also contributing to daily physical activity goals.[48,49] Sedentary activities such as screen time are related to adiposity and risk factors in children independent of MVPA.[50]

• *Body composition*: Body composition data are key health related data that have the potential to change, or at least stabilise, in response to a physical activity programme. As adolescent girls have been found to be inaccurate when self-reporting height and weight,[51] it will be directly measured by trained research staff. BMI changes, including obesity onset, in adolescence are likely to persist into adulthood[52] and have been related to cardiometabolic risk in young adulthood.[53] Height and weight will be measured using a portable stadiometer and paediatric scales and BMI will be calculated and converted to a BMI percentile based on UK reference data.[54] Participants will be asked to remove their shoes and large items of clothing such as jumpers and to remove any items from their pockets. Body fat percentage will be estimated using body composition scales specifically designed for youth. Body weight and composition will be measured in a private area or room, only female assessors will take the measurements, weight will be measured using scales with either remote display or covered display so that the participants themselves will not see their weight. The girls will be reassured that all measurements are confidential and research data will only be linked via a non-identifiable participant number.

• *Biological maturation*: Maturation is a potential moderator of intervention success (for example, late maturing girls may respond better to the programme). Age at peak height velocity (APHV), an indicator of physical maturity reflecting the maximum growth rate in stature during adolescence, will be predicted in all girls. This requires a measurement of sitting height to be taken using the portable stadiometer with the participant sitting fully erect and legs hanging freely on a high table/box. A sex-specific multiple regression equation[55] that includes standing height, body mass, sitting height, leg length (subtract sitting height from standing height), age, and their interactions will be used. This technique estimates maturity status to within an error of +1.18 years 95% of the time in boys and +1.14 years 95% of the time in girls[71] and has been utilised successfully in a number of studies.[56-58] The predicted years from APHV will be combined with the age at time of measurement to provide a predicted APHV. APHV will used to categorize girls into maturity groups (i.e. early, average and late maturing).

• *Psycho-social measures*: Health-related quality of life will be assessed using the Child Health Utility -9D (CHU-9D) which will be used in the cost-effectiveness analysis. The remaining psychological constructs (self-efficacy, motivation, social support, enjoyment, perceived school provision and perceived importance of physical activity; and physical self-perceptions i.e., body image) will be assessed using existing questionnaires that have demonstrated reliability and validity for use with this age group.

Health behaviours: We will also collect data on negative health behaviours that might develop over time. Data on smoking and alcohol in adolescents have been collected in the Health Survey for

England (HSE)[59] and by the ALSPAC cohort.[60] Whether the participant has ever smoked or drank an alcoholic beverage will be queried using two simple questions from the Health Survey for England.[59] These data will be used to assess any potential unintended consequences of the Girls Active programme. A service use questionnaire will also be included where participants will report the number of time they have seen their GP and school health professionals in the last 7 months. These data will be used for the health economics analysis.

- *Demographics*: We will also collect basic demographic information for each child - age, ethnic background and postcode (to be used to determine Index of Multiple Deprivation as an indicator of socio-economic status).

- *Environment:* School provision for activity (e.g. availability of changing facilities and sports facilities), policies and practices towards physical activity (e.g. sex split PE classes) and demographics of the school will be reported by the teacher. We will collect the participants' perceptions of their neighbourhood environment using subscales of the Youth Neighbourhood Environment Walkability Scale.[61]

7.3 Process Evaluation

Due to the flexibility of programme implementation afforded to schools within the 'Girls Active' intervention, process evaluation will be particularly important. The process evaluation will be used to help explain any discrepancies between expected and observed outcomes, to understand the influence of context on outcomes and to provide insight for further intervention development and implementation.[62] Process evaluation will be undertaken throughout the intervention from project initiation to conclusion. We will employ a variety of techniques (e.g., observations, log books, questionnaires, interviews and focus groups with teachers and girls) to record information on recruitment, the implementation/delivery of the intervention, the extent to which the intervention reached the intended targets and the degree to which the targets engaged with 'Girls Active' (dose, fidelity, reach and exposure). More specifically, lead teachers in each intervention and control school as well as any support teachers (if applicable) who have assisted on Girls Active delivery will be interviewed using a flexible topic guide. We will also undertake interviews with staff members of the Youth Sport Trust and the hub school who have had contact with Girls Active in any way (for example the project manager, those doing 1-to-1 phone calls etc). At 14 months we will also undertake focus groups with the peer leaders at each school, a random sample of boys from Key Stage 3 at each school and a sub-group of girls from the original sample of ~80 pupils in the measurements. The lead teacher at each school will identify the relevant pupils. Each participant in the process evaluation, who hasn't already consented to take part in the main study, will be provided with a pack containing a

