

**NATIONAL PREVENTION RESEARCH INITIATIVE:
LIST OF AWARDS AND ABSTRACTS FOR PHASES 3**

NPRI Phase 3 Awards (n=15) Awards Announced 2009

Name	Institution	Title
Prof Annie Anderson	Dundee	BeWEL the impact of a BodyWEight and physical activity intervention on adults at risk of developing colorectal adenomas
Prof Paul Aveyard	Birmingham	Testing the feasibility of nicotine assisted reduction to stop in pharmacies. The RedPharm Study
Prof Stuart Biddle	Loughborough	An intervention to decrease sedentary behaviour in young adults at risk of type 2 diabetes mellitus
Prof Janet Cade	Leeds	Smart phone: promoting weight loss and improved health using mobile phone technology
Prof Simon Capewell	Liverpool	Prevention IMPACT: developing and evaluating economic models for planning optimal cardiovascular prevention strategies
Prof Joan Duda	Birmingham	A intervention fostering autonomous motivation, physical activity and cardiovascular fitness in rheumatoid arthritis
Dr Frank Eves	Birmingham	Prompting Increases in Stair Climbing at Work to Promote Physical Activity
Prof Martin Gulliford	Kings	Role of primary care in translating effective lifestyle modification strategies
Dr Melvyn Hillsdon	Bristol	The feasibility of a simple, low-cost, general practitioner delivered intervention to promote physical activity
Dr Russell Jago	Bristol	Development of an after-school programme to increase physical activity and dance skills in 11-12 year old girls
Prof Frank Kee	Queens, Belfast	Physical Activity and the Regeneration of Connswater (the PARC Study)
Prof Laurence Moore	Cardiff	Preventing substance misuse: Randomised Controlled Trial of the Strengthening Families 10-14 Programme
Dr Sharon Simpson	Cardiff	Healthy Eating and Lifestyle in Pregnancy
Prof Jane Wardle	UCL	Randomised controlled trial of habit-based advice for weight control in general practice (The 10TT Trial)
Prof Robert West	UCL	The development and evaluation of an internet-based smoking cessation intervention (ISCI)

Phase 3: Abstracts of awards

Professor Annie Anderson (Centre Public Health Nutrition Research, Dundee)

BeWEL the impact of a BodyWEight and physical activity intervention on adults at risk of developing Colorectal adenomas

Colorectal cancer (CRC) is a major public health problem and often co-exists with other disorders including obesity, type 2 diabetes mellitus (T2DM) and cardiovascular disease (CVD). The proposed work aims to evaluate the impact of the "BeWEL" intervention programme on body weight changes, cardiovascular risk factors, diet and physical activity in healthy individuals with excess body weight attending routine NHS clinics who have had pre-cancerous bowel polyps removed, but are at risk of developing future cancer and other obesity related conditions. Men from the poorest backgrounds have the highest rates of screen detected adenomas and the proposed work offers a rare opportunity to engage with a hard to reach group. The 3 year study will be a two-arm, multi-centre, randomised controlled trial of the BeWEL intervention against usual care. Participants will be men and women aged 50 to 74 years, with a BMI $\geq 25\text{m/kg}^2$, who have been treated for the removal of a colorectal adenoma. They will be recruited after discharge from follow-up clinics. The pre-trial development will take 6 months, participants will be recruited over a 12 month period and undertake the intervention and follow up for 12 months with a further 6 months for data collection, analysis and interpretation. The Intervention Group (IG) will receive the "BeWEL" personalised, multiple contact, intervention programme (based on the clinically successful US diabetes prevention programme), personal body weight scales and invitations to undertake supervised monthly body weight recordings. The impact of the programme will be assessed by quantitative, qualitative and economic analysis. The main outcomes measures will be physical activity, dietary intake and psycho-social variables as well as body weight, markers of insulin resistance and cardiovascular risk. The research will also provide information on what factors influence decisions to engage in the programme, the response to the intervention by deprivation category, patients' experience of the intervention, and the NHS cost implications. The findings will be relevant to increasing understanding of how the NHS can deliver effective lifestyle interventions to people from diverse social backgrounds and has particular relevance for combining disease prevention strategies with early detection procedures.

