

# NIHR Dissemination Centre THEMED REVIEW

# ON THE LEVEL

Evidence for action on type 2 diabetes



# **FOREWORD**

ype 2 diabetes is one of the most significant public health challenges of our time, and affects around 2.8 million people in England. It can lead to blindness, kidney failure and limb loss, it contributes to greater risks of heart attack, heart failure and stroke, and it is associated with compromise to life expectancy. The cost of caring for people with type 2 diabetes and its complications has been estimated to consume around 10% of the NHS budget. The number of people affected is increasing year-on-year. The most important single modifiable risk factor is being overweight or obese. But there is much that can be done.

We have recently entered the first phase of national roll out of the Healthier You: NHS Diabetes Prevention Programme, the first type 2 diabetes prevention programme to be implemented nationally. This is exclusively for people at high risk of developing ype 2 diabetes, those with what is termed "non-diabetic hyperglycaemia".

For those that already have the disease we are focusing on tackling variation in achievement of treatment targets for glucose, blood pressure and cholesterol, and are promoting better access to structured education for people newly diagnosed, all supported by the new Clinical Commissioning Group Improvement and Assessment Framework.

Research supported by the NIHR has contributed significantly to the evidence behind these national programmes.

Research from the NIHR is continuing to evolve evidence around lifestyle interventions and their effect to delay or prevent the onset of type 2 diabetes. We also know much more about the importance of everyday good care to live well with diabetes. Research has shown how structured care and education can help, but we know from the National Diabetes Audit that not everyone is getting this. This review provides a useful round-up of evidence which should help those commissioning, providing and using diabetes services. We have seen how published research has shaped our work on prevention, monitoring and management of the disease. It is also good to see major trials underway of promising interventions from new physical activity programmes to treatments for diabetes-related eye disease. At the same time, qualitative research helps explain why people might not attend education sessions and what approaches work for different populations. We need all of this research to help drive best practice to deliver our shared goal of improving the lives of all those touched by type 2 diabetes.

## Professor Jonathan Valabhji,

National Clinical Director for Obesity and Diabetes, NHS England



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#### Disclaimer

This independent report by the NIHR Dissemination Centre presents a synthesis of NIHR and other research. The views and opinions expressed by the authors of this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR or the Department of Health. Where verbatim quotations are included in this publication the views and opinions expressed are those of the named individuals and do not necessarily reflect those of the authors, the NHS, the NIHR or the Department of Health.

# WHAT IS THIS REVIEW?

his review brings together recent evidence from research which may be of interest to those delivering, planning or using diabetes services. It focuses on studies funded by the National Institute for Health Research (NIHR). The NIHR was set up in 2006 as the research arm of the NHS to provide a health research system focused on the needs of patients and the public. Over the last ten years, the NIHR has funded a number of programmes, projects, research centres, work streams and researchers working in diabetes prevention, management and care. Evidence from these different studies has not been brought together in this way before.

This is not a comprehensive review of all research findings in diabetes, which is a vast area of knowledge and practice. It complements other initiatives, including the comprehensive public health and clinical guidelines provided by the National Institute for Health and Care Excellence (NICE), and other policy initiatives to improve diabetes prevention and care.

This review focuses on type 2 diabetes, which makes up more than 90% of all cases of diabetes.

Unless stated otherwise, all references to diabetes in this report are to type 2 diabetes. The issues around type 1 diabetes with onset from early childhood are distinct and fall outside the scope of this report. However, we do touch on the growing issue of younger adults with type 2 diabetes.

This review gives a short account of completed and ongoing NIHR-funded studies on diabetes and how they have informed practice. More information on this research is available in the Appendices, and many full reports and protocols can also be downloaded at the NIHR Journals Library website.

Unless otherwise stated, all research mentioned in this report is funded entirely or substantively by NIHR, or the researcher or research centre has been supported through NIHR infrastructure or fellowship funding.

Our hope is that this represents an accessible digest of NIHR research on type 2 diabetes and forms both a useful summary for people wishing to see an overview and a starting point for those wishing to know more.

## **WHAT IS TYPE 2 DIABETES?**

Diabetes is a long term condition that causes a person's blood sugar level to become too high. This can lead to a number of health problems.

Sugar levels in the blood are controlled by the hormone insulin which is produced by the pancreas.

There are two main types of diabetes:

- » In type 1 diabetes the pancreas doesn't produce any insulin.
- » In type 2 diabetes either the pancreas doesn't produce enough insulin or the body's cells don't react normally to insulin.

This review is about type 2 diabetes.

# ABBREVIATIONS USED FREQUENTLY IN THIS REVIEW:

**GP** General Practitioner

**HbA1c** Glycated Haemoglobin (a test that indicates blood glucose levels over a period of time)

National Health Service

**NICE** The National Institute for Health

and Care Excellence

NIHR National Institute for Health Research

**SIGN** Scottish Intercollegiate Guidelines

Network

NHS

## **EVIDENCE HIGHLIGHTS**

ere we highlight just some of the findings from NIHR research which have helped to shape diabetes policy and practice. Details of all the studies in this report are given in the Appendices.

# PREVENTING TYPE 2 DIABETES IN PEOPLE AT RISK

- » Lifestyle interventions to change diet and activity work in delaying or preventing diabetes in those at risk.
- » For people with impaired glucose tolerance, walking for just 20 minutes a day over a year reduces cardiovascular risk.
- » New diabetes prevention programmes are building on NIHR research, from tools to identify those at risk to programmes of activity and education.
- » New trials are testing promising approaches to prevention, from recruiting people with diabetes as mentors to providing education and activity programmes for those at risk.
- » For those who are very overweight, bariatric surgery reduces the risk of developing type 2 diabetes fourfold over seven years. This surgery can even lead to remission of diabetes in around a third of obese people with the condition.
- "One size fits all' social marketing campaigns or interventions may not work to prevent diabetes, owing to diverse cultural beliefs and traditions.
- » With more people developing type 2 diabetes at an early age, research efforts are underway to identify the best ways of preventing the condition in young people.

## **IDENTIFYING PEOPLE WITH TYPE 2 DIABETES**

- » For people at high risk, HbA1c rather than fasting glucose is better for assessing vascular risk.
- » Evidence does not support screening for diabetes in the general population.
- » Where screening is considered appropriate (such as in high risk populations), using a risk stratification tool followed by a screening blood test is the most cost-effective approach.

# DELIVERING CARE AND REDUCING THE RISK OF COMPLICATIONS

- » It is safe for people found to be at low risk to have their eyes checked for diabetic retinopathy every three years, rather than every year – a finding which has reduced costs and may be better for patients.
- » The most cost-effective way of testing people with diabetes for kidney disease is to measure albumin to creatinine ratio in the urine.
- » New technologies may help detect complications and reduce costs, as shown in automated detection of macular oedema (one form of diabetes-related eye disease).

#### **SELF-MANAGEMENT**

- » Structured education can work but few attend, particularly those at greatest risk of complications. Research shows more explanation and encouragement by health professionals would make a difference to patients. Follow-up after an initial session is also important.
- » Early research suggests computer-based packages could help patients manage their diabetes and mobile phone apps may also be helpful.
- » Group clinics currently more popular in the US than here – show promise as a means of offering patients better access to specialist care with the benefits of peer support.
- » Patients value personalised care plans and treatment targets.
- » Breaking up sedentary time with even short bouts of activity can help improve metabolic health, both for people with diabetes and those at risk.
- » Self-monitoring of blood glucose levels for patients with type 2 diabetes who are not on insulin has only a small impact and is unlikely to be costeffective.

NIHR Themed Review: On the Level

## WHAT DOES THIS MEAN FOR ME?

his evidence raises questions that you and your organisation may want to consider in order to improve the care of people with diabetes or those at risk of developing it. These questions do not cover all aspects of care (as given in NICE guidance) but are prompted by the particular research studies featured in this review.

Our questions are aimed at everyone concerned with type 2 diabetes: patients, commissioners, managers, GPs, community nurses, and other professionals working in diabetes care. Some particular questions for people with type 2 diabetes, or those at risk, are shown in blue.

# PREVENTING TYPE 2 DIABETES IN PEOPLE AT RISK

- » Are we consistent in how we identify people at risk in our locality, using agreed tools and risk scores?
- » Do we know how to refer patients to the local diabetes prevention programme and what services are on offer?
- » For people with obesity, what is the provision and uptake of bariatric surgery in our area compared with others?
- » If I am at risk, am I doing all that I can to prevent diabetes and related complications – for instance, walking an extra 20 minutes a day?

