Summary of Study Results for Primary Care

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Date: June 2018

**Introduction**

Over the past decade, more than 200 practices within the area covered by the CRN West Midlands South, i.e. Coventry, Warwickshire, Worcestershire and Herefordshire, have been active in recruiting to at least one research study taking place within a primary care setting. To date there have been more than 13,000 local patients included in research studies, a magnificent achievement.

The topics covered by these studies includes:

* Management of lower back pain
* Smoking cessation initiatives
* Blood pressure control
* Self-monitoring in diabetes control
* Targeted identification and treatment of COPD
* Diagnosis and treatment of UTIs in children

This research generated a number of high profile publications, and has contributed to important changes in the way patients are treated in primary care.

As part of our commitment to research, and to thank all the practices and CCGs who have assisted us, we are pleased to provide a short digest of publications resulting from some studies that involved local patients. We hope you may find it of interest.

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**Study Results**

# PRIMIT

**Aim:** The PRIMIT study examined the effectiveness of a web-based programme, aiming to reduce the transmission of respiratory infections by encouraging more frequent hand-washing.

**Method:** Across three winters from January 2011 to March 2013, in the midst of the season for flu and other respiratory infections, 20,066 adult patients aged 18 years and older took part from 344 general practices across the UK. Volunteers were randomly assigned access to the PRIMT website or no intervention. Participants were followed for 16 weeks and questionnaires were used to measure episodes of respiratory infections, duration of symptoms, and to check whether other household members had a similar illness.

The programme consisted of four weekly sessions which encourage users to plan and learn how to use simple techniques to avoid catching and passing on viruses, monitor handwashing behaviour and provide tailored feedback.

**Results/conclusion:** At 16 weeks, 4,242 individuals (51%) in the PRIMIT group reported at least one respiratory infection compared with 5,135 individuals (59%) in the control group, equivalent to a 14% reduction in risk. There was a similar reduction in transmission of viruses to family members.

The risk of catching a flu-like illness was about 20% lower in the PRIMIT group compared to the control group, as was the risk of getting a gastrointestinal infection (diarrhoea, or diarrhoea and vomiting). The need for primary care consultations and antibiotic prescriptions were also reduced by 10-15%.

**Importance:** The first worldwide study to show that handwashing can reduce respiratory infections within the home – not only for the person who washes their hands but also for the other family members.

In non-pandemic years this effective web-based programme could have an important effect in reduction of infection transmission and is likely to help during a pandemic.

**Publication:** The Lancet Volume 386, No. 10004, p1631-1639, 24 October 2015

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# Morning versus Afternoon Flu Vaccination

**Aim:** To examine whether diurnal variations in immune responses might extend to the antibody response to vaccination.

**Method:** 24 general practices in the West Midlands, UK, were analysed between 2011 and 2013 in a cluster-randomised trial during the annual UK influenza vaccination programme.

276 adults aged over 65 were vaccinated against three strains of influenza, either in morning surgeries (09:00 - 11:00) or afternoon surgeries (15:00 - 17:00).

**Results/conclusion:** In two of the three given influenza virus strains, those in the morning cohort saw a significantly larger increase in antibody concentration one month following vaccination, when compared with those in the afternoon cohort. In the third strain, there was no significant difference between morning and afternoon vaccination.

**Importance:** Administering vaccinations in the morning, rather than the afternoon, could induce greater, and thus more protective, antibody responses. Thus by ‘shifting the time of those vaccinations to the morning we can improve their efficiency with no extra cost to the health service’.

**Publication:** "Morning vaccination enhances antibody response over afternoon vaccination: a cluster-randomised trial," by Joanna E Long, Mark T Drayson, Angela E Taylor, Kai M Toellner, Janet M Lord, and Anna C Phillips\*, online in Vaccine on 26 April 2016, published by Elsevier, with the DOI:10.1016/j.vaccine.2016.04.032

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# STarT Back

**Aim**: To test the main hypothesis that a stratified approach to primary care management for low back pain results in clinical and economic benefits compared with current best practice.

**Method:** 1573 adults (aged ≥18 years) with back pain (with or without radiculopathy) consultations at ten general practices in England responded to invitations to attend an assessment clinic. Eligible participants were randomly assigned by use of computer-generated stratified blocks with a 2:1 ratio to intervention or control group. Primary outcome was the effect of treatment on the Roland Morris Disability Questionnaire (RMDQ) score at 12 months.

**Results/conclusion:** 851 patients were assigned to the intervention (n=568) and control groups (n=283). Overall, adjusted mean changes in RMDQ scores were significantly higher in the intervention group than in the control group at 4 months and at 12 months. At 12 months, stratified care was associated with a mean increase in generic health benefit (0·039 additional QALYs) and cost savings (£240·01 vs £274·40) compared with the control group.

**Importance:** The STarT Back approach uses a simple tool to match patients to treatment packages appropriate to them. This has been shown to significantly decrease disability from back pain; reduce time off work and save money by making better use of health resources**.** The IMPaCT study showed that this approach can be successfully embedded into normal primary care.

**Publication:** The Lancet Volume 378, No. 9802, p1560–1571, 29 October 2011

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# COPERS

**Aim:** A pragmatic RCT to establish the effectiveness and cost-effectiveness of a new self-management (COPERS) course for those with chronic MSK pain, versus usual care plus a CD recording of simple relaxation exercises

**Method:** Nationally 700 patients (388 from West Midlands South) from primary, intermediate and secondary care services in NE London and Coventry & Warwickshire.

**Intervention***:* Used psychological approaches shown to promote behaviour change e.g. pain education, attention control, relaxation and visualisation techniques, social interaction and new activity unrelated to pain. Learning was facilitated through group discussion, an educational DVD, role play, attention and distraction techniques and ‘good’ posture.

The course lasted 15 hours over 3 days, with a 2 hour follow-up session 2 weeks later. It was delivered by trained facilitators- a healthcare professional (physiotherapist, osteopath, chiropractor, occupational health practitioner or psychologist) and a lay person with experience of living with chronic pain.

**Control***:* An audio CD of breathing and relaxation sequences to practise at least 1/day for 3 weeks (same duration as intervention) and as often as they liked thereafter and a booklet, ‘The Pain Toolkit’.

**Results/conclusion:**  After 6 months those who attended the COPERS course were coping with their pain better, had more self-confidence, were less depressed and anxious and more socially integrated than those who did not. At 1 year post-receiving intervention, they were still less depressed and more socially engaged than those who had not. The COPERS course did not make any difference to ‘function despite pain’ or health care utilisation.

**Importance:** Using the group based COPERS course enabled people to discuss their conditions and learn non-drug pain management techniques which helped psychological wellbeing. The study team hope that the course will be introduced into the NHS as they also found that it was cost-effective.

**Publication:** Study Protocol published BMJ Open 2013; 3:e002492

Final results due to be published with JAMA)

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# TASMIN-SR

**Aim:** To determine the effect of self-monitoring with self-titration of antihypertensive medication versus usual care on SBP among patients with CVS disease, diabetes, or CKD.

**Method:** 540 patients (57 patients recruited from West Midlands South) aged > 35 years with a history of stroke, coronary heart disease, diabetes, or CKD baseline BP > 130/80 mm Hg treated at 59 practices between March 2011 and January 2013.

**Intervention - Self-management***:* Patients were trained to self-monitor BP using a validated monitor, with self-titration of medication following a predetermined plan. BP was taken twice/morning for the first week of each month using simple colour-coded instructions. ≥ 4 BP readings recorded above target during the measurement week for 2 consecutive months led to a change in medication according to the algorithm.

For very high or very low readings (BP>180/100 mm Hg or <100 mm Hg systolic), patients were told to contact their practice. GPs were informed of any medication change.

**Control - Usual care:**Patients booked a routine BP check and medication review with their GP.BP measurement, BP targets, or adjustment of medication for these patients were at the discretion of GP.

**Results/conclusion:** Primary outcome was the BP at the 12-month visit. Data was available on 450 patients (81%). Baseline characteristics were well-matched. The mean baseline BP was 143.1 / 80.5mmHg in the intervention group and 143.6 / 79.5mmHg in the control group.

