1. Project Title

Effectiveness and cost-effectiveness of a Physical Activity Loyalty Scheme to maintain behaviour change: A cluster randomised controlled trial

2. Background

2.1 Existing Research

It is estimated that physical inactivity is responsible for 6 –10% of all deaths from non-communicable diseases[1,2], at a cost to the NHS of £1.06 billion/year[3] and so the potential public health dividend of increasing physical activity (PA) in the population is substantial. Recent data for Northern Ireland[4] show that over 60% of adults are not meeting current recommendations[5] while in England the figure is even higher at 80%[6]. Previous initiatives have had only modest effects, with maintained changes in PA behaviour being difficult to achieve[7-9]. Thus the Public Health White Paper[10] has called for a major re-think in our approach to public health interventions.

Interventions in the workplace have the potential to contribute significantly to the formation of patterns of healthy behaviour, because many people spend a large proportion of their waking time in work. However, there has been an expansion of sedentary occupations, with less than 1% of adults in NI doing at least 10 minutes of PA at work in the previous week[4]. Increasing activity levels in the workplace can have physical and mental health benefits for the employee and provide potential economic benefits through reduced absenteeism and increased productivity[11]. Current evidence to support the effectiveness of such interventions is mixed[12], with recent reviews[13-15] calling for more robust research on workplace interventions and well designed randomised controlled trials (RCTs). Recent NICE guidelines recommend the promotion of PA in and around the workplace, particularly through walking and cycling[9]. Previous meta-analyses of workplace PA interventions have shown small, positive, short term effects[13-15] on levels of walking but little long term effectiveness is evident[9]. Thus there is a recognised need to develop interventions that encourage maintained changes in PA. Further, most existing interventions are delivered 1-to-1 and so are expensive and unlikely to have the reach to impact on population level change.

Certain behaviour change techniques have been shown to be effective in workplace settings, including self-monitoring and goal setting[13,16]. However, a review of economic literature reported little evidence on the cost-effectiveness of such interventions[17]. The UK Government is encouraging the use of incentives for promoting healthy lifestyles, but we know little about whether they offer effective or sustainable means to promote PA[18-20]. The use of financial incentives for health-related behaviour change has been met with some scepticism[21], although their acceptability may be contingent on their effectiveness, type, and the target behaviour[22]. There is evidence to support the use of incentives for changing some behaviours e.g. smoking, substance abuse[18,23], but the evidence for other health behaviours is sparse. Some financial[24] and non-financial incentives[25] have been shown to increase levels of PA, at least in the short term and mainly with respect to structured exercise programmes[25], rather than free-living PA. To address such gaps in the evidence base, we are proposing to conduct a cluster RCT of a financial incentive intervention encouraging workplace PA.

2.2 Risks and Benefits

Benefits: Physical inactivity has been strongly linked to many of today's most prevalent morbidities including coronary heart disease, diabetes, some cancers, stroke and obesity[2,26]. As well as physical health benefits, regular PA has been shown to improve mental wellbeing[27] and quality of life (QoL)[28]. If such improvements to physical and mental health are realised, they could lead to lower healthcare utilisation and costs[29]. The costs of lost productivity are estimated to be £5.5 billion a year from sickness absence and £1 billion a year from the premature death of people of working age[30]. Furthermore, high sickness absence rates in public sector organisations incur significant costs[30]. Workplace PA interventions can have positive impacts on PA ((effect size (ES) d=0.21)), BMI (ES d=0.08), work attendance (ES

d=0.19) and job stress (ES d=0.33)][13-15]. As well as benefitting the health of employees, workplace interventions have the potential to benefit the organisation, through reduced absenteeism and increased productivity, and the wider economy as a whole by keeping people economically active for longer. However, we need to know more about the long term health, social and environmental impact of short term interventions[9], and as highlighted above, there is a need for more robust evaluation of workplace PA interventions[9]. We must also be mindful of the fact that any intervention focussed on a single behaviour (such as PA) may have positive or negative compensatory effects on other behaviours (e.g. diet)[31]. Working in partnership with large public sector employers, we have developed a public health intervention to help address this issue and generate new knowledge through the development of a sustainable workplace PA intervention that can be aligned with current organisational health and wellbeing plans[9].

The Intervention and its Rationale: The Physical Activity Loyalty (PAL) scheme is a multi-component intervention based on concepts similar to those that underpin a high-street loyalty card aimed at encouraging repeated behaviour (i.e. loyalty)[32]. Components include the provision of points and rewards (financial incentives) contingent on the targeted behaviour (PA), and the provision of feedback on the targeted behaviour, prompting and messaging to encourage the targeted behaviour, through a tailored website. In line with the recommendations of recent NICE guidance[9], our proposal will gather new evidence for effective and cost-effective workplace PA interventions. Although recent studies show some evidence of effect[13-15], there are 3 problems that our proposal addresses: 1) very few studies have used objective measures of PA; 2) relatively little is known about the use of financial incentives for workplace PA and free-living activity, and 3) even less about their cost-effectiveness. Further, our proposal will address key knowledge gaps outlined by NICE[9], including how individual interventions interact with environmental factors in encouraging people to walk, how to make walking habitual and elucidating factors that influence longer term behaviour change. Previous studies have used significant cash payments (up to $750)[33] which are not sustainable for the long term[32]. Further, to elicit a maintained behaviour change, the intervention should incorporate a phasing strategy to "shift" the focus from extrinsic to intrinsic motivation[18]. Our proposal has the potential for considerable reach at little cost and will generate new knowledge in this area through the development of a sustainable business model using a 'points' based loyalty platform, whereby local businesses 'sponsor' the incentive (retail vouchers) in return for increased footfall to their business. This model is aligned to precepts of the Public Health Responsibility Deal[10]. Our formative work has shown that we can recruit and retain office-based employees to this intervention and that the intervention has the potential to positively influence their PA levels. This information has helped us design a full-scale cluster RCT.

2.3 Findings from the Feasibility Study and Rationale for Current Study

Feasibility Study: We recently completed a study providing pilot data on the feasibility of conducting a RCT investigating the use of financial incentives for PA in the workplace[32] which: assessed the recruitment process and retention of office-based employees to a trial; tested outcome measures and data collection processes; assessed the feasibility of programme implementation in a public sector organisation. Firstly, a high uptake rate (63% of those invited took part) indicated that our recruitment strategy was successful and the intervention acceptable to the target population. Our data showed that over 50% of participants recruited at baseline were categorised as having low PA levels, indicating that the intervention was acceptable to a wide range of individuals, including those currently physically inactive, and therefore has the potential for significant reach in the population. Furthermore, this strategy was successful in recruiting a representative sample, in terms of gender, age and ethnicity, from office-based public sector organisations. Secondly, high retention rates at 6 months (85%) showed that our electronic method of data collection was acceptable, and the outcome measures feasible. Although there was no significant difference in PA levels (ascertained by the Global Physical Activity Questionnaire (GPAQ)) between the intervention and control groups, the study was not powered to demonstrate an effect size of Cohen's d~0.21 (suggested by the current literature) which has informed our trial design. Finally, over 90% (n=331) of participants

were satisfied with taking part in the scheme with 89% (n=322) stating that the PAL card was 'very helpful' in encouraging them to undertake more PA.