parent/guardian information sheet, a parent opt out consent form, and a participant information sheet. Assent will be taken from all focus group participants. We will also document any environmental factors (for example context, contamination by other similar programmes, movement of any teachers from intervention to control schools and secular trends) that may have an influence on intervention effectiveness. As intervention acceptability predicts continued use of intervention strategies,[63] student enjoyment and teacher acceptability will also be assessed. Details of the process evaluation

components are included in Table 1.**Table 1. Summary of process evaluation methods.**

Indicators	Data sources	Timing
Recruitment		
Number of schools invited, number of school accepting invitation	Project records, include socio-demographic information (e.g., school size, ethnicity, SES, etc.)	On-going throughout project
Number of possible participants at each school, number of participants recommended or invited to attend activities, actual number who do attend each activity	School rolls, project records, attendance records	
Number who opt out, drop-out and non-compliance	Attendance records; short questionnaire to explore reasons for opt out and drop out and non-compliance to the accelerometer protocol	
Delivery of Girls Active		
Number of activities delivered, changes to school policy, number of peer leaders recruited, resource use, funding applied for, training conducted and attendance at training	School 'Mission Analysis' self-review and action plan, school environment questionnaire, teacher and peer mentor logs, policy review, project records for funding and training, interviews with lead teacher and peer mentors, logs from and interviews with intervention deliverers, audit of school provision	Monthly collection of logs/records, brief interviews at regular intervals throughout project, final exit interviews including review of initial 'mission analysis', end of intervention policy review and, school environment questionnaire (pre-, post-)
Contamination - whether new staff have been recruited to the school over the life of the programme	Control schools will provide a record of any new staff members recruited and which school they were recruited from and give brief details of whether they have made any changes to school provision for physical activity, PE and sport since being recruited	Exit survey
Description of unintended events		
It is useful to note whether there were any unexpected side effects or outcomes from the intervention. For example, did participants take up one type of physical activity but stop doing another during the project? Unexpected outcomes do not necessarily have to be negative and there may be unanticipated positive health outcomes.	Survey with pupils, attendance logs	Monthly collection of attendance, exit survey
Participant satisfaction, acceptability and enjoyment		
Satisfaction/dissatisfaction with the programme; likes and dislikes	**Lead teacher** interview; **teachers** focus groups; **peer leaders** focus groups; **pupils** brief exit survey to all pupils, focus groups with subset. All conducted by person independent of the intervention delivery to encourage honest opinions	Midpoint (brief) and exit interview
Sustainability		
Whether plans have been made to continue with Girls Active in some way	Interview with lead teacher	Exit interview