Dr Paul Aveyard (Primary Care and General Practice, Birmingham)

Testing the feasibility of nicotine assisted reduction to stop in pharmacies. The RedPharm Study

Harm reduction in nicotine addiction means providing treatments such as nicotine replacement therapy to smokers who cannot or do not want to quit with the aim of reducing the harm they suffer from continued smoking. The least controversial step would be to provide NRT to smokers who are prepared to reduce smoking and provide advice on how to reduce with a view to one day quitting. A systematic review and meta-analysis and cost-effectiveness analysis shows that such a strategy is effective and cost-effective but it is not currently recommended in either British or US smoking cessation guidelines because of uncertainty as to how this fits with current practice. We propose a pilot randomised trial to examine whether pharmacists can be trained to implement NARS, how well they do so, and how this is received by smokers and by pharmacists. These pharmacists will be selected from those providing NHS stop smoking support. We will use this to prepare for a future definitive factorial trial of short versus standard reduction and behavioural support versus no support. About 160 participants will be randomised to test the acceptability, take up, adherence, and feasibility of trial follow up procedures. We propose using minimal contact procedures initially by email to monitor process and outcome of the trial and qualitative interviews with trial therapists and participants to examine how they integrated reduction programmes into their brief interventions and cessation work and how this is understood by participants. This would assess some of the barriers precluding use of reduction programmes and prepare for a further trial to assess the effectiveness of behavioural support and length of programme.

Professor Stuart Biddle (School of Sport, Exercise and Health Sciences, Loughborough)
An intervention to decrease sedentary behaviour in young adults at risk of Type 2 Diabetes Mellitus

Sedentary behaviour is ubiquitous and recent evidence suggests that excessive bouts of time spent sitting may be a risk factor for Type 2 Diabetes Mellitus (T2DM). However, young adults at risk of T2DM are a neglected yet growing group. In addition to the study of moderate-to-vigorous physical activity (PA), there is now a greater recognition of the potential importance of studying sedentary behaviours. However, little is known about whether we can change sedentary behaviour in young adults at risk of T2DM or whether an intervention will produce meaningful change in behavioural and biological markers of T2DM. Consequently, our key research proposes a proof-of-concept trial with key research questions being: 1. Can a structured education programme decrease sedentary behaviour in young adults at risk of T2DM? 2. Does this programme produce favourable changes in key behavioural and biological markers of T2DM risk?

We propose a structured educational intervention, with prompts, designed to decrease sedentary behaviour in young adults aged 18-30y. Participants will be recruited from those with a family history of T2DM or cardiovascular disease or a BMI at or over 25 (23 for south Asians). Participants will be randomised to a control or intervention (I) arm. I participants are given an education programme aimed at decreasing sedentary behaviour, based on the PREPARE programme, a group-based, 3-hr educational intervention with a theory-driven curriculum aimed at behaviour change. PREPARE will be modified to allow for the targeting of a reduction in sedentary behaviour. Prompts and behavioural self-monitoring will be provided by innovative new Bluetooth technology ('MiLife'). The control group will receive an information leaflet focusing on key illness perceptions surrounding IGT and the importance of increasing physical activity and reducing sedentary behaviour.

The primary outcome measure is sedentary behaviour (time below 100 counts/min assessed by accelerometry) with secondary outcome measures including physical activity, various biomarkers (e.g., fasting glucose, TNF-alpha, IL-6), anthropometry, and psychological measures. The trial is powered for N = 89 per arm.

This will be the first UK study to address sedentary behaviour change in this population. The trial will inform behaviour change programmes for this at-risk group and provide a major new direction of behaviour change alongside the more conventional use of encouraging increases in moderate-to-vigorous physical activity.

Professor Janet Cade (Centre for Epidemiology and Biostatistics, Leeds)
Smart phone: promoting weight loss and improved health using mobile phone technology

Mobile phone use is ubiquitous throughout the adult population. In the USA, they have been used successfully to support weight loss activity. We will develop an intervention approach using support delivered via mobile phone technology to treat obesity in adults. This can later be evaluated in a definitive RCT which is not part of this proposal.