## **IDENTIFYING PEOPLE WITH TYPE 2 DIABETES**

- » Are we using HbA1c rather than fasting plasma glucose to detect diabetes in people judged to be at high risk after health checks?
- » Am I in a group at higher risk of having type 2 diabetes? Should I get tested?

# DELIVERING CARE AND REDUCING THE RISK OF COMPLICATIONS

- » How well are we delivering standard care processes across our area compared with others in the national audit?
- » Are we consistently achieving all three NICE treatment targets (glucose, blood pressure and cholesterol control) in the majority of people with type 2 diabetes?
- » How can we improve our call and recall service and patient attendance for diabetic retinopathy screening?
- » Have we considered automating to check for macular oedema in people with diabetes?
- » Have we looked at ways of improving monitoring and routine care for patients? Could group clinics with a full team of health professionals work here?
- » Have I been for my regular diabetes checks? Do I know when and how to get my eyes and feet seen?
- » How could I give advice on healthy eating and staying active to people who have just been diagnosed or are at risk of diabetes?

## **SELF-MANAGEMENT**

- » Are we commissioning structured patient education that meets national standards? Does this include some form of follow-up or reinforcement?
- » Do we know who attends education sessions? Do we understand the reasons why patients do not attend, and have we got a plan to tackle this?
- » Have we tailored sessions to meet the needs of our population, for instance appropriate dietary advice for different groups?
- » Are GPs and practice nurses clear about the education programmes we offer and are they able to describe the benefits to patients?

- » What sort of ongoing support is offered to patients? Is there flexibility to accommodate different patient needs and preferences?
- » When did I last attend a patient education programme? Should I find out if this is available locally?
- » Has my GP or practice nurse asked about my personal treatment goals and discussed options for managing my diabetes with me?



# WHY DOES DIABETES MATTER?

e know that diabetes is a major public health challenge. Over 4 million people in the UK live with type 2 diabetes and this number is rising year on year. We know that many people do not know they have diabetes, and many more are at risk of developing the disease. Weight is the most important risk factor for type 2 diabetes that can be changed. Yet two out of three adults in this country are now overweight or obese. We also know that type 2 diabetes affects some people more than others. For instance, South Asian and black communities are two to four times more likely to develop diabetes than others.

Diabetes is a serious condition, which can have devastating consequences for individuals and their families. It mainly affects adults, although is becoming increasingly common in younger age groups. There is an increased risk of complications particularly related to blood vessels - either 'macrovascular' (affecting large blood vessels such as the coronary vessels, causing heart disease and stroke) or 'microvascular' (affecting small blood vessels such as those in the eye, kidney and nerves causing a wide range of other problems in the feet and elsewhere). Having type 2 diabetes doubles the risk of such cardiovascular disease. It is the most common reason for severe kidney disease and the second most common cause of blindness in working age adults. Overall, it is estimated that type 2

diabetes accounts for 22,000 premature deaths a year in England.

Treating and managing the disease directly costs the health service around £10 billion each year. This is around a tenth of all health spend, and it is estimated that 80% of these costs are in treating complications which could be avoided. Regular checks and monitoring are critical to good type 2 diabetes care, but the National Diabetes Audit shows us that not everyone receives the care and checks they need to keep well. Similar findings are seen in reports describing quality of care for people with a diagnosis of diabetes in Scotland, Wales and Northern Ireland.

These statistics explain why national and local leaders have identified type 2 diabetes as a top priority for action and investment. The facts are compelling. But behind each fact are real life patient stories.

Behind much of what we know now about how best to prevent and manage this disease is research of different kinds. This report highlights some of the research funded by NIHR along the patient pathway from prevention to early identification to management of the disease. We have illustrated aspects of this journey with comments and insights from a number of people using services and living with diabetes.

When we think about the experience of someone with type 2 diabetes, it is important to remember that the time we spend with healthcare professionals represents just a fraction of the total experience. For the rest of the time, we are very much on our own, so equipping us with the knowledge, skills and motivation to manage our conditions is always key to successful outcomes.

**Robin Swindell, London** 



## DIABETES – A PRIORITY FOR EVERYONE

Diabetes is a global concern and a health priority in all parts of the UK. Important strategic initiatives range from an ambitious five-year vision for diabetes care in Wales in 2013 to a compelling study of variations in care in Scotland in 2015. A partnership approach to diabetes in Northern Ireland was shared with stakeholders in 2016.

In England, a framework in 2014 set out actions for commissioners to drive prevention and early detection of diabetes as well as better management of diabetes in primary care. These aims will be realised through local sustainability and transformation plans in every locality, including specific commitments to improve diabetes services. At the same time, a national diabetes prevention programme was launched in 2016, flagged in the Five Year Forward View, to roll out structured evidence-based support for those at risk in all parts of the country.



## **USEFUL STRATEGIC RESOURCES**

Action for diabetes (NHS England 2014):

https://www.england.nhs.uk/wp-content/uploads/2014/01/act-for-diabetes.pdf

Together for Health (Welsh Government 2013): http://gov.wales/docs/dhss/publications/130923diabetesen.pdf

Age of Diabetes: Health of the Nation Report (Diabetes Scotland 2015):

https://www.diabetes.org.uk/In\_Your\_Area/Scotland/Diabetes\_in\_your\_area\_Scotland/

Diabetes Strategic Framework Consultation (Northern Ireland Department of Health 2016):

https://www.health-ni.gov.uk/consultations/diabetes-strategic-framework-consultation

# PREVENTING TYPE 2 DIABETES IN PEOPLE AT RISK



I think for me, personally, I started to think about what I'm putting in my mouth and I started to think about an increase in exercise. The pedometer was brilliant because it made me go out ... I was doing zilch exercise, and it gave you that incentive to go for a fifteen minute walk on my lunch break. I started doing that, just to get my steps up. It made me change a lifestyle thing, change a habit into a good habit and then start doing more exercise.

Participant in activity programme

I would love to see greater representation of diverse communities in all organisations that support the prevention, treatment and control of type 2 diabetes. Influential policy and patient organisations need to reach out to local community groups such as ours and individuals from diverse communities need to apply to get involved – that's how change will happen.

**Kirit Mistry, Leicester** 

## WHAT DO WE KNOW?

round 5 million people in this country are at high risk of developing diabetes. Risk factors include being overweight, taking little exercise and having high blood pressure and cholesterol levels. We know that being obese is the single most important modifiable risk factor (Public Health England 2014). Much attention now is focused on doing what we can to identify and support healthier lifestyles in those at greatest risk.

We highlight some important NIHR studies, but these do not provide a complete overview of evidence on preventing diabetes. Comprehensive guidance is provided by NICE on diabetes prevention. This includes 2012 guidance for clinicians on identifying individuals at risk and referring them for lifestyle change interventions (NICE 2012 (PH38)). Earlier guidance on population and community-based interventions was targeted at commissioners (NICE 2011 (PH35)).

There is good evidence that lifestyle interventions such as keeping to a healthy weight and staying active can greatly reduce or delay the onset of type 2 diabetes. A review published in 2012 confirmed that structured diet and activity programmes were effective and cost-effective in reducing risk of disease progression. But this review also showed that not all people benefited to the same degree. Health benefits were greatest when people stuck closely to the programme, but this was often hard to do.



An important five year research programme assessed a staged approach to type 2 diabetes prevention in general practice. This included testing a new risk score which uses routine data held at the practice, followed by blood tests in those found to be

at high risk. Those found to have high glucose levels (but not high enough to be diagnosed with diabetes) were referred to structured group-based education and a support programme based on a successful model for people with established type 2 diabetes.

This approach was evaluated in a trial which reported in 2016. It found that although there were benefits in patient health and wellbeing, there was no significant reduction in the number of people developing type 2 diabetes. However, for those attending all sessions, there was real impact with significant reductions in those developing the disease. A version of this programme is now being rolled out as part of the Healthier You: NHS Diabetes Prevention Programme in England.



Another ambitious ongoing study on diabetes prevention has a particular focus on increasing physical activity, building on earlier NIHR funded work ('Walking Away from Type 2 Diabetes') showing that structured education with pedometer use can improve activity and health. This will be tested in a large randomised trial of over thirteen hundred individuals with a high risk of type 2 diabetes in two regions in England, half of whom will receive the intervention.