Risks: There are no anticipated risks to participants, employers or public sector organisations. Employers have assured us that participants can complete the study questionnaires and assessments during the working day. We believe that any unanticipated risks are minimal and that the expected benefits outlined above justify the risks.

3. Research Objectives

The proposed cluster RCT has the following objectives:

1. To investigate the effectiveness of the PAL Scheme to increase employee's PA levels in an office-based occupational setting;
2. To investigate if any change in PA behaviour is maintained over time;
3. To conduct cost-effectiveness and cost-benefit type analyses of the PAL Scheme;
4. To investigate how the intervention impacts on other health behaviours and outcomes;
5. To investigate wider work-related effects including sickness absenteeism and work presenteeism;
6. To investigate the mediators of (a) uptake and use of the loyalty card, (b) initiation, and (c) maintenance of behaviour change;
7. To conduct a parallel qualitative study to further characterize those who benefitted from the intervention, how and why it worked for them, and explore mediators of behaviour change;
8. To conduct a Discrete Choice Experiment (DCE) to investigate the possible optimal levels of incentives for such interventions;
9. To conduct a behavioural economic field experiment on inter-temporal preferences to investigate the relationship between behavioural change, discounting and incentives.

4. Research Design

Design: A cluster RCT will evaluate the PAL scheme, incorporating nested behavioural economic experiments, and process evaluation. A protocol for the intervention and its evaluation has been developed using the MRC framework[34] and SPIRIT guidelines[35] and tested in a feasibility study[32,36].

Population: The study will target office-based employees from public sector organisations.

Intervention Development: To tailor the intervention, as advocated by NICE[9], a purposive sample of employees (both men and women across a range of ages) will participate in 3 focus groups (max. 10/group) prior to the intervention to explore aspects such as the availability of, and preferences for opportunities for PA proximal to the workplace. We consider 3 focus groups sufficient to represent the different types of organisations participating in the trial. Semi-structured interviews with 5 retail sector representatives will help inform the design of the rewards element. To design the incentive levels we will use revealed preferences and stated preferences of the participants (from the DCEs) to assess their mean Willingness to Accept (WTA), Willingness to Pay (WTP) and the trade-offs they would make for the attributes[37] of the incentive programme, prior to the intervention. This information will help us fix the level of the rewards available for earned "points", however, the level of rewards for any given number of points achieved will not vary across individuals. The data from the revealed preferences and the stated preferences questions, including the DCE questions, will provide information on the distribution of the monetary value of one minute of physical activity in different contexts (e.g. walking to the office, walking a flight of stairs, cycling to work, etc.), under current and hypothetical scenarios. These values will be used to estimate the monetary value that people in our sample currently attach to physical activity and the likely cost of the incentives necessary to achieve the recommended amount of 150 minutes of moderate/vigorous physical activity per week. We will then estimate the mean monetary value of achieving 150 minutes of physical activity in our sample, from which we can set the average value of our reward to achieve a

given goal such as the recommended 150 minutes of physical activity/week for a given proportion of our sample.

Post intervention, this information will also inform us about possible moderators of intervention impact. A behavioural economic field experiment[37] will be conducted at the end of the intervention to elicit the discount rates of participants, i.e. the degree to which they value present over future rewards. This will help us investigate whether there is a relationship between behaviour change, discounting, and incentives.

Refinements to the Trial Informed by the Pilot Data: Following the success of our feasibility study, we have added the following elements to the full trial: the inclusion of a detailed pre-intervention development phase employing both DCEs to help determine an effective level of incentive and a comprehensive qualitative component to ensure that the intervention is tailored to the participating workplaces; a detailed process evaluation; inclusion of additional outcome measures to capture potential mediators of behaviour change and subsequent mediation analyses to determine pathways of impact; inclusion of an objective measure of PA; and, outcome measures to conduct cost-effectiveness and cost-benefit type analyses.

Allocation: To reduce contamination, participants will be randomly allocated by cluster to one of two groups: 1) Intervention Group or 2) Control Group. Clusters have been defined as the smallest organisational unit (e.g. a department or office/floor) within each participating public sector organisation[11]. A random allocation sequence will be drawn up by the trial statistician and group allocation placed in sequentially numbered, sealed opaque envelopes. Group allocation will be stratified to ensure similar numbers of clusters in the Intervention and Control Groups in each participating organisation. The envelopes will not be opened until the baseline questionnaires have been completed, at which point the allocation will be revealed to participants.

Protecting against Bias: 1) Organisation level: smallest organisational unit will be used as the cluster unit. It is impossible to rule out all contamination but a cluster RCT design will reduce contamination between groups, and any biases will tend towards the null, and should yield a more conservative effect estimate. Participants will be asked who they usually walk with during working time to assess for contamination between groups. The randomisation schedule will be drawn up once organisations have consented to participate and after the baseline survey, guarding against selection biases at entry of clusters and participants to the trial. Organisations, managers and participants cannot be blinded to allocation status. However, the Post-doctoral Research Fellow (PDRF) undertaking data collection and analyses will be blinded. Retention of control clusters will be maximised by ensuring regular liaison with nominated managers within the participating organisations and the opportunity for participants in the Control Group to take part in the intervention after the study. 2) Participant level: participants in the Control Group will not have access to the intervention components on the study website. Based on the results of our feasibility study, we are confident that we can recruit and retain a high participation level in both the Intervention and Control Group in the full trial.

Power and Sample Size:
During the recruitment phase for the study, a revised power calculation was undertaken assuming an effect size estimate taken from the recent literature together with our actual baseline data on mean and variance of cluster size and an intra-class correlation co-efficient of 0.029. In the original protocol, the sample size calculation for the trial was determined using an anticipated effect size of d = 0.21 (based upon a previous meta-analysis of workplace based physical activity interventions).
However none of the included studies were incentive-based interventions for physical activity. More recent literature has been published [38, 39], including a meta-analysis in which a mean effect size for incentive based interventions of 16 min of MVPA per day was estimated, equating to an effect size of approximately 1600 steps (d = 0.40). Additionally, in the TRIPPA

study [39], which is examining the influence of financial incentives on the effectiveness of a wireless-upload pedometer to encourage weekly physical activity goals, the study was powered to detect a difference of a minimum of 30 min of MVPA per week between groups and power calculations were based on considerably higher effect size than assumed in our original protocol (0.35). Therefore, under the assumption that our original estimate was too conservative, the power calculation has been updated. For an effect size of 0.40, a study of 330 per group (or 660 in total) would have 90 % power at the 5 % significance level. Assuming a 15 % drop-out, the study would need to randomise 776 participants.

Analysis Plan: For the primary analysis (at 6 months), pedometer measured mean steps/day will be the dependent variable. A random intercept will be fitted at the cluster level, before employing organisation (in categories), group allocation and baseline mean steps/day are added to the model. Further, mediation analyses will determine pathways of effect**.** An economic evaluation will include a cost-effectiveness analysis involving collection of health service utilisation, and a cost-benefit type analysis from the employer perspective.