Study objectives are:

- To develop a mobile Smartphone package to support weight loss by testing and further adaptation of two existing systems MobileDANTE and the Nutracheck system
- To develop components of the intervention by applying a framework of four key determinants of obesity: appetite control; the force of dietary habits; the level of physical activity and the level of psychological ambivalence
- To develop personalized feedback components and reminder prompts for subjects
- To assess baseline diet, physical activity and obesity measures
- To implement an exploratory (phase II) trial using the intervention, assessing its feasibility and acceptability, prior to a definitive trial, in order: i) to obtain evidence of potential recruitment rates ii) to identify an appropriate control group iii) to pilot instruments for outcome assessment of obesity, diet and physical activity iv) to estimate effect sizes to be achieved in a full trial with regard to change in weight; waist circumference; blood lipids and blood pressure.
- To validate dietary and physical activity data captured on the Smartphone

The project will be carried out in three stages. Part 1 will develop the intervention by testing and further technical development of existing mobile phone systems. Five focus groups with 30 potential users will be undertaken to test the components of the intervention on the phone.

Part 2 will validate the measures of diet and physical activity using the phone. 50 adults will record diet and activity using the phone and a gold standard paper based detailed diary. In addition, energy expenditure will be assessed using Actigraph measures.

The third stage will be a pilot trial of the intervention. Overweight adults from a large NHS Teaching Hospital Trust will be recruited, 200 subjects will be randomised to receive either the Smartphone or usual advice. The intervention group will use the phone for 6 months. Baseline and follow up measures will be taken. The pilot trial will test the drop out rates; compliance; participant evaluation. Effect size data will be collected for use in derivation of sample size estimates for a full trial.

Professor Simon Capewell (School of Population, Community and Behavioural Sciences, Liverpool)

Prevention IMPACT: developing and evaluating economic models for planning optimal cardiovascular prevention strategies

The prevention of future cardiovascular disease (CVD) remains problematic. Planning and prediction challenges include: complex causes, diverse manifestations, increasing costs, population ageing and conflicting trends in obesity, diet, smoking and inequalities.

Our multi-disciplinary group will therefore:

- systematically review the scientific evidence;
- elicit the views of NHS decision-makers;
- identify a range of policy options;
- further develop a validated coronary policy model to include stroke and other CVD;
- compare the effectiveness and cost-effectiveness of different risk factor reduction strategies in high risk;
- individuals and in entire populations; and
- share results with planners, policy-makers, professionals and patient groups.

Professor Joan Duda (School of Sport and Exercise Sciences, Birmingham)

An intervention fostering autonomous motivation, physical activity and cardiovascular fitness in Rheumatoid Arthritis

Rheumatoid arthritis (RA) is associated with increased cardiovascular morbidity and mortality. The beneficial effects of physical activity (PA) on physical and psychological health are well documented in both normal and clinical populations, including RA patients. In clinical populations, exercise promotion has been primarily carried out via supervised, hospital-based exercise programmes; although these exhibit short-term effects, there is no compelling evidence for sustained long-term improvements. Regardless of the known beneficial effects of PA, patients with RA tend to lead a sedentary lifestyle, due to fear of disease aggravation and lack of encouragement by health professionals. Thus, it is important to develop psychological interventions that optimise the motivation to adopt as well as maintain PA in this population. Grounded in Self-Determination Theory (SDT), a psychological intervention will be developed and evaluated that centres on fostering more autonomous reasons for PA engagement. Autonomy support for PA will be provided via one-on-one exercise consultations with a counsellor trained up in SDT-based behavioural change strategies. Autonomy support will also be offered by exercise instructors during supervised exercise sessions. SDT proposes that autonomy-supportive interactions with significant others contribute to satisfaction of the needs for competence, autonomy, and relatedness. This, in turn, improves an individual's autonomous motivation towards the behaviour at hand (e.g., PA). The impact of the intervention on the magnitude and sustainability of PA engagement, as well as PA-induced cardiovascular, physical function and QOL/mental health adjustments in patients with RA will be assessed. The patients will be randomly allocated to either a conventional 3-month individualised exercise programme (control group) or a 3-month individualised exercise programme combined with the psychological intervention (experimental group). Following the exercise programme, all patients will be left to their own devices to continue PA but either brief telephone-based autonomy-centred support (experimental arm) or more standard encouragement to maintain PA levels (control arm) will take place two months following the cessation of the exercise programme. Six months and one year following the start of the

