

Scientific title: A cluster randomised controlled trial to evaluate the effectiveness and cost-effectiveness of the GoActive programme to increase physical activity among 13-14 year-old adolescents.

Lay title: GoActive

Logo:



Protocol date: 30.6.16

Protocol version: 2.0

Principal Investigator:

Dr Kirsten Corder, Senior Investigator Scientist, MRC Epidemiology Unit, University of Cambridge

Co-Investigators:

Dr Caroline H.D. Croxson, Senior Researcher, Department of Primary Care Health Sciences, University of Oxford

Dr Esther M.F. van Sluijs, Group Leader, MRC Epidemiology Unit, University of Cambridge

Prof Anna Vignoles, Professor of Education, University of Cambridge

Dr Paul Wilkinson, University Lecturer and Honorary Consultant in Child & Adolescent Psychiatry,
University of Cambridge

Dr Edward Wilson, Senior Research Associate in Health Economics, University of Cambridge

Sponsor: University of Cambridge

Contact Mrs Carolyn Read, University of Cambridge School of Clinical Medicine, Box 111
Cambridge Biomedical Campus, Cambridge, CB2 0SP, United
Kingdom cad50@medschl.cam.ac.uk

Study Coordinator: Miss Fiona Whittle, MRC Epidemiology Unit, University of Cambridge

Post-doctoral researcher: Dr Helen Elizabeth Brown, MRC Epidemiology Unit, University of Cambridge

Trial registration number: ISRCTN31583496

Funding reference: NIHR-PHR 13/90/18

Ethics approval: Cambridge Psychology Ethics Committee PRE.2015.126

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1. Background

1.1 Existing research

Physical activity declines rapidly throughout adolescence, with low levels of activity increasing the risk of obesity and other metabolic disorders in young people. Most adolescents are insufficiently active[1, 2] and this inactivity tracks into adulthood[3, 4] increasing the risk of diabetes, cancer and mortality.[5, 6] Adolescence is a critical period to increase physical activity, both due to the aforementioned decline and because pubertal, brain and social development during this time leads to new capacity for health behaviours[7], increasing the likelihood of long term change. On average, the physical activity of all adolescents rapidly decreases and all groups of adolescents are therefore in need of physical activity promotion.[1, 8] Reviews however highlight **limited effectiveness of adolescent physical activity promotion**. [9-12] In a recent meta-analysis of 30 studies with objective outcomes, [11] only two of the included studies focused on adolescents over the age of 13 years. [13, 14] This highlights the lack of high quality research in this important group and **an urgent need for the development and evaluation of potentially successful strategies**.

We have identified several reasons for this previous lack of intervention effectiveness and have designed the GoActive intervention and evaluation to overcome these limitations:

- Activity declines among all groups[1] but many interventions only target subgroups (for example, girls only). [1, 15] A **whole population approach** overcomes stigmatization and detrimental mental health consequences, [16] and is likely to be more effective in engaging those subgroups that are hard to reach (including girls, those with low activity levels/high shyness); [17]
- The decline in activity mainly occurs out of school[1] but many interventions only target specific school-based times e.g. school time [10, 12] or PE lessons. [18] Although *set* in schools, GoActive explicitly **targets whole day physical activity**;
- Adolescent focus groups are mainly used to feedback on existing programmes; [19] little research uses adolescent views to develop strategies. [1] GoActive was developed via focus groups with 16-18 year olds, and as such, is likely to be more **salient and relevant to the target group**;
- Recruitment is vital to intervention success but adolescent recruitment has challenges [17, 20] including transitioning social priorities, biological changes and recruitment of minors through schools; [7, 21] involving adolescents in intervention design **improved recruitment** in feasibility/pilot work compared to previous studies; [1]

- Preferences for activity type, co-participants, timing and location of physical activity differ on an individual level.[1] Individual tailoring by researchers is not feasible on a large scale but GoActive gives participants the **flexibility** to decide when, where and who to be active with. GoActive targets key psychosocial drivers of adolescent physical activity and behaviour change: enjoyment, mastery, socialisation and goal setting; [19]
- There is a lack of cost-effectiveness evaluation in adolescent physical activity promotion, although the limited evidence available in studies targeting children indicates that physical activity promotion is likely to be highly cost-effective.[22] The proposed evaluation of GoActive includes **an assessment of the cost-effectiveness**, which increases its value for impact on decision making and policy.
- The current evidence in adolescent physical activity promotion is limited by the lack of assessment at follow-up, whereas achieving sustained behaviour change is a key priority.²⁴ The proposed evaluation includes assessment of post-intervention effect which will enable conclusions regarding trajectories of change (such as whether initial behaviour change was maintained), as well as testing causal pathways. We will also endeavour to obtain consent to enable potential longer term follow-up (including obtaining GCSE results).

Brief overview of the GoActive intervention

GoActive aims to increase physical activity through increased peer support, self-efficacy, self-esteem and friendship quality, and is implemented using a tiered-leadership system. Tutor groups choose two weekly activities each; Mentors (older adolescents within the school) and weekly Peer Leaders (one boy and one girl within the class) encourage students to try these. Students gain points for trying new activities; points are entered into a between-class competition. GoActive will run for two terms: weekly facilitation support from a council funded health trainer will be offered in Term 1, with more distant support in Term 2. More details about the GoActive intervention are included in Section 6.

1.2 Why is this research needed now?

Existing literature highlights the importance of adolescent physical activity promotion and the rapid decline throughout adolescence.[1, 23] From a policy perspective, the 2012 Chief Medical Officer's report states the importance of physical activity among young people,[24] and the recently published report from the All-Party Commission on Physical Activity calls for the creation of active schools, including the provision of a more diverse and inclusive physical offer of physical activity.[25] A recent international expert panel additionally concluded that **developing effective and sustainable interventions to increase physical activity among young people long term** is the number one **priority** in the physical activity research field,[23] and the proposed project addresses this priority.

Inactive adolescents are likely to become inactive adults [3]. Physical inactivity is one of the leading causes of death in developed countries, estimated to be responsible for 22-23% of coronary heart disease.[26] The overall cost of inactivity is reported to be £8.2 billion/year in England with an additional £2.5 billion/year estimated for the contribution of inactivity to obesity.[26] Efforts to increase adolescent physical activity therefore have implications for reducing public spending on health consequences of physical inactivity. Cost-effectiveness analyses would be conducted as part of this proposal. A preliminary estimate of the intervention costs is £8/student. If shown to be effective, this low-cost intervention (~£5 million for all Year 9 students in England) could represent a highly cost-effective use of public resources.

The results of the GoActive Study are expected to substantially add to the limited evidence on adolescent physical activity promotion, by including an objective measure of physical activity, assessing medium-term effect, testing causal pathways and following an evidence-based iterative approach with adolescent input for the intervention strategy.

1.3 Benefits and risks

Benefits to health: Low physical activity is a risk factor for obesity and related metabolic disorders in youth,[27, 28] with a 10-minute difference in moderate-to-vigorous activity (MVPA) associated with smaller waist circumference (-0.52 cm) and lower fasting insulin (-0.028 pmol/L).[28] In adolescence, physical activity declines 7% per year,[8] with low physical activity in adolescence likely to progress to adulthood inactivity,[3] with later health consequences.[5] Adolescence is a critical period to increase physical activity with potential for long term benefits to both the participants and the wider public health landscape.

Potential benefits of taking part in the GoActive intervention

Potential short-term benefits of being more physically active may include improved well-being, self-efficacy, group cohesion and self-esteem. Pubertal, brain and social development during adolescence leads to new capacity for health behaviours [7] increasing the likelihood of long term change, including increased physical activity.

Potential benefits of taking part in the GoActive RCT evaluation

Participants in all schools (including those in the control group) stand to benefit, both directly and indirectly, from taking part in the GoActive RCT evaluation. The school incentive of a £200-voucher to spend on sports equipment may directly benefit participants, and a collaborative relationship between the school and the University of Cambridge /

Cambridgeshire Council / Active Essex over a 2 year period can provide multiple additional indirect benefits to students including: access to teaching resources e.g. 'dummy data' for processing; access to university 'experts' or council staff to provide presentations on a range of curriculum topics from science to PE, psychology, statistics or careers; access to work experience placements at the University/Council; opportunities to get involved in other research activities (e.g. participation as a lay member on a scientific advisory panel); research team contributions to school communications, (e.g. newsletters, Parentmail, end-of-term assemblies); opportunities to work with local media promoting the study. Students receive a direct reward/'thank you' each time they return an activity monitor to the study team in the form of a small low-cost gift (e.g. GoActive pen or t-shirt). Teachers whose tutor groups complete the study will receive a small gift in appreciation for taking part (e.g. £20 gift voucher class sports equipment voucher). In addition, the teacher whose class wins the class-competition with the highest number of points will get an additional prize (e.g. class trophy). At the start of their role mentors will receive a GoActive Mentor T-shirt. After finishing the study, they will receive a £20 high street shopping voucher to say thank you for taking part. In addition, the mentors whose class wins the class-competition with the highest number of points will both get an additional prize (e.g. tickets for an adventure park). Finally, the experience of participating in health research may be an interesting learning experience for both students and teachers, and they may benefit from the knowledge that they are contributing to science and improving the health of future generations.

Potential risks of taking part in the GoActive Intervention

The GoActive intervention encourages adolescents to do more physical activity and to try new types of physical activity in new settings. All physical activity carries with it an element of risk of injury. The activities included in the GoActive programme have been selected because they are safe, age-appropriate and pose very low risk to participants if they are done correctly. The flexible nature of the GoActive programme means that Year 9s can participate in the programme at any time and unsupervised which is developmentally appropriate and safe for this age group.