Dissemination/Implementation: The protocol subscribes to the precepts of the WIDER statement on behavioural interventions[40]. Intervention components have been coded by a trained rater (MT) using the Behaviour Change Technique (BCT) taxonomy[41]. The elements of the intervention have also been mapped onto the Behaviour Change Wheel[42]. Together, these steps allow accurate replication of the intervention, as well as better dissemination of the precise contents of the intervention.

5. Study Population

The study will target public sector employees involved in predominantly inactive office-based occupations whose workplaces are based within a 2km radius of Belfast and Lisburn city centres. People in predominantly desk-based jobs spend a large proportion of their day physically inactive while public sector organisations have been reported to have higher sickness absence rates than private sector workplaces[30,43]. The workplace has been acknowledged as a suitable environment for making modest changes in PA, to benefit the health of employees[12].

Recruitment of Workplaces: We have recruited a number of large public sector organisations to participate in the study using similar methods to those successfully employed in our feasibility study[32]. Within Lisburn, 5 large public sector organisations have been recruited and additional recruitment took place at agreed sites in Belfast. Their commitment to participate in the project is evidenced by the Letters of Support. Organisations were purposively sampled within a 2km radius of the city centre, or offered similar PA opportunities with 2km, and had at least 100 employees.. Meetings were held with senior management of these organisations explaining the purpose of the study and what their involvement would entail.

Recruitment of Participants: Given the success of recruitment in the feasibility study[32] we plan to use similar strategies in the current trial. These include email invitation to employees, posters around the workplace advertising the study and a web-link on the organisations' intranet sites. These recruitment methods directed potential participants to the study website where they were able to access further information (including the Participant Information Sheet) and register their interest to participate. Potential participants will be asked to complete a screening questionnaire via the study website or by telephone, to confirm their eligibility, based on the following inclusion criteria: based at recruited worksite at least 4 hours/day (within core hours of 8am-6pm) and 3 days/week; current contract lasts for duration of the study (i.e.18 months) (this is to exclude temporary workers); access to internet at work; able to give informed consent; able to communicate in English; no self-reported recent history of myocardial infarction or stroke or physical limitations that would limit ability to participate in PA (assessed using the Physical

Activity Readiness Questionnaire)[44]. All participants who meet the eligibility criteria and consent to participate will be contacted by a member of the research team by telephone or email to complete the baseline assessment (see Section 9). Following this, clusters of participants will be randomised to the Intervention or Control Group using computer generated random numbers.

6. Socio-economic Position (SEP) and Inequalities

Although a universal intervention, the PAL scheme is intended to reduce health inequalities by addressing individual level determinants of PA as well as some economic and environmental factors that shape the broader choice architecture[45]. To explore this we will collect data on the staff grade, gross annual household income and education level of participants, and home postcode data to assign a measure of deprivation using the Northern Ireland Multiple Deprivation Measure 2010[46]. Our statistical analyses will examine whether intervention effects are moderated by individual and area level measures of SEP, and a sensitivity analysis will investigate whether there is a differential impact of the intervention according to SEP. Such analyses will have less power than our primary evaluation of mean intervention effects and will be exploratory.

7. Planned Interventions

Intervention Group: The study will involve the implementation of a multi-component intervention (PAL Scheme) which includes provision of points and rewards (financial incentives) contingent on meeting targeted behaviour goals (PA). Participants will be encouraged to undertake 150 mins/week of PA which is in line with current guidelines[5]. The PAL scheme integrates a novel PA tracking system with web-based monitoring and evidence-based behaviour change tools. The tracking system uses Near-Field Communication (NFC) technology and a loyalty card (PAL Card) which contains a passive Radio Frequency Identification (RFID) tag to monitor participant's PA as part of the intervention. This affords the opportunity to promote PA in specific locations, linking people to local opportunities, as recommended by NICE[9]. Participants swipe their PAL card at sensors when undertaking PA (e.g. walking) which logs the place, date and time of the card scan. Participants log onto their account on the study website and receive real-time feedback on aspects of their PA, including minutes of activity. Minutes will be converted to points (10 points for 1 minute of activity recorded), and collected points are redeemed for rewards (retail vouchers) sponsored by, and redeemable at, local businesses. Reward levels ranged from £2.60-£60.00 in our feasibility work, which is on a par with reward levels which would incentivise PA behaviour change, as ascertained by a recent small Contingent Valuation Survey[47], but these will be tailored using DCEs for this study. Over the intervention period, rewards will be phased, with rewards being offered less frequently in the latter phase of the intervention, in order to reduce the emphasis on the extrinsic motivation (i.e. reward) and increase the emphasis on intrinsic factors[18]. The proposed 6-month intervention will involve placing sensors in the indoor and outdoor environments at specific locations to encourage PA within a 2km radius of the participant's worksites, including along footpaths, the local park, leisure centre, shopping mall, bus stops and train stations. Maps of various walking routes and details about PA opportunities tailored to the workplace will be provided on the study website[9]. In addition to the financial incentives part of the intervention, the intervention has several other components designed to enhance the effectiveness of the incentives as advocated by Marteau et al[18]. These components are designed to have multiple effects: (a) to increase usage of the website reporting financial incentives, (b) as effective BCTs in their own right, and (c) as techniques designed to aid the transition from more extrinsically motivated behaviour to more intrinsically motivated behaviour that is habitual, as the financial incentives are reduced. The techniques delivered via the website include the provision of regular tailored motivational emails, tailored feedback, and links to other resources. It also includes self-regulation techniques of goal setting, self-monitoring, and prompts to behaviour, which reviews have shown to increase effectiveness of PA interventions[48]. This intervention was successfully piloted in a workplace setting[32].

Underpinning Theoretical Framework: The financial reward component of the intervention is based on principles of Learning Theory by providing an immediate reward (extrinsic motivation) for behaviours that offer health gains in the future. It also contains elements based on other approaches, such as goal setting, prompts, self-monitoring, and habit formation which fit with a self-regulation control theory framework[49], motivational messages (persuasion), and social support (vicarious experience) which should increase self-efficacy according to Social Cognitive Theory[50]. Social Cognitive Theory also holds that satisfaction with the consequences of behaviour change can act as a reinforcing mechanism, in addition to the reinforcement of financial rewards. Thus financial incentives are embedded in a complex intervention and delivered as part of an evidence-based behaviour change programme, as previously advocated[18]. A complex intervention such as this has multiple strands operating at several levels and these will be explored through mediation analyses to allow the identification of assumed pathways of change.

Control Group: Those assigned to the control condition will constitute a waiting list Control Group and will be offered the opportunity to participate in the intervention after the 12-month follow-up period. Participants in this group will complete outcome measures at the same time points as the Intervention Group.