7.4 Cost Effectiveness

In this economic analysis we will fully cost the delivery of the 'Girls Active' programme and the associated costs such as teacher time and other materials used. We will give a diary log to school leads asking them to complete a record of the additional time, or displaced time, taken to offer the 'Girls Active' programme. This log will be supplemented with a phone call where a research team member will administer a survey asking for specific details of what the school has done and to query anything that is not clear. We will use Local Education Authority teacher costs, accounting for overheads. From a public sector, multi-agency perspective, taking into account NICE guidance on economic evaluation of public health interventions,[64] and based on our experience of evaluating the Wales National Exercise referral programme,[65,66] we will undertake a primary cost-effectiveness analysis of the 'Girls Active' programme, using minutes of MVPA as the outcome effect, and a secondary cost per QALY analysis (embedded in a wider cost consequence analysis), using the Child Health Utility-9D (CHU-9D) questionnaire. The CHU-9D has been validated with children 11-17 years as a self-report measure. In the validation study of the measure with 150 healthy school-children it took on average 3.8 minutes to complete. Thus, this short questionnaire should be of minimal burden for our sample. The questionnaire design and scoring allows for the calculation of QALYs. This questionnaire consists of 9 dimensions (worried, sad, pain, tired, annoyed, schoolwork/homework, sleep, daily routine, able to join in activities). These dimensions take account of the physiological, psychological and daily routine which makes it very suitable to our sample who are likely to be in good health and includes dimensions that are complementary to the overall aims of the study. This will be collected at baseline, 7 months and 14 months. We will pay particular attention to equity considerations through subgroup analysis (age, ethnicity, socio economic status and BMI at baseline). We will account for clustering in our analysis, producing cost-effectiveness planes and cost effectiveness acceptability curves (CEACs) in order to convey to policy makers the probability that 'Girls Active' is cost-effective at different payer thresholds. We will undertake 5,000 boot-strapped replications in order to generate confidence intervals around point estimates. In addition to this traditional approach we will also discuss the costs to this geographical area of "shifting the curve" – the cost of potentially shifting a proportion of girls from inactive to moderately active or moderately active to very active, depending on the findings of the trial as we did in a recent public health trial.[67] The service use questionnaire will also allow us to take into account the impact on services from intervention participation. This impact could be a reduction, an increase or a shift in use of services and is important to consider this when rolling out a new programme or increasing the roll out of an existing programme.

7.5 Sample Size

We will recruit 20 schools (10 schools per group) in total to this programme. This number of schools and pupils will provide adequate power to detect a difference in objectively measured MVPA of 10 minutes/day between groups, a magnitude that is associated with a meaningful difference in cardiometabolic risk factors in youth.[35] In order to detect a difference of 10 minutes/day between groups, assuming a standard deviation of 18 minutes in MVPA,[68] a power of 90%, a significance of 0.05, a cluster size of 56 girls and an intra-class correlation of 0.1, the sample size needed is 18 schools, increasing to 20 schools (10 schools per group) to allow for cluster attrition. To allow for 30% loss to follow up and non-compliance we will recruit a random sample of 80 girls per cluster.

8. TRIAL PARTICIPANTS

8.1 Recruitment Strategy

School Recruitment Strategy: The intervention and evaluation will be advertised through Crown Hills Community College, Leicester in collaboration with the Youth Sport Trust (YST) using a recruitment letter. Crown Hills Community College is a Health and Wellbeing School, one of only 50 such schools in the country. The Sports Development Managers at Crown Hills have links with Principals and PE teachers through the Leicester City Schools Sport Partnership and County Sports and Physical Activity Partnership (Leicester-Shire and Rutland Sport). This initial letter will contain brief information about the Girls Active intervention, state that a robust evaluation will also be conducted and invite the interested school teachers to a briefing event that will be held by the Youth Sport Trust. At the briefing event the teachers will receive a presentation by the Youth Sport Trust about the Girls Active intervention and the evaluation. At the end of briefing event the school representative will be given written information to take back to the head teacher on the intervention and the evaluation along with a consent form. If schools are interested in being involved they will return the signed consent form by the head teacher. On receipt of this each interested school will be contacted to arrange the baseline assessment.

All schools involved in the evaluation will receive a £500 honorarium at the end of the study (i.e., once they have completed all evaluation measures) to encourage participation in the evaluation and discourage dropout.

Participant (pupil) Recruitment Strategy for the Evaluation: 'Girls Active' is specifically targeting all girls in Key Stage 3 (11 - 14 years old; year groups 7, 8, 9) so only girls in these year groups will be invited to participate in the evaluation. An invitation pack, containing an invitation letter to parent(s)/guardian(s), parent/guardian information sheet, an opt out consent form and participant information sheet, will be provided to all girls aged 11-14 to take home to their parent/guardian. Only ~80 girls are needed for evaluation assessments therefore the research team, in collaboration with the school, will randomly select the girls to be involved.

8.2 School and Pupil Inclusion and Exclusion Criteria

School Inclusion:

- Government funded secondary schools within Leicester, Leicestershire and Rutland (LLR) and schools in areas bordering the LLR along the M1 corridor.