The study will also test different levels of support, from intensive coaching by trained educators to text reminders around goals set by patients. People taking part will be followed up for four years to see whether the programme leads to sustained increases in physical activity and a reduced risk of diabetes. The cost-effectiveness of the different approaches will also be tested.





A study analysing data from a group of over 9,000 people with impaired glucose tolerance (i.e. people at high risk of type 2 diabetes) found that increasing activity levels by 2,000 steps per day over a year led to an 8% reduction in the risk of cardiovascular disease or cardiovascular death over a five year period. Two thousand steps per day equates to just 20 minutes of walking. This study was the first to quantify the importance of making simple and attainable changes to walking activity to the future cardiovascular health in those with a high risk of type 2 diabetes.



**READ MORE (Study 4)** 



An interesting approach is being tested to train volunteers with established diabetes to coach, support and mentor those at risk of developing the disease. Early findings suggested this approach was acceptable and feasible. These diabetes prevention mentors are now part of a larger seven year evaluation of a comprehensive diabetes prevention programme. This will also look to see if the mentors experience any improvement in their own diabetes control and health through participating in the programme.



The NIHR has also funded a number of studies on the effectiveness of different approaches to change behaviour and encourage healthier lifestyles. Not all of them are featured here, but one example is an initiative sited in football clubs, targeted at overweight men who were recruited through the club they support. Participants attended fitness and weight-loss sessions at the club and lost over 5kg more than a control group. The programme was structured to include behaviour change techniques known to be effective for improved physical activity and weight loss and many felt they had benefited from the camaraderie and support offered by the football club setting.



While much focus has been on behaviour change, other studies have looked at the effect of particular treatments to reduce weight on developing type 2 diabetes. An NIHR-funded review in 2009 showed that bariatric (weight reducing) surgery was effective and cost-effective for moderately to severely obese people.

More recently, a population-based cohort study of over 2,000 people undergoing surgery found that it reduced the risks of developing diabetes by four-fold for up to seven years after the operation. Looking at a wider dataset, this study also found that severely obese people who do not have surgery find it difficult to lose weight. Recent work by the same team has shown that, for around a third of people with obesity and type 2 diabetes, bariatric surgery can induce remission of diabetes. This effect was seen in patients followed up for six years after surgery.



This section has considered research on strategies once people have been identified with established risk factors for diabetes. Other NIHR research has contributed to our understanding of healthy populations and mechanisms of prevention and development of disease, though this important upstream research is beyond the scope of this review. The NIHR also issued a call at the end of 2015 for new research on obesity prevention and management with a particular focus on preventing diabetes. Research is now underway which should add to what we know in this area.

## ONE SIZE FITS ALL? TAILORING HEALTH ADVICE

People from black and minority ethnic groups have a much higher risk of developing type 2 diabetes and experiencing complications. Prevention strategies need to take account of people's knowledge, understanding and beliefs about developing the disease. These may be different in different communities. One research project in Leicester is working with diverse ethnic groups to inform a social marketing campaign to raise awareness of diabetes risk and prevention.



# **HOW HAS RESEARCH HELPED DECISION- MAKERS?**

IHR research has helped us to establish that lifestyle interventions are effective in preventing and delaying the onset of type 2 diabetes. This informed the move towards free checks of vascular risk and comprehensive NICE guidance on diabetes prevention for populations and individuals. This included use of risk scores developed and validated by NIHR funded work.

NIHR research has also examined the way in which particular interventions to reduce weight, such as bariatric surgery, can reduce risks of developing the condition and may also be a treatment option for people with type 2 diabetes who are obese.

NIHR studies have looked at different ways of supporting healthier lifestyles for people identified as high risk. This includes evidence which is being tested more widely showing the impact of structured activity programmes on reducing cardiovascular risk for those at risk of diabetes. Other approaches being evaluated include use of diabetes prevention mentors to educate those at risk, and different kinds of coaching and support by health staff. Building on these approaches, this year the Healthier You: NHS Diabetes Prevention Programme – an ambitious programme of structured patient education for those at risk of type 2 diabetes – is being rolled out in England. NIHR is funding research to evaluate these services.

There is encouraging evidence on the potential of structured lifestyle programmes to make a difference in preventing diabetes for those at risk. Research also shows us how hard it can be for individuals and populations to take these steps. It will be important to continue to share learning and identify emerging good practice from services to help people at risk of diabetes stay healthy for as long as possible.

# WHAT WORKS? ORGANISING DIABETES PREVENTION SERVICES

The NIHR will be funding new research alongside the Healthier You: NHS Diabetes Prevention Programme which is currently being rolled out in England. Research is needed to generate early learning from sites which are trying out different ways of designing and delivering prevention programmes. For instance, an NIHR evaluation is underway on a programme in Salford which combines telephone support, exercise and targeted prevention work with hard to reach groups. This builds on previous work in Manchester to develop and test coaching and other support to change health behaviours.



# GET THEM YOUNG? PREVENTING TYPE 2 DIABETES IN CHILDREN

More people are now developing type 2 diabetes at an early age. There is an increasing need to focus effort on healthy lifestyles for children and young people. A team in South London is conducting studies related to type 2 diabetes prevention in children. This includes work to develop and pilot interventions based on changes in diet and behaviour to prevent insulin resistance in children from ethnic groups at high risk for type 2 diabetes.



Another group of researchers in London are emphasising the importance of considering all stages of life when tackling diabetes, particularly in communities that may be at higher risk.

One study is exploring factors influencing feeding practices of infants aged 6-24 months in the Bangladeshi community. These may be a driver for increased risk of type 2 diabetes, cardiovascular disease and obesity in adulthood. The aim is to inform a participatory health intervention to improve infant feeding practices in this community in Tower Hamlets.



There is also some important ongoing work studying the best ways of providing integrated community-based diabetes prevention and care services for children and young people in Newham, which has high prevalence of type 2 diabetes in its youth population. This involves using action research to inform and influence the re-design of children and young people's diabetic services and improve peer education, including the creation of 'Youth Commissioners' who have contributed to the production of the commissioning guidance.





# IDENTIFYING PEOPLE WITH TYPE 2 DIABETES



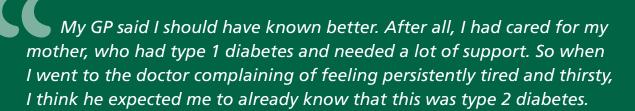
THE INCREASED RISK OF DEVELOPING SUBSEQUENT TYPE 2 DIABETES FOR WOMEN WHO HAVE DIABETES IN PREGNANCY

**7**x

I thought I knew about diabetes. My father had had diabetes and was insulin-dependent so I had seen at first-hand how tricky it could be to manage the disease.

As I got into my early sixties, though, with my husband being treated for cancer, life became very stressful. So much so that I put my frequent trips to the loo down to the stress, never thinking about the possibility of diabetes. Thank goodness, then, for GP screening for type 2, based on risk factors that include family history. I was called in for a blood test. My blood sugar showed up very high and off I went for another glucose tolerance test. This time type 2 diabetes was confirmed.

Jenny Stevens, London



**Kirit Mistry, Leicester** 



ver half a million people in this country have type 2 diabetes without knowing it. This matters, as some people already have complications when they are diagnosed, which could have been prevented. This might suggest that everyone should be screened for type 2 diabetes, but setting up an expensive national screening programme is not always the right thing to do. NIHR research has played an important part in this debate.

An ambitious international trial looked at this question. It took 20,000 people from practices in UK, Netherlands and Denmark and allocated them to screening with intensive management, screening with usual management or no screening. Patients were followed up for almost ten years. The study showed problems in attendance for screening. Even when

type 2 diabetes was identified by screening, there was no benefit in reduced deaths. The study concluded there was no evidence to support general population screening.



One of the main problems is that no perfect screening test exists. An earlier review suggested that screening using current tests would find more people with impaired glucose tolerance (prediabetes) than with type 2 diabetes itself and that screening the general population would not prevent future complications. Screening was therefore not recommended.



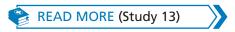
NIHR studies have, however, provided authoritative evidence around testing strategies. A recently published study in people over 40, who would be offered an NHS health check, provided categorical evidence that using haemoglobin A1c (HbA1c) to screen for type 2 diabetes was cost-effective compared with fasting plasma glucose for high-risk individuals.