We will work with intervention schools to carry out a school-specific risk assessment, considering the potential risks to participants of taking part in GoActive within their individual school's context. We aim to reduce the risk of injury by including safety information on all suggested activities using the 'Activity Quickcards'. Mentors, teachers and peer-leaders will be trained about safety issues.

We will actively elicit information on all ***intervention-related adverse events*** and monitor these in real-time so that we can modify or stop the programme if it is proving unsafe. We will

collect this information with the help of form tutors, intervention facilitators, mentors, parents and the students themselves.

The GoActive intervention uses a whole population approach that promotes inclusivity and participation, and will therefore be implemented across a whole year group. This approach has been designed in consultation with adolescents and successfully implemented in feasibility and pilot testing, with high acceptability and participation. It is possible that some parents of children in the intervention schools may have concerns about their son/daughter taking part in the **GoActive programme** since it is not part of the usual school curriculum. Full information about the programme will be provided to parents of children in intervention schools and parents are encouraged to discuss any concerns with the school and can withdraw their son/daughter from the programme if they wish. A suitable solution will be arranged with the school on a case-by-case basis, such as organising alternative activities during tutor time.

Potential risks of taking part in the GoActive RCT

Anthropometric measures are limited to height, weight and body-fat percentage using bio-electrical impedance analysis (participants with an implanted electronic device will not complete this measure) and will be carried out using MRC Epidemiology Unit SOPs by trained research assistants from the MRC Epidemiology Unit field team. Participants will be measured in light clothing and asked to remove their shoes and socks but will not be undressed further.

There is a small risk that some participants might find some of the questions, particularly those assessing well-being and self-esteem, upsetting. When answering their questionnaires, the research team will ensure that students are seated so that other students cannot see their responses. The Year 9 questionnaire is similar to that used previously in a similar age group of adolescents in the SPEEDY[1] and ROOTS[2] studies.

Participants will be asked to wear a wrist-worn physical activity monitor for up to 7 days before collection the following week. An explanation regarding monitor use will be given, as well as an information sheet for participants. Some participants may feel uncomfortable about wearing the monitor which is a small, watch-sized device that is worn on a strap around the wrist. We have successfully used accelerometers to objectively measure physical activity in a large sample of Year 9 participants in Norfolk schools in the SPEEDY-3 study.

All study measurements will be done so that no other students can see the results of measurements and no information will be vocally repeated during the sessions. If participants request details of their anthropometric measurements, they will be shown the written values of height, weight, and body fat percentage. No routine feedback will be given to participants. We

will ensure that all provided data will be treated as confidential and stored securely. Electronic data is held on secure computer systems with at minimum password access and all identifiable data will be held on a separate computer system with access limited to appropriate staff by group and password permissions. Data will only be accessed and used by study specific staff of the MRC Epidemiology Unit/CEDAR at the University of Cambridge or by persons under the direct control of the Chief Investigator. Personal data will be stored and accessed up to 20 years after study completion.

2. Prior work

2.1 Development study

For the *development of the GoActive intervention and trial*, we conducted focus group interviews with 4 teachers and 26 16-18 year-olds in 2013. We used an older age group than the target age for the GoActive intervention as we hypothesised that if older adolescents like programme ideas, they may be especially likely to appeal to younger adolescents, as shown for substance use and sexual activity.[29, 30] Additional interviews with adolescents identified as high shyness and low activity focused on the development of an intervention that appeals to all adolescents including those with high shyness and low physical activity who may be less likely to engage with physical activity promotion programmes. The following *intervention components* were identified: choice, novelty, mentorship, competition, rewards, flexibility and teacher involvement. Together with existing evidence, this work forms the basis for the GoActive intervention (described in detail in Section 7) and aided the development of a hypothesised *logic model* (Figure 1).[31]

2.2 Feasibility study

In the Summer term of 2013, we conducted a *feasibility study* in a large Cambridgeshire secondary school (234 Year 9 students). We tested the feasibility of study recruitment and consent procedures, and implemented the intervention across Year 9. All Year 9 students were exposed to the intervention and 82.4% were recruited to the evaluation. Process evaluation questionnaires and focus groups with teachers and Year 9 students indicated that the intervention was generally positively received. As a result of feasibility testing, more emphasis was put on the inclusion of Mentors and weekly Peer-Leaders for the delivery of the intervention, the GoActive website was developed and the measurement procedures were streamlined.

2.3 Pilot cluster-randomised controlled trial

In Autumn term 2013/Spring term 2014 we conducted a *cluster-randomised controlled pilot trial* in 3 schools (2 intervention) (ISRCTN31583496). The aim was to assess preliminary effectiveness and to test full study procedures, including the measurement logistics, randomisation, and training of intervention deliverers outside of the research team. Focus groups with teachers, mentors and intervention deliverers enabled further refinement of the

GoActive intervention. Measurements were conducted at baseline and 6-8 weeks after baseline.

Recruitment and retention: Across the three pilot schools, 596 Year 9 students were invited to participate in the evaluation of GoActive; 463 provided valid written consent and were measured (78% response rate, average n=154/school). Non response was due to parental opt-out (N=29, 4.9%), student negative consent (N=8; 1.3%) and non-attendance of measurement visit (N= 96; 16.1%). 86% of baseline participants attended the follow-up measurement and completed questionnaire-based measures; 58% of participants providing baseline objective physical activity data were available for analysis (N=220).

Process evaluation with mentors, teachers and intervention facilitators was largely positive. 71% of boys and 74% of girls agreed that taking part in the intervention was ‘fun’; 56% (boys) and 69% (girls) said that it encouraged them to do more activity and 38% (boys) and 32% (girls) said that it gave them more confidence. Moreover, 61% of intervention participants indicated it fairly likely that they would continue with an activity they had tried during GoActive (64% boys, 59% girls). Participant focus groups revealed occasional sex-imbalance in activity choices, and with that differential motivation to participate. Of those who had been involved as Peer Leaders, 81% reported that they thought that was ‘fun’, and 55% that it had ‘improved their leadership skills’. In focus groups, mentors indicated that although they found it difficult “to get their head around” the GoActive intervention, they quickly picked it up and enjoyed it. Useful suggestions for improvements were made regarding electronic points collection, ‘Quick Card’ explanations and tutor involvement, which will be incorporated in the full trial. The *results* of this pilot trial provide an indication of the potential effect of GoActive on the main outcome measure (Table 1, proposed primary outcome in bold).

Table 1: Average daily minutes in ActiGraph-derived MVPA by study group at baseline and post-intervention, and preliminary intervention effect of GoActive pilot trial.

	Control (SD)	Intervention (SD)	Difference adjusted for baseline (SE)
MVPA (baseline)	48.6 (15.4)	51.9 (15.3)	
MVPA (post-intervention)	42.1 (15.0)	49.4 (18.2)	
MVPA (change)	-6.5 (14.0)	-2.5 (15.4)	5.1 (2.1) p=0.014

MVPA: Minutes in moderate-to-vigorous physical activity; SD: Standard deviation; SE: Standard error

School-level clustering is not taken into account due to insufficient clusters.

2.4 Lessons learnt from prior work and resulting modifications to project design

- To facilitate efficient intervention delivery, we will provide more intensive initial support to help tutors/mentors/peer leaders **familiarise** with the intervention.
- To encourage a balanced choice of activities of interest to both sexes, a **male and female Peer Leader** will be appointed each week.
- Further development of the **website** platform to enable electronic submission and tracking of points.
- Despite high retention, the number of participants available for analysis of the main outcome was lower than expected, predominantly due to difficulties with **monitor wear and return** at follow-up. Feedback from the pilot also revealed that two measurement sessions in relatively quick succession (2-3 months apart) affected students' commitment to wearing the accelerometer. The measurement protocol has been revised to allow more time between measurements and enable intensified research team involvement in return. Moreover, incentives will be offered to encourage monitor wear and return.
- We scheduled one measurement day per school, and non-attendance on this day affected recruitment and retention. The revised measurement protocol allows for a **minimum of 2 measurement days** per school, minimising the impact of non-attendance.

3. Aims

The overall objective is **to assess the effectiveness of the GoActive intervention in increasing daily MVPA in 13-14 year-old (Year 9) adolescents and to establish its cost-effectiveness**. We will evaluate GoActive in a two-arm cluster randomised controlled trial in 16 secondary schools, ensuring a mixture of socio-economic status to represent national variability.

The **specific aims** of the project are:

- 1) To assess the post-intervention (T3) and 10-month (T4: primary outcome) effectiveness of the GoActive programme to increase average (including weekday and weekend) daily objectively measured MVPA among 13-14 year-old adolescents.
- 2) To assess the effect of GoActive on the following secondary outcomes:
 - a. Objectively assessed activity intensities during school time, weekday evenings and weekends (sedentary, light, moderate and vigorous activity); including change in intensity distribution
 - b. Student-reported physical activity participation, self-efficacy, peer support, group cohesion, self-esteem, friendship quality (proposed mediators), and well-being, and school-level attendance and academic performance;
 - c. Body composition (body fat percentage and BMI z-score).
- 3) To assess short term (within-trial) and potential long term cost-effectiveness of the programme.
- 4) To assess programme acceptability, facilitators, barriers, uptake, maintenance and dose.
- 5) To investigate potential moderation of intervention effects by sex, socio-economic status, ethnicity, baseline activity level and weight status, and to explore potential mechanisms of effect by proposed mediators using a mixed-methods approach

4. Research design

4.1 Overall design

We will conduct a two-arm school-based cluster randomised controlled trial primarily assessing whether the GoActive intervention increases daily MVPA in 13-14 year-olds at 10-month follow-up (primary outcome). After baseline measurements, schools will be randomly allocated to deliver the GoActive intervention to the whole of Year 9, or to a no-treatment control group. This is because we will endeavour to follow-up these adolescents at a later date and therefore, we do not want to compromise the potential of long term follow-up in this sample. This protocol will be conducted and reported in accordance with SPIRIT guidance (Standard Protocol Items: Recommendations for Interventional Trials)[32-34]. Participant data collection will occur at baseline (T1), 6 weeks (T2), 14-16 weeks (T3) and 10 months (T4; main outcome). Cost-effectiveness will be assessed and a mixed-methods process evaluation will explore intervention acceptability, barriers and facilitators to participation and maintenance, ideas for improvement and potential mechanisms of effect.