- Schools with at least 80 Key Stage 3 girls

School Exclusion:

- Private or independent schools and designated special needs schools
- Schools that do not have any Key Stage 3 pupils

Pupil Inclusion:

- Key Stage 3 girls (must be aged 11, 12, 13 or 14 years)

Pupil Exclusion:

- Girls outside of the targeted age range
- Parent opt-out consent returned.

9. STUDY PROCEDURES

9.1 Informed Consent

All girls within the required age range will be provided with an invitation letter for themselves and their parent(s)/guardian(s), a parent/guardian information sheet, a participant information sheet for themselves and an opt out consent form to give to their parent/guardian. As this is an opt out consent, parents that do not want their child to participate will sign the opt out consent and return it with the child to the school. Even if parents do not choose to opt their child out at baseline, they, and the child themselves, will be free to withdraw from the study if they wish. Opt-out consent is acknowledged standard practice for school-based studies in the UK, has been used by members of our investigator team previously and is currently being used by other school-based research funded through the NIHR Public Health Research Programme (http://www.nets.nihr.ac.uk/programmes/phr). Furthermore, evidence shows that using opt-out consent procedures leads to more representative samples and higher response rates. If a parent/guardian returns a completed opt-out consent form then their child will not take part in the evaluation. Originals of the opt out consent forms that are returned will be retained at the study site within the trial master file.

At the beginning of the baseline measurement session all methods will be fully explained to the participants (girls aged 11-14 years) by a team member who is suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator as detailed on the delegation of authority and signature log for the study. Each participant will then give verbal assent if they are happy to participate. They will be free to withdraw at any point. Verbal assent will be requested again at each follow up measurement session.

9.2 Visit and Measurement Schedule

Data will be collected at baseline and 7 and 14 months after baseline assessment. All outcomes at each measurement time point will be collected over one day in each school. The schedule of measurements and each girl's participation is shown in Table 2.

Table 2. Assessments at each measurement visit

	Dates	**Measurements Planned**	**Duration for each participant**
Baseline assessments	February and March 2015	• Overview of the methods, verbal assent • Accelerometer • Questionnaires • Anthropometric measurements	100 minutes
7 month follow-up	September and October 2015	• Overview of the methods, verbal assent • Accelerometer • Questionnaire • Anthropometric measurements	100 minutes
14 month follow-up	April and May 2016	• Overview of the methods, verbal assent • Accelerometer • Questionnaires • Anthropometric measurements	100 minutes

For each data collection session (baseline, 7 and 14 month) we will have six core research team members and additional students (with a full Disclosure and Barring Service check) from the Leicester Diabetes Centre and/or Loughborough University as appropriate. It is envisaged that each group of participants in each school (n=80) will be divided into three groups of ~27 pupils and each group will be seen separately for the measurements (e.g., group 1 (n=27) will be seen early morning, group 2 (n=27) will be seen in the late morning and group 3 (n=27) will be seen in the afternoon). Each group (n=27) will be split into three groups (of ~9 pupils) for the measurement session and each group will rotate around three stations as seen in Figure 1. Following the study explanation and verbal assent to the full

group of ~27 pupils, the group will be spilt as mentioned above and will rotate through the body measurement and the two questionnaire stations before all the group comes together again at the end for the accelerometer explanation and distribution. At each follow-up visit (7 and 14 months), we will revisit schools to do a second measurement session if >10% of the pupils involved in baseline measurements are absent from school. Figure 2 shows the flow of the study from start to finish.