A further modelling study provided evidence on the cost-effectiveness of a range of different screening strategies by considering the cost per case identified of over 212 different combinations of tests. The study concluded screening a population using a non-invasive risk stratification tool followed by a screening blood test was the most cost-effective method of screening for type 2 diabetes and abnormal glucose tolerance.

Uptake of invitation-based screening for type 2 diabetes is a barrier to identifying people with undiagnosed type 2 diabetes. A recent trial looked at opportunistic screening where either individuals were encouraged to fill in a self-assessment risk score when visiting a GP (for other reasons) or a computer-based risk score was run through GP databases to flag individuals at risk. People identified would then be advised to book for a blood test next time they visited their GP. Both approaches successfully identified new people with type 2 diabetes, with the computer-based risk score potentially the most promising strategy as it resulted in greater attendance to an initial blood test when compared to the self-assessment score.





# LOOKING FOR DIABETES? DOING MORE FOR PEOPLE WITH LEARNING DISABILITIES

We know that people with learning disabilities tend to have poorer health, be more overweight, and be less active and could therefore be at greater risk of diabetes. But not much research has been done with this particular community. An NIHR funded study is developing and testing a structured screening and lifestyle intervention for early detection and management of diabetes for people with learning disabilities. This study will find the best ways of identifying those at risk, developing and evaluating a tailored programme with input from people with learning disabilities, carers and staff.



# HOW HAS RESEARCH HELPED DECISION-MAKERS?

e know that a significant number of people have undiagnosed type 2 diabetes. We know that the NHS health check programme and other opportunistic screening efforts will detect some people with the condition. NIHR research has shown

the benefits of using HbA1c over fasting blood glucose tests to assess vascular risks in people at highrisk. But it has also shown that there is no evidence currently to justify general population screening. There is some uncertainty about whether early detection leads to longer term benefit. Ongoing research will explore the value of case finding in specific groups, such as those with learning disability.



# EXPECTING THE BEST? DEVELOPING DIABETES DURING PREGNANCY

The number of women developing diabetes during pregnancy is increasing. Poorly controlled diabetes can lead to complications for mothers and babies. But having diabetes during pregnancy also increases the risk of developing subsequent type 2 diabetes about sevenfold. It is therefore important to identify these women early and give them appropriate support during pregnancy and after birth, given the window to prevent or delay later diabetes (although uptake of postnatal screening is poor).

An ongoing NIHR funded study is reviewing best ways of screening and treating women with gestational diabetes. As part of this work, the team used population data to look at the association between glucose levels in pregnancy and birth outcomes in different ethnic groups. They found that lower fasting and post-load glucose thresholds improved accuracy in the diagnosis of gestational diabetes in South Asian women. These findings suggest that current NICE diagnostic criteria may underestimate the prevalence of gestational diabetes in this population.



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# DELIVERING CARE AND REDUCING THE RISK OF COMPLICATIONS

INCREASED LIKELIHOOD OF HEART DISEASE OR STROKE IN ADULTS WITH TYPE 2 DIABETES

2 – 4 times that of people without diabetes

PROPORTION OF PEOPLE WITH TYPE 2 DIABETES DYING OF KIDNEY DISEASE

1/10

At first I didn't want to hear about the disease and how to control it, I just wanted it all to be reversed. But then I started to worry about the risks to my eyesight and the chances of losing my driving licence, which would have taken away my independence... I do make sure, now, that I get all the regular checks: eyes, feet and kidney function, as it's vital to monitor these.

Kirit Mistry, Leicester

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My GP and I agreed that tackling my newly-diagnosed condition is a collaboration between him and me. He provides the metformin and the monitoring checks. I focus on the diet and exercise, keeping a record of when I have various tests done and all the results. I take these with me when I go to see him so we can review the pattern. I can discuss concerns with him at any time or use my judgement to wait until my six-monthly check-up....

So, to anyone who's getting to grips with their type 2 diabetes, I would say this: work on the partnership with your GP. Talk to him or her about how the practice can support you to manage the condition. Take responsibility for your part in the management of your diabetes – find out what you need to know and track your tests and other indicators of your condition – and make sure you get all your important annual checks, such as foot care, and keep a record to remind you.

Jenny Stevens, London



## **WHAT DO WE KNOW?**

egular monitoring of people with type 2 diabetes is important, for example checking blood glucose and other factors such as blood pressure and cholesterol. General practitioners and nurses in primary care are central to delivering this routine care. The key aim is to prevent complications arising from compromised large or small blood vessels. These can lead to heart disease and problems with kidneys, eyes, nerves and feet. For this reason, standards have been introduced with nine key care processes. Although diabetes care has improved over the years, the National Diabetes Audit has shown that there is still variation in the uptake of these care processes in practice. One important finding is that younger, working age people with

type 2 diabetes tend to receive fewer checks and have poorer outcomes than average.

# NICE TYPE 2 DIABETES RECOMMENDED CARE PROCESSES

- » Body mass index measurement
- » Blood pressure measurement
- » Haemoglobin A1c (HbA1c) measurement
- » Cholesterol measurement
- » Record of smoking status
- » Foot examination
- » Urinary albumin to creatinine ratio
- » Serum creatinine measurement
- » Eye examination

This section covers research addressing particular aspects of treating and preventing complications arising from diabetes. The wider issue of how people with diabetes manage their disease day to day and how best to support them is covered in the next section. But the important care processes outlined here provide structured points of contact for patients with health services. Two recent studies have looked at tools to give patients with diabetes more information before consultations to make better treatment choices. This includes a study in primary care focusing on decisions for people with type 2 diabetes about when to start insulin.

A further study examined the value of using a patient decision aid to make treatment choices in general practice.



Given the increasing options and complexity of treatment choices in diabetes, this focus on shared decision-making is very welcome.



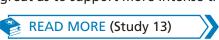


## HEART AND CIRCULATION

A large study looked at whether early intensive management of people with type 2 diabetes reduced the risk of developing cardiovascular disease or other type 2 diabetes-related problems such as diabetic retinopathy. This trial included over three hundred GP practices in the UK, Netherlands and Denmark. Even though intensive treatment improved type 2 diabetes control compared with standard care, there was no significant reduction in cardiovascular events (cardiac arrests or stroke) or deaths after five years. This was partly because standard care for people with type 2 diabetes in these countries is now good, so the differences between this and the more intensive approach were not so great. A further study from this team modelled the potential effect over a longer period (ten years). This suggested that in the longer term, risk of cardiovascular disease may be reduced.



As well as looking at the impact on cardiovascular risk, the study also investigated the impact of early intensive treatment on microvascular outcomes, relating to problems with the kidneys, eyes and nerves. Although there was a slightly higher risk of retinopathy for those receiving standard care, the difference was not so great as to support more intense treatment.



Lowering blood glucose is an important part of reducing the risk of microvascular complications. NIHR studies have contributed to evidence on the effectiveness of blood glucose-lowering medication. This has included a number of technology assessment reports contributing to NICE guidance for clinical staff. For example, one review suggested that agents such as the 'gliptins' were clinically effective and cost-effective for blood glucose control in type 2 diabetes compared to existing treatments.



This is a rapidly changing area of research and large studies have been funded by pharmaceutical companies to evaluate newer drugs and their impact on cardiovascular events in people with type 2 diabetes. This includes the recently published non-NIHR EMPA-REG OUTCOME trial on sodium-glucose cotransporter 2 inhibitors (Wanner 2016) and 'LEADER' study on the effects of liraglutide (Marso 2016). NIHR funded studies can complement some of these large pharmaceutical trials by focusing on areas which may be less attractive to industry, including comparative effectiveness and cost-effectiveness studies of older drugs.

# EYES

Diabetic retinopathy and diabetic macular oedema are important complications of type 2 diabetes, both of which can lead to sight loss. Retinopathy is caused by high blood sugar levels damaging the back of the eye. This can get worse over time. At first, small vessels at the back of the eye (retina) can become blocked and leak small amounts of fluid or blood. This does not usually affect the sight and is known as background retinopathy. Over time though if enough blood vessels become blocked, new vessels start to grow and can cause significant bleeding. The retina can also detach from the back of the eye causing blindness.

Many people with type 2 diabetes have no symptoms until retinopathy is advanced. For this reason, a national eye screening programme has been set up to identify patients with early eye problems. Skilled individuals working in GP practices, mobile units, opticians or hospital clinics take digital photographs and assess results. People with retinopathy are referred for assessment and treatment by specialists. People with type 2 diabetes are currently invited for screening once a year unless background retinopathy was detected. But there was uncertainty about the optimal frequency of screening. This has big implications for the NHS, so NIHR studies were commissioned to address this.