4.2 Monitoring of risk and potential discontinuation

The declining physical activity among British adolescents represents a major public health challenge. GoActive aims to increase adolescent physical activity levels and therefore has the potential to improve health in adolescence and adulthood.

Risk assessments indicate that participation in GoActive is unlikely to be harmful to participants.

Reducing risk

The following procedures will be used to ensure that the potential risk for participants and mentors is minimal:

- 1) All example activities available as part of the GoActive programme have risk assessments clearly included on their descriptions
- 2) Mentors will be trained to complete weekly risk assessments and to have these reviewed and signed off by teachers:
 - a. Mentors and tutors will be encouraged to complete these risk assessments prior to the introduction of any new activities to Year 9 students to ensure that all risks have been identified and can be dealt with appropriately.

- b. In cases where medium-to-high risks are identified, continuation with the activity is to be decided upon in communication with the school and study team.
- c. Mentors, teachers and students are encouraged to report any instances of harm or dis-benefit to the school, who will take appropriate action in liaison with the study team;

Monitoring adverse events

Adverse events will be monitored by:

- 1) Tutors will be trained to keep a weekly adverse events log during the GoActive programme delivery sessions and will send a completed serious adverse events monitoring form to the project manager if a serious adverse event occurs (e.g. they hear about or experience during the sessions a death, hospital admission, fall or injury requiring prolonged medical attention).
- 2) At the beginning of the GoActive intervention programme, school contact teachers will be provided with contact details of the Project Manager for reporting to the MRC Epidemiology Unit any adverse events occurring during the research period (e.g. newly diagnosed medical condition, hospitalisation, and injury requiring prolonged medical attention.) A reminder will be provided at the (T4) follow-up.
- 3) The Project Manager will report all adverse and serious events to the PI, the Project Group and the Trial Steering Committee.
- 4) We will record any evident or potential harms (e.g. bullying by or of a mentor) and report these to the school contact. We will provide school contacts with details of the Project Manager to report any incidents which they believe to be study-related for recording.

Focus groups with participants after the programme will explore any adverse outcomes.

5. Study population

Target setting: 16 secondary schools with Year 9 students. The study will be conducted in all-ability, mixed-sex, non-fee-paying (state) secondary schools including Year 9 students in Essex and/or Cambridgeshire, UK. We will recruit 16 secondary schools with a mixture of socio-economic status and academic performance representative of UK variability.

Target population: 2400 Year 9 students (13-14 year-olds). All Year 9 students (13-14 year olds) in participating schools will be eligible to participate in study measurements. As in feasibility and pilot work we plan to include disabled participants after discussion with schools. This is appropriate due to the inclusive nature of GoActive and to avoid stigmatisation of any groups within schools.[16] Therefore, no exclusion criteria will be applied.

The intervention targets Year 9 students; we have previously shown that their activity levels are declining and generally insufficient.[1] They are also at a level of maturity that enables them to provide student assent, and have a relatively low testing/examination burden (as opposed to Years 10/11).

- *Consent for study participation:* All students in Year 9 in recruited schools will be eligible to take part in both the trial and the intervention programme as run by the schools. We will seek **passive parental consent** and **written student assent** for Year 9 participation in study measurements. Obtaining student assent to participate is sensitive to the increasing autonomy at this stage of adolescence. We have previously obtained ethical approval for this approach in both feasibility and pilot work. Parental opt-out responses ranged from 2 (<1%) to 18 (7%) in feasibility/pilot schools with 72-88% of eligible students assenting to participate. Recruitment rates using this strategy are substantially higher than previous UK-based research in this age group using parental opt-in consent (23% of eligible participants),[1] therefore increasing the external validity of the research.

- *Intervention participation:* The recruited (intervention) schools agree to run GoActive with all Year 9 students. Schools encourage all students to participate irrespective of student participation in study measurements. In the feasibility/pilot work teachers reported **100% student participation in intervention activities** during school time with 80% students returning intervention points to intervention staff.

- *Inclusivity:* Parental passive consent and school-level intervention delivery ensures that we reach as many students as possible, including those who do not usually take part in physical activity promotion (including girls, those with low activity levels or high shyness).

5.1 Socioeconomic position and inequalities

We will consider socioeconomic and health inequalities in our sampling strategy, intervention delivery and analyses:

- As mentioned above, schools will be sampled to ensure a mixture **representative of UK variability**. The average number of pupils obtaining five A*-C grade GCSEs (including

English and Mathematics) in 2012 was 56.9% in Cambridgeshire and 58.6% in Essex (national average: 58.6%).

- In 2012, secondary schools in Cambridgeshire had an average of 9.2% of pupils receiving free school meals, this was 10.1% in Essex; the national average in 2012 was 14.8%.
- To aid representativeness we will invite all-ability, non-fee-paying (state) secondary schools including Year 9 students in Essex and/or Cambridgeshire, UK. We will not approach private (fee-paying) schools.
- We will utilise our existing local networks and school contacts to facilitate school recruitment but if we do not successfully recruit 16 schools from Cambridgeshire (there are currently 31 eligible schools within the county), we will approach schools from the neighbouring counties. There are 50 eligible schools in Essex and due to links with Essex County Council and Active Essex, we plan to approach schools in Essex if we are not able to recruit sufficient schools in Cambridgeshire.
- All Year 9 students within participating schools will be invited and our pilot research has shown that participants come from a wide variety of socioeconomic backgrounds. GoActive has been designed **to include and be attractive to all students** but to be particularly appealing to students with low activity levels, high shyness and low friendship quality (irrespective of sex, ethnicity or socioeconomic background). Previous feasibility and pilot testing has shown that it has high acceptability among school students and teachers, and we have successfully included disabled participants after discussion with schools.

The inclusive design of the GoActive intervention increases the likelihood of affecting all students and enabling the identification of subgroups for whom this approach may be particularly effective. We will conduct pre-specified (but not sufficiently powered) **subgroup analyses** to establish differences in intervention effect, using pre-specified moderator variables (sex, socio-economic status, ethnicity, baseline activity level, weight status).

6. Planned interventions

6.1 GoActive intervention

The development of the GoActive intervention with supporting rationale has been described in detail previously [31].

The intervention is titled “GoActive” which stands for “Get Others Active”. Briefly, each Year 9 class (tutor group) chooses two activities each week: 19 example activities are currently available, utilising little or no equipment, and appealing to a wide variety of students. These activities are:

- American Touch Football
- Athletics
- Boxing
- Dodgeball
- Football
- Hula Hoop
- Juggling
- Kabaddi
- Kickball
- Pilates
- Rounders
- Skipping
- Softball
- Tennis
- Tug of War
- Ultimate Frisbee
- Volleyball
- Walking
- Yoga
- Zumba

Materials available on the GoActive website include activity instructions (Quick Cards) which offer an overview of the chosen activity, a short explanation, suggestions for adaptations, and provide advice, safety tips and ‘factoids’. GoActive is implemented using a tiered-leadership system where Mentors (older adolescents within the school) and Peer-Leaders (within each

class) encourage students to try these activities each week. The Mentors remain paired with each class for the duration of the intervention whereas the Peer-Leaders (two per class each week, one male and one female) change every week. Teachers are encouraged to use one tutor time weekly to do one of the chosen activities as a class, however, students gain points for trying these new activities at any time in or out of school. Points are gained every time they try an activity; there is no expectation of time spent in the activity as points are rewarded for the taking part itself. Individual students keep track of their own points privately on the study website and their points are entered into the between-class competition so that each class competes against each other. Class rankings are circulated each week to encourage teacher support and students receive small rewards (such as frisbee, water bottle) for reaching points thresholds (such as 20/50/100). As GoActive runs on a weekly cycle, the length of the intervention can vary as appropriate for each individual school but will run for two terms during the RCT. In addition to the student leaders, a council-funded intervention facilitator will support the programme during the first term of delivery and will provide reduced support thereafter.

The description of the intervention provided below follows the TIDieR guidance[35]. Although not based on one specific psychological theory, various behaviour change techniques are used in the programme, Table 2 describes the behaviour change techniques used.[36]

Name: Get Others Active (GoActive)

Why: GoActive aims to increase physical activity through increased social support, self-efficacy, self-esteem and friendship quality (Figure 1). The following describes the key themes of GoActive, and how they are implemented.

- **Choice and Novelty:** Adolescents given an activity choice have better programme attendance.[37] Choice may improve intrinsic motivation, self-efficacy and self-esteem, important for long-term activity maintenance.[38, 39] Introducing adolescents to new activities is important; those given the opportunity to try new activities are more likely to want to do more.[1]
 - Each tutor group chooses two different activities weekly; 19 example activities are currently available, utilising little or no equipment, and appealing to a wide variety of students (incl. Ultimate Frisbee, Zumba and Hula Hoop). Materials available on the GoActive website include activity instructions (Quick Cards).
- **Mentorship:** Peers are crucial for adolescents to attain the best health behaviours in the transition to adulthood.[7] Cross-age mentorship can successfully improve adolescent health behaviours e.g. substance use,[30, 40] sexual health[29] and nutrition[41] but is understudied in physical activity research,[42] particularly in young people.[43]

- GoActive aims to increase peer support through the introduction of a mentorship scheme in which older adolescents in the school (Mentors, Year 10 or 11) are paired with each Year 9 tutor group and encourage them to participate in the chosen activities.
- Year 9 in-class leaders (Peer Leaders) from both sexes are elected each week to assist Mentors.
- **Competition and Rewards:** Competitions and rewards improve engagement and retention in health promotion,[44] and reward-based interventions appear effective in improving weight management behaviours in children.[45]
 - Students gain points every time they try an activity; there is no expectation of time spent in the activity as points are rewarded for the taking part itself. All activity participation generates points. Individual points are private for personal achievement; class totals are announced to encourage inter-class competition, encouraging peer support and increased friendship quality. Students can enter points on the programme website with individual login details.
 - Students receive small rewards (e.g. frisbee, water bottle) for reaching points thresholds (e.g. 20/50/100); classes/tutor groups receive rewards for achieving highest weekly points score.
- **Flexibility:** A range of co-participants, timing and locations for activity are preferred by Year 9 adolescents with preferences differing on an individual level.[1]
 - During feasibility/pilot work, one tutor time weekly was used for activity; students were additionally encouraged to participate at other times both at and outside of school.