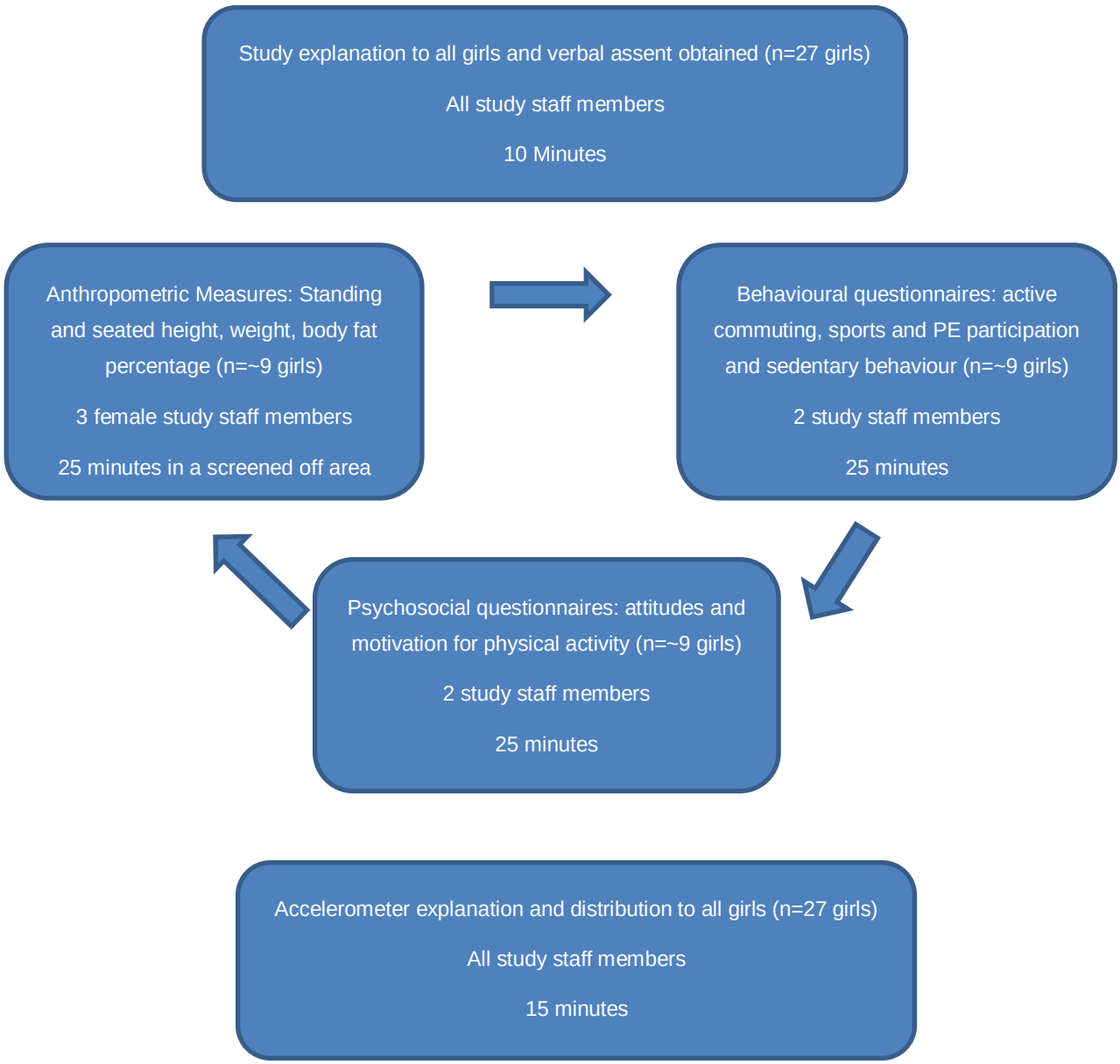

Figure 1. Measurement session procedure.