exercise programme, the two groups of patients will be compared on cardiovascular, self-reported PA (and objective PA, in a sub-sample), psychosocial/motivational, and RA-related outcomes. It is hypothesised that patients in the experimental group will have a better cardiovascular profile and exhibit greater psychological well-being at the 6 and 12 ms follow ups than those in the control group, due to enhanced autonomous motivation and better maintenance of PA after the initial supervised exercise programme.

Dr Frank Eves (School of Sport and Exercise Sciences, Birmingham)

Prompting Increases in Stair Climbing at Work to Target Weight Control

The seminal Harvard Alumni study demonstrated dose-response effects of stair climbing on health, observations subsequently supported by experimental work. Increased stair climbing at work can reduce both cardiovascular risk and weight. To increase stair climbing, messages are positioned at the point-of-choice between the stairs and lift, outlining the health benefits. These prompts function by interrupting habitual behaviour at the point of occurrence allowing its replacement with a health enhancing alternative. Two recently completed interventions recast the science behind stair climbing in lay terms. For the first time, the messages specified the amount of stair climbing required to achieve the benefits. Further, the main campaign message was reinforced by additional messages in the stairwell. This approach produced greater effects in overweight individuals, a finding recently confirmed in a metro station. Stair climbing may be a particularly attractive method of exercise to overweight individuals.

The project will improve further the effectiveness of these simple interventions. Optimal message content will be explored with focus groups followed by product testing in field interviews. For the intervention phase, quasi-experimental interrupted time series designs will be used. For example, a 3-week baseline is followed by an intervention, with a step change at the point of interruption in the time series providing strong evidence of effectiveness. Matched comparison sites can test the relative merits of different interventions whereas workforce details allow estimates of threats to generalisation. Stair and lift use will be monitored with automated counters. For the main messages, a balanced design will compare three different messages in six workplaces. Two further studies of message delivery will assess the effects of changing the message on adaptation of its effects. In the first study, simultaneous presentation of three main messages for 12 weeks will be compared with a matched worksite where a single main message is changed every four weeks. The second study on message delivery will compare simultaneous presentation of six additional stairwell messages with a single stairwell message that changes each week.

Rolled out regionally, these interventions are cheap – 5p per employee for a 500-strong workforce. Links with Directors of Public Health in Birmingham ensures dissemination to practitioners at a regional and national level. A reciprocal arrangement to share materials with NHS Health Scotland, ongoing consultation with DoH, Catalunya and the PIs membership of the working group on worksite health promotion for the Health Enhancing Physical Activity network (HEPA Europe) ensure wider dissemination.

Professor Martin Gulliford (Dept of Public Health Sciences, King's)

Role of primary care in translating effective lifestyle modification strategies

Background: The Wanless Report proposed a vision of health services promoting the maintenance of good health. This proposal investigates how this objective can be achieved.

Aims: The key questions for this research are: 'How can existing research evidence on the effectiveness of behavioural lifestyle interventions be translated into strategies for disease prevention in primary care?'; and 'What are the potential long-term outcomes and costs of different intervention strategies?'