What (materials): GoActive uses activity 'Quick Cards', which offer an overview of the chosen activity, a short explanation to help students familiarise, and suggestions for adaptations, and provide advice, safety tips and 'factoids' to increase interest and motivation. 19 example activities are provided but students can choose any activity they want; options to design their own 'Quick Cards' for peers will be offered at the end of the 'facilitated' intervention phase in Term 1. These student-designed quick cards will be submitted to the intervention facilitator, where they will be reviewed by the Chief Investigator, and edited if necessary, before being uploaded to the 'For schools' section of the GoActive website. Equipment will be provided where possible. Rewards and prizes (for example, GoActive branded Frisbees and sports bags) are awarded to encourage participation. Each activity will have a short video-clip available on the password protected intervention section of the study website for use in tutor time. These videos will provide a brief explanation and examples of each activity. They will serve as a reminder of the intervention as well as providing standardised and easy-to-use intervention materials for teachers and mentors.

What (procedures): Each week, each tutor group selects two new activities and students are encouraged by the Mentors and Peer Leaders to try at least one within a specified period (usually one week). Points are rewarded for trying the activity, irrespective of time, location and activity partners; engagement in other activity throughout the week is also rewarded. Students and mentors enter points online and report back to facilitator. Points are also entered into a between-class competition. Students are encouraged to try new activities by their form teachers, Mentors and Peer Leaders. The facilitator will encourage Mentors to model the behaviour, discuss their experiences and to organise an activity session for the whole group to engage in the activity.

Table 2: Behaviour change techniques[36] applied in the GoActive intervention.

<i>Behaviour Change Technique</i>	<i>How?</i>
1.1 Goal setting (behaviour)	Group sets goal to try two new activities. Mentors encourage students to plan when and with whom they will try the activity
2.3 Self-monitoring of behaviour	Students record their participation in weekly new activities by entering points online
3.1 Social support (unidentified)	Mentors, peer-leaders, tutors and peers provide encouragement and support
4.1 Instruction on how to perform behaviour	Quick Cards and Mentors provide activity instructions/tips
6.1 Demonstration of the behaviour	Mentors are encouraged to model the behaviour; Quick Cards show adolescents engaging in the behaviour.
6.2 Social comparison	Points are awarded for trying activities. Anonymised individual points ranking will allow individual-level comparison; class-level competition will be open via leader boards
10.1 Material incentive (behaviour)	Students will be informed of the GoActive reward system
10.2 Material reward (behaviour)	Students will be rewarded for obtaining points; classes will be rewarded for leading the leader board
10.4 Social reward	Rewards are given out in front of peers; trophy awards (e.g. Development Award) are handed out at full year assembly at programme end
10.5 Social incentive	Students are informed that verbal praise will be provided
12.2 Restructuring the social environment	A regular short (~20 minutes) intervention session is incorporated into the school timetable

13.1 Identification of self as role model	Weekly elected Year 9 Peer Leaders act as role models; they support and encourage fellow students to try the chosen activities
14.9 Reduce reward frequency	Students receive individual rewards on reaching milestones (20/50/100 points)

Who provided: The tiered leadership structure of GoActive encourages Mentors and Peer Leaders to primarily deliver the intervention, supported by teachers and a council-funded intervention facilitator taking responsibility for facilitating programme delivery (funded by Cambridgeshire County Council). Facilitators in pilot work required 2hr/week per school in addition to training and administration tasks; a part-time post is therefore sufficient for the proposed trial. Schools are responsible for recruiting Mentors with an appropriate skill set and attitude. Mentors will be trained by the facilitator; initial training will focus on intervention delivery and problem solving. They are additionally provided with brief, simple and ready-to-use intervention materials for every day of the week which require no preparation. This distances researchers from intervention delivery to Year 9 students to make it more appealing to students; [43, 46] mentorship also increases self-efficacy and support for physical activity [42]. Limited external facilitation also increases the feasibility of future potential programme roll-out.

How: The facilitator will receive a training manual and all aspects of the GoActive intervention will be discussed in detail at a one-day training session. The facilitator will subsequently provide training for the Mentors (during a one-day training session), meet regularly with Mentors during the facilitated intervention phase to discuss progress and work out solutions to any problems. After this, support will predominantly be provided via telephone and email. Mentors then deliver the intervention during tutor-time, as well as spontaneously throughout the week. In feasibility and pilot testing, GoActive has been successfully implemented by schools with traditional form structures (Year 9 tutor groups include only Year 9 students) and with vertical forms (tutor groups contain students from all year groups). The flexible nature of GoActive means that it fits within existing school structures and focuses on mentorship, which is increasingly popular within schools.

Where: 16 secondary schools (Year 9) in Essex and/or Cambridgeshire.

When and how much: Core intervention elements are delivered once per week (choose activity, points feedback, leadership board, rewards, Mentor support), but Mentors, Peer Leaders and tutors/teachers are encouraged to provide encouragement and social support throughout the week. During the first term, Mentors are encouraged to meet with the

facilitator weekly. For the following term, the school will be encouraged to run the programme with limited outside facilitation. This allows for establishing the ability of the programme to run without outside input to better inform feasibility of potential dissemination.

6.2 Control condition

The control group will receive no-treatment or 'usual care', and no intervention will be implemented. Control group schools will not be able to access intervention sections of the GoActive website (which will be password-protected). This is because we will endeavour to follow-up these adolescents at a later date. If we were to offer the control group the intervention after follow-up measures, it would prevent us from potentially assessing longer term impact of the programme.

7. Methods

7.1 Recruitment and randomisation

All all-ability, co-educational, non-fee-paying (state) secondary schools with Year 9 students within Cambridgeshire and Essex are eligible to participate. The decision regarding which county schools will be invited from depends on confirmation of council funding for the intervention facilitator. Invitations will be sent to Head Teachers, Year 9 leaders, and Physical Education leaders of eligible schools within Cambridgeshire and/or Essex; this invitation will describe the study and will invite participation. The school will be contacted by phone by the research team approximately two weeks after sending the invitation to request a meeting to discuss the study and to request consent. If we do not successfully recruit 16 schools from Cambridgeshire we will approach schools from the neighbouring counties (e.g, Essex); we will utilise our existing local networks and school contacts to facilitate school recruitment but. Schools who do not agree to take part will be asked to select the most relevant reason for their refusal from a pre-determined list:

- Lack of interest in the study
- Staff too busy to be involved
- Concerns over measurement
- Would not want to be randomised to a control school
- Other (please specify)

To reduce school level attrition, school involvement will be made clear at the start; in case of school drop-out prior to randomisation, new schools will be recruited. The Head Teacher is requested to allow four measurements with Year 9 students and to run the GoActive programme if randomised to the intervention group. Participating schools will receive £200 of sports equipment and will be offered aggregate feedback on the school's results upon completion of the study. Using these procedures, our pilot trial has demonstrated feasibility to recruit and randomise schools.

At consenting schools, all Year 9 students and their parents will receive invitation packs with information regarding the study and invitations for students to participate in study measurements. In addition, all potential participants will be directed to the study website, which houses general information about GoActive, and a video explaining the intervention.

Passive parental consent

As approved by the ethical committee for feasibility and pilot work, parents will be asked to provide passive consent (active opt-out consent) for their child to take part in the study measures. We will give parents at least two weeks to respond. Additionally we will send parents a reminder a week after the first contact, in order that they are prompted to respond before any measurements have taken place. In these communications, parents will also be told the final date by which they need to respond for their son/daughter to be excluded from the study. Parents will be given the option to phone or email the study team in lieu of returning a form to facilitate parents' ability to respond. Reminders and information about the study would additionally be included in all relevant school media, including newsletters and emails and the usual reminders sent from the school. These processes should ensure that all parents are well informed about the study and have adequate chance to respond.

Written assent will be obtained from the students by research assistants trained in Good Clinical Practice prior to any baseline measurements taking place. We will ask form tutors to advise us of any students who may need additional assistance in understanding the procedures and participant information sheet (e.g. due to a learning disability), GoActive should be fully inclusive for students capable of assent but if the school feels any students should not be included for some reason we will respect this. Following this protocol, an average recruitment rate of 78% was achieved in pilot work.

Randomisation will occur after baseline measurements are completed. Eight schools will be randomised to deliver the GoActive intervention and eight to a no-treatment control condition. Schools will be stratified based on county medians of Pupil Premium (proxy for socio-economic status) and a statistician will prepare randomisation lists to ensure a balance of socio-economic status between groups. If schools are recruited from different counties then we will ensure an even balance of control and intervention schools from each county. When a school has completed baseline measures, they will be randomised. This will provide intervention schools with as much time as possible to prepare for delivering the intervention while still allowing randomisation to occur after baseline measurements. The recruited (intervention) schools will run GoActive with all Year 9 students.