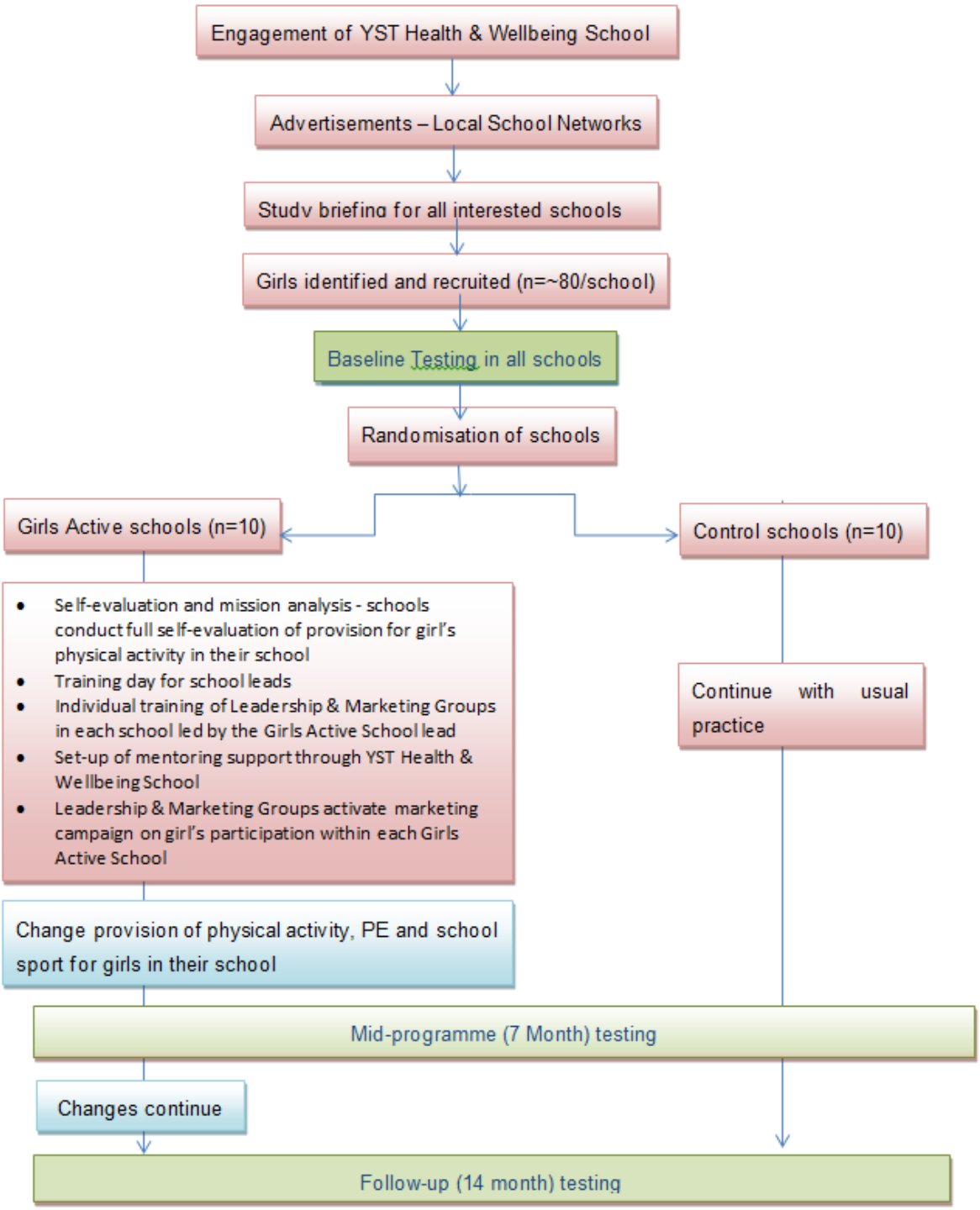

Figure 2. Flow of the study.

9.3 Randomisation

Once all participants have gone through baseline measurements, all 20 schools will undergo randomisation by an independent statistician. They will stratify the randomisation based on school size (<median, >= median) and percentage of BME pupils (<median, >= median).

In order to reduce bias at the measurement sessions, the research team members conducting measurement sessions within the schools will be blinded to randomisation where possible The team lead for the measurement sessions will not be blinded. The trial statistician will not be blinded. However, the statistical analysis plan will signed off prior to database lock and any deviations from the statistical analysis plan will be reported.

9.4 Definition of End of Trial

The end of trial is the date of the last focus group/interview with the teachers and pupils at the exit interview as part of the process evaluation.

9.5 Withdrawal of Participants from Study

Each participant has the right to withdraw from the study before study completion and their parent/guardian has to right to withdraw them at any time and for any reason. If a participant decides to withdraw from the study, this will be recorded in the study records. If a participant specifically withdraws consent their data will not be used in the analysis but if they withdraw because they cannot attend the follow up measurement sessions their data will still be used in the analysis.

9.6 Source Data

In this study the participant CRF will be used as the source document for demographics and anthropometric information. The individual paper questionnaires will be considered source data for health behaviours and psychosocial constructs. Raw accelerometer files will be source data for objectively measured physical activity and will only contain the participant's unique identifier and will be stored on the Leicester CTU drive. All paper documents will be stored safely in locked filing cabinets within the Leicester Diabetes Centre.