At 12 months, mean BP was less in the intervention group (Intervention group: 128.2 / 73.8mmHg and control group: 137.8 / 76.3mmHg) with a difference of 9.2 mmHg (95%CI, 5.7-12.7) in systolic and 3.4 mmHg (95%CI, 1.8-5.0) in diastolic following correction for baseline BP.

In both groups the numbers and doses of medications were increased, but significantly more in intervention group although there was no significant difference in adverse effects between the groups. The main changes were in prescription of calcium channel blocker and thiazides.

In conclusion clinically significant reductions in SBP and DBP without any increase in adverse events were achieved and the results were sustained over the 12 month trial.

**Importance:** Self-monitoring and self-titrating antihypertensive medication in patients with hypertension at high risk of CVD is feasible. Patients at high risk of CVD whose BP is not optimally controlled should be considered for self-management.

**Publication:** JAMA August 27, 2014, Vol 312, No. 8

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# BP-Eth LogoBP-ETH

**Aim:** To investigate whether ethnicity influences BP measured in clinic and by ambulatory BP monitoring (ABPM) in individuals with and without a diagnosis of hypertension.

**Method**: A primary care observational study (2010-12) of 28 practices involving 770 patients (White British, South Asian, African Caribbean) from Central England.

**Results/conclusion**: BP differences between ethnic groups where BP is carefully measured on multiple occasions are small and unlikely to alter clinical management. When BP is measured casually on a single occasion or in routine care, differences appear that could approach clinical relevance and affect clinical management.

**Importance**: The study emphasizes the importance of careful BP measurement irrespective of ethnic group and suggests that where this is not undertaken, erroneous difference may occur which could impact clinical decisions.

**Publication:** Martin et al Am J Hypertension 2014; DOI:10.1093/ajh/hpu 211

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# OPERA – Older Peoples Exercise in Residential Accommodation

**Aim:** To test whether moderate intensity exercise reduces depressive symptoms in residents of care homes

**Method**: A cluster randomised controlled trial – in NE London; Coventry and Warwickshire. 78 care homes with 891 residents ≥65 years.

*Intervention:* Depression awareness training for care-home staff, 45 min physiotherapist-led exercise session twice per week and whole home encouragement in more physical activity.

*Control:* Depression awareness training only.

**Results/conclusion:** The primary outcome was the number of depressive symptoms on the GDS-15 over 12 months. The results showed no significant impact on depressive symptoms.

**Importance:** A very robust study which obtained a clear answer to the research question. Future research should consider evaluating a multifactorial intervention targeted specifically at care home residents with depression.

**Publication:** Underwood et al., 2013 Lancet; 382: 41-9.

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# TXT2STOP

**Aim:** To assess the effect of an automated smoking cessation programme delivered via mobile phone text messaging on continuous abstinence.

**Method:** A RCT of 5800 smokers who were willing to make a quit attempt. 2915 smokers were allocated to the txt2stop intervention and 2885 were allocated to the control group.

**Intervention***:* A mobile phone text messaging smoking cessation programme comprising of motivational messages and behavioural-change support. The group received five text messages per day for the first five weeks, then three per week for the next 26 weeks. They also had the option of texting the word ‘crave’ or ‘lapse’ to receive an instant message of support when a craving struck.

**Control***:*  Text messages were sent unrelated to quitting.

**Results/conclusion:** The primary outcome was self-reported continuous smoking abstinence, biochemically verified at 6 months. This was available for 5524 (95%) participants. Biochemically verified continuous abstinence at 6 months was significantly increased, double in fact, in the txt2stop group (10·7% txt2stop vs 4·9% control).

**Importance:** A very successful study with an intervention that is cost effective, easy to replicate and has been proven to work well across all age and social groups. It is now available as part of the NHS SMOKEFREE campaign.

**Publication:** The Lancet Volume 378, No.9785, p 49-55, 2 July 2011

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# M:\WMS\HS_SSSH\PCRN\Shared PCRN Data\Participate\@Archive\2014 Autumn\2014 Autumn add stuff\ESTEEM logo.pngESTEEM

**Aim:** To assess the effectiveness and cost consequences of GP-led and nurse-led telephone triage compared with usual care for patients seeking same-day consultations in primary care.

**Method:**  A cluster RCT and economic evaluation between March 1, 2011, and March 31, 2013, at 42 practices in four centres in the UK. Practices were randomly assigned (1:1:1) to GP-led triage, nurse-led computer-supported triage, or usual care. Patients who telephoned the practice seeking a same-day face-to-face consultation with a GP were included.

**Results/conclusion:** The primary outcome was primary care workload (patient contacts, including those attending accident and emergency departments) in the 28 days after the first same-day request. 42 practices were randomly assigned to GP triage (n=13), nurse triage (n=15), or usual care (n=14), and 20 990 patients (n=6695 vs 7012 vs 7283) were randomly assigned, of whom 16, 211 (77%) patients provided primary outcome data.

GP triage was associated with a 33% increase in the mean number of contacts per person over 28 days compared with usual care (2·65 [SD 1·74] vs 1·91 [1·43]); and nurse triage with a 48% increase (2·81 [SD 1·68]). Although triage interventions were associated with increased contacts, estimated costs over 28 days were similar between all three groups (roughly £75 per patient).

**Importance:** Evidence supporting the use of telephone triage to manage workload in primary care has been scarce until this study was undertaken. Although the introduction of GP-led or nurse-led telephone triage was associated with an increase in the number of primary care contacts in the 28 days after the first same-day request, costs were similar to those of usual care. The study team concluded that ‘telephone triage might be useful in aiding the delivery of primary care’ but that the whole-system implications should be assessed when introducing such a system.

**Publication:** The Lancet Volume 384, No. 9957, p1859–1868, 22 November 2014

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# PAST-BP

**Aim:** An open label RCT to assess whether using intensive BP targets leads to lower BP in a community population of people with prevalent cerebrovascular disease.

**Method:** The study ran in 99 general practices throughout England recruited from 2009-11. Participants included people with a history of stroke or transient ischaemic attack whose SBP was 125 mm Hg or above.

**Intervention***:* Intensive SBP target (<130 mm Hg or 10 mm Hg reduction from baseline if this was <140 mm Hg) or standard target (<140 mm Hg).

**Control***:* Participants were allocated to the standard target of < 140mm Hg.

Apart from the different target, patients in both arms were actively managed in the same way with regular reviews by the primary care team (practice nurse to monitor the BP and a GP responsible for modifying BP treatment). The practice nurse saw all patients at three month intervals (if their BP was below target) or after one month (if previous BP was above target). The research nurse (separate to the practice nurse) measured participant’s BP at baseline, six and twelve months. GPs were provided with treatment protocols that reflected national guidelines at the time of the trial and had access to a computer based algorithm that actively suggested drugs and dosage if the participant was above target.

**Results/conclusion:** Primary outcome measure was a change in SBP between baseline and 12 months. 529 patients (mean age 72) were enrolled, 266 to the intensive target arm and 263 to the standard target arm. 379 were included in the primary analysis (182 (68%) intensive arm; 197 (75%) standard arm).

Treatment to a more intensive target was associated with a significantly greater reduction in SBP at 12 months but associated with increased workload (one extra consultation a year each for GP and nurses) but not more side effects, although more changes to treatment occurred because of side effects during the trial.

In the intensive target arm mean SBP dropped by 16.1 mm Hg to 127.4 mm Hg. In the standard arm it reduced by 12.8 mm Hg to 129.4 mm Hg (difference between groups 2.9 (95% confidence interval 0.2 to 5.7) mm Hg; P=0.03).

Aiming for a SBP target below 130 mm Hg rather than 140 mm Hg in people with cerebrovascular disease in primary care led to a small additional reduction in BP. Furthermore, active management was associated with clinically important reductions in blood pressure in both arms—the 13 mm Hg reduction achieved in the below 140 mm Hg arm equates to more than 40% and 20% reduction in the risk of stroke and coronary heart disease respectively

**Importance:** Decreasing BP after stroke is associated with a lower risk of stroke recurrence, but uncertainty exists about what the target BP should be. This trial showed that patients set a target of <130 mm Hg or a 10 mm Hg reduction if initial BP was <140 mm Hg achieved lower SBPs than those set a target of <140 mm Hg. However, the difference (about 3 mm Hg) in the context of the reductions seen in both arms (13mm Hg and 16 mm Hg) was small. Active management of BP after stroke/transient ischaemic attack is more important than the target that is set.