One study used data from screening services and GPs to develop statistical models to test the cost-effectiveness of different screening intervals. The study found that continuing to do annual screening for people who have no indication of sight-threatening retinopathy on two consecutive screening visits was unnecessary and screening every three years was most cost-effective. A further model using individual risk scores found that people at low risk could be safely and effectively screened every five years. This has significant implications for resource use in the NHS, which has recommended a change in routine screening interval to every two years for low risk groups.

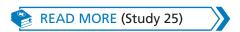
An interesting ongoing programme of research in Liverpool aims to further explore the possibility of varying the time between retinopathy screening for individuals based on their degree of risk. It will explore whether it would be safe and acceptable to patients if the time between screenings was longer for people at lower risk. Based on around 18,000 people, it will measure the risk of progression to treatment and visual impairment as well as using qualitative methods to assess patient and professional experience.



Particular screening approaches have also been explored. One study investigated whether colour vision testing could work as a way of detecting and monitoring the progress of diabetic retinopathy, although it found insufficient evidence to recommend it as an effective method.



Another ongoing study in London is exploring whether the efficiency of retinopathy screening could be improved by automating the first part of the retinal image assessment process. This could generate savings for the NHS with more effective deployment of trained image graders.



A recent Cochrane review looked at the effect of blood pressure control on diabetic retinopathy. It found some modest effect on preventing eye disease for up to four years but no good evidence on delaying progression of retinopathy. The authors concluded that although reducing blood pressure may have overall benefits for people with diabetes, current evidence does not justify treatment to delay or prevent diabetic retinopathy alone.





A multicentre study involving over 3000 patients investigated the best method of detecting macular oedema. The study found that a fully automated approach identifying patterns of surrogate markers was more costeffective than current manual methods. The study also found that adding optical coherence tomography (a form of ultrasound scanning) prior to referral resulted in cost savings without reducing health benefits.



In terms of treating diabetic macular oedema if it is detected, a new study will compare the effectiveness and cost-effectiveness of a specific laser therapy (Diode Subthreshold Micropulse Laser) compared with standard laser treatment for adults with the condition. The study aims to recruit patients across ten UK hospitals with a two year follow-up, and results are expected in late 2020.



Evaluating treatments for diabetic retinopathy is important too. If it is detected, there are a number of options that depend on the nature and extent of the retinopathy. For proliferative retinopathy this usually involves laser treatment to remove the fragile new blood vessels, resulting in reduced risk of the bleeding that can lead to blindness. A recent study investigated the cost-effectiveness of different treatments, including a particular form of laser (pan-retinal photocoagulation), for background retinopathy at an earlier stage of the disease. The study found that evidence for this newer approach was not strong enough for it to be routinely recommended.



## EYES ON THE PRIZE? HOW TO IMPROVE ATTENDANCE FOR RETINOPATHY SCREENING

A new NIHR study will review the evidence for the best ways of encouraging attendance at retinopathy screening and explore the reasons for people not attending. The outputs from this project will be used to make recommendations on the design of evidence-based and cost-effective screening interventions in areas or population subgroups with low uptake and to make recommendations for future research to inform UK screening policy.



# KIDNEYS

An important microvascular complication of type 2 diabetes is kidney damage, which can lead to chronic kidney disease and potentially end stage kidney failure. Over one in ten people with type 2 diabetes die of kidney disease. One of the key challenges is detecting the onset of kidney disease and an NIHR study investigated the best way of testing for kidney damage. They found that once yearly screening with albumin to creatinine ratio (a urine test) appeared to be the most cost-effective method, and this supported NICE guidance to test annually. The same study also found benefits of reducing kidney damage by using medications that inhibit the renin angiotensin aldosterone system in people with type 2 diabetes.



Recently published information from the EMPA-REG OUTCOME trial (not NIHR funded) has shown that, in patients with type 2 diabetes at high cardiovascular risk, empagliflozin was associated with slower progression of kidney disease (Wanner 2016).



Type 2 diabetes can also lead to nerve damage,

which causes particular problems in the legs and feet due to neuropathy (nerve damage, which is often painful) and risk of ulceration. Again, early detection is important and so a study was funded to explore the best ways of identifying people at risk of developing foot ulcers. They found that people at greatest risk had a previous history of foot ulceration, inability to feel the pressure from a specific sensation-testing instrument, at least one absent foot pulse, and longer time after diagnosis.

An interesting new approach to identifying the early signs of diabetic neuropathy in limbs is being explored. Corneal confocal microscopy is a non-invasive eye test which can be delivered in community optometry practices alongside routine retinal screening. A feasibility study is underway.





**READ MORE (Study 32)** 

## WHAT ABOUT THE SYSTEM? USING ROUTINE INFORMATION TO UNDERSTAND DIABETES SERVICES

Information collected by hospitals and GP practices can tell us a lot about how people with type 2 diabetes use services and what can be improved. Two studies used national data collected routinely to study associations between different parts of the system. One study looking at those people identified with diabetes over five years found that those with better access to primary care whose diabetes was managed well in general practice were less likely to have hospital admissions related to diabetes complications.

Another large population set showed that hospital records did not always identify diabetes-related admissions. This means that there could be more hospital admissions than currently estimated for people with diabetes. These observational studies can be useful in identifying markers for improvement and further work.

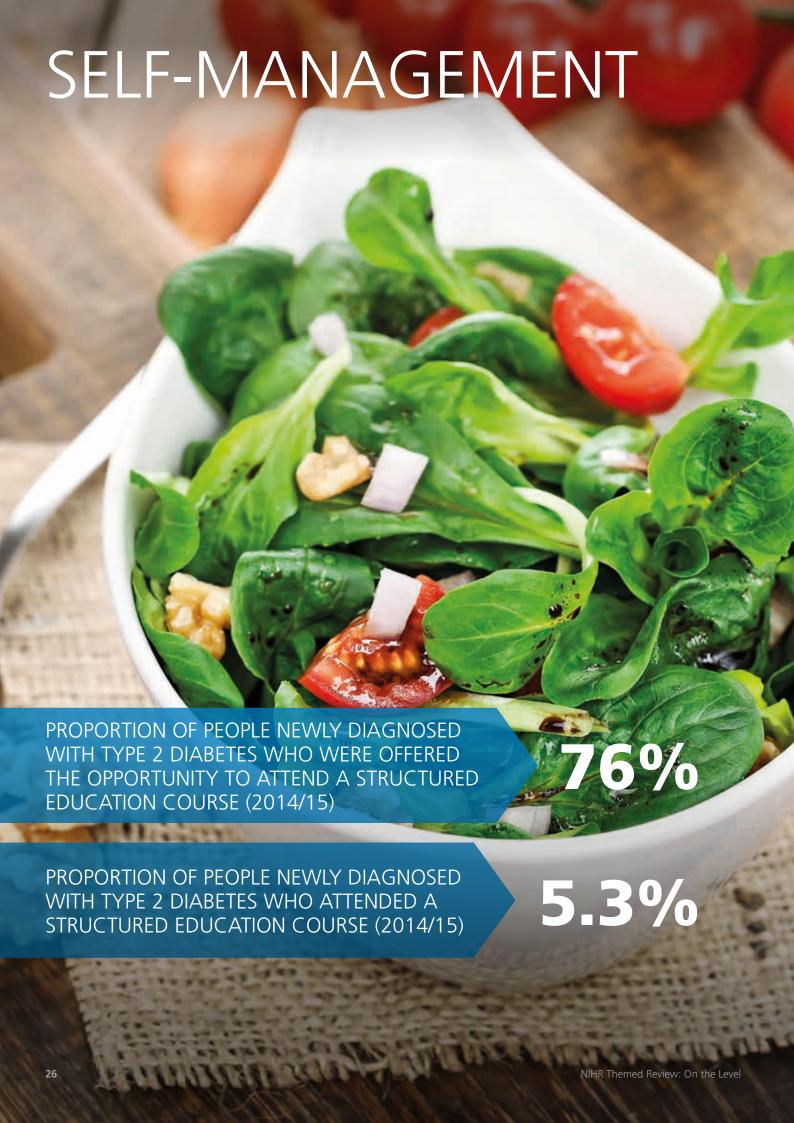


READ MORE (Studies 34 & 35)

## HOW HAS RESEARCH HELPED DECISION-**MAKERS?**

e know that regular checking and supporting patients to live well with the disease are key components of good type 2 diabetes care, but this is often hard to do. NIHR research has addressed key uncertainties for clinical staff and service leaders and has contributed to NICE and SIGN guidelines on type 2 diabetes. This includes drug treatments, treatment targets and recommendations on the optimal screening interval for diabetic retinopathy and diabetic kidney disease.