7.2 Measurement procedures

Measurements will be conducted at four time points by trained researchers; (T1) **baseline**, pre-randomisation (T2) **interim assessment** (week 6), (T3) **post-intervention** (week 14-16), and (T4) **10-month follow-up (primary outcome)** (see Figure 2). The main measure of intervention effectiveness will be change in accelerometer-measured average daily objectively-measured MVPA at 10-month follow-up (T4). Measurement sessions will be

scheduled after discussion with participating schools to minimise disruption and take account of school events and exams. All primary and secondary outcomes will be assessed at T1, T3, and T4; T2 will focus on assessing the questionnaire-based measures (including self-reported physical activity and mediators of change). This protocol reduces measurement burden on participants and staff, increasing the likelihood of high retention for the main outcome measure, but enabling the assessment of causal pathways and intermediate outcomes. Intervention and control schools will be measured simultaneously to minimise seasonal influences. Trained staff will measure anthropometry following standardised operating procedures; participants will complete a questionnaire about secondary outcomes/potential mediators/moderators. We have successfully used this process in feasibility/ pilot work, measuring up to 250 participants in one day with seven research staff. In order to assess acceptability of the current protocol, a practice measurement day will be conducted in a non-trial school prior to baseline measurements.

To prevent artificially inflated school-level clustering (due to weather conditions or school events) and facilitate recruitment and retention, measurements will be staggered over ≥ 2 measurement sessions at each school using a predetermined schedule. In addition to three grant-funded research assistant staff, we have agreement that additional research assistant staff from the MRC Epidemiology Unit will be available to assist on measurement days at large schools.

Baseline measurements will be conducted pre-randomisation, however, after allocation it will not be possible to blind participants to their study condition as the intervention group will receive the GoActive intervention. Measurement staff will be blinded to the intervention condition; they will be trained by the field epidemiology team at the MRC Epidemiology Unit, and will remain separate from the intervention delivery team. Process evaluation with the measurement team will assess the success of blinding.

Accelerometry – primary outcome

At the end of sessions T1, T3 and T4, participants will be asked to wear a wrist-worn accelerometer for seven days. The validity of accelerometry to assess adolescent physical activity has been demonstrated previously [47]. To optimise accelerometer-wear compliance, we have developed a monitor wear and return protocol which is led by researchers (and not teachers) and includes an incentive. Strategies will include reminders to wear the monitor (e.g. via student email, teacher reminders, materials placed around the school), researcher presence on the day of scheduled monitor return allowing immediate incentive hand-out, and regular follow-up visits. We will also remain in contact with participants in-between measurements through newsletters and email updates via the school. We have previously

successfully applied these strategies in adolescent cohorts to obtain high levels of valid accelerometry data (ROOTS: 825/930 - 89%[2]; SPEEDY-3: 428/480 - 89%[1]). We also received feedback during the GoActive feasibility and pilot work that two measurement sessions in relatively quick succession (2-3 months apart) affected students' commitment to wearing the accelerometer so this measurement protocol allows more time between measurements. This has the added benefit of freeing up time for the research team to focus on monitor return. Throughout the project, we will continuously monitor response rates and take appropriate action if it drops below 70% for the primary outcome. In cases where participants do not return their accelerometer after frequent requests, they may not be issued a monitor at subsequent measurements based on the study team's opinion of their likelihood of losing another monitor, but will be allowed to continue their participation in the study and all other (secondary) measures. We deem this appropriate as sample size calculations indicate that we will retain 95% power should retention drop to 55% (80/150).

The primary outcome of average daily minutes of objectively measured MVPA will be derived from accelerometer data. The accelerometers sample continuous waveform data. Participants will be advised to wear the devices on a strap on their non-dominant wrist, continuously for seven consecutive days, (including when in water and when asleep).

Data from the accelerometers will be downloaded. Non-wear time will be removed, using a criterion of consecutive runs of zero counts for a minimum duration of 60 minutes. Remaining data will be included if accelerometer wear time ≥ 480 mins, on at least two days. Cut-points comparable to those used previously for ActiGraph accelerometers will be used to classify time spent sedentary (equivalent to ≤ 100 ActiGraph cpm), or in light (equivalent to 101 - 1999 ActiGraph cpm), moderate-vigorous (equivalent to ≥ 2000 ActiGraph cpm) or appropriate vector magnitude equivalents. Monitor output will be visually reviewed prior to analysis to confirm that these decisions are appropriate for the population. Prior to analysis we will consult physical activity measurement experts to ensure we can be aware of relevant new methodology and apply where appropriate.

Anthropometry

Trained staff will measure height and weight, and waist circumference following standardised operating procedures. Body fat percentage will be calculated from bio-electrical impedance, age- and sex-specific BMI z-score will be calculated from height and weight. Quality checking of researchers' anthropometry measurements will be conducted prior to baseline measurements and before 10-month follow-up.

Questionnaires

At each measurement session participants will complete a questionnaire concerning secondary outcomes/potential mediators/moderators and items to monitor any adverse intervention effects. These questionnaires have been validated, and used previously in adolescent cohorts. Physical activity type will be assessed using the 30-item Youth Physical Activity Questionnaire (YPAQ), which has previously been validated in 12-17 year olds.[48] Self-efficacy[49] and social support for physical activity[50] will be assessed using two scales (each with 3 items). Further items include friendship quality (8 items)[51], wellbeing (14-item Warwick-Edinburgh Wellbeing scale),[52] self-esteem (10-item Rosenberg Self Esteem Scale)[53], group cohesion (participants will be provided with a list of members of their tutor group and asked to select names of their friends), and shyness and sociability (two 5-item measures from EAS temperament scale)[54] and overall health related quality of life (9-item Child Health Utility instrument, CHU-9D).[55] Questionnaires will be completed in a large open space on the school premises (e.g. sports hall, assembly hall) under examination conditions wherever possible (i.e. participants will not be able to see or discuss the responses of others). Questionnaires will be checked for completion before the end of the measurement sessions and participants will be asked to complete any missing items. We will also collect school-level attendance and academic performance data (from National Pupil Database - publicly available).

7.3 Process evaluation

Intervention process data will include mixed-methods assessment of student, mentor and teacher experiences and perspectives on intervention delivery, feasibility, acceptance, and barriers/facilitators to participation. Uptake, maintenance, dose will be established using the points entries on the study website, download statistics for intervention materials and mentor reported participation. Given the purposeful flexible, spontaneous and informal nature of the intervention (mentors/leaders attend the same school and can therefore encourage/motivate Year 9 students at any time during the week), observation of intervention delivery is not deemed feasible. However, existing and emerging school practices which may affect students' physical activity behaviour will be documented and monitored in a structured manner using checklists.

Facilitator and mentor logs

We will include a GoActive logbook for the intervention facilitator and mentors to assess frequency of intervention delivery, and a checklist to monitor existing and emerging school practices related to physical activity (housed on the GoActive website, and to be completed electronically). The facilitator and mentors will be responsible for completing weekly logs online specifying the intervention activities chosen by each class, the facilitation support they provided and the costs and time required for the intervention plus any other comments or information deemed valuable. Members of the study team will review these comments on a

weekly basis, follow-up where necessary and send reminders for completion of logs where necessary.

Process Questionnaires will be administered at T2 and T3 for (intervention and control) participants, mentors, and form teachers. Control participants will also be asked to complete process questionnaires to determine possible contamination.[56]

Semi-structured focus groups after the facilitated intervention phase will be conducted with representatives from all relevant intervention groups (Year 9 students, mentors, and teachers) in each intervention school and will focus on all aspects of intervention delivery, feasibility and acceptance, and barriers/facilitators to participation. Each focus group (separate for students, mentors, and teachers) will comprise 3-8 individuals with two facilitators. Students will be purposively sampled to ensure a mix of sex and ethnicity, and grouped by level of participation and physical activity. A topic guide will be developed and updated as new issues and themes emerge; participants will be encouraged to discuss additional issues. Issues arising will be incorporated into the next round of questionnaires and subsequent focus groups so that additional mechanisms of change can be investigated.

Subsequent interviews with a purposive sample of inactive and shy participants at intervention schools will provide a deeper understanding of their intervention views and experiences and barriers/facilitators to participation (we anticipate these individuals will be more comfortable participating in one-to-one interviews). Interviews will be semi-structured using a flexible topic guide which will be expanded as data collection and analysis proceed.

At T4, additional semi-structured focus groups and interviews with students will explore maintenance of physical activity behaviour change, including who did/did not maintain physical activity behaviour change and why, did GoActive help and why/how, and what else helped or hindered physical activity maintenance. T2 participants will be re-invited, supplemented by additional students if needed. This gives us a unique opportunity to explore physical activity maintenance across time in the context of a trial and better understand barriers and facilitators to physical activity maintenance.

Students will be asked to indicate their willingness to contribute to a focus group or individual interview at T1; eligibility is subsequently based on the data collected at T1; eligible students and their parents will receive full information about process evaluation focus groups/individual interviews. As with the quantitative measures, passive informed parental consent and written informed student assent will be obtained. For mentors and teachers, full study information will be provided with at the start of the study and discussed fully with both groups. In order to

build on lessons learnt from the pilot study, where data were wasted due to consent forms not being returned, we will gain 'consent by questionnaire completion'. For mentors under the age of 16, we will use the same method of 'consent by questionnaire completion' with additional passive informed parental consent, as described for study measurements. In this questionnaire the students will be asked to agree to the focus group being recorded and the data being used in the study. Focus groups/interviews will take place on school premises; recruitment will be rolling until the research team agree that saturation of themes has been reached.

Participants will be informed that focus group and interview recordings will be transcribed verbatim by a transcription service company and made anonymous before any analysis occurs with names replaced by codes. Recordings will not be played back to anyone within the school and will only be checked by one study staff member before sending to the transcription company; therefore no one at the schools will hear the recordings. There will be no video used for these focus groups or interviews. Only anonymous comments will be included in any publications using this data.