Intervention Delivery: In line with recent guidance[9], our intervention comprises an integrated package of measures, with relevant stakeholders assisting in the delivery. Representatives from Lisburn City Council and the South Eastern Health Trust, who have a remit for employee health and wellbeing and for public health of the entire South East population, will assist in the implementation of the intervention. This will include maintenance staff installing and maintaining the RFID sensors in the local environment and administrative staff providing retail vouchers to participants at various time points throughout the intervention; an arrangement that parallels the modus operandi in our successful feasibility study[32]. Maintenance staff will attend a half day training session on the set-up of the sensors, how to check the sensors and how to test and change the battery. During the intervention, these facilitators will be given access to a member of the research team for advice/support and will be contacted by the project manager at least once per week to identify any matters of concern. Health and wellbeing representatives from all participating organisations will attend two half day training sessions explaining 1) how the scheme works, components of the website, how employees can participate; and 2) the technology involved, management and maintenance aspects of the intervention.

Funding: The intervention will be funded by the Public Health Agency, the South Eastern Trust and Lisburn City Council as evidenced by the Letters of Support. This funding covers cost of the equipment, delivery of intervention, maintenance, and fees for the marketing consultant responsible for provision of rewards from local retailers.

Setting: The study will target large public sector organisations located within a 2km radius of Lisburn and Belfast city centre which is the third largest city in Northern Ireland. The intervention will be delivered to employees of large public sector employers with a significant proportion of office-based staff. In line with the recent NICE guidance[9], we have developed a co-ordinated, cross-sectoral intervention to promote PA based on best practice and addressing an identified need by our partners. Given that the public sector accounts for approximately 20% of employment in the UK, higher levels of sickness absence has a significant economic impact, estimated at £4.5 billion a year in wage costs[30].

8. Compliance and Follow-up

Organisational-level Compliance: This will be ensured by standardisation of training of staff delivering the intervention and regular monitoring of intervention elements by the PDRF. We will evaluate organisational-level compliance and fidelity via our process evaluation described in Section 9. We do not intend to interfere with any other health and wellness programmes that

might operate routinely within the participating organisations (which might affect our intervention and control groups equally) but will make a record of their nature and scope.

Individual-level Compliance: During the feasibility study, compliance was measured and monitored automatically via the transaction data collected when participants swiped their PAL card at the sensors while undertaking PA around the workplace. Results from this data showed a high level of compliance in the Intervention Group. Various mechanisms were implemented to aid compliance including advice to place the PAL card in staff pass holders (worn on a lanyard around the neck) to enhance card carrying by staff. The PAL card usage data was automatically mined on a regular basis in order to send tailored, motivational messages (dependent on level of usage) to participants throughout the intervention period to encourage usage. Furthermore, we promoted strategies to increase website compliance including interactive tools such as tailored feedback, goal setting, and links to other resources[51]. To combat issues of "playing the system", we placed a daily cap on the number of points that could be earned and implemented cleaning rules to avoid multiple swipes on the same sensor. These will be employed in the full trial.

Follow-up: Our feasibility study showed a high retention rate at 6 month (85%) follow-up in both the Intervention and Control group. We will therefore retain key features from this study that we believed enhanced retention, including: 1) random group allocation after baseline assessment; 2) feedback of headline findings (not data on individual performance) to the employing organisations who highly valued this information to monitor and change policy and practice. Our sample size estimates are conservative and, based on results from our feasibility study, allow for drop out of 15% of participants at 6 months and 1 year post-intervention.

9. Proposed Outcome Measures

Outcome measures are grouped into the following categories: measures (i) of PA; (ii) of health and well-being; (iii) of work-related impacts; (iv) of proposed mediators of behaviour change; (v) of compensatory behaviours; (vi) for use in economic evaluation; (vii) for use in process evaluation. The intervention will last for 6 months and the proposed timing and frequency of outcome assessments reflect this.

(i)Physical Activity: The primary outcome is mean steps/day objectively measured by a sealed pedometer (to blind participants to the output) worn on the waistband (Yamax Digiwalker CW-701, Japan), for which reliability and validity has been established[52,53]. Participants will wear the pedometer for 7 consecutive days, complete a wear time diary, and the GPAQ to elucidate the context of activity undertaken[54]. These measures will be collected at baseline, 6 months (immediately post-intervention) and 12 months (6 months post-intervention). This schedule ensures that we can account for seasonality of PA behaviours. The GPAQ was successfully piloted during our earlier work.

(ii)Health and Wellbeing: Secondary outcome measures of health (Short Form-8 (SF-8))[55], QoL (EQ-5D-5L)[56,57], and well-being (Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS))[58,59], are included. These validated measures will be collected at baseline and 6 months. Items from the SF-8 questionnaire can be derived to give an indication of both physical and mental health[57]. The WEMWBS comprises 14 positively worded statements, where scores are summed with higher scores indicating greater mental well-being. The EQ-5D-5L questionnaire is based on 5 dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, and a visual analogue scale (0-100) that assesses the participants' health state[56,57]. Both the SF-8 and EQ-5D measures were successfully piloted during our formative work[32].

(iii)Work-related Impacts: Measures of work-related impacts, including absenteeism and presenteeism[60], will be collected at baseline and 6 months. Work absenteeism will be measured by asking participants to state the number of day's sick leave in the past 6 months. This method was successfully employed during our feasibility study and the self-report data will

be verified objectively by each organisations' Human Resource Department. Presenteeism is defined as the measurable extent to which physical or psycho-social symptoms and conditions adversely affect the work productivity of those in work[61,62]. Specific questions from the WHO Health and Work Performance Questionnaire[60] will be used to measure work presenteeism. This validated method comprises 3 questions with answers on an 11-point Likert scale asking participants to rate their job performance levels. This questionnaire has been claimed to be more sensitive for detecting change following a PA intervention[63].

(iv)Mediators: We will collect data that are hypothesised to mediate loyalty card use, initiation (4 weeks) and maintenance of PA behaviour (6 months). These theoretical constructs and associated outcome measures have been informed from the mapping of BCT's from the feasibility study and evidence from the relevant literature on behavioural initiation and maintenance[41,64-68].Common core theoretical constructs of behaviour change including outcome expectancy[69], social norms[70], self-efficacy[71], financial motivation [72], planning [73], identified regulation[74], integrated regulation[75], intrinsic motivation and intention[76] will be collected at baseline and 4 weeks to assess initiation of behaviour change. Further, perceptions of workplace environment[77] and objective measures of the workplace environment using GIS data including walkability[78], street connectivity, access to PA opportunities (shops, parks, leisure facilities, train/bus stations) will be measured[79] at baseline. Other measures of web engagement, confidence in using the internet and loyalty card usage (described in the "Process Evaluation" below) which may mediate intervention "dose"[51] and therefore behaviour change have been included. To assess mediators of behaviour change maintenance, habit using the Self-Report Habit Index[80], recovery self-efficacy[81], maintenance self-efficacy [81], planning [82], identified regulation, integrated regulation, intrinsic motivation [83,84] , workplace norms [85], social norms[70] and satisfaction with outcome expectancies[69,86] will be captured at baseline and 6 months. It is hypothesised that change in mediators should be apparent at 4-6 weeks and that mediators of early behaviour change are distinct from those affecting maintenance[86-88]. To minimise participant burden, mediator data are collected via the website, a method which worked well in our feasibility study. Our pragmatic approach is to focus our efforts to obtain early mediator data (at 4 weeks) on initiation and uptake of behaviour, while at 6 months, the focus will be on mediators of maintenance of behaviour. This approach has recent empirical support[78].