**Publication:** BMJ 2016;352:i708

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# DUTY – Diagnosis of Urinary Tract infection in Young children

**Aim:** To develop algorithms to accurately identify pre-school children in whom urine should be obtained; assess whether or not dipstick urinalysis provides additional diagnostic information; and model algorithm cost-effectiveness

**Method**: One hundred and seven clinical characteristics (index tests) were recorded from the child’s past medical history, symptoms, physical examination signs and urine dipstick test. Prior to dipstick results clinician opinion of UTI likelihood (‘clinical diagnosis’) and urine sampling and treatment intentions (‘clinical judgement’) were recorded. All index tests were measured blind to the reference standard, defined as a pure or predominant uropathogen cultured at ≥ 105 colony-forming units (CFU)/ml in a single research laboratory. Urine was collected by clean catch (preferred) or nappy pad. Index tests were sequentially evaluated in two groups, stratified by urine collection method: parent-reported symptoms with clinician-reported signs, and urine dipstick results. Diagnostic accuracy was quantified using area under receiver operating characteristic curve (AUROC) with 95% confidence interval (CI) and bootstrap-validated AUROC, and compared with the ‘clinician diagnosis’ AUROC. Decision-analytic models were used to identify optimal urine sampling strategy compared with ‘clinical judgement’.

**Results/conclusion**: A total of 7163 children were recruited, of whom 50% were female and 49% were < 2 years old. Culture results were available for 5017 (70%); 2740 children provided clean-catch samples, 94% of whom were ≥ 2 years old, with 2.2% meeting the UTI definition. Among these, ‘clinical diagnosis’ correctly identified 46.6% of positive cultures, with 94.7% specificity and an AUROC of 0.77 (95% CI 0.71 to 0.83). Four symptoms, three signs and three dipstick results were independently associated with UTI with an AUROC (95% CI; bootstrap-validated AUROC) of 0.89 (0.85 to 0.95; validated 0.88) for symptoms and signs, increasing to 0.93 (0.90 to 0.97; validated 0.90) with dipstick results. Nappy pad samples were provided from the other 2277 children, of whom 82% were < 2 years old and 1.3% met the UTI definition. ‘Clinical diagnosis’ correctly identified 13.3% positive cultures, with 98.5% specificity and an AUROC of 0.63 (95% CI 0.53 to 0.72). Four symptoms and two dipstick results were independently associated with UTI, with an AUROC of 0.81 (0.72 to 0.90; validated 0.78) for symptoms, increasing to 0.87 (0.80 to 0.94; validated 0.82) with the dipstick findings. A high specificity threshold for the clean-catch model was more accurate and less costly than, and as effective as, clinical judgement. The additional diagnostic utility of dipstick testing was offset by its costs. The cost-effectiveness of the nappy pad model was not clear-cut.

**Importance**: Clinicians should prioritise the use of clean-catch sampling as symptoms and signs can cost-effectively improve the identification of UTI in young children where clean catch is possible. Dipstick testing can improve targeting of antibiotic treatment, but at a higher cost than waiting for a laboratory result. Future research is needed to distinguish pathogens from contaminants, assess the impact of the clean-catch algorithm on patient outcomes, and the cost-effectiveness of presumptive versus dipstick versus laboratory-guided antibiotic treatment.

**Publication**: **doi: 10.1370/afm.1954** Annals of Family Medicine **July/August 2016** vol. 14 no. 4 **325-336** [**http://www.annfammed.org/content/14/4/325**](http://www.annfammed.org/content/14/4/325)

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# OSAC

**Aim:** The majority of UK adults experience at least one lower respiratory tract infection (LRTI, or acute bronchitis) a year. Despite an absence of evidence in this patient group, some GPs prescribe inhaled or oral corticosteroids. OSAC sought to demonstrate ‘proof of concept’ symptomatic effectiveness of a moderate dose of oral corticosteroid for adults without asthma or COPD with acute LRTI.

**Method**: OSAC was a double blind, placebo controlled RCT set in GP practices in England, powered to investigate if oral prednisolone reduces the duration of moderately bad or worse cough and/or the severity of its associated symptoms, when compared to placebo, by at least 20%. Adults (≥18 years) with acute (≤28 days) cough, for whom same-day antibiotics were not clinically indicated, and without asthma or COPD, received 40 mg oral prednisolone or matched placebo for 5 days. Symptom diaries, completed for up to 28 days, measured two primary outcomes: the duration of moderately bad or worse cough; and the average severity of all symptoms on days 2 to 4 on a scale of 0–6. We sought to demonstrate a minimum clinically important reduction of 20% in each outcome.

**Results/conclusion**: 398 participants were randomised to either prednisolone or placebo tablets (198 and 200 respectively) from 54 UK primary care sites. Attrition was lower than expected, giving over 85% power for the two primary outcomes. Data were analysed on an intention-to-treat basis. The median duration of moderately bad or worse cough was 5 days in both groups (IQRs 2–8 and 3–8 for prednisolone and placebo respectively). Adjusting for trial centre and baseline characteristics, this gave a hazard ratio of 1.11 (95% CI 0.89 to 1.39, p = 0.35). Symptom severity was lower in the prednisolone group (mean 1.99 vs 2.16), adjusted difference -0.090 (-0.212 to 0.003, p = 0.152).

**Publication**: *Thorax* 2015;70:A50 doi:10.1136/thoraxjnl-2015-207770.93

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# WALKING

**Aim:** Perceived behavioural control (PBC) is a consistent predictor of intentions to walk more. A previously successful intervention to promote walking by altering PBC has been adapted for delivery in general practice. This study aimed to evaluate the effect of this intervention on Theory of Planned Behaviour (TPB) constructs in this context.

**Method**: Cluster randomized controlled trial, with n = 315 general practice patients. Practice nurses and Healthcare Assistants delivered a self-regulation intervention or information provision (control). Questionnaires assessed TPB variables at baseline, post-intervention, 6 weeks and 6 months. Walking was measured by pedometer.

**Results/conclusion:** The control group reported significantly higher subjective norm at all follow-up time points. There were no significant differences between the two groups in PBC, intention, attitude or walking behaviour. TPB variables significantly predicted intentions to walk more, but not objective walking behaviour, after accounting for clustering. The lack of effect of the intervention was probably due to a failure to maintain intervention fidelity, and the unsuitability of the behaviour change techniques included in the intervention for the population investigated.

**Importance**: This previously successful intervention was not successful when delivered in this context, calling into question whether practice nurses are best placed to deliver such interventions.

**Publication**: Williams, SL et al. The effects of a brief intervention to promote walking on Theory of Planned Behavior constructs: A cluster randomized controlled trial in general practice. Patient Educ Couns (2015) <http://dx.doi.org/10.1016/j.pec.2015.01.010>

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# ICCD

**Aim:** Configuring high quality care for the rapidly increasing number of people with type 2 diabetes (T2D) is a major challenge worldwide for both providers and commissioners. In the UK, about two thirds of people with T2D are managed entirely in primary care, with wide variation in management strategies and achievement of targets. Pay for performance, introduced in 2004, initially resulted in improvements but disparities exist in ethnic minorities and the improvements are levelling off. Community based, intermediate care clinics for diabetes (ICCDs) were considered one solution and are functioning across the UK. However, there is no randomised trial evidence for the effectiveness of such clinics.