10. SAFETY REPORTING

Due to the nature of the intervention we do not foresee any adverse events above those of participating in school activities including PE class. We will follow the University of Leicester guidelines for managing and reporting any serious adverse events (SAE), which follow those outlined in Good Clinical Practice (GCP) guidance for non-CTiMP (Clinical Trial of an Investigational Medicinal Product) trials and are based upon Medicines and Healthcare Products Regulatory Agency feedback. Adverse events which do not fall into the GCP categories of an SAE are defined as non-serious. Teachers will be made aware of any potential adverse events that may occur and will be asked to keep a log of any adverse events that take place to the study participants and also whether any incidents occurred during any of the designated Girls Active events. All SAEs will be reported internally and to the sponsor (University of Leicester) using appropriate reporting forms, within 24 hours of the study team becoming aware of the event. The immediate report may be made orally or in writing and shall be followed by a detailed written report of the event. Additional information can be provided if requested to the sponsor and the main Research Ethics Committee. The principal investigator is responsible for the review and sign off the SAE, or in their absence, another member of the team (in order to avoid a delay). The investigator site file will contain documentation for SAE reports and evidence of submission of SAEs to the sponsor within 24 hours of the team becoming aware of an event.

11. STATISTICS

This study will be analysed and reported according to the CONSORT statement for cluster RCTs. The statistical analysis plan detailing the analyses will be finalised prior to database lock. Data will be analysed on an intention-to-treat basis in the first instance, therefore all randomised schools will be included in the main analysis. To allow intention-to-treat analyses, missing data will be imputed using multiple imputation methods. The purpose of the primary analysis is to examine whether objectively measured MVPA at 14 months is higher in the intervention group than the control group. This will be examined using a linear multilevel model with MVPA as the outcome variable, levels to indicate the clustering of pupils within schools, a binary indicator for randomisation group as the explanatory variable, and terms for the stratification factors as confounders. Secondary outcomes, including those measured at other time-points, will be analysed using the same strategy with linear multilevel models used for continuous outcomes and logistic multilevel models used for categorical variables. Any changes in MVPA will be explored by extending the multilevel models to investigate whether the measured individual or school level characteristics mediate these changes. Sub-group analyses involving interaction and stratified analyses will be performed for non-active vs. active participants (defined as below or above the median MVPA level at baseline), single vs. mixed sex schools, white vs. BME participants and the degree of social deprivation based on the English indices of deprivation for the school location. These sub-group analyses will use the same models as the main analysis. Missing data will be replaced using multiple imputation methods. As a sensitivity analysis, we will also perform a per protocol analysis of those who were compliant with the protocol and follow-up visits. No formal interim analyses are planned. The baseline characteristics of those who did and did not drop-out will be compared to determine whether and how they differ. All tests and reported p-values will be two-sided. Estimates will be presented with 95% confidence intervals.

12. QUALITY CONTROL AND QUALITY ASSURANCE PROCEDURES

The study will be conducted in accordance with the current approved protocol, ICH GCP, relevant regulations and standard operating procedures.

Regular monitoring will be performed according to ICH GCP. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents. Following written standard operating procedures, the monitors will verify that the clinical trial is conducted and data are generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements.

13. CODES OF PRACTICE AND REGULATIONS

13.1 Ethics

Ethics approval will be obtained from the College of Medicine and Biological Sciences Research Ethics Committee' prior to commencement and will comply with the ESRC framework at all times. For ethical approval consideration we will be required to provide details on the research purpose and proposed methods, a risk checklist, a full protocol document, participant information sheet, consent form and any advertising/recruitment materials for the committee to consider.

13.2 Participant Confidentiality

Only those in the research team will have access to the anonymised participant research data. It will not be possible to identify any individual from the published data. Each participant will be assigned a unique study number once recruited and data will be collected and analysed during the study using this number to ensure anonymity.