Methods: A Markov simulation model will be implemented. The model will be populated with data from two sources. Systematic literature reviews will provide estimates of intervention effects and the association of behaviours with disease risk. Interventions to be modelled include behavioural interventions to promote healthy eating and physical activity through primary care. Analysis of a large cohort of subjects registered from the General Practice Research Database (GPRD) will provide data for the incidence and prevalence of conditions of interest, and associated resource utilisation, according to age, sex and risk strata under usual

care. Outcomes will include all-cause mortality, incidence of type 2 diabetes, coronary heart disease, stroke and other outcomes including renal failure, neoplasms and depression. Costs will be estimated based on GPRD- and model-derived estimates of resource utilisation. Main outputs: This research will provide researchers and health decision-makers with estimates of the long-term cost-effectiveness of implementing pragmatic behavioural interventions to modify diet and physical activity in primary care. Different strategies for intervention will be compared. A population-wide approach will be compared with a high-risk approach based on risk stratification. These estimates will be securely grounded in generalisable data drawn from a large primary care population. Estimates will include cost per case of diabetes, CHD, stroke and other health outcome (including renal failure, neoplasms and depression) prevented and cost per QALY gained. Sensitivity analyses will evaluate the effect of varying key assumptions. The smallest intervention effect that may be of value will be estimated.

Team: The research will be implemented through a collaboration between King's College London, London School of Economics and GPRD Division, Medicines and Healthcare Products Regulatory Agency (MHRA). Our team has expertise in epidemiology, statistics, health economics, health psychology and primary care.

Dr Melvyn Hillsdon (Exercise, Nutrition and Health Sciences, Bristol)

The feasibility of a simple, low-cost, general practitioner delivered intervention to promote physical activity

The National Institute for Health and Clinical Excellence (NICE), has advised that all General Practitioners (GPs) should whenever possible, identify inactive patients and advise them to increase their physical activity. How best to advise patients to increase their physical activity in a cost effective way is unknown. A randomised, controlled trial testing the effectiveness and cost effectiveness of a simple, low cost, GP delivered walking message to reduce the number of inactive patients is urgently needed. However, there are a number of methodological and practical uncertainties that preclude immediate progress to a full trial. A feasibility study is proposed in order to address a number of uncertainties that preclude immediate progress to a full trial. A randomised 2x2 trial factorial design will be used to explicitly compare methods of randomisation (practice or patient) and methods of patient recruitment (opportunistic or systematic). Additional uncertainties the feasibility study will explore are GP willingness and ability to follow NICE guidance on screening and advice; patient acceptability of GP screening and advice; expected patient recruitment rates and loss to follow up. In addition the effect size in terms of physical activity and intra-class correlation coefficients will be estimated to inform the sample size and power of the full trial. Three interventions delivered at the level of general practice will be compared. All consenting patients will be informed that the GP is participating in a study assessing the effect of physical activity information on physical activity. They will all be asked to take away a physical activity information booklet and wear a sealed pedometer to measure routine physical activity.

(i) Arm A (Usual care - Control). Written information about the benefits of physical activity as well as local opportunities for physical activity. (ii) Arm B (Brief GP advice). In addition to receiving the written physical activity information in Arm A, patients will be advised by the GP to "walk at least a mile per day (15-20 minutes) at a brisk to fast pace, each day of the week." (iii) Arm C (Brief GP advice + pedometer). Following the GP walking advice, patients will be given an unsealed pedometer to self monitor their daily walking and will be given daily targets. Main outcome measures will be assessed at 12 weeks post intervention.

Dr Russell Jago (Exercise, Nutrition and Health Sciences, Bristol)

Development of an after-school programme to increase physical activity and dance skills in 11-12 year old girls

Objective: To examine how a 10-week after-school dance program can increase 11-12 year olds girl's habitual physical activity levels and provide the girls with a desire and the skills to engage in dance once the initial contact sessions have ended. Research will be conducted in 2 phases.