Possible moderators of effect include the participants' rate of time preference, their stated WTP and WTA derived from the DCEs for the attributes of the incentive programme. The data for the DCEs will be elicited at baseline, whilst the data on inter-temporal preferences will be collected at 6 months only (immediate post-intervention) (see below). The reasons for conducting the behavioural economic field experiment *after the intervention* are as follows: (i) we want to avoid the possibility that participating in a lottery (part of the experimental protocol) might contaminate or perturb participants' views of or response to the incentive-based intervention; and (ii) there is little evidence that one's personal rate of time discounting varies over short periods or would be affected by our intervention[89].

(v)Compensatory Behaviours: To assess the impact of the intervention on compensatory behaviours, data on smoking[90], alcohol[90] and diet (short Food Frequency Questionnaire (FFQ))[91,92] will be collected at baseline and 6 months. Participant's dietary habits will be analysed in relation to food groups.

(vi)Economic Evaluation: The primary economic evaluation will take the form of a within trial cost-effectiveness analysis, with health outcomes expressed in terms of Quality-adjusted Life Years (QALYs). Changes in health-related QoL (as expressed using QALYs using EQ-5D data) will be measured from the participant's perspective. The EQ-5D is a validated measure and has been used extensively for cost-effectiveness analyses. Utilisation of healthcare resources will be captured using an adapted version of the Annotated Cost Questionnaire[9,93]. These measures will be completed at baseline and 6 months. Intervention costs will be obtained using

a modified template[94], explicitly discriminating between intervention and research costs. Briefly these include, website development, software (e.g. license fee), hardware (e.g. sensors, loyalty cards), and intervention running costs (e.g. maintenance of sensors), the costs of negotiating incentives from local businesses, and the delivery of vouchers.

Participants (n=776 will be administered a computer-based questionnaire using revealed preferences[95], stated preferences and DCE[22,96] questions to gain information on the optimal level of the incentives necessary to trigger behaviour change. Revealed preferences questions will investigate the current amount of time participants spend on activities including sleeping, leisure, work, transportation, home, PA and sedentary activity. The key behavioural decisions in this model are the distinct but related decisions to participate in PA and duration of each session of activity[97]. We will then investigate how participants' wages, hours worked, fixed costs of PA (e.g. gym membership fees), and variable costs of PA, affect the amount of time participants spend doing PA[98,99] to assess how income and substitution effects affect PA. Stated preferences questions and DCE questions will investigate participants' WTP and WTA for PA, and the rate of trade-offs between PA, other time-related activities and money[22,100] to estimate the optimal mean level of the financial incentives that would trigger behaviour change. Such information will also be used in exploratory moderator analysis (see later). Information on participants' discount rates, WTP and WTA for behaviour change, and behaviour change rates will provide an understanding on how the incentive alters the costs and benefits of this healthy behaviour and why it successfully results in changed behaviour in some participants and not others

After the intervention (at 6 months), a random sample of 200 participants from the Intervention and Control Group) will participate in a behavioural economic field experiment aimed at eliciting individuals' inter-temporal preferences and discount rates to identify participants who exhibit exponential discounting, hyperbolic discounting or quasi-hyperbolic discounting[101]. Under the assumption that this is not affected by the intervention, this information will also be used in exploratory moderator analysis. In our previous feasibility study, a subsample of 200 participants took part in a similar post hoc field experiment and all but one completed the tasks (unpublished).

(vii) Process Evaluation: The process evaluation methodology will be informed by the logic model developed from the feasibility study and guided by the evaluation planning framework for public health interventions and research[102]. This will enable further assessment of whether the articulated theoretical change pathways are occurring in practice, including mediation analyses, and an assessment of implementation fidelity. Evaluation will employ a triangulated design using both quantitative and qualitative data. A process evaluation will run alongside the implementation of the programme, throughout the 6-month intervention period. The process evaluation is concerned with 5 core research questions: i) What was participants' exposure to the intervention? ii) To what extent was the intervention implemented across the participating organisations? iii) How, for whom and under what circumstances does the intervention bring about behaviour change? iv) How, for whom and under what circumstances does the intervention maintain behaviour change?; (v) Whether there were any unintended consequences of the intervention. The process evaluation will encompass the following:

1) Study context: recording of current health improvement programmes and policies in each participating organisation collected throughout the duration of the study period. This will be supplemented by environmental measures, (such as distance to the nearest green space and neighbourhood walkability)[78] and free car parking at work[79] collected at baseline, which will assess the extent of PA opportunities for each participating organisation.

2) Intervention fidelity and "dose": fidelity of the intervention will be supported by the use of standardised training manuals and training sessions for those assisting with intervention delivery. They will be asked to keep a daily record of any problems with implementation using a

customised proforma, and report to the project manager on a weekly basis throughout the 6-month intervention period. The research team will assess delivery fidelity using a quality assurance form. Weekly feedback on fidelity will be given to those involved in the delivery of the intervention to assist standardisation and completeness. Establishing intervention "dose" will draw on data regarding PAL card usage (minutes of PA/week recorded using the PAL card) and website exposure (e.g. frequency of visits; number of hits; number of visitors that accessed specific website content; mean duration of visits[51]). These data will automatically be collected throughout the 6-month intervention. Extent of internet use will be assessed by asking participants how many hours per week on average they spend on the internet and to rate their confidence on using the internet on a 10-point likert scale[51]. In addition, information on those who redeemed their points for rewards and who subsequently reimbursed their rewards at nominated retailers will be collected. Compliance with the intervention will be monitored via the PAL card usage data, objectively recorded using the tracking system, and the use of the web resources as outlined above. This has been informed by recommendations from the NIH Behaviour Change Consortium[103].

3) Participation and reach: participation will be assessed by collating the actual number of participants recruited versus the number invited to participate. Reach will be assessed by investigating the representativeness of study participants in regards to gender, age, ethnicity, SEP (compared to aggregate demographics of workforce in participating departments).

4) Responsiveness: we will assess the experiences of participation, aspects of acceptability for those who engaged versus those who didn't, and any barriers or facilitators to this. This will draw on exit questionnaires completed at 6 months to assess level of engagement and focus groups at 6 months (at least one per site) which will explore their experiences of the intervention and determine the types of participants who benefitted from the intervention, how and why it worked for them. We will purposively sample participants (max. n=10/group) to ensure a representative sample, including those actively engaged in the intervention and those not (i.e. dropped out) are recruited. Focus groups will be repeated at 12 months with the same participants who attended the 6 month focus group to ascertain the views of those who have maintained behaviour change and those who have not, and why. A schedule of open-ended questions will be used to elicit information about reactions to the intervention; knowledge of PA recommendations and benefits; barriers to PA, and; suggestions for future roll-out of the intervention if proven effective[91]. This focus group will also seek confirmation of the results from the previous focus groups via triangulation of the data. Semi-structured interviews with senior managers of participating employers (n=7) will be used to explore their perceptions of being involved in the study.