Research and personal information that is collected during the course of the study will be kept confidential and anonymous. However, in some circumstances disclosure of personal information to third parties (including the lead teacher, school principal, study principal Investigator, Local Safeguarding Children Board) may be justified where the researcher believes that such disclosure is in the participant's interest (for example, where information arises which indicates that the young person may be subject to abuse/neglect). Where researchers have concerns about a participant who has disclosed personal information, it is essential that these concerns are acted upon and information is given promptly to the Principal Investigator (PI), i.e, within 24 hours or as soon as is practically possible. The PI will then advise on the appropriate course of action. This course of action may differ depending on the level of risk they face. The traffic light system for referrals (similar to those used by University Hospitals Leicester) will be followed to ensure the correct action for the situation faced. Any issues deemed serious will be escalated to the appropriate Local Safeguarding Children Board for where the school is located as per Every Child Matters (2003).

13.3 Storage and security of data

Paper copies of case report forms will be stored in a locked filing cabinet in the relevant research office. Hard copies and electronic files containing personal details will not be removed from the research office. The research team will comply with the Data Protection Policy of the University of Leicester.

13.4 Archiving of data

All research data will be kept in a secure location within Leicester Diabetes Centre, Leicester General Hospital during the active phase of the study and until the data have been analysed. It will then be archived in line with University of Leicester policy.

14. STUDY DATABASE

The Leicester Clinical Trials Unit (CTU) is a UK Clinical Research Collaboration fully registered CTUs and has been involved in this application from the beginning and will be involved throughout the project. The CTU has a well-established IT infrastructure and will be providing support for this study through database development and data management. They will use a Clinical Data Management System called InferMed Macro v4 to set up a tailored data capture method that meets the needs of the study. This is a secure and validated database solution, with quality control mechanisms to ensure that the data collected are complete and accurate. The CTU has a robust quality management system (QMS). All staff working on this project will work within this QMS framework ensuring that the relevant staff are adequately trained, fully supported and working to common standard operating procedures. The CTU will ensure compliance with the appropriate governance, stipulations and trial protocol. The database solutions that the CTU implement using MACRO are designed to meet the requirements of International Conference on Harmonisation GCP and the Medicines for Human Use (Clinical Trials) Regulations 2004. The installation of InferMed Macro and the hosting environment is fully validated is configured using an automatic backup and failover architecture. The hosting agreement sets out a target of 99.95% availability excluding scheduled downtime for maintenance.

15. SPONSORSHIP AND INDEMNITY

Sponsorship for the study will be provided by the University of Leicester. If a participant is harmed due to negligence this would be covered by the University of Leicester's indemnity arrangements. If a study participant wishes to make a complaint about any aspects of the way they have been treated or approached during the research project, the University of Leicester complaint system will be available to them.

16. STUDY GOVERNANCE

The study will be sponsored by the University of Leicester. Three groups will be created to oversee the study; a trial steering committee (TSC), a study investigators group (SIG) and an operational committee (OC).

The TSC will meet every 6 months and every year thereafter and include the primary investigator (Prof Davies), an independent chair, an independent statistician, one independent external member, two lay representatives and one of the research team members (the University of Leicester project manager or co-investigator when necessary). The TSC will act as an independent strategic oversight body and will ensure transparency and that the work is reaching the relevant milestones. The TSC will provide advice and updates to the OCs.

All named study investigators as well as the project manager from the evaluation and intervention teams will be invited to a SIG teleconference every 3 months.

The OCs will meet every month or more regularly when necessary. One of the co-investigators at the University of Leicester will act as the chair and this group will also include at least one other co-investigator, a financial representative from the University of Leicester and those concerned with the day to day running of the study at University of Leicester and a key representative from the Youth Sport Trust. As there are two distinct components of this work - the evaluation component and the intervention delivery – the team at the YST will also convene an operations group independently with communications occurring through the Youth Sport Trust representative on the main OC. The OC will provide an update report to the TSC through the University of Leicester project manager.

The TSC and the study investigators will be responsible for the strategic direction and performance monitoring of this research including study delivery, risk management, public and stakeholder engagement, dissemination of results, communications, and strategic planning. This project will also be subsumed into the Leicester Diabetes Centre Study Progress Meeting that is held every 3 months. This meeting is chaired by Professors Davies and Khunti and provides a platform to discuss best practice, to discuss any current or potential risks to the delivery of the project and to monitor progress.

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