Methodology: In phase one, we will conduct 9 focus groups with Year 7 girls to identify factors that would affect their attendance at an after-school dance program and how contact sessions could increase girls' ability to engage in dance without instructors. We will also conduct 24 interviews with the parents of 11-12 year old girls to examine how they could support the project. We will then conduct interviews with expert dance teachers on how to make the sessions as enjoyable as possible and strategies for longer-term dance participation. Draft recruitment materials and content will then be piloted in one school, participant responses obtained and content adjusted accordingly. A 4-week pilot study will then be conducted to assess the program content and if further refinement is necessary. Phase 2 will be an exploratory trial in 6 schools, (3 intervention and 3 control). The intervention will be a 10-week dance program, that is provided free of charge, during the extended school day. The dance program will be provided for an hour, 3-times per week. Sessions will focus on obtaining MVPA in an enjoyable, supportive environment that increases the girls' intrinsic motivation and self-efficacy to engage in dance. Sessions will also focus on building dance related skills and personal capacity to engage in dance. We will recruit 30 girls per school (90 intervention and 90 control). Assessments will be made at baseline (time 0), immediately after the intervention (time 0+10 weeks), and 3-months after the intervention has ended (time 0+22 weeks). Accelerometer derived minutes of moderate to vigorous intensity activity will be the primary outcome. Secondary outcomes will include self-determination theory related questionnaires. Preliminary information on costs will also be obtained to facilitate future cost-effectiveness calculations.

How results will be used: The results will provide all of the information necessary to design an adequately powered cluster RCT to increase girls' short and long-term physical activity via dance including the school associated intra-class correlation for all outcomes. Once this study has been completed we will submit a further application for full-trial funding.

Professor Frank Kee (UKCRC Centre of Excellence in Public Health, Queens Belfast)

Physical activity and Regeneration of Connswater (the PARC Study)

The Connswater Community Greenway (CCG) is one of three 2008 Big Lottery Living Landmarks awards and is a major environmental improvement project in East Belfast, which will connect 379 acres of public open space, building 43 bridges and 19kms of cycle and walkways. Around 40,000 people, most from inner city deprived neighbourhoods and living adjacent to CCG, will, by 2013, benefit from a better living environment, opportunities for leisure, exercise, recreation and support for healthier lifestyles. We will use the opportunity afforded by this "natural experiment" to design a systems-based approach to the promotion of physical activity (PA) and thereby determine the ability of individual, community and organizational networks and of the characteristics of the local environment to change behaviours. The cost effectiveness of this socio-ecological approach will also be assessed. Using a PRECEDE-PROCEDE framework, a multi-stakeholder team will first engage with the targeted communities and devise a logic model for a suite of PA promotion interventions involving statutory and voluntary bodies in the CCG area. A baseline survey will be conducted of a random sample of households in the electoral wards of the CCG area before the urban regeneration project begins. This will assess attitudes to and levels of habitual physical activity, perceptions of the characteristics of the environment associated with active travel and physical activity, individual and social networks and their potential influence on their behaviour. A contemporaneous survey by SportNI of PA behaviours across Northern Ireland will generate a number of "comparator" communities with which CCG will be compared. Process measures to judge the "dose", fidelity and costs of implementing interventions will include an assessment of the changes in "walkability", awareness and take-up of PA promoting interventions, the trends and patterns of activity of novel PA "loyalty" scheme

users, and the use made of new environmental amenities or different types of transport. These will be enriched by a qualitative and quantitative study of the voluntary and statutory stakeholder partnerships during the implementation period (2009-2013). A repeat survey of CCG households, more than six months after the completion of the Connswater Greenway construction will be timed to coincide with a further province wide survey of physical activity behaviours conducted by SportNI.

Primary endpoints will be the change in the proportion of residents in the CCG area who achieve recommended levels of PA (150mins per week), over the period 2009-2013, compared to other parts of Belfast and Northern Ireland.

Professor Laurence Moore (Cardiff Institute of Society, Health and Ethics, Cardiff)
Preventing substance misuse: Randomised Controlled Trial of the strengthening Families 10-14 Programme

Adolescent risk behaviour, including substance misuse (alcohol, tobacco and illegal drugs), anti-social behaviour and crime has a substantial impact on the UK economy and the health of its population. These behaviours are associated with morbidity and mortality among adolescents, poor education, social exclusion and health damaging behaviours, and poor health over the life course. They contribute substantially to social inequalities in health in adolescence and adulthood.