School questionnaire

Schools will be given a questionnaire at baseline T1 and follow-up (T4) so that we can assess the school environment and any potential changes which may influence our results. This questionnaire will be based on one used previously in East of England secondary schools (SPEEDY-3 study) and will assess the school physical and social environment, culture and policy regarding physical activity. We will also ask for any organised events such as sports days or school trips which occur during the measurement period. We will ask the Physical Education leader within the schools to complete this in the first instance, and if not then another teacher nominated by the school.

Cost-effectiveness

To enable cost-effectiveness analyses, we will collect the following economic data during the intervention. This will include intervention-related facilitator time, travel, and expenses collected by schools/researchers. Quality adjusted life years (QALYs) will be calculated from the CHU-9D responses and converted to health state utilities using UK specific valuations [57]. Change in objectively-measured physical activity observed will be inputted into a previously developed model to predict longer term QALYS and cost and hence cost-effectiveness.

Data management and monitoring

Range checks for plausible data values will be conducted and all questionnaire data will be professionally double data entered. Data will be stored at the MRC Epidemiology Unit; the MRC Epidemiology Unit specialist teams will provide support for training, quality assessment and

quality control of measurements and this support will ensure that collection, processing, protection and management of data are timely and of high quality. We will ensure that all provided data is treated as confidential and stored securely. Where this is electronic data, it is held on secure computer systems with at minimum password access and all identifiable data will be held on a separate computer system with access limited to appropriate staff by group and password permissions. Data will only be accessed and used by study specific staff of the MRC Epidemiology Unit at the University of Cambridge or by persons under the direct control of the Principal Investigator. No interim analyses of study outcomes will be conducted. The data will not be used or given to any other third party without written permission of the participant. Personal data will be stored and accessed up to 20 years after study completion.

As the trial is not that of a medicinal product we will not have a formal data monitoring committee but the Trial Steering Committee (TSC) will receive regular reports from the investigators and will monitor trial conduct. The TSC will consist of an independent chair, one independent expert, two lay representatives (including a representative from educational sector) and at least two investigators. The study coordinator and a sponsor representative will be invited as observers. Minutes will be recorded and distributed to all members of the TSC (with occasional voice-recording to aid note-taking). The TSC will meet 1x/year, or more frequently if needed. The TSC is responsible for communicating any issues of concern to the Sponsor, specifically where the integrity of the study or data or patient safety could be comprised. The study coordinator will also monitor trial conduct and will report independently to the MRC Epidemiology Unit Clinical Research Manager twice per month. Potential harms will be monitored by the study team and will be reviewed by the study coordinator, Principal Investigator and Trial Steering Committee and will include reported adverse events e.g. injuries or psychological indicators such as well-being. While we do not expect harm as a result of the GoActive intervention or this trial, it is insured by the University of Cambridge who would provide compensation in case of harm.

The council-funded intervention facilitator will work closely with Mentors and research staff to monitor protocol adherence. Poor adherence will be discussed with the research team and TSC and strategies will be put in place if necessary. No activities are prohibited during the trial as students are expected to do their normal physical activities, including school PE.

Any protocol amendments will be proposed to the TSC and subsequently altered if necessary before submission to NIHR for approval. Protocol updates will then be uploaded to the NIHR website and trial registry if relevant.

The intervention will be delivered by a council-employed facilitator, as well as older Mentors and weekly Peer Leaders. Uptake, maintenance, dose will be established using the points entries on the GoActive website, download statistics for intervention materials and mentor reported participation. In addition, the facilitator and Mentors will be asked to keep log books to assess intervention fidelity. Given the purposeful flexible, spontaneous and informal nature of the intervention (mentors/leaders attend the same school and can therefore encourage/motivate Year 9 students at any time during the week), observation of intervention delivery is not deemed feasible. However, existing and emerging school practices which may affect students' physical activity behaviour will be documented and monitored in a structured manner using checklists.[58]

7.4 Proposed outcome measures

Outcome measures have been tested in feasibility/pilot studies.

The **primary efficacy outcome measure** will be accelerometry-assessed **change in average daily MVPA at 10-month follow-up**. Participants will be asked to wear a **wrist** worn accelerometer for seven days at T1, T3 and T4. Accelerometry has validity to assess adolescent physical activity[47]. Applicants have extensive experience with using accelerometers in adolescent populations and have established effective procedures to ensure monitor wear and return.[1, 2] The MRC Epidemiology Unit has extensive experience of processing data from activity monitors.

Secondary accelerometry outcomes will be change in average minutes spent in sedentary and light activity, as well as overall physical activity (counts per minute) during school, weekdays after school and at weekends. These secondary outcome measures are relevant to investigate because the age-related change in physical activity differs by intensity and time of week.[1] Change in intensity distribution between measurements will also be investigated.

The following outcomes will be assessed to identify any adverse intervention effects, and mediation of intervention effect. All questionnaires have been validated and used previously in adolescent cohorts:

- **Physical activity type** will be assessed using the 30-items Youth Physical Activity Questionnaire (YPAQ), which has previously been validated in 12-17 year olds.[48]
- **Anthropometry**: body fat% (from bio-electrical impedance), age- and sex-specific BMI z-score (from height and weight).
- **Self-efficacy**[49] and **social support for physical activity**[50] (both 3 items).

- **Friendship quality** (8 items)[51] and **group cohesion**[62] (participants will be provided with a list of members of their tutor group and asked to select names of their friends)
- **Well-being** (14-item Warwick-Edinburgh Wellbeing Scale),[52] **self-esteem** (10- item Rosenberg Self Esteem Scale)[53], and **shyness and sociability** (two 5-item measures from EASD temperament scale).[54] School-level **attendance and academic performance** (from National Pupil Database).

To enable cost-effectiveness analyses, we will collect the following **economic data**:

- Intervention-related facilitator time, travel, and expenses collected by schools/researchers.
- Quality adjusted life years (QALYs) gained using (9-item Child Health Utility instrument, CHU-9D)[55] converted to health state utilities using UK specific valuations.[57]
- Change in physical activity observed will be inputted into a previously developed model to predict longer term QALYs and cost and hence cost-effectiveness.

Qualitative data will include student, mentor and teacher experiences and perspectives on intervention delivery, feasibility, acceptance, and barriers/facilitators to participation.

Outcome	Assessment tool	T1	T2	T3	T4
<i>Primary: physical activity</i>					
Change in average daily minutes of moderate-to-vigorous physical activity	Accelerometry (7 day protocol)	○	○		○
<i>Secondary: physical activity</i>					
Change in average daily minutes spent in sedentary intensity activity	Accelerometry (7 day protocol)	○	○		○
Change in average daily minutes of light intensity physical activity		○	○		○
Overall physical activity (counts per minute) during school		○	○		○
Overall physical activity (counts per minute) during weekdays after school		○	○		○
Overall physical activity (counts per minute) at weekends		○	○		○
Change in intensity distribution		○	○	○	○
Physical activity type	Youth Physical Activity Questionnaire (YPAQ: 30 item)	○	○	○	○
<i>Secondary: anthropometry</i>					
Body fat %	Bioelectrical impedance (scales)	○	○	○	○
Age- and sex-specific Body Mass Index (BMI) z-score	Height (stadiometer) and weight (scales)	○	○	○	○
<i>Secondary: psycho-social</i>					
Self-efficacy	Items taken from Reynolds (Psychosocial Predictors of Physical Activity: Self-esteem: 10 item)	○	○	○	○
Social support for physical activity	Items taken from Ommundson (European Youth Heart Study: 3 item)	○	○	○	○
Friendship quality	Items taken from the ROOTS project (8 item)	○	○	○	○
Group cohesion	Adapted social network modelling tool (participants provided with a list of tutor group members and asked to select names of their friends)	○	○	○	○
Well-being	Warwick-Edinburgh Wellbeing Scale (14 item)	○	○	○	○
Self esteem	Rosenberg Self Esteem Scale (10 item)	○	○	○	○

Shyness and sociability	Early Adolescent Temperament Questionnaire (EATQ-R) (two 5 item measures)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Secondary: educational					
Attendance	National Pupil Database (school-level only)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Academic performance		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Secondary: cost-effectiveness					
Intervention-related facilitator time, travel, expenses	Log books completed by intervention facilitator and mentors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Quality-adjusted life years (QALYs), converted to health state utilities using UK-specific valuations	Child Health Utility instrument (CHU-9D: 9 items)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Secondary: process evaluation					
Perspectives on:		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Intervention delivery	Student, mentor, teacher focus groups (interviews where appropriate)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Intervention feasibility		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Intervention acceptance		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Barriers/facilitators to participation		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Secondary: process evaluation school factors					
School environment	Teacher-completed school questionnaire	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Events during measurement		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
School level demographics		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
School level activity policies		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

7.5 Assessment and follow up

Assessment of effectiveness

The **primary measure of intervention effectiveness will be change in average daily MVPA at 10-month follow-up**. The current evidence in adolescent physical activity promotion is limited by the lack of assessment at follow-up, whereas achieving sustained behaviour change is a key priority.[23] The additional inclusion of assessment of post-intervention effect will enable conclusions regarding trajectories of change (such as whether initial behaviour change was maintained), as well as testing causal pathways. We will endeavour to obtain consent to enable potential longer term follow-up (including obtaining GCSE results).

Assessment of harms

Overall, the GoActive intervention and evaluation are considered **low-risk, with high potential benefits**. We distinguish harms associated with intervention participation from harm associated with evaluation participation. Intervention-related harm will initially be reported to and dealt with by the school. GoActive comes with simple risk assessments that Mentors/tutors are encouraged to complete prior to the introduction of a new activity to ensure that all risks have been identified and can be dealt with appropriately. In cases where medium-to-high risks are identified, continuation with the activity will be decided upon in communication with the school and governors. All students are encouraged to report any instances of harm or dis-benefit to the school, who will take appropriate action in liaison with the study team; summary reports will be sent to the study team in an anonymised form.