Other research is helping develop more efficient approaches to screening, with use of automation and new technologies. A large-scale European study (the ADDITION trial) has shown that, although early intensive management did not reduce risk of deaths and cardiovascular events after five years, it did result in better diabetes control and potential longer term cardiovascular benefits. NIHR has also contributed to evidence on comparative effectiveness of medicines to control blood sugar levels, adding value to other research funded by industry and charities.



In the three years since my type 2 diabetes diagnosis I have spent less than an hour in total with health care professionals talking about my condition.

During the same period I have spent more time thinking about my health than in the thirty years previously. My condition impinges on my life and thoughts at every turn. Very rarely does a couple of hours go by in which I don't make a decision relevant to managing my diabetes.

Most of these are very small, but cumulatively they take up a great deal of my thinking.

**Robin Swindell, London** 

I was recently diagnosed with type 2 diabetes. Although aware of what diabetes was because of the family history, I was a bit lost as to how to manage it... I did not know what to expect from the course but it has given me a big encouragement to carry on changing my life and determine to live a long life with this illness. I have already signed up for a sponsored walk to raise money for Diabetes UK.

Person with diabetes attending education programme, Leicester



eople with type 2 diabetes may see their GP or another healthcare professional for a short appointment once or twice a year – the rest of the time they must manage their condition by themselves. Supporting people to do this successfully is crucial to avoiding complications. Self-management may include a number of elements, such as attending eduction programmes, seeking psychological support, diet and exercise management, and some form of blood glucose monitoring. Balancing these complex elements is challenging and patients need support to develop the right knowledge and skills.

Provision of this support is a clinical and policy priority. Current NICE guidance recommends that everyone newly diagnosed with type 2 diabetes should be offered access to a structured education programme, with annual 'refresher sessions'.

They should also have ongoing, individualised nutritional advice from a qualified healthcare professional, in addition to regular support from a GP and/or specialist nurse.

From 2016/17 commissioners in England will be expected to report against two key indicators, one of which is the number of people with new type 2 diabetes (diagnosed within the previous year) who attend a structured education course. Recent data from the National Diabetes Audit suggests that in 2014-15, although more than three quarters of recently diagnosed patients had been offered structured education, only 5.3% had attended (HSCIC 2016). A report from Diabetes UK suggests that over a third of commissioners are not supporting specific courses for people with type 2 diabetes (Diabetes UK, 2015).

## **STRUCTURED EDUCATION**

The NIHR has supported research in a number of areas to explore the most effective approaches to self-management, of which structured education is one of the most important. It is usually delivered in groups and provides an opportunity for patients to learn more about food choices, physical activity, self-monitoring and medication, and to set personal goals and action plans.

In the UK, two programmes are commonly offered which meet the national standards: Diabetes Education and Self-Management for Ongoing and Diagnosed (DESMOND: one or two half-day sessions, delivered in a group of up to 10 patients) and X-PERT (six shorter weekly group sessions and annual follow-up).

A Diabetes UK-funded evaluation of the DESMOND programme found that it helped attendees improve in some areas, such as weight loss, smoking and depression, though no benefit was shown on blood glucose. The evidence of sustained health benefits is not as strong: improvements were sustained for one year, but not for three years, suggesting that follow-up support and/or refresher sessions are important (Davies, 2008; Khunti, 2012).

Patients at high risk of type 2 diabetes complications – men, smokers, and those who struggle to achieve good glycaemic control – are less likely to attend education. Patients report a range of barriers including access issues (such as timing of sessions or parking); personal preferences (for example, some were uncomfortable with the group format); or feelings of shame or stigma around their diagnosis. But the most commonly reported reason for non-attendance in one qualitative study was that the healthcare professional had either not mentioned education at all, or had not clearly spelt out the benefits to the patient.



Similarly, early work undertaken to support a new study identified a degree of scepticism about structured education among some GPs and practice nurses, so new research is aiming to understand the reasons for this and to develop guidance and practical support to help Clinical Commissioning Groups embed education in their areas.



# DIGITISING DIABETES? ROLE OF NEW TECHNOLOGY TO HELP PEOPLE MANAGE THEIR DIABETES

Evidence suggests that using computer-based packages to help patients manage blood glucose can have a small but positive effect – and mobile phone apps may be even better. So far, the packages tested haven't been shown to affect other outcomes, such as blood pressure or weight – but research is limited to date, and not always of good quality. The NIHR has funded new work to develop a computer-based management programme for people with type 2 diabetes (due to publish shortly).



An NIHR systematic review of evaluations of educational interventions in type 2 diabetes found mixed results. Overall, the review indicated that programmes that include a range of different components are more likely to be successful, particularly those delivered by a team. There is a

strong suggestion that education which is reinforced through further contact after the initial session is more likely to make a difference.



## **MOTIVATING AND SUPPORTING PATIENTS**

NIHR research has explored some of the behaviours, techniques and strategies that may improve type 2 diabetes management. For example, a review of patients' views of self-managing type 2 diabetes found that having a sense of ownership of their management was important. This included being able to set their own treatment goals and having an individualised treatment plan.



These findings are echoed by a review of selfmanagement interventions for men with long term conditions (not just type 2 diabetes), which found that tailoring support to individual preferences was important and that multicomponent approaches (such as combined education, physical activity and peer support) improved quality of life.



Another study identified the potential of psychological training for nurses to improve the support they are able to offer to patients around self-management, and an ongoing study will explore the potential benefit of psychological interventions for patients.



For some people there are particular challenges to managing type 2 diabetes. For example, several ongoing NIHR projects are exploring how to support self-management of type 2 diabetes among people with learning disability (or help prevent its occurrence in the first place). Part of this study has involved exploring ways of identifying people with learning disability who are not on GP registers. Early findings suggest that people with learning disability are at greater risk of type 2 diabetes because of high prevalence of overweight and obesity and that obesity may be a bigger health problem than glycaemic control.



## **MONITORING BLOOD GLUCOSE**

Self-monitoring of blood glucose – usually done with a portable glucose meter – is not recommended by NICE for the majority of people with type 2 diabetes who are not taking insulin, but an NIHR review has explored whether it should be considered in certain circumstances. Results were mixed, but overall self-monitoring of blood glucose was linked to small decreases in HbA1c - though only when accompanied by education or some form of feedback to patients about their results. Simply asking patients to monitor without education or support did not lead to reductions in blood glucose. Improvements were unlikely to be clinically significant, and therefore self-monitoring for this group would probably not be cost-effective. The review also found self-monitoring was not suitable for all. While some patients found it empowering and reassuring, others experienced feelings of guilt and depression.



# GROUP CLINICS: COULD LEARNING FROM THE US HELP IMPROVE SERVICES HERE?

At the moment, apart from structured education, most diabetes care is provided at individual GP or nurse appointments. But in the US, there is more widespread use of 'group clinics' – a form of specialist-led care that is delivered in groups, and may include aspects of clinical management as well as education and support. This could offer patients better access to specialists and the benefits of peer support, whilst holding the potential for cost savings too. A review of mainly US evidence found group clinics were associated with improved blood glucose and blood pressure, and in some cases improved quality of life. There is a need for clearer evidence on cost, and to explore how this promising approach could translate to the UK.



# BUILDING BLOCKS? GROWING THE EVIDENCE BASE ON DIET AND EXERCISE

NIHR Biomedical Research Units (BRU) are based in the NHS with a role to drive innovation in healthcare and ensure research advances are converted into benefits for patients. Several BRUs are investigating the effectiveness of different dietary and activity schedules for people with type 2 diabetes. New findings include:

» Encouraging people with type 2 diabetes to break up sedentary time with even short bouts of activity could lead to improvements in metabolic health. Similarly, breaking up prolonged sitting seems to have a positive effect on blood glucose for women at risk of developing type 2 diabetes



» Short bouts of very vigorous exercise show potential for being more effective than moderate exercise in managing blood glucose levels. This is now being explored further in the South Asian population



» An intensive dietary intervention with monthly dietary consultations showed benefits in glycaemic control



# HOW HAS RESEARCH HELPED DECISION-MAKERS?

e know that the role of the patient is key to effective management of type 2 diabetes, but for many people this is challenging. NIHR research has included a strong patient focus, seeking to understand the motivations, preferences and perspectives of patients in order to improve care. For instance, NIHR research has explored why so many patients do not attend structured education, finding that the role of the health professional in explaining and encouraging attendance is important. Other studies have shown how patients value individualised care with tailored goals. Research into self-monitoring of blood glucose for patients with type 2 diabetes looked not only at its effectiveness, but also how patients felt about it - which showed that for some it was associated with negative feelings. This research informed NICE guidelines on self-monitoring.