This research application is for a randomised controlled trial of a substance misuse prevention intervention – the Strengthening Families Programme (SFP) 10-14 UK. The SFP10-14 for young people aged 10-14 years and their parents is a population-based universal prevention programme for alcohol, tobacco and drug misuse in young people. Research in the United States has found the SFP10-14 to be effective in delaying the onset of alcohol use, and reducing levels of smoking. In other studies, later onset of alcohol and drug use has been shown to be associated with reduced lifetime prevalence of alcohol and drug problems. US-based cost-benefit assessments have indicated that the SFP10-14 can be cost-effective at the population level for preventing alcohol misuse, other alcohol problems and also for tobacco use prevention. The SFP10-14 is thus a promising intervention and has recently been culturally adapted for use in the UK where it is gaining popularity. However, the current evidence base for the programme is derived exclusively from the US from just two trials conducted by the same research team, and there is a need to evaluate the SFP10-14's effectiveness in a UK context, particularly in relation to the contrasting legislative frameworks and cultures surrounding alcohol in this country.

The proposed trial will take place in six local authority areas in Wales. Families who are referred to the programme will be screened for eligibility before being allocated to intervention/control groups. Key outcome measures (measured at 2 years) will include: number of occasions young people report ever having been really drunk; reported use of cannabis; weekly smoking; unauthorised absence from school; GCSE performance; and age of initiation of alcohol and tobacco consumption. A process evaluation of programme delivery will be undertaken to examine fidelity and acceptability of the intervention to participating families, and key changes in family functioning. Economic analysis will also be conducted to examine the cost effectiveness of the SFP10-14. Findings from the research will be used to directly inform policy and practice in the field of substance misuse prevention.

Dr Sharon Simpson (Dept of Primary Care & Public Health, Cardiff)
Healthy Eating and Lifestyle in Pregnancy

Around 1 in 5 pregnant women in the UK are obese. Obesity is linked generally to poor health and also pregnancy complications. Retaining weight gain following pregnancy can lead to long-term obesity. There is evidence that excess maternal weight gain during pregnancy is associated with obesity in the child at 3 years and in adolescence, which suggests there is potential for influencing not only the mother's lifestyle but the new child's weight and the family's health behaviour. Intervening with pregnant obese women and equipping them with the skills, knowledge and support necessary to manage their weight effectively during pregnancy and after childbirth is an important step in tackling overweight and obesity among women of child bearing age. This study is a cluster randomised controlled trial which will

examine whether a weight management intervention for obese pregnant women, which targets physical activity and healthy eating, is effective in reducing women's BMI at 12 months from giving birth and at what cost. Secondary outcomes include; pregnancy weight gain, quality of life, mental health, waist-hip ratio, child weight centile, admission to neonatal unit, diet, physical activity, pregnancy and birth complications, social support, self regulation and self efficacy. Twenty maternity units will be recruited and midwives will be trained in recruitment and the intervention. These units will be randomised, ten to the intervention group and ten to the control group. We will recruit women over 18 with a BMI of ≥ 30 between 12 and 20 weeks gestation, 570 women will be recruited allowing for a drop out of 30%. Those women attending the maternity units randomised to the intervention group will attend a weekly, 1.5 hour specialist weight management and physical activity support group run jointly by 'Slimming World' and midwives. At each session weight will be monitored and advice given regarding diet, lifestyle and pregnancy. Slimming World advice is similar to that advised for pregnancy and for breastfeeding mothers and offers a balanced unrestricted diet. Additional exercise recommendations will encourage graded, supervised increases in daily physical activity through a walking programme. Women attending control units will receive usual care and a leaflet giving advice on diet and physical activity. Women will be followed up at 36 weeks gestation, 6 weeks post birth, six months and one year after birth. Positive results are likely to lead to refinement and roll-out of the intervention.

Professor Jane Wardle (Dept of Epidemiology and Public Health, UCL)
Randomised controlled trial of habit-based advice for weight control in general practice (The 10TT Trial)

Increases in obesity prevalence over recent decades have made weight control a key issue for public health. The cross-government strategy Healthy Weight, Healthy Lives identifies primary care as the 'first port of call' for advice about weight control, creating an urgent need for simple, effective interventions that can be delivered by the primary care team without specialist therapeutic skills.