RE-AIM Framework: All data will be interpreted in the context of the RE-AIM framework[104]. This will ensure that we have a clearer understanding of the **R**each, **E**ffectiveness, **A**doption, **I**mplementation and **M**aintenance of any changes wrought by the intervention. This framework allows concurrent evaluation of dimensions considered relevant to 'real world' implementation, such as the capacity to reach target population and to change PA. In particular, we will examine differences across social groups and whether the intervention has impacted on inequalities in PA participation in the study population.

10. Assessment and Follow-up

Assessment of Effectiveness: All outcome measures will be collected and analysed by a PDRF blinded to group allocation. The primary outcome measure (mean steps/day using pedometer) will be collected at baseline, 6 and 12 months, with sealed pedometers being issued and collected in person by the research team. This schedule permits behaviour change maintenance to be assessed with full account taken of seasonal effects. At baseline, before the intervention begins and before group allocation, participants will be asked to wear the pedometer (sealed to blind the participant to the output and prevent reactivity[105]) at all times, except during water activities and when sleeping, for 7 consecutive days (including weekend

days). A researcher will attach the pedometers and will train participants regarding proper placement and use. Participants will complete a wear time diary, and adverse events will be recorded on a standard proforma. The 7 days of steps will be averaged to yield mean pedometer steps for each participant at each time-point and subsequently manually entered by the PDRA onto the study database, and independently checked by the PDRF. At the end of the 7 days, participants will complete the GPAQ via the study website to give context to the PA undertaken in the past week. Physical activity undertaken specific to the intervention will be recorded using the tracking system. Minutes of PA will be generated using the time accumulated between timestamps recorded when a participant swipes their PAL card at the sensors when doing activity and used to assess intervention "dose". Physical activity outside the workplace will be captured using the pedometer and the GPAQ.

Other self-reported outcome measures will be collected at baseline and 6 months, electronically via the study website and automatically collated. This method was successfully employed in our feasibility work. It has the advantage of streamlining the data collection process and significantly saves researcher time. Monitoring of compliance and intervention fidelity have been outlined above (Sec 8+9, respectively). The behavioural economic field experiment will be conducted in maximum groups of 15 participants during lunchtime, for a total of 200 participants selected at random from the Intervention and Control Group. Participants will be offered £20 in cash for taking part in the behavioural economic field experiment. Participants will face several dichotomous decision tasks: 4 monetary discount rate tasks, 2 monetary risk aversion tasks and 2 monetary loss aversion tasks. After the choice tasks, the participant will randomly select the choice occasion and the alternative that will count for payment, and will throw a 10-sided die to determine whether the final payment will take place. A sample of 200 participants has been chosen for logistical and pragmatic reasons: the sample size is feasible to accomplish given time and resource constraints, is comparable to or larger than previous research[100,106,107] and is justifiable for what is intended as an exploratory moderator analysis.

Assessment of Harms: There are no anticipated risks associated with this study. Adverse events will be recorded using a standardised proforma and monitored on a regular basis by the PDRF. Any adverse events will subsequently be reported to the Project Management Team. If any major harms are detected, the Project Management Team will inform the Trial Steering Committee (TSC) who will review each case independently and deal with it appropriately using an *a priori* agreed decision framework.

11. Proposed Sample Size

Previous meta-analyses of workplace PA interventions suggest effects range in magnitude between d=0.21 and d=0.27[13-15]. Previous workplace PA cluster RCTs have used intra-class correlation coefficients (ICC) between 0.01 and 0.05 as they assumed that participants within the same workplace (cluster) would be reasonably independent[11,108]. We have assumed an ICC of 0.01, calculated from a recent workplace PA cluster RCT[11]. With an average organisational unit size of 75 employees (ranging from 50 to 100), anticipated recruitment rate of 63% (based on Pilot Data) and an attrition rate of 15% at 6 months (Pilot Data) and 30% at 12 months[11], this gives an estimated mean cluster size at the end of the trial of 30. Our sample size calculation assumes a coefficient of variation (standard deviation divided by mean) of 0.5 in cluster size[109]. With these assumptions, it is estimated that for the proposed trial to be able to detect the lower bound anticipated effect size of d=0.21 (meaningful change of 2500 steps/day which is equivalent to 30 minutes/day of moderate-intensity PA[106]), with 90% power (for ICC 0.01), a sample size of 690 participants per arm would be required (1380 in total). The proposed sample will consist of 46 clusters (smallest organisational unit) in 5 public sector organisations. With 23 clusters in each arm of the trial, this gives an anticipated 690 participants per arm or 1380 in total.

12. Statistical Analysis

Outcome Analyses: In compliance with SPIRIT guidelines[35], the primary analysis has been pre-specified. For the primary analysis, mean steps/day at 6 months will be the dependent variable. A random intercept will be fitted at the cluster level (all other variables will be fixed effects), with group, organisation (in categories), and baseline mean steps/day added to the model (Objective 1). The main focus for the analysis will be the estimated coefficient representing the difference in mean steps/day between the Intervention and Control Group, adjusted for baseline differences. The model will then be extended through the inclusion of interactions involving group and relevant covariates to test for any differential effects of the intervention (e.g. age, sex, SEP, time discounting function). In light of the multiple testing involved, these subgroup analyses will be cautiously reported as hypothesis generating rather than confirmatory. The primary analysis will then be repeated using 12-month follow-up data to investigate the effectiveness of the intervention for behaviour change maintenance (Objective 2). These analyses will be repeated with secondary health and wellbeing outcomes, and work-related outcomes (Objective 4 and 5). Further, sensitivity analyses will assess the impact of missing data using MICE (Multiple Imputation by Chained Equations), testing first whether missingness-at-random is plausible[111].

Mediation Analyses: To assess mediators of initiation and maintenance of physical activity behaviour change, single mediator models will be run for all mediators of initiation and maintenance individually based on the structural equation modelling-based (SEM) product-of-coefficients method [112]. In each model, the independent variable (IV) is group assignment, the mediating variable (MV) is the mediator follow-up score (four weeks or six months), and the dependent variable (DV) is the PA outcome (i.e. pedometer steps/day at six months). All analyses will be adjusted for randomisation stratum, season, and baseline values of the mediator and outcome, with standard errors (SEs) corrected for clustering. The significance of indirect effects will be determined using 95% confidence intervals (CI) estimated using the bias-corrected bootstrap (with 10,000 iterations) procedure recommended by MacKinnon et al. (2004) [113] and MacKinnon (2007) [114]. Bootstrapping is generally advocated as it does not impose assumptions of normality on the sampling distribution, has increased power and reasonable control over type 1 error rates. Model fit will be assessed using the coefficient of determination (CD), and standardized root mean square residual (SRMR) which are reported with SEM models adjusting SEs for clustering. A cut-off value of close to 0.08 for SRMR will required to consider the model a relatively good fit to the data in line with established guidelines [115]. For mediators showing significant indirect effects in single mediator models, and moderators showing significant interaction effects, single moderated-mediation models will be run using the moderated product-of-coefficients approach to provide a fuller understanding of the working mechanisms of the intervention[116].