NIHR research has also explored the effectiveness of key components of self-management, particularly education. This found that multi-component packages, delivered by a team and with follow-up contact afterwards, were most effective. Future research will explore the role of psychological therapies in helping patients self-manage. NIHR research has informed NICE and SIGN guidelines on the management (including self-management) of diabetes.



# DEVELOPING A SYSTEM TO SUPPORT DIABETES RESEARCH

In an environment where the funding available for health services is being squeezed, it is increasingly important that the decisions we make around the commissioning and de-commissioning of health services are informed by robust evidence. This can be extended beyond specific treatments and interventions to how the system organises itself in response to wider health system reform.

Research offers an important independent perspective to what may seem like intractable system-wide issues to commissioners. It can support commissioners in both evaluating existing services and commissioning new services."

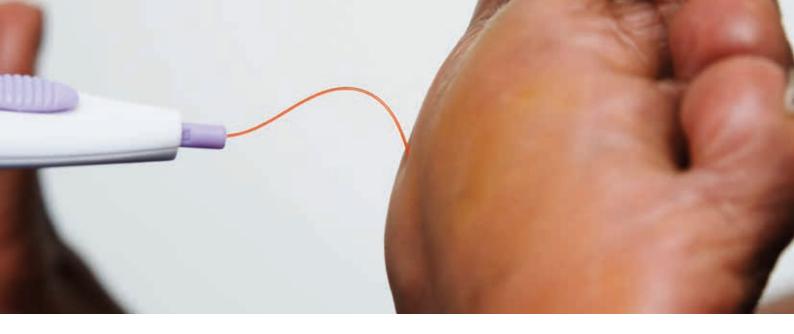
**Bristol CCG Transformation Team** 

## WHY RESEARCH MATTERS TO COMMISSIONERS

his review has highlighted some of the important programmes and projects on diabetes prevention, management and care funded by the NIHR. These include population-based studies, trials comparing effectiveness of different treatments, and mixed methods research considering how to tailor services to particular needs. NIHR funding programmes decide which studies to fund, using panels of clinicians, managers, patients and researchers. They help to prioritise research and to identify the most pressing problems where evidence is needed.

As well as these national needs-led programmes, the NIHR also supports thirteen local Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) which encourage partnership between universities and service organisations. Each of the thirteen CLAHRCs in England have active programmes of work around diabetes and other long-term conditions. Only some of these diabetes projects are featured in this report; information on all CLAHRC funded research is available at <a href="https://www.clahrcpp.co.uk">www.clahrcpp.co.uk</a>. The NIHR working as a whole system can test interventions at scale and pull through research of different kinds. An example of this is a small study in one CLAHRC of a promising intervention to increase physical activity which is now being tested in a multicentre trial funded by a national NIHR programme (see Study 3).

There is also infrastructure funding for more basic research and centres of excellence, some particularly relevant to diabetes. The NIHR provides some core and project-based funding for Cochrane review groups, which synthesised published evidence such as the review of blood pressure management to prevent retinopathy cited in this report (see Study 26).



See www.cochranelibrary.com for details of all the reviews undertaken through Cochrane.

The NIHR has also helped support research in other ways. This includes support for local clinical research networks and a national specialty network focused on diabetes (www.crn.nihr.ac.uk). These provide valuable help from research nurses collecting data to help in recruiting patients to trials and other studies in hospitals, practices and the community.

The NIHR also enables individual researchers through fellowships and training posts with a focus on diabetes (www.nihr.ac.uk/funding/training-programmes.htm).

There are other kinds of research supported by NIHR which are less visible. These include Technology Assessment Reports which provide robust evaluation of treatments, including evidence submitted by drug manufacturers. This helps to inform decisions about therapies by NICE. A recent US Preventive Services Taskforce review on prevention of type 2 diabetes cited a Technology Assessment Report as the most comprehensive previous review.

Looking ahead, the NIHR also tries to identify new and emerging technologies of the future through its Horizon Scanning Centre.

# WHAT'S NEXT? NEW APPROACHES TO NON-INVASIVE BLOOD GLUCOSE MONITORING

Monitoring blood glucose levels is key to successful self-management. At present this is done through fingerprick tests which can be inconvenient and painful. New approaches are now being developed for non-invasive blood glucose monitoring by tests on skin, tear fluid, saliva and breath. A helpful review has been published of these new and emerging technologies by the NIHR Horizon Scanning Research & Intelligence Centre. www.hsric.nihr.ac.uk/topics/review-new-and-emerging-non-invasive-glucose-monitoring-technologies/ These have not yet been fully evaluated and none are currently in routine use. New research will be needed to identify the cost-effectiveness of different approaches – watch this space.

Diabetes is an important disease and many advances have been made through research supported by research councils, charities, industry and independent organisations. The NIHR is one player in this landscape. Through its networks, units, programmes and grants it supports research with a particular focus on the needs of NHS decision-makers. These include those planning, commissioning, delivering and using services.

Evidence is needed at a population level to inform better services and at an individual level to enable clinicians and patients to make better decisions about treatments and approaches to living well with diabetes. NIHR research complements other research activity and aims to build research capacity and infrastructure to support diabetes research which will address key uncertainties in the future.

#### **ACKNOWLEDGEMENTS**

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- » Dr Bob Young, Consultant Diabetologist in Salford (Demonstrator Site); Clinical Lead of the National Diabetes Audit

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# **APPENDICES**

## **SUMMARIES OF FEATURED NIHR STUDIES**

These studies were funded by the NIHR through a wide range of funding programmes, research centres and collaborations, workstreams and individual research fellowships. They include a variety of studies, from large, long-term primary research projects to smaller grants and reviews of published research. To find out more about these programmes and other funded work, visit www.nihr.ac.uk.

#### STUDY 1 (PUBLISHED)

Non-pharmacological interventions to reduce the risk of diabetes in people with impaired glucose regulation: a systematic review and economic evaluation

Published 2012, Gillett

The aim of this study was to review the clinical and cost-effectiveness of non-pharmacological interventions, such as diet and physical activity, aimed at preventing type 2 diabetes in people with intermediate hyperglycaemia. Nine randomised trials with a total of 5875 participants were identified that compared lifestyle interventions (mainly dietary and physical activity advice) with standard care. The primary outcome was progression to diabetes. In most trials, progression was reduced – in some cases, by more than half. The greatest effects were seen in participants who adhered best to the lifestyle changes. The most cost-effective option of those studied appeared to be lifestyle change followed after a year with medication for those finding it difficult to make the changes.

Health Technol Assess 2012 doi: 10.3310/hta16330

#### STUDY 2 (PUBLISHED)

A community based primary prevention programme for Type 2 Diabetes integrating identification, lifestyle intervention and community services for prevention.

Published 2016, Davies

This was a cluster randomised trial involving over 700 patients from 44 practices over four years. Patients at risk of diabetes were identified by general practitioners using a predictive risk tool developed and validated by the team. Those at risk could be allocated (by practice) either to a structured education programme, Let's Prevent Diabetes (LP) or a control. LP is an initial 6 hour group lifestyle modification programme with three hour refresher sessions at years one and two and was developed by the team based on an effective initiative for people with established diabetes (DESMOND). Participants were followed up at yearly intervals over three years from the start. The study found that there was a reduced risk of developing diabetes in those who received the education programme, but this did not reach statistical significance. However, participants did demonstrate improvements in blood glucose, cholesterol and activity levels, and analysis suggested that the programme is likely to be cost-effective.

Preventive Medicine 2016 doi:10.1016/j.ypmed.2015.12.012

#### STUDY 3 (ONGOING)

The PRomotion Of Physical activity through structured Education with differing Levels of ongoing Support for those with prediabetes (PROPELS): randomised controlled trial in a diverse multi-ethnic community.