The GoActive evaluation includes an assessment of potential harm and dis-benefit, including assessment of well-being, self-esteem, and academic performance indicators. Ethical concerns related to evaluation participation are discussed in section 9. A trial steering committee will be set up whose role will include the monitoring of potentially serious harm, advising on appropriate action and communicating concerns to the study sponsor and funder.

7.6 Proposed sample size

We aim to detect a **5-minute difference in mean change in MVPA/day at 10-month follow-up**, as observed in the pilot study. A 5-minute increase is relevant at population level as it would increase the proportion of adolescents meeting the guidelines of 60 minutes of MVPA per day from 43% to 50% (based on baseline data), with significant impact on population health.[28] To estimate the required sample size, the following parameters have been used: power=85%, significance level=5%, standard deviation=17.8 (observed in GoActive pilot), intraclass correlation coefficient=0.034 (observed in SPEEDY-3, N=57 schools),[1] correlation between baseline and follow-up MVPA=0.59 (observed in GoActive pilot, to account for adjustment for baseline MVPA), cluster size=100. Based on these parameters, we estimate N=1310 participants will be required for the primary effect analysis. To account for potential school drop-out and an estimated lost to follow-up of 30-40%, we aim to recruit 16 schools with 150 participants (total N=2400; average recruitment per school in pilot=154). Long-term participant retention will be facilitated by recruitment of as near to a whole Year group as possible with it being the norm to be involved in the study. Recruitment will be maximised with opt-out parental consent and multiple school-based measurement sessions.

7.7 Analytical procedures

Quantitative analyses

The primary analysis of efficacy will use an **Intention To Treat (ITT) population**, which includes all participants in the group to which they were randomised, regardless of the intervention received. A secondary analysis of the primary outcome only will use a **Per Protocol (PP) population**. Inclusion in the PP population will be based on the degree of usage of the intervention website / submission of points and will be defined once clean data are available (but before the start of any trial analyses), when the distributions of degree of usage of the intervention website/points submission can be inspected.

Main outcome analysis: The primary efficacy outcome, MVPA, will be compared between the intervention and control group using analysis of covariance (ANCOVA), with adjustment for baseline MVPA; robust standard errors will be calculated to allow of the non-independence of individuals within each school. Where baseline values of MVPA are missing, the missing indicator method will be used to enable these participants to be included in the analysis.[59] An estimate of the intervention effect, 95% confidence interval and p-value will be calculated. Baseline characteristics of individuals with missing MVPA data at 10 month follow-up will be summarised and compared with those of individuals who have follow-up MVPA. Pre-specified (but not specifically powered) *subgroup analyses* by pre-specified moderators (sex, socio-economic status (using Index of Multiple Deprivation), ethnicity, baseline activity level, weight status) will be performed for the primary outcome. The interaction between randomised group and each moderator will be tested, and if the p-value is <0.05 , the intervention effect and 95% confidence interval will be estimated within each subgroup. The effect on of the intervention on other secondary outcome variables will initially be estimated as described above, although only 95% confidence intervals, not p-values will be calculated. We will subsequently conduct formal *mediation analyses* using the product of coefficient method[60] to assess the underlying causal effect of the intervention.

Cost-effectiveness analyses

Cost-effectiveness analyses will follow good practice methods.[61] The main economic outcome will be the incremental cost-effectiveness ratio expressed as incremental costs per incremental change in objectively-measured physical activity (METs) and per QALY gained (based on CHU-9D) for the trial period (including follow-up). The analytic perspective will be that of the school / school funder. Data collected will include intervention time, travel, expenses, resource use and study-specific costs. In addition, if GoActive increases physical

activity, this should reduce adult chronic disease via changes in metabolic health outcomes (e.g weight/BMI, blood glucose). To establish whether GoActive could increase length and/or quality of life and at what cost, it is not practical to conduct lifetime follow-up, therefore we propose adapting an existing decision-analytic model to estimate the impact of physical activity on disease risk, quality-adjusted life expectancy (QALY) and cost [63]. This modelling study will be from the perspective of the public sector, defined as education and health care budgets.

Qualitative analysis

Focus groups and interviews will be audio recorded and transcribed verbatim. Data will be analysed using constant comparative analysis, facilitated by QSR NVivo. Coding will be inductive, incorporating emerging themes as well as topics presented a priori in the topic guide. Initial analyses will inform future data collection and analysis. Interim themes will be discussed by the research team to reach consensus.

Further analyses

The inclusive design of the GoActive intervention increases the likelihood of affecting all students and enabling the identification of subgroups for who this approach may be particularly effective. We will conduct subgroup analyses to establish differences in intervention effect, using pre-specified moderator variables (sex, socio-economic status, ethnicity, baseline activity level, weight status).

Further research questions can be addressed using the cohort data, including assessment of the predictors of activity maintenance, and the longitudinal association between physical activity/sedentary behaviour and a) academic performance; b) shyness and sociability; and c) friendship quality.

8 Dissemination

In addition to peer-reviewed publications, it would be appropriate to disseminate this programme to schools and councils nationwide. Dissemination plans will be developed in discussion with our public and patient involvement (PPI) panel and following deliberative dialogue workshops. Dissemination will be facilitated through the study website and could lead to a major public health impact.

Towards the end of the project a deliberative dialogue workshop will be held with parents, teachers, school governors and representatives from local/national government. Study findings will be summarised and this workshop will focus on how to present the results to the right people and next steps for programme dissemination. This will include discussing the necessity and process for adaptation to diverse settings and development of a tangible plan for dissemination to secondary schools. We will additionally discuss our results and dissemination strategy with a group of older adolescents. This will inform ways to increase appeal of the programme to a diverse population and how to best disseminate findings to our participants and other adolescents.

During the study, the study website will be developed to more efficiently disseminate intervention materials, study information and future results. This website will be updated so that schools can download everything required for the intervention from the website including instructions and materials. If the intervention is successful, it would be easily accessible for dissemination to schools and councils nationwide.

Informed by the deliberative dialogue workshop, we will develop an Evidence Brief to be disseminated to relevant public policy makers and members of the public through existing CEDAR networks and those of stakeholders involved in the project.

9. Ethical arrangements

Ethical approval for the conduct of the study will be sought from the Cambridge Psychology Research Ethics committee, who previously provided ethical approval for the development, feasibility and pilot studies following similar procedures.

9.1 Recruitment procedures

- See section 7.1

9.2 Other ethical considerations

We do not anticipate that any participant in the GoActive Evaluation Study will experience any discomfort or inconvenience as a result of any of our measurements or procedures. As mentioned, participants are free to opt out of all or parts of the measurement process and this will be clarified both in written information and verbally on the measurement day. The **non-invasive measurements** (height, weight, body composition, waist circumference) will be conducted following standard operating procedures during school time; away from peers; in light clothing; and no information will be vocally repeated during the sessions. This protocol has been applied in pilot and feasibility testing with 99% and 96% of participants providing baseline data for height and weight, respectively. Eligibility for bio-impedance measurement will be checked before measurements (e.g. pacemaker). If appropriate, all staff on this project will have an enhanced Criminal Records Bureau check or an appropriate Disclosure and Barring Service check before study start. Measurement by a same-sex individual will be accommodated if required. **Questionnaire completion** will be organised so that other students cannot see responses. Researchers will be available to help participants with reading difficulties or who have difficulty understanding the questions. It is possible that some parents of children in the intervention schools may have concerns about their son/daughter taking part in the **GoActive programme** since it is not part of the usual school curriculum. The programme is designed to be implemented in an entire school year group. Full information about the programme will be provided to parents in the intervention group and parents are encouraged to discuss any concerns with the school and withdraw their son/daughter from the programme if they wish. A suitable solution will be arranged with the school on a case-by-case basis, such as organising alternative activities during tutor time.

9.3 Research Governance

The University of Cambridge sponsors the project, and collaboration with Oxford University will occur under a formal collaboration agreement. Grant-administration and financial management will follow well-established processes at the MRC Epidemiology Unit; the PI and Finance Manager will review monthly budget updates.

A **Trial Steering Committee (TSC)** will be set up with the following responsibilities:

- To provide overall independent supervision of the project and ensure that it is being conducted in accordance with the principles of Good Clinical Practice and the relevant regulations.
- To review protocol amendments, detailed statistical analysis plan, and provide advice on any aspect of the study.
- To make decisions about continuation or termination of the trial or substantial amendments to the protocol.

The TSC will consist of an independent chair, one independent expert, two lay representatives (including a representative from educational sector) and at least two investigators. The study coordinator and a sponsor representative will be observers. The TSC will meet at least once per year, or more frequently if needed. The TSC is responsible for communicating any issues for concern to the Sponsor, specifically where the issue could compromise the integrity of the study or data or patient safety.

9.4 Project timetable and milestones

The project is planned to last 42 months starting September 2015. A detailed timeline is included in Appendix 2. The planned recruitment rate is based on previous experience, which showed that the use of parental opt-out consent and active student assent enabled the efficient recruitment of a large proportion of Year 9 students in each school. Key milestones are detailed below.