A novel approach to health behaviour change draws on 'habit-theory'. Diet and activity behaviours are often loosely termed 'habits', but few behaviour change interventions are based explicitly on the theory of habit-formation. The essential feature of habits is that they are automatic (i.e. require minimal deliberate effort). Habits are learned responses to environmental cues resulting from multiple repetitions in a consistent environmental context. They are more resistant to extinction than non-habitual behaviours because they don't depend on deliberate self-control.

There has been growing interest in the role of habits in health behaviours, but existing research focuses largely on bio-behavioural mechanisms. In one of the first attempts to translate habit theory to practice, we used it to develop a simple weight-control programme. We took a set of simple behaviours known to be associated with weight control and presented them in leaflet format (TenTopTips) along with advice on how to make them habitual (repetition in consistent contexts, self-monitoring until automaticity developed). No further clinical contact was involved. Users involved in the development found it easy and effective. A trial in a volunteer population ($n=104$) showed that individuals randomised to receive the TenTopTips leaflet lost significantly more weight than the wait-list control group (-2.0kg vs -0.4kg in an intention-to-treat analysis; Lally et al, 2008). Weight loss was maintained over 32 weeks follow-up, with 54% (ITT=26%) achieving the 5% weight loss associated with health benefits. Weight loss was associated with increased automaticity of the behaviours, suggesting that development of habits underpinned the intervention's effectiveness.

These results provide a strong basis for conducting a controlled trial of the effectiveness of the TenTopTips intervention in Primary Care and incorporating clinical outcomes and health-economic analyses. This application is for an individually-randomised, controlled trial of 520 obese adults across 10 General Practices comparing the TenTopTips leaflet with a usual-care control condition. The primary outcome is loss of body-fat, with secondary outcomes including clinical risk-factors, behaviour change and automaticity, and quality-of-life. A full

cost-effectiveness analysis will be carried out and surveillance will continue for 24 months to establish longer-term maintenance.

Professor Robert West (Dept of Primary Care & Population Sciences, UCL)
The development and evaluation of an internet-based smoking cessation intervention (ISCI)

Background and aims: There is a need for effective smoking cessation support that can reach large numbers of smokers including the 90% not willing to seek telephone or face-to-face support. There is also a need to develop a system for developing an incremental technology of behaviour change. The internet could meet both those needs. NHS LifeCheck and the NHS Health Trainers programme targeting hard-to-reach individuals have a need for a behaviour change module that focuses on aiding smoking cessation. Internet-based interventions have been found to be effective in aiding smoking cessation, but none thus far have high reach or would be suitable or universally available. The advent of LifeGuide, an innovative platform for developing and evaluating internet-based behaviour change interventions makes it much more cost efficient to develop and evaluate a smoking cessation intervention than would have previously been the case. This proposal is to develop an interactive internet-based smoking cessation programme and evaluate its effectiveness, attractiveness and usability in comparison with a system that delivers non-interactive smoking cessation advice.

Methodology: The project is in two phases: Phase 1 (12 months) involves development and preliminary evaluation of the internet-based intervention. Special emphasis will be placed on maximising user engagement, particularly for smokers in routine and manual occupational groups. Engagement will be assessed using Level 1 criteria recommended by the Science Panel on Interactive Communication and Health. Short-term smoking cessation outcomes will also be assessed. Phase 2 (24 months) is an RCT of the intervention with special focus on recruiting and helping smokers from routine and manual occupational groups. Although a decision on funding this phase is being sought now, a stop-go decision will be made by an independent review panel at the end of Phase 1. The RCT will recruit 4000 smokers using Health Trainers and NHS websites. The interactive intervention will be compared with a simple untailed website. The primary outcome measure will follow the Russell Standard with 6-months of continuous abstinence verified by expired-air carbon monoxide.

Attractiveness and measures of user engagement will be important secondary outcome measures. Data analyses will involve mediation analyses using bootstrapping and moderator analyses involving important baseline measures, particularly occupational group. The study will be powered to estimate effect size in routine and manual smokers separately. Application of the findings: If effective, this system would form a module for the NHS LifeCheck programme and the NHS Health Trainers Programme.