Economic Analyses: The economic evaluation will involve a cost-effectiveness analysis from the public sector perspective and a cost-benefit type analysis from the employer's perspective (Objective 3). A cost-effectiveness analysis will compare costs and outcomes associated with the Intervention to those associated with the Control Group at 3 time-points. For the initial within study analysis, the outcome measures used will be (a) changes in mean steps/day; and (b) a within study measure of QALYs determined from EQ-5D. QALYs will be adjusted for any imbalances between arms at baseline[117]. Thus, the initial analysis will present an estimate of cost-effectiveness of the intervention in terms of costs associated with increasing PA and cost/QALY gained. The uncertainty surrounding the estimates of cost and effects for the Intervention and Control Group will be investigated through the use of bootstrapping[118]. In a sensitivity analysis we will compare subgroups and assess the uncertainty in their incremental cost-effectiveness ratios (ICERs) by plotting the associated cost-effectiveness acceptability curves. The longer term analysis will employ a decision model, populated with reference to the literature, to link short term study outcomes to longer term impacts on health and wellbeing. The model structure will be informed by a review of other models undertaken in this area, including the modelling work undertaken for NICE in 2008[17]. Data will be embodied in the model through the specification of probability distributions for each parameter, to reflect the

uncertainty. Probabilistic sensitivity analysis will be undertaken, using Monte Carlo simulation, to investigate the uncertainty surrounding the longer term estimates of costs, effects and cost-effectiveness of the intervention.

From the public sector perspective, the analysis will involve firstly generating ICERs using healthcare utilisation data and EQ-5D data. Secondly, from the employer's perspective, the effect of PA on absenteeism will be used to estimate potential cost savings to employers (absenteeism model); and thirdly, we will employ an algorithm to translate changes in EQ-5D into quantifiable changes in productivity (productivity model[17]). EQ-5D scores will be converted into productivity estimates using a recently developed algorithm[119]. Since QoL can be an indication of someone's degree of health or illness and different levels of health/illness lead to different levels of productivity, then it has been suggested that QoL can be used as a proxy for productivity[120]. Therefore, by utilising studies demonstrating the relationship between QoL and productivity, researchers have developed an algorithm to translate changes in QoL into quantifiable changes in productivity[119,121]. The algorithm combines two equations which predict an individual's level of absenteeism and presenteeism, based on their EQ-5D scores, to give an overall productivity estimate between 0-1. Individual EQ-5D scores at baseline and 6 will also be converted into estimated levels of productivity using this algorithm and the total productivity gain over 6 months for each group will be calculated. To calculate the ICER, from an employer's perspective, the additional costs will be divided by the additional gain in total employee productivity by the Intervention Group.

Analysis of Discrete Choice and Economic Experiments (Objective 8 and 9): To analyse the revealed preferences data we will use a two-step modelling approach to explain an individual's PA in relation to his/her characteristics[94,95]. The revealed preferences data will be analysed with a Cragg's double hurdle model[122-124] to first address PA participation, and then to analyse the amount of PA. We will run separate models for different types of PA (e.g. walking, gym) to produce estimates for the effect of wage, cost of PA and participants' characteristics on the amount of PA. This model will provide us with a 'revealed' implicit monetary value for units of PA. A random utility econometric model will be fitted to the DCE data to determine the implied individual thresholds inducing behaviour change[101]. Estimation will take place in a panel specification, and Bayesian posterior estimates of threshold values will be informed by the sequence of responses. Data from the field experiment to assess time preferences will be analysed using maximum likelihood estimates, allowing for within-subject clustered standard errors, as each participant answers more than one time preference choice[97]. The data collected on the amount of PA at baseline and after the intervention will allow us to run another Cragg's double hurdle model for behaviour change, and explore how differences in inter-temporal preferences, baseline PA levels, incentives and other participant's characteristics affect behaviour change. The Cragg's double hurdle model will allow us to investigate the two-step process in behaviour change: firstly, relating to the decision to do more PA compared to baseline; secondly, the decision of how much PA to do.

Process Evaluation Analyses: Focus groups and semi-structured interviews will be audio-recorded and analyzed using thematic content analysis[125] whereby identified themes will be represented in a matrix for further analysis and interpretation[126,127](Objective 7). Qualitative data will be entered into NVivo, which will be used to manage and code the transcripts, facilitating thematic content analysis, and how the themes inter-relate in order to develop an analytical framework. Each transcript will be coded independently by 2 researchers to indicate age, gender and organisation, allowing analytical themes to be explored in relation to different groups' experiences and to compare processes across clusters. Analysis will explore implementation and receipt of rewards and contextual factors affecting these, as well as potential causal pathways in order to develop hypotheses to examine in secondary moderator and mediator analyses. Additionally, quantitative data from PAL card usage and web usage will be used in the analyses of intervention fidelity, using simple descriptive statistics. Within the context of the RE-AIM Framework, we will compare the characteristics of our trial population

with the target population, to gauge the potential generalisability and impact of our results. Propensity scores will be used to compare the characteristics of trial participants with the inactive working population as a whole in Northern Ireland, using available population-level data[128]. These propensity scores will also be used as the basis for a diagnostic test to ascertain whether a weighting method can be employed, using the scores, to generalise the results to the target population.

Synthesis of Quantitative and Qualitative Data: Informed by the RE-AIM framework, the data generated from both elements of the study will be subject to an interpretative synthesis using a narrative summary approach to provide a broader interpretation of the study findings[129]. This will include description of quantitative findings with the addition of a reflexive commentary based on the qualitative findings. Complex narratives will explore dynamic processes, offering explanations that emphasise the temporal and dependent nature of PA behaviour to explore behaviour change maintenance. This approach is theory-led, can deal effectively with and triangulate different types of evidence. Such an approach, that takes on board the role of all stakeholders in our complex intervention, including the retail sector sponsoring the rewards, is congruent with the logic model for an evaluation of any "Responsibility Deal" as described by Petticrew et al[130].

13. Ethical Arrangements

Ethics Review: Ethics will be informed by recent guidance on ethical issues on cluster RCTs[131] and comply with the ESRCs Research Ethics Framework. Ethical approval will be sought from the Office of Research Ethics Committees (OREC) prior to the start of the study. Fully informed consent will be obtained from all participants prior to their inclusion in the study. Participants will be asked to confirm that they have read and understood the information sheet prior to agreeing to participate. Participants will be given an opportunity to ask any questions and ensure that these are answered satisfactorily prior to completing the consent form. We will also seek Research Governance approval from the South Eastern Trust and Belfast Trust.

Duty of Care and Confidentiality: Due to the nature of the intervention it is anticipated that there is minimal risk to participants. All information will be held according to the Data Protection Act 1998. All information that is collected during the course of the study will be kept strictly confidential. Participant's data will only be available under a personal identification number to maintain confidentiality. All information relating to the study will be kept in a locked filing cabinet, and on a password protected computer available only to the study researchers. No personal level detail will be published.

14. Research Governance

Trial Registration and Conduct: The trial will be registered with ISRCTN and we will follow the MRC guidelines on Good Clinical Practice in clinical trials. The PI and the majority of CIs have been trained in Good Clinical Practice for clinical trials, and new research staff will also be required to undertake this training.