Jan/Feb 2016	Obtain ethics approval
Mar/Jun 2016	School recruitment (N=16)
Jul 2016	Publication of protocol paper online
Sept/Dec 2016	Participant recruitment (N=2400) & baseline assessment (T1)
Nov 2016/Jan 2017	Randomisation
Feb/Apr 2017	Interim assessment (T2)
Mar/Jul 2017	Independent intervention continuation
May/Jul 2017	Post-intervention assessment (T3)
May/Jul 2017	Qualitative data collection (mixed methods process evaluation)
Aug/Dec 2017	Quantitative data entry and cleaning (release data set: Dec 2017)
Dec 2017/Jan 2018	Main effect analyses
Jan/Feb 2018	Participant & school feedback
Apr/Jun 2018	Follow up assessment (T4, primary outcome) & qualitative data collection
Jul/Nov 2018	Quantitative data entry and cleaning (release data set: Nov 2018)
Jan/Feb 2019	Produce and disseminate Evidence Brief
March 2019	Submit Draft Final Report to NIHR

10. Expertise

10.1 Applicant team

This **multi-disciplinary application** brings together researchers from universities in Cambridge and Oxford. The project team spans the disciplines of epidemiology, education, physical activity, social science, public health, trial methodology, and health economics. Together, they bring expertise in observational (KC, EvS, PW) and intervention research (KC, EvS, AV, PW), intervention development (KC), school-based research (KC, EvS, AV, CC, PW), physical activity assessment (KC, EvS), economic evaluation (EW), educational research (AV), qualitative research (CC, KC), mixed-methods approaches (CC, PW) and process evaluation (KC, CC, EvS). In addition, the wider research environment in which they are embedded provides expertise in physical activity data collection and processing, anthropometry assessment, trial methodology, and knowledge translation and dissemination. Intervention delivery costs will be borne by the local council (supporting letter attached). The PI, Dr Corder (MRC Epidemiology Unit and CEDAR, University of Cambridge) will have overall responsibility for project progress and direction. Dr Corder led the formative, feasibility and pilot work for GoActive and has substantial experience of recruitment/ retention of schools/adolescents in physical activity research, managing data collection, physical activity measurement, intervention development, evaluation and process evaluation. Dr Van Sluijs, Dr Wilkinson and Prof Vignoles (all University of Cambridge) will advise on study procedures and evaluation from their respective disciplines; Dr Wilkinson will additionally lead the design and evaluation of psychosocial outcomes. Dr Croxson (Oxford University) will lead the qualitative and mixed methods research. Dr Wilson (University of Cambridge) will lead the economic evaluation.

10.2 Wider research environment

The GoActive trial will benefit from **in-house knowledge on trial methodology, physical activity assessment and statistical analyses**. The trial will be conducted through the infrastructure of the MRC Epidemiology Unit which has extensive experience of conducting clinical trials. These include the ADDITION, ProActive, FAB, DRCT, Get Moving and Baby Milk Trials. The Unit's expertise in trial methodology has been recognised and there are on-going discussions about the Unit being recognised as an affiliate of the Cambridge Clinical Trials Unit. Specifically, the Unit has developed a matrix management model where specialist teams (anthropometry, statistics, data management, study coordination, field epidemiology) operate across a range of different studies. The teams include core-funded specialists with expert knowledge of particular areas of research support who ensure that the methods used for data collection and analysis are at the forefront of their respective fields. Each of these teams operates a flexible staffing strategy allowing for the development of a highly professional core

funded by the Unit with the ability to expand and contract the size of additional staff members with grant income according to need. We are able to draw upon this structure for the GoActive trial. Moreover, the unit has existing **formal processes for monitoring study progress and recruitment targets** (through monthly Science Operations Meetings). Stephen Sharp, senior statistician at the MRC Epidemiology Unit will conduct the randomisation and advice on the trial analyses. The project will additionally benefit from the Faculty of Education's excellent links and partnerships with local schools.

10.3 Partner Collaboration

Our Partner organisation is Cambridgeshire County Council and/or Active Essex at Essex County Council. They will support the research team in liaising with secondary schools and will fund the intervention delivery (GoActive Facilitator) with a half-time health trainer or equivalent for 9 months.

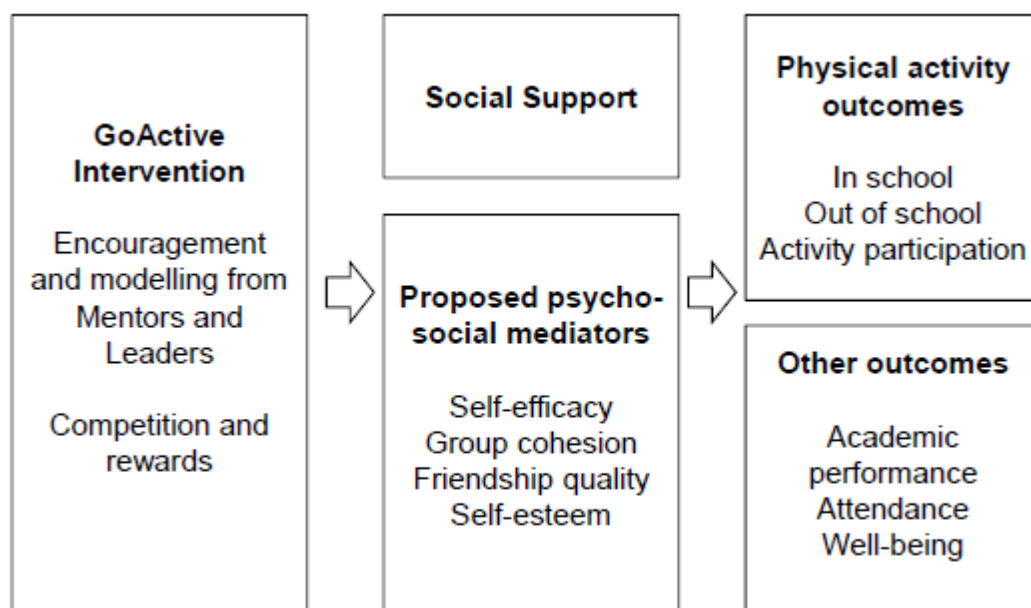
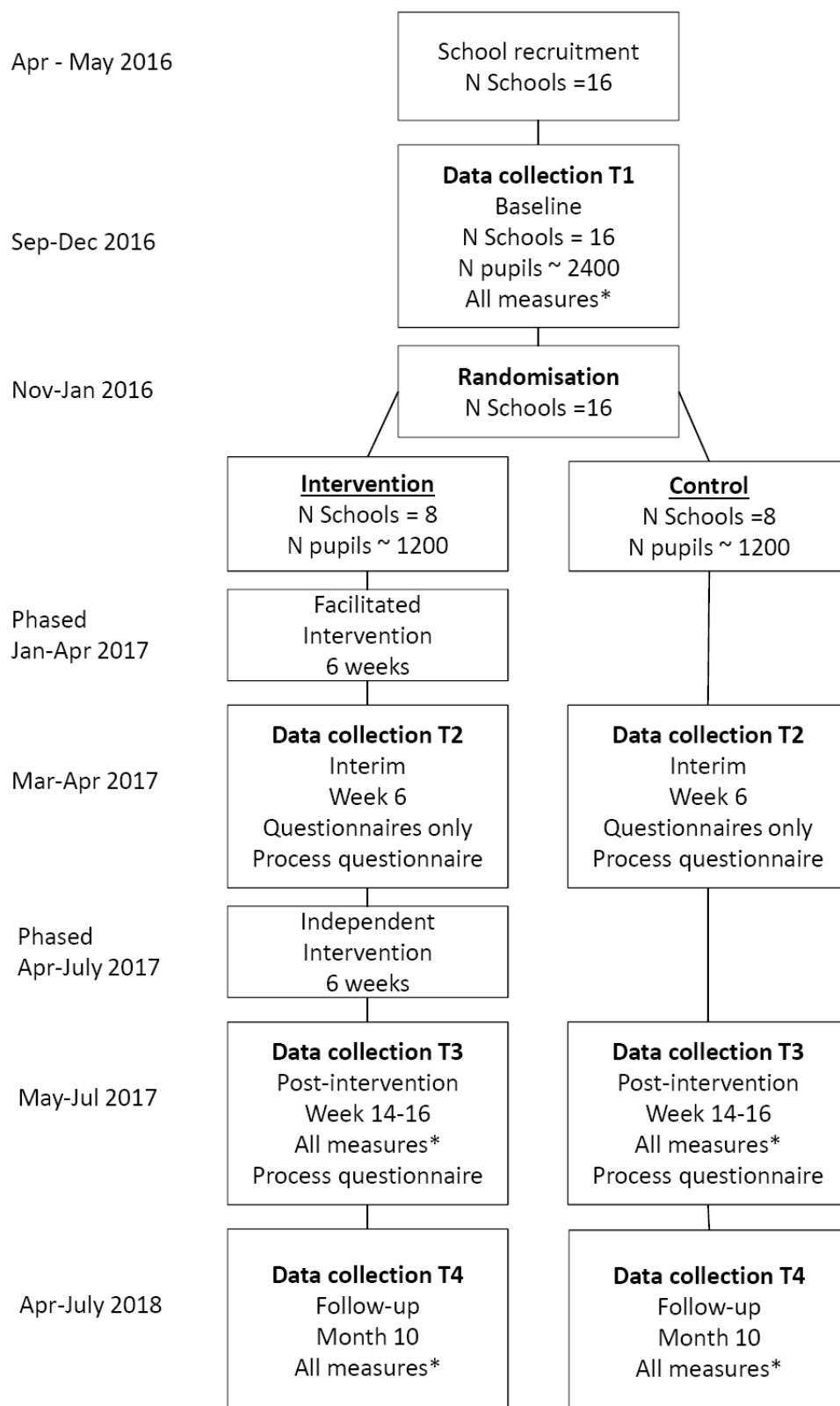


Figure 1. GoActive proposed logic model



*All measures includes accelerometry, anthropometry and outcomes questionnaire (student-reported physical activity participation, self-efficacy, peer support, group cohesion, self-esteem, friendship quality, and mood).

Figure 2. GoActive CONSORT diagram

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