**Method:** This is a cluster-randomised trial, involving 3 primary care trusts, with 49 general

practices randomised to usual care (n = 25) or intervention (ICCDs; n = 24). All eligible adult patients with T2D were invited; 1997 were recruited and 1280 followed-up after 18-months intervention. Primary outcome: achievement of all three of the NICE targets [(HbA1c#7.0%/53 mmol/mol; Blood Pressure ,140/80 mmHg; cholesterol ,154 mg/dl (4 mmol/l)]. Primary outcome was achieved in 14.3% in the intervention arm vs. 9.3% in the control arm (p = 0.059 after adjustment for covariates). The odds ratio (95% CI) for achieving primary outcome in the intervention group was 1.56 (0.98, 2.49). Primary

care and community clinic costs were significantly higher in the intervention group, but there were no significant differences in hospital costs or overall healthcare costs. An incremental cost-effectiveness ratio (ICER) of +£7,778 per QALY gained, indicated ICCD was marginally more expensive at producing health gain.

**Results/conclusion:** Intermediate care clinics can contribute to improving target achievement in patients with diabetes. Further work is needed to investigate the optimal scale and organisational structure of ICCD services and whether, over time, their role may change as skill levels in primary care increase.

**Publication**: Wilson A, O’Hare JP, Hardy A, Raymond N, Szczepura A, et al. (2014) Evaluation of the Clinical and Cost Effectiveness of Intermediate Care Clinics for Diabetes (ICCD): A Multicentre Cluster Randomised Controlled Trial. PLoS ONE 9(4): e93964. doi:10.1371/journal.pone.0093964

<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0093964>

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# BEST

**Aim:** Low-back pain is a common and costly problem. We estimated the eﬀ ectiveness of a group cognitive behavioural intervention in addition to best practice advice in people with low-back pain in primary care.

**Method**: In this pragmatic, multicentre, randomised controlled trial with parallel cost-eﬀ ectiveness analysis undertaken in England, 701 adults with troublesome subacute or chronic low-back pain were recruited from 56 general practices and received an active management advisory consultation. Participants were randomly assigned by computergenerated block randomisation to receive an additional assessment and up to six sessions of a group cognitive behavioural intervention (n=468) or no further intervention (control; n=233). Primary outcomes were the change from baseline in Roland Morris disability questionnaire and modiﬁ ed Von Korﬀ scores at 12 months. Assessment of

outcomes was blinded and followed the intention-to-treat principle, including all randomised participants who provided follow-up data. This study is registered, number ISRCTN54717854

**Results/conclusion:** 399 (85%) participants in the cognitive behavioural intervention group and 199 (85%) participants in the control group were included in the primary analysis at 12 months. The most frequent reason for participant withdrawal was unwillingness to complete questionnaires. At 12 months, mean change from baseline in the Roland Morris questionnaire score was 1·1 points (95% CI 0·39–1·72) in the control group and 2·4 points (1·89–2·84) in the cognitive behavioural intervention group (diﬀerence between groups 1·3 points, 0·56–2·06; p=0·0008).

The modiﬁed Von Korﬀ disability score changed by 5·4% (1·99–8·90) and 13·8% (11·39–16·28), respectively (diﬀ erence between groups 8·4%, 4·47–12·32; p<0·0001). The modiﬁed Von Korﬀ pain score changed by 6·4% (3·14–9·66) and 13·4% (10·77–15·96), respectively (diﬀerence between groups 7·0%, 3·12–10·81; p<0·0001). The additional quality-adjusted life-year (QALY) gained from cognitive behavioural intervention was 0·099; the incremental cost per QALY was £1786, and the probability of cost-eﬀectiveness was greater than 90% at a threshold of £3000 per QALY. There were no serious adverse events attributable to either treatment.

**Publication**: Lancet 2010; 375: 916–23 Published Online February 26, 2010 DOI:10.1016/S0140- 6736(09)62164-4

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# M:\WMS\HS_SSSH\PCRN\STUDIES\CLOSED STUDIES\@STUDY RESULTS & PUBLICATIONS\BLISS\BLISS Logo.JPGBLISS

**Aim:** The aim of this programme was to recruit a unique UK primary care COPD cohort, as a platform for testing novel health service interventions resulting in patient benefit, both within this proposal and in future outside the programme. The cohort comprised both new and existing cases of COPD recruited using the local PCRN-CE network of general

practices, and will also reflect the ethnic diversity of the West Midlands.

**Method**: In this cluster-randomised controlled trial, participating general practices in the West Midlands, UK, were randomly assigned (1:1), via a computer-generated block randomisation sequence, to either a targeted case-finding group or a routine care group. Eligible patients were ever-smokers aged 40–79 years without a previously recorded diagnosis of COPD. Patients in the targeted case-finding group were further randomly assigned (1:1) via their household to receive either a screening questionnaire at the general practitioner (GP) consultation (opportunistic) or a screening questionnaire at the GP consultation plus a mailed questionnaire (active). Respondents reporting relevant respiratory symptoms were invited for post-bronchodilator spirometry. Patients, clinicians, and investigators were not masked to allocation, but group allocation was concealed from the researchers who performed the spirometry assessments. Primary outcomes were the percentage of the eligible population diagnosed with COPD within 1 year (defined as post-bronchodilator forced expiratory volume in 1 s [FEV1] to forced vital capacity [FVC] ratio <0·7 in patients with symptoms or a new diagnosis on their GP record) and cost per new COPD diagnosis. Multiple logistic and Poisson regression were used to estimate effect sizes. Costs were obtained from the trial. This trial is registered with ISRCTN, number ISRCTN14930255.

**Results/conclusion**: From Aug 10, 2012, to June 22, 2014, 74 818 eligible patients from 54 diverse general practices were randomly assigned and completed the trial. At 1 year, 1278 (4%) cases of COPD were newly detected in 32 789 eligible patients in the targeted case-finding group compared with 337 (1%) cases in 42 029 patients in the routine care group (adjusted odds ratio [OR] 7·45 [95% CI 4·80–11·55], p<0·0001). The percentage of newly detected COPD cases was higher in the active case-finding group (822 [5%] of 15 378) than in the opportunistic case-finding group (370 [2%] of 15 387; adjusted OR 2·34 [2·06–2·66], p<0·0001; adjusted risk difference 2·9 per 100 patients [95% CI 2·3–3·6], p<0·0001). Active case finding was more cost-effective than opportunistic case finding (£333 vs £376 per case detected, respectively).

**Importance**: In this well-established primary care system, routine practice identified few new cases of COPD. An active targeted approach to case finding including mailed screening questionnaires before spirometry is a cost-effective way to identify undiagnosed patients and has the potential to improve their health.

**Publication**: Lancet Vol. 4, No. 9 18th July 2016 ; Published Online September DOI: <http://dx.doi.org/10.1016/S2213-2600(16)30149-7>

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# Rapid Reduction

**Aim:** To examine the success of quitting smoking by gradual compared with abrupt quitting.

**Method**: Participants quit smoking abruptly or reduced smoking gradually by 75% in the 2 weeks before quitting. Both groups received behavioural support from nurses and used nicotine replacement before and after quit day.

The primary outcome measure was prolonged validated abstinence from smoking 4 weeks after quit day. The secondary outcome was prolonged, validated, 6-month abstinence.

**Results/conclusion**: At 4 weeks, 39.2% (95% CI, 34.0% to 44.4%) of the participants in the gradual-cessation group were abstinent compared with 49.0% (CI, 43.8% to 54.2%) in the abrupt-cessation group (relative risk, 0.80 [CI, 0.66 to 0.93]). At 6 months, 15.5% (CI, 12.0% to 19.7%) of the participants in the gradual-cessation group were abstinent compared with 22.0% (CI, 18.0% to 26.6%) in the abrupt-cessation group (relative risk, 0.71 [CI, 0.46 to 0.91]). Participants who preferred gradual cessation were significantly less likely to be abstinent at 4 weeks than those who preferred abrupt cessation (38.3% vs 52.2%; P = 0.007).

**Importance**: Quitting smoking abruptly is more likely to lead to lasting abstinence than cutting down first, even for smokers who initially prefer to quit by gradual reduction.

**Publication**: Gradual Versus Abrupt Smoking Cessation: A Randomized, Controlled Non-inferiority Trial, Ann Intern Med. 2016;164(9):585-592. doi:10.7326/M14-2805

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# SCOT

**Aim:** Selective cyclooxygenase-2 inhibitors and conventional non-selective non-steroidal anti-inflammatory drugs (nsNSAIDs) have been associated with adverse cardiovascular (CV) effects. We compared the CV safety of switching to celecoxib vs. continuing nsNSAID therapy in a European setting.