Sponsor: Queen's University Belfast will be the study sponsor. The University has clear and rigorous procedures in place for granting ethical approval, agreeing contracts, monitoring expenditure and preparing financial reports.

Trial Steering Committee: will oversee the study, including an independent chair (Prof McAuley), PPI reps (Elaine Campbell and Caroline Magee), expertise rep (Prof Sindelar, Yale University), methodology expert (Prof Clarke), investigator reps (Kee and Patterson), other independent reps from local statutory and non-statutory agencies with a remit for workplace health and wellbeing (including Prof Addley, NICSOHS), and will meet every 6 months to monitor progress.

Project Management Team: will comprise of the named co-investigators and meet quarterly throughout the trial. They will assume responsibility for meeting project milestones, data

integrity and quality. A monitoring schedule covering the roles and responsibilities of the researcher, project team, and TSC for monitoring recruitment, data quality, compliance, safety and ethics will be developed and agreed. Data quality, follow-up and trial monitoring will be facilitated through the development of a trial specific database, including validation, verification, monitoring and compliance reports. Day-to-day management of the study will be undertaken by the appointed PDRF under close supervision provided by FK (PI) and RH (CI).

15. Project Timetable and Milestones

Milestone	***Start Date***	***End Date***
Pre-award Phase:		
• Ethics and Trust Governance application and approval	Mar 2014	Aug 2014
• Develop research protocol and study SOPs	Jun 2014	Aug 2014
Set-up Phase:		
• Establish Trial Steering Committee	Sept 2014	Sept 2014
• Develop randomisation procedure; develop and implement database specifications	Sept 2014	Sept 2014
Recruitment Phase:		
• Recruit participants (n=1380)	Jan 2015	April 2015
Intervention Tailoring Phase:		
• Conduct focus groups with participants (n=3)	Nov 2014	Nov 2014
• Conduct semi-structured interviews with retailers (n=5)	Nov 2014	Nov 2014
• Conduct DCEs and analysis of DCE data (n=1380)	Nov 2014	Jan 2015
• Analysis of focus group, semi-structured interview	Dec 2014	Jan 2015
• Refine intervention based on data above	Jan 2015	Feb 2015
Intervention Phase:		
• Conduct baseline data collection, data entry and cleaning	Feb 2015	Dec 2015
• Conduct randomisation of clusters	Feb 2015	Dec 2015
• Deliver intervention (6 months)	Mar 2015	Jun 2016
Follow-up Phase:		
• Conduct 6 month follow-up data collection	Sept 2015	Oct 2016
• Conduct behavioural economic field experiment (n=200)	Apr 2016	June 2017
• Conduct 6 month focus groups with participants (n=5)	Mar 2016	Oct 2016
• Conduct semi-structured interviews with senior management (n=7) and retailers (n=5)	May 2016	July 2016
• Conduct qualitative data analysis	Nov 2016	Jun 2017
• Conduct 12 month follow-up data collection	Feb 2016	Mar 2017
• Complete data entry and cleaning	Jan 2017	Sept 2017
• Conduct 12 month focus groups with participants	Apr 2017	Jun 2017
• Complete 12 month qualitative data analysis	Jul 2017	Oct 2017
• Complete data analysis and write up	Oct 2017	Jan 2018
• Disseminate study findings	Jan 2018	Feb 2018

16. Expertise

The proposed study is a mixed methods evaluation addressing the latter stages of the MRC framework for complex interventions. As such it requires a wide range of expertise to undertake successfully which we believe is reflected in the study team.

Study Team: ***Kee***, Prof. of Public Health Medicine and Director of the UKCRC CoE, has expertise in evaluating complex interventions and strong links with policy and practice. He is PI with responsibility for project oversight, line management of research staff, dissemination activities, administration of funds and submitting reports. ***Hunter***, Research Fellow, is Project Manager of the PARC Study (NPRI-funded) and has led the development of the PA loyalty card scheme. She will assume the role of study director, and aid with intervention design, development of study methodology and process evaluation, provide practical advice on the study and fieldwork logistics, and support the PI in terms of staff management. ***Tully***, Lecturer in PA, has expertise in walking measurement and promotion. He will train research staff in PA data collection methods, ensure quality control of PA data, and oversee analysis of PA data. ***Patterson***, Prof. of Medical Statistics, will advise on the sample size calculation, cluster RCT

design, undertake randomisation, and advise on outcome and mediation analyses. ***Prof Hutchinson***, expert in experimental economics, will supervise the behavioural economic field experiment. ***Longo***, Lecturer in economics will supervise the behavioural economics PDRF and advise on the conduct and analysis of the DCEs and time preferences questions. *Prof* ***Prior***, an experienced qualitative researcher, will supervise the PDRF responsible for the qualitative aspect of the study, oversee the analysis of the qualitative process evaluation and advise on the merging of quantitative and qualitative data. ***McIntosh***, Reader, Health Economics, Glasgow University, will supervise the health economics PDRF and oversee the design and analysis of the cost-effectiveness and cost-benefit analysis. ***French***, Prof. of Health Psychology, Manchester University, will refine the intervention and its theoretical framework based on his expertise in behaviour change techniques, and advise on outcome measures employed throughout the study. ***Adams***, Newcastle University, NIHR Career Development Fellow investigating financial incentives, will help with refinement and timing of incentives used in the intervention based on her fellowship work. ***White***, Assistant Director of Health and Wellbeing, South Eastern Trust, has implemented a range of public health programmes, will facilitate implementation of research findings and future roll-out of the scheme, if proven effective. He will also provide a key role liaising with both study investigators and stakeholders.

Supervision Arrangements for Junior Staff: The PI will assume overall responsibility for the management of junior staff, assisted on a day-to-day management basis by Hunter. Given the various expertise of the PDRF's in behavioural economics, health economics and qualitative research, Longo, McIntosh and Prior will oversee the day-to-day supervision of the PDRF's respectively, given their expertise in these areas.

Clinical Trials Unit (CTU) Involvement: An independent TSC, chaired by the Director of the Northern Ireland CTU, will be established to oversee the conduct of the study and monitor data for completeness and quality.

17. Partner Collaboration

Partner Organisations: The intervention will be delivered in partnership with Lisburn City Council and South Eastern Trust. Representatives from Lisburn City Council and the South Eastern Trust who have a remit for employee health and wellbeing will assist in the implementation of the intervention. Intervention funding will be provided by the Public Health Agency, the South Eastern Trust and Lisburn City Council as evidenced by the Letters of Support.

Workplace and Retail Networks: Barbara Porter, Health and Social Wellbeing Improvement Senior Officer, Public Health Agency oversees a network of over 3000 businesses in Lisburn City Centre. She will help to facilitate recruitment and examine potential scalability of the intervention should it be proven effective. Hazel King, Economic Development Manager, Lisburn City Council will work in partnership with Kathie Edwards (Director, Club Marketing Services Ltd) to collaborate with a consortium of 700 business partners to design the rewards scheme. This aspect of the study will be facilitated through collaboration with the Lisburn City Centre Management Group and Chamber of Commerce.

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