**Method**: Patients aged 60 years and over with osteoarthritis or rheumatoid arthritis, free from established CV disease and taking chronic prescribed nsNSAIDs, were randomized to switch to celecoxib or to continue their previous nsNSAID. The primary endpoint was hospitalization for non-fatal myocardial infarction or other biomarker positive acute coronary syndrome, non-fatal stroke or CV death analysed using a Cox model with a pre-specified non-inferiority limit of 1.4 for the hazard ratio (HR).

**Results/conclusion**: In total, 7297 participants were randomized. During a median 3-year follow-up, fewer subjects than expected developed an on-treatment (OT) primary CV event and the rate was similar for celecoxib, 0.95 per 100 patient-years, and nsNSAIDs, 0.86 per 100 patient-years (HR = 1.12, 95% confidence interval, 0.81–1.55; P = 0.50). Comparable intention-to-treat (ITT) rates were 1.14 per 100 patient-years with celecoxib and 1.10 per 100 patient-years with nsNSAIDs (HR = 1.04; 95% confidence interval, 0.81–1.33; P = 0.75). Pre-specified non-inferiority was achieved in the ITT analysis. The upper bound of the 95% confidence limit for the absolute increase in OT risk associated with celecoxib treatment was two primary events per 1000 patient-years exposure. There were only 15 adjudicated secondary upper gastrointestinal complication endpoints (0.078/100 patient-years on celecoxib vs. 0.053 on nsNSAIDs OT, 0.078 vs. 0.053 ITT). More gastrointestinal serious adverse reactions and haematological adverse reactions were reported on nsNSAIDs than celecoxib, but more patients withdrew from celecoxib than nsNSAIDs (50.9% patients vs. 30.2%; P < 0.0001).

**Importance**: In subjects 60 years and over, free from CV disease and taking prescribed chronic nsNSAIDs, CV events were infrequent and similar on celecoxib and nsNSAIDs. There was no advantage of a strategy of switching prescribed nsNSAIDs to prescribed celecoxib. This study excluded an increased risk of the primary endpoint of more than two events per 1000 patient-years associated with switching to prescribed celecoxib.

**Publication**: DOI: <http://dx.doi.org/10.1093/eurheartj/ehw387> ehw387 First published online: 4 October 2016

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# Final_logo_031210.jpgSTART2QUIT

**Aim:** National Health Service Stop Smoking Services (SSSs) offer help to smokers motivated to quit; however, attendance rates are low and recent figures show a downward trend. We aimed to assess the effectiveness of a two-component personalised intervention on attendance at SSSs.

**Method:** We did this randomised controlled trial in 18 SSSs in England. Current smokers (aged ≥16 years) were identified from medical records in 99 general practices and invited to participate by their general practitioner. Individuals who gave consent, were motivated to quit, and had not attended the SSS within the past 12 months, were randomly assigned (3:2), via computer-generated randomisation with permuted blocks (block size of five), to receive either an individually tailored risk letter and invitation to attend a no-commitment introductory session run by the local SSS (intervention group) or a standard generic letter advertising the local SSS (control group). Randomisation was stratified by sex. Masking of participants to receipt of a personal letter and invitation to a taster session was not possible. The personal letter was generated by a research assistant, but the remainder of the research team were masked to group allocation. General practitioners, practice staff, and SSS advisers were unaware of their patients' allocation. The primary outcome was attendance at the first session of an SSS course within 6 months from randomisation. We did analysis by intention to treat. This trial is registered with Current Controlled Trials, number ISRCTN 76561916.

**Results/conclusion:** Delivery of personalised risk information alongside an invitation to an introductory session more than doubled the odds of attending the SSS compared with a standard generic invitation to contact the service. This result suggests that a more proactive approach, combined with an opportunity to experience local services, can reduce patient barriers to receiving treatment and has high potential to increase uptake

**Importance:** There has been a significant decrease in the number of smokers accessing the SSS in the past few years. Efforts to reverse this trend should be a priority as services offer smokers a significantly higher chance of stopping smoking compared with trying to quit without support.

**Publication:** <https://www.sciencedirect.com/science/article/pii/S0140673616323790?dgcid=raven_sd_aip_email>

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# FLU-CATs

**Background**: During pandemics of novel influenza and outbreaks of other emerging infections, surge in healthcare demand can exceed capacity to provide normal standards of care. In such circumstances, triage tools may aid decisions about which patients are most likely to benefit from higher levels of care. A number of triage tools have been developed (CATs, PMEWS) but they remain untested in a pandemic situation.

**Aims:**

1. To develop the IT infrastructure and processes required to allow near real-time assessment of GP assessments, management decisions and patient outcomes for people presenting with influenza-like illness.

2. To conduct a pilot study evaluating the performance of the *Community Assessment Tools* and *Pandemic Medical Early Warning Score* triage tools in predicting hospital admission and death in patients presenting to GPs with influenza-like symptoms during inter-pandemic winter seasons.

**Method**: Prospective near real-time analysis of structured clinical assessments and anonymised linkage to data from electronic health records of patients at 30 GP practices in England, Scotland and Wales participating in the Clinical Practice Research Datalink (CPRD). Outcomes collected included hospital admission within 24hrs, death (all causes) within 30 days, GP decision to prescribe antibiotics or antivirals and/or refer to hospital, higher level of care needed and length of stay. User (GP) experience was evaluated using semi-structured interviews.

**Results/Conclusion**: Data from 704 adult and 159 child consultations were captured in the 24 months to April 2015. Eleven adults (1.6%) and six children (3.8%) were referred to hospital. There were 13 adults (1.8%) and two child (1.3%) deaths. There were too few outcome events in the data set to draw reliable conclusions about the performance of the triage tools. Although there were some installation issues, GPs found the web-based triage tools quick and easy to use.

**Importance:** This study has developed and tested the processes required to check that triage tools are ‘fit for purpose’ at the start of a pandemic, ready for use should that pandemic become severe.

**Publication:**

Venkatesan S, Myles PR, McCann G *et al.* (2015). *Health Technology Assessment* **19:** 89 <https://www.journalslibrary.nihr.ac.uk/hta/hta19890/#/abstract>

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# BWeL

**Aim:** Obesity is a common cause of non-communicable disease. Guidelines recommend that physicians screen and offer brief advice to motivate weight loss through referral to behavioural weig ht loss programmes. However, physicians rarely intervene and no trials have been done on the subject. This was done to establish whether physician brief intervention is acceptable and effective for reducing bodyweight in patients with obesity

**Method:** In this parallel, two-arm, randomised trial, patients who consulted 137 primary care physicians in England were screened for obesity. Individuals could be enrolled if they were aged at least 18 years, had a body-mass **index** of at least 30 kg/m2 (or at least 25 kg/m2 if of Asian ethnicity) , and had a raised body fat percentage. At the end of the consultation, the physician randomly assigned participants (1:1) to one of two 30 second interventions. Randomisation was done via preprepared randomisation cards labelled with a code representing the allocation, which were placed in opaque sealed envelopes and given to physicians to open at the time of treatment assignment. In the active intervention, the physician offered referral to a weight management group (12 sessions of 1 h each, once per week) and, if the referral was accepted, the physician ensured the patient made an appointment and offered follow-up. In the control intervention, the physician advised the patient that their health would benefit from weight loss. The primary outcome was weight change at 12 months in the intention-to-treat population, which was assessed blinded to treatment allocation. We also assessed asked patients’ about their feelings on discussing their weight when they have visited their general practitioner for other reasons. Given the nature of the intervention, we did not anticipate any adverse events in the usual sense, so safety outcomes were not assessed. This trial is registered with the ISRCTN Registry, number ISRCTN26563137.

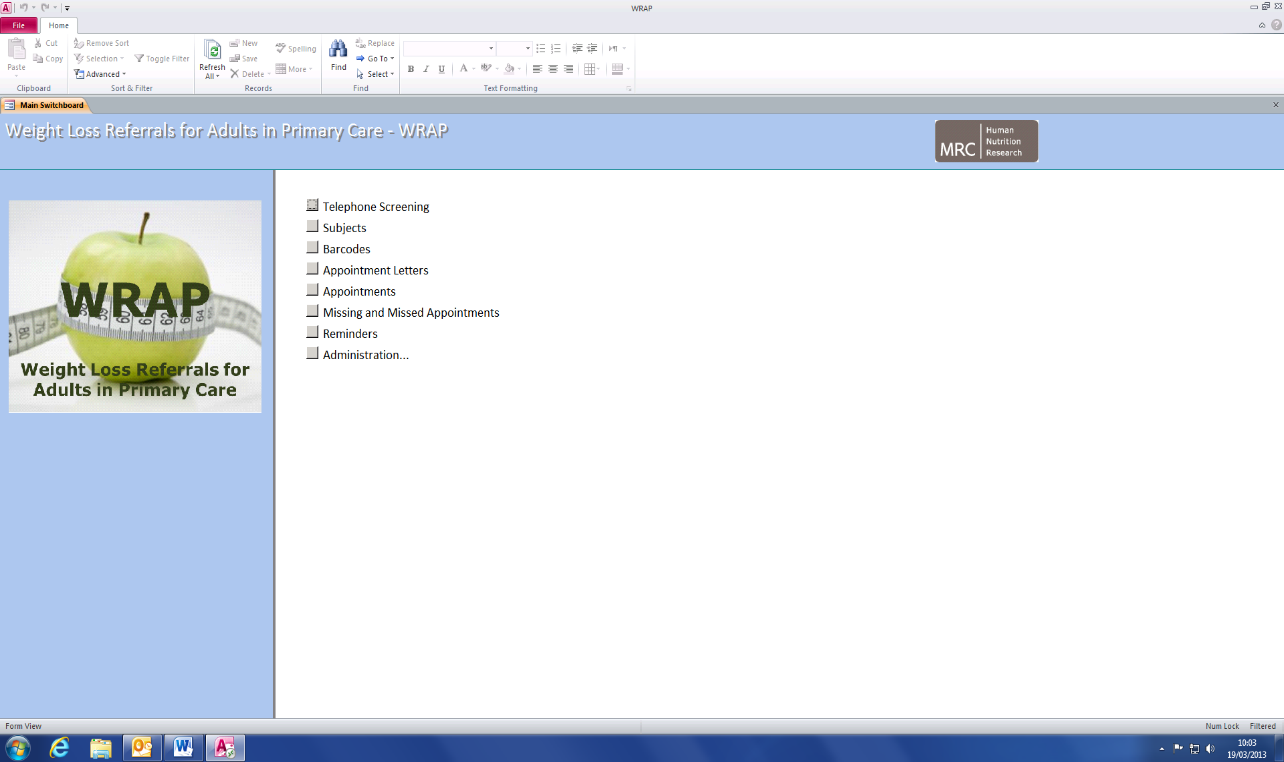
**Results**: Between June 4, 2013, and Dec 23, 2014, we screened 8403 patients, of whom 2728 (32%) were obese. Of these obese patients, 2256 (83%) agreed to participate and 1882 were eligible, enrolled, and included in the intention-to-treat analysis, with 940 individuals in the support group and 942 individuals in the advice group. 722 (77%) individuals assigned to the support intervention agreed to attend the weight management group and 379 (40%) of these individuals attended, compared with 82 (9%) participants who were allocated the advice intervention. In the entire study population, mean weight change at 12 months was 2·43 kg with the support intervention and 1·04 kg with the advice intervention, giving an adjusted difference of 1·43 kg (95% CI 0·89–1·97). The reactions of the patients to the general practitioners’ brief interventions did not differ significantly between the study groups in terms of appropriateness (adjusted odds ratio 0·89, 95% CI 0·75–1·07, p=0·21) or helpfulness (1·05, 0·89–1·26, p=0·54); overall, four (<1%) patients thought their intervention was inappropriate and unhelpful and 1530 (81%) patients thought it was appropriate and helpful.

**Importance**: A behaviourally-informed, very brief, physician-delivered opportunistic intervention is acceptable to patients and an effective way to reduce population mean weight.

**Publication**: <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31893-1/fulltext> Volume 388 November 19 2016

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# WRAP: Weight Loss Referrals for Adults in Primary Care

**Background** Evidence exist that primary care referral to an open-group behavioural programme is an effective strategy for management of obesity, but little evidence on optimal intervention duration is available. We aimed to establish whether 52-week referral to an open-group weight-management programme would achieve greater weight loss and improvements in a range of health outcomes and be more cost-effective than the current practice of 12-week referrals.

**Method:** In this non-blinded, parallel-group, randomised controlled trial, we recruited participants who were aged 18 years or older and had body-mass index (BMI) of 28 kg/m2 or higher from 23 primary care practices in England. Participants were randomly assigned (2:5:5) to brief advice and self-help materials, a weight-management programme (Weight Watchers) for 12 weeks, or the same weight-management programme for 52 weeks. We followed-up participants over 2 years. The primary outcome was weight at 1 year of follow-up, analysed with mixed-effects models according to intention-to-treat principles and adjusted for centre and baseline weight. In a hierarchical closed-testing procedure, we compared combined behaviouralprogramme arms with brief intervention, then compared the 12-week programme and 52-week programme. We did a within-trial cost-effectiveness analysis using person-level data and modelled outcomes over a 25-year time horizon using microsimulation. This study is registered with Current Controlled Trials, number ISRCTN82857232.

**Findings** Between Oct 18, 2012, and Feb 10, 2014, we enrolled 1269 participants. 1267 eligible participants were randomly assigned to either the brief intervention (n=211), the 12-week programme (n=528), and the 52-week programme (n=528). Two participants in the 12-week programme had been found to be ineligible shortly after randomisation and were excluded from the analysis. 823 (65%) of 1267 participants completed an assessment at 1 year and 856 (68%) participants at 2 years. All eligible participants were included in the analyses. At 1 year, mean weight changes in the groups were –3·26 kg (brief intervention), –4·75 kg (12-week programme), and –6·76 kg (52-week programme). Participants in the behavioural programme lost more weight than those in the brief intervention (adjusted difference –2·71 kg, 95% CI –3·86 to –1·55; p<0·0001). The 52-week programme was more effective than the 12-week programme (–2·14 kg, –3·05 to –1·22; p<0·0001). Differences between groups were still significant at 2 years. No adverse events related to the intervention were reported. Over 2 years, the incremental cost-effectiveness ratio (ICER; compared with brief intervention) was £159 per kg lost for the 52-week programme and £91 per kg for the 12-week programme. Modelled over 25 years after baseline, the ICER for the 12-week programme was dominant compared with the brief intervention. The ICER for the 52-week programme was cost-effective compared with the brief intervention (£2394 per quality-adjusted life-year [QALY]) and the 12-week programme (£3804 per QALY).

**Results**: For adults with overweight or obesity, referral to this open-group behavioural weight-loss programme for at least 12 weeks is more effective than brief advice and self-help materials. A 52-week programme produces greater weight loss and other clinical benefits than a 12-week programme and, although it costs more, modelling suggests that the 52-week programme is cost-effective in the longer term.

**Publication**: [www.thelancet.com](http://www.thelancet.com) Published online May 3, 2017 <http://dx.doi.org/10.1016/S0140-6736(17)30647-5>

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# FAST: Four Fold Asthma

**Aim:** Asthma exacerbations are frightening for patients and are occasionally fatal. We tested the concept that a plan for patients to manage their asthma (self-management plan), which included a temporary quadrupling of the dose of inhaled glucocorticoids when asthma control started to deteriorate, would reduce the incidence of severe asthma exacerbations among adults and adolescents with asthma.

**Method**: We conducted a pragmatic, unblinded, randomized trial involving adults and adolescents with asthma who were receiving inhaled glucocorticoids, with or without add-on therapy, and who had had at least one exacerbation in the previous 12 months. We compared a self-management plan that included an increase in the dose of inhaled glucocorticoids by a factor of 4 (quadrupling group) with the same plan without such an increase (non-quadrupling group), over a period of 12 months. The primary outcome was the time to a first severe asthma exacerbation, defined as treatment with systemic glucocorticoids or an unscheduled health care consultation for asthma.

**Results**: A total of 1922 participants underwent randomization, of whom 1871 were included in the primary analysis. The number of participants who had a severe asthma exacerbation in the year after randomization was 420 (45%) in the quadrupling group as compared with 484 (52%) in the non-quadrupling group, with an adjusted hazard ratio for the time to a first severe exacerbation of 0.81 (95% confidence interval, 0.71 to 0.92; P=0.002). The rate of adverse effects, which were related primarily to local effects of inhaled glucocorticoids, was higher in the quadrupling group than in the non-quadrupling group.

**Conclusions:** In this trial involving adults and adolescents with asthma, a personalized self-management plan that included a temporary quadrupling of the dose of inhaled glucocorticoids when asthma control started to deteriorate resulted in fewer severe asthma exacerbations than a plan in which the dose was not increased. (Funded by the Health Technology Assessment Programme of the National Institute for Health Research; Current Controlled Trials number, [ISRCTN15441965](http://www.controlled-trials.com/ISRCTN15441965).)

**Publication**: <http://www.nejm.org/doi/full/10.1056/NEJMoa1714257?query=recirc_curatedRelated_article&>

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# Child-Parent Familial Hypercholesterolemia

**Background**: Child–parent screening for familial hypercholesterolemia has been proposed to identify persons at high risk for inherited premature cardiovascular disease. We assessed the efficacy and feasibility of such screening in primary care practice.

**Method**: We obtained capillary blood samples to measure cholesterol levels and to test for familial hypercholesterolemia mutations in 10,095 children 1 to 2 years of age during routine immunization visits. Children were considered to have positive screening results for familial hypercholesterolemia if their cholesterol level was elevated and they had either a familial hypercholesterolemia mutation or a repeat elevated cholesterol level 3 months later. A parent of each child with a positive screening result for familial hypercholesterolemia was considered to have a positive screening result for familial hypercholesterolemia if he or she had the same mutation as the child or, if no mutations were identified, had the higher cholesterol level of the two parents.

**Results**: The use of a pre-specified cholesterol cut-off value of 1.53 multiples of the median (MoM, corresponding to a percentile of 99.2) identified 28 children who had positive screening results for familial hypercholesterolemia (0.3% of the 10,095 children; 95% confidence interval [CI], 0.2 to 0.4), including 20 with a familial hypercholesterolemia mutation and 8 with a repeat cholesterol level of at least 1.53 MoM. A total of 17 children who had a cholesterol level of less than 1.53 MoM also had a familial hypercholesterolemia mutation. The overall mutation prevalence was 1 in 273 children (37 in 10,095; 95% CI, 1 in 198 to 1 in 388). The use of an initial cholesterol cutoff value of 1.35 MoM (95th percentile) plus a mutation, or two cholesterol values of at least 1.50 MoM (99th percentile), identified 40 children who had positive screening results for familial hypercholesterolemia (0.4% of the 10,095 children, including 32 children who had a familial hypercholesterolemia mutation and 8 who did not have the mutation) and 40 parents who had positive screening results for familial hypercholesterolemia.

**Conclusion:** Child–parent screening was feasible in primary care practices at routine child immunization visits. For every 1000 children screened, 8 persons (4 children and 4 parents) were identified as having positive screening results for familial hypercholesterolemia and were consequently at high risk for cardiovascular disease. (Funded by the Medical Research Council.)

**Publication**: <http://www.nejm.org/doi/full/10.1056/NEJMoa1602777>

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# Families for Health

**Background**: Effective programmes to help children manage their weight are required. Families for Health’ focuses on a parenting approach, designed to help parents develop their parenting skills to support lifestyle change within the family. Families for Health version 1 showed sustained reductions in mean body mass index (BMI) z-score after 2 years in a pilot project.

**Aim**: The aim was to evaluate its effectiveness and cost-effectiveness in a randomised controlled trial (RCT).

**Design**: The trial was a multicentre, investigator-blind RCT, with a parallel economic and process evaluation, with follow-up at 3 and 12 months. Randomisation was by family unit, using a 1 : 1 allocation by telephone registration, stratified by three sites, with a target of 120 families. Participants were children aged 6–11 years who were overweight (≥ 91st centile BMI) or obese (≥ 98th centile BMI), and their parents/carers. Recruitment was via referral or self-referral.

Results: The study recruited 115 families (128 children; 63 boys and 65 girls), with 56 families randomised to the Families for Health arm and 59 to the ‘usual-care’ control arm. There was 80% retention of families at 3 months (Families for Health, 46 families; usual care, 46 families) and 72% retention at 12 months (Families for Health, 44 families; usual care, 39 families). The change in BMI z-score at 12 months was not significantly different in the Families for Health arm and the usual-care arm [0.114, 95% confidence interval (CI) –0.001 to 0.229; p = 0.053]. However, within-group analysis showed that the BMI z-score was significantly reduced in the usual-care arm (–0.118, 95% CI –0.203 to –0.034; p = 0.007), but not in the Families for Health arm (–0.005, 95% CI –0.085 to 0.078; p = 0.907). There was only one significant difference between groups for secondary outcomes. The economic evaluation, taking a NHS and Personal Social Services perspective, showed that mean costs 12 months post randomisation were significantly higher for Families for Health than for usual care (£998 vs. £548; p < 0.001). The mean incremental cost-effectiveness of Families for Health was estimated at £552,175 per QALY gained. The probability that the Families for Health programme is cost-effective did not exceed 40% across a range of thresholds. The process evaluation demonstrated that the programme was implemented, as planned, to the intended population and any adjustments did not deviate widely from the handbook. Many families waited more than 3 months to receive the intervention. Facilitators’, parents’ and children’s experiences of Families for Health were largely positive and there were no adverse events. Further analysis could explore why some children show a clinically significant benefit while others have a worse outcome.

**Conclusions**: Families for Health was neither effective nor cost-effective for the management of obesity in children aged 6–11 years, in comparison with usual care. Further exploration of the wide range of responses in BMI z-score in children following the Families for Health and usual-care interventions is warranted, focusing on children who had a clinically significant benefit and those who showed a worse outcome with treatment. Further research could focus on the role of parents in the prevention of obesity, rather than treatment.

Trial registration: Current Controlled Trials ISRCTN45032201.

**Reference**: Robertson W, Fleming J, Kamal A, Hamborg T, Khan KA, Griffiths F, *et al*. Randomised controlled trial evaluating the effectiveness and cost-effectiveness of ‘Families for Health’, a family-based childhood obesity treatment intervention delivered in a community setting for ages 6 to 11 years. *Health Technol Assess* 2017;**21**(1).

*Health Technology Assessment* is indexed and abstracted in *Index Medicus*/MEDLINE, *Excerpta Medica*/EMBASE, *Science Citation Index Expanded* (SciSearch®) and *Current Contents*®/ Clinical Medicine.

**Publication**: Volume 21 Issue One January 2017 DOI: 10.3310/hta21010 <https://www.ncbi.nlm.nih.gov/pubmed/21463350>

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# PLEASANT

**Background:** Asthma episodes and deaths are known to be seasonal. A number of reports have shown peaks in asthma episodes in school-aged children associated with the return to school following the summer vacation. A fall in prescription collection in the month of August has been observed, and was associated with an increase in the number of unscheduled contacts after the return to school in September.

**Objective:** The primary objective of the study was to assess whether or not a NHS-delivered public health intervention reduces the September peak in unscheduled medical contacts.

**Main outcome measures:** The primary outcome measure was the proportion of children aged 5–16 years who had an unscheduled medical contact in September 2013. Supporting end points included the proportion of children who collected prescriptions in August 2013 and unscheduled contacts through the following 12 months. Economic end points were quality-adjusted life-years (QALYs) gained and costs from an NHS and Personal Social Services perspective.

**Conclusions:** The intervention did not reduce unscheduled care in September, although it succeeded in increasing the proportion of children both collecting prescriptions and having scheduled contacts in August. After September there is weak evidence in favour of the intervention. The intervention had a favourable impact on costs but did not demonstrate any impact on QALYs. The results of the trial indicate that further work is required on assessing and understanding adherence, both in terms of using routine data to make quantitative assessments, and through additional qualitative interviews with key stakeholders such as practice nurses, GPs and a wider group of children with asthma.

**Trial registration:** Current Controlled Trials ISRCTN03000938.

**Reference:** Julious SA, Horspool MJ, Davis S, Bradburn M, Norman P, Shephard N, *et al*. PLEASANT: Preventing and Lessening Exacerbations of Asthma in School-age children Associated with a New Term – a cluster randomised controlled trial and economic evaluation. *Health Technol Assess* 2016;**20**(93).

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**Publication**: HTA Volume 20 Issue 93 December 2016 DOI 10.3310/hta20930 ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

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# POWER+

**Aim**: Behavioural counselling with intensive follow-up for obesity is effective, but in resource-constrained primary care settings briefer approaches are needed. The aim of the study was to estimate the clinical effectiveness and cost-effectiveness of an internet-based behavioural intervention with regular face-to-face or remote support in primary care, compared with brief advice.

**Method**: Positive Online Weight Reduction (POWeR+) is a 24-session, web-based weight management intervention completed over 6 months. Following online registration, the website randomly allocated participants using computer-generated random numbers to (1) the control intervention (n = 279), which had previously been demonstrated to be clinically effective (brief web-based information that minimised pressure to cut down foods, instead encouraging swaps to healthier choices and increasing fruit and vegetables, plus 6-monthly nurse weighing); (2) POWeR+F (n = 269), POWeR+ supplemented by face-to-face nurse support (up to seven contacts); or (3) POWeR+R (n = 270), POWeR+ supplemented by remote nurse support (up to five e-mails or brief telephone calls).

**Conclusion:** Clinically valuable weight loss (> 5%) is maintained in 20% of individuals using novel written materials with brief follow-up. A web-based behavioural programme and brief support results in greater mean weight loss and 10% more participants maintain valuable weight loss; it achieves greater enablement and fewer participants undertaking other weight-loss activities; and it is likely to be cost-effective.

**Trial registration:** Current Controlled Trials ISRCTN21244703.

**Reference**: Little P, Stuart B, Hobbs FDR, Kelly J, Smith ER, Bradbury KJ, *et al*. Randomised controlled trial and economic analysis of an internet-based weight management programme: POWeR+ (Positive Online Weight Reduction). *Health Technol Assess* 2017;21(4).

*Health Technology Assessment* is indexed and abstracted in *Index Medicus*/MEDLINE, *Excerpta Medica*/EMBASE, *Science Citation Index Expanded* (SciSearch®) and *Current Contents*®/ Clinical Medicine.

**Publication**: DOI 10.3310/hta21040 HTA Volume Issue 4 January 2017 ISSN 1366-5278

<https://www.journalslibrary.nihr.ac.uk/programmes/hta/0912719/#/documentation>

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# REFER (REFer for EchocaRdiogram)

**Aim**: To evaluate the performance of a clinical decision rule (CDR) with or without a natriuretic peptide assay for identifying heart failure in symptomatic patients presenting to primary care.

**Method**: Prospective, observational, diagnostic validation study and economic evaluation. Participants**:** Primary care patients aged ≥ 55 years presenting with recent new-onset shortness of breath, lethargy or peripheral ankle oedema of > 48 hours’ duration.

The CDR included a clinical element (male, history of myocardial infarction, crepitations at the lung bases and oedema) and N-terminal pro-B-type natriuretic peptide (NT-proBNP) blood test. The reference standard was an expert consensus panel of three cardiology specialists.

**Main outcome measure:** The main outcome measure was test performance of the CDR and the natriuretic peptide test alone, and in combination, in estimating sensitivity and specificity, positive predictive value (PPV) and negative predictive value (NPV) for a diagnosis of heart failure. Economic evaluation of a decision tree with a NHS/Personal Social Services perspective determined the cost per quality-adjusted life-year (QALY) gained.

**Conclusions**: Natriuretic peptide testing alone performed as well as the validated CDR in determining which patients presenting with symptoms went on to have a diagnosis of heart failure. The current NT-proBNP cut-off point of 400 pg/ml used in the UK is too high and means that one in five patients with heart failure may not be appropriately referred for further investigation and diagnosis, but this threshold was cost-effective in the REFer for EchocaRdiogram (REFER) trial. The study found only three patients with heart failure with reduced ejection fraction (HFREF), which might limit the benefits of early detection. The other diagnostic strategies with lower NT-proBNP referral levels become more cost-effective as the proportion of HFREF patients increases. International consensus on the optimal cut-off point for natriuretic peptide testing in patients with symptoms suggestive of heart failure should be sought.

**Trial registration**: Current Controlled Trials ISRCTN17635379.

**Reference**: Taylor CJ, Monahan M, Roalfe AK, Barton P, Iles R, Hobbs FDR on behalf of the other REFER investigators. The REFER (REFer for EchocaRdiogram) study: a prospective validation and health economic analysis of a clinical decision rule, NT-proBNP or their combination in the diagnosis of heart failure in primary care. *Efficacy Mech Eval* 2017;**4**(3).

**Publication**: Efficacy and Mechanism Evaluation Volume 3 issue 4 April 2017 ISSN 2050-4365

DOI 10.3310/eme04030

<https://www.journalslibrary.nihr.ac.uk/eme/eme04030#/abstract>

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# M:\WMS\HS_SSSH\PCRN\Shared PCRN Data\Participate\2018 Spring\Archive\DAPA LOGO.jpgDAPA (Dementia and Physical Activity)

**Objective**: To estimate the effect of a moderate to high intensity aerobic and strength exercise training programme on cognitive impairment and other outcomes in people with mild to moderate dementia.

**Design**: Multicentre, pragmatic, investigator masked, randomised controlled trial.

**Setting**: National Health Service primary care, community and memory services, dementia research registers, and voluntary sector providers in 15 English regions.

**Participants**: 494 people with dementia: 329 were assigned to an aerobic and strength exercise programme and 165 were assigned to usual care. Random allocation was 2:1 in favour of the exercise arm.

**Interventions**: Usual care plus four months of supervised exercise and support for ongoing physical activity, or usual care only. Interventions were delivered in community gym facilities and NHS premises.

**Main outcome measures**: The primary outcome was score on the Alzheimer’s disease assessment scale-cognitive subscale (ADAS-cog) at 12 months. Secondary outcomes included activities of daily living, neuropsychiatric symptoms, health related quality of life, and carer quality of life and burden. Physical fitness (including the six minute walk test) was measured in the exercise arm during the intervention.

**Results**: The average age of participants was 77 (SD 7.9) years and 301/494 (61%) were men. By 12 months the mean ADAS-cog score had increased to 25.2 (SD 12.3) in the exercise arm and 23.8 (SD 10.4) in the usual care arm (adjusted between group difference −1.4, 95% confidence interval −2.6 to −0.2, P=0.03). This indicates greater cognitive impairment in the exercise group, although the average difference is small and clinical relevance uncertain. No differences were found in secondary outcomes or preplanned subgroup analyses by dementia type (Alzheimer’s disease or other), severity of cognitive impairment, sex, and mobility. Compliance with exercise was good. Over 65% of participants (214/329) attended more than three quarters of scheduled sessions. Six minute walking distance improved over six weeks (mean change 18.1 m, 95% confidence interval 11.6 m to 24.6 m).

**Conclusion**: A moderate to high intensity aerobic and strength exercise training programme does not slow cognitive impairment in people with mild to moderate dementia. The exercise training programme improved physical fitness, but there were no noticeable improvements in other clinical outcomes.

Trial registration Current Controlled Trials ISRCTN10416500.

**Publication**: *BMJ* 2018; 361 doi: <https://doi.org/10.1136/bmj.k1675> (Published 16 May 2018)

Cite this as: BMJ 2018;361:k1675



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