Due to publish 2020

This study builds on earlier NIHR work to test different versions of an intervention to increase physical activity in a diverse population at risk of diabetes. The aim is to recruit over 1300 people at risk of diabetes from two regions in England including ethnically diverse populations. Participants will receive one of the following: information in a leaflet (control); a structured half-day education intervention, tailored where needed to particular ethnic groups; or the education session plus monthly support through email and mobile phone. Physical activity, measured by an accelerometer will be the primary outcome, together with blood glucose levels and other markers. The study will test different levels of support, including intensive telephone follow-on coaching by trained educators and text feedback and goal setting support. A four year follow-up will determine whether the programme leads to sustained increases in physical activity and a reduced risk of diabetes, and whether the intervention is cost-effective.

http://www.nets.nihr.ac.uk/projects/hta/0916202

#### STUDY 4 (PUBLISHED)

Association between change in daily ambulatory activity and cardiovascular events in people with impaired glucose tolerance (NAVIGATOR trial): a cohort analysis

Published 2014, Yates

This international study, supported by the NIHR Leicester-Loughborough Diet, Lifestyle and Physical Activity Biomedical Research Unit, analysed data from a large international cohort of 9306 individuals with impaired glucose tolerance (denoting a high risk of type 2 diabetes) and found that changing activity levels by 2000 steps/day over a 12 month period led to an 8% reduction in the risk of cardiovascular disease or cardiovascular death over a 5 year period. 2000 steps/day equates to just 20 minutes of walking. During 45,211 person-years follow-up, 531 cardiovascular events occurred. Baseline ambulatory activity (hazard ratio [HR] per 2000 steps per day 0.90, 95% CI 0.84-0.96) and change in ambulatory activity (0.92, 0.86-0.99) were inversely associated with the risk of a cardiovascular event. This study was the first to quantify the importance of making simple and attainable changes to walking activity to the future cardiovascular health in those with a high risk of type 2 diabetes.

Lancet doi: 10.1016/S0140-6736(13)62061-9

#### STUDY 5A (PUBLISHED)

A motivational peer support program for type 2 diabetes prevention delivered by people with type 2 diabetes: the UEA-IFG feasibility study.

Published 2012, Murray

This study investigated the feasibility of developing a peer support program for people at high risk of type 2 diabetes. It investigated whether lay members of the public who had existing type 2 diabetes could become 'type 2 trainers' and be trained to offer phone support to people who are at risk of developing the condition. It also considered the costs of doing so. The training

involved seven sessions covering issues such as exercise, healthy eating, motivations and barriers. The researchers successfully recruited and trained 25 lay people to be type 2 trainers. There was a high degree of retention of type 2 trainers (89% still involved at 20 months). The study therefore found that recruiting and training lay volunteers with diabetes to support people at risk of developing diabetes was a feasible strategy and probably cost effective compared to employing salaried health care professionals.

Diabetes Educ 2012 doi: 10.1177/0145721712440332.

#### STUDY 5B (PUBLISHED)

A qualitative assessment of using lay trainers with type 2 diabetes in an intervention programme for people at risk of type 2 diabetes.

Published 2011, Sampson

This qualitative study explored the acceptability, perceived effectiveness and sustainability of using lay trainers with type 2 diabetes as part of a dietary and exercise intervention programme to reduce incidence of diabetes among people at risk. The study used a series of focus groups involving lay trainers, people who had received their support and health professionals working with the lay trainers. Lay trainers were seen as a complementary method to motivate individuals to reduce their risks of diabetes. Advantages included lay trainers' ability to communicate ways of coping with type 2 diabetes in a way that people could understand.

Health Education Journal 2012 doi: 10.1177/0017896911430562

#### STUDY 5C (ONGOING)

Delivering a Realistic Diabetes Prevention Programme in a UK Community: The Norfolk Diabetes Prevention Study (Norfolk DPS) – ongoing

Due to publish 2018

Building on these two studies, a programme grant is now underway as part of a larger diabetes prevention evaluation. The mentoring element will be tested in a clinical trial. As a new element, the study will also measure any improvement in diabetes control for the mentors themselves, as well as those at risk of diabetes receiving the education and support.

http://www.norfolkdiabetespreventionstudy.nhs.uk/

## STUDY 6 (PUBLISHED)

## **FFIT Football Fans in Training scheme**

Published 2015, Wyke

An NIHR-funded trial, evaluating the effectiveness of a programme to help football fans lose weight, feel better and live a healthier lifestyle, was delivered via the Scottish Professional Football League Football (SPFL) Trust. The Football Fans in Training (FFIT) scheme is a free, 12-week programme which ran at 13 SPFL clubs. Men attended 12 weekly sessions at their local club to learn useful skills and techniques to help them improve their physical activity and diet. A team of researchers funded by the PHR Programme developed the evidence-based programme and evaluated its effectiveness. It was one of the world's first randomised controlled trials of a health programme delivered through professional sports clubs. It proved extremely popular, recruiting around 750 men to take part. The study found that men who participated in the FFIT scheme lost more than nine times as much weight as those who did not take part in the programme. Participants also benefited from reduced waist size, less body fat and lower blood pressure.

Public Health Res doi: 10.3310/phr03020

#### STUDY 7 (PUBLISHED)

Costs and outcomes of increasing access to bariatric surgery for obesity: Cohort study and cost-effectiveness analysis using electronic health records

This study carried out an analysis of electronic health records in order to explore the impact of increasing access to bariatric surgery for obesity. The specific outputs below describe the findings; an overall account of the work can be found in the NIHR Journals Library:

http://www.journalslibrary.nihr.ac.uk/hsdr/volume-4/issue-17#

a) Incidence of type 2 diabetes after bariatric surgery: population-based matched cohort study.

Published 2014, Booth

This research aimed to consider the costs and outcomes of increasing access to bariatric surgery. This large-scale population study used routine practice data (from the Clinical Practice Research Datalink) and modelling techniques to compare outcomes, including progression to diabetes, in over 2000 obese people undergoing bariatric surgery with matched controls. The team was able to track long-term health outcomes. The researchers followed their progress for an average of about three years (maximum of seven years) to investigate the relationship between having bariatric surgery and risk of developing Type 2 diabetes. They found that only 4% of people who had received bariatric surgery developed diabetes compared with 16% of matched controls. The researchers concluded that bariatric surgery is associated with reduced risk of developing clinical diabetes in people with obesity for up to seven years after the procedure.

Incidence of type 2 diabetes after bariatric surgery:population-based matched cohort study. doi: 10.1016/S2213-8587(14)70214-1

b) Probability of an Obese Person Attaining Normal Body Weight: Cohort Study Using Electronic Health Records.

Published 2015, Fildes

In a related study, drawing on a larger population (from the same data source) over a longer time, the investigators looked at the impact of community obesity programmes other than surgery. They analysed data for 76,704 obese men and 99,791 obese women for up to nine years. They found that the chances of an obese man with BMI in the range 30-34.9 attaining normal weight in any given year was 1 in 210 and this figure was 1 in 124 for women. The chances were smaller for higher levels of BMI (for example the annual probability of a man with BMI 40-44.9 achieving normal BMI was 1 in 1290). They also looked at the probability of people achieving a 5% reduction in body weight (used because it is a widely recommended target for weight loss) and found that, for people with BMI 30-34.9, they chance was 1 in 12 for men and 1 in 10 for women. However, they also found that the majority of people losing 5% of their weight went on to regain it in the following 2-5 years. In the light of these findings, the authors suggest that community-based weight management programmes for obesity may have trouble succeeding.

Am J Public Health 2015 doi: 10.2105/AJPH.2015.302773.

c) Effect of Contemporary Bariatric Surgical Procedures on Type 2 Diabetes Remission. A Population-Based Matched Cohort Study.

Published 2016, Gulliford

In a further related study, 826 obese patients with type 2 diabetes were followed up after bariatric surgery (gastric banding, gastric bypass and sleeve gastrectomy) and compared with a control group. About 30% were found to be in

remission of their diabetes in the second year of follow up (this varied slightly by type of procedure). This remission was found to persist up to the end of the six year follow up period.

Obesity Surgery doi: 10.1007/s11695-016-2103-6

#### STUDY 8 (ONGOING)

#### **East Midlands CLAHRC Radiate project**

People from black and minority ethnic (BME) groups are at a disproportionate risk of developing type 2 diabetes and experiencing associated complications. Prevention strategies should be aware of these groups' experiences, knowledge and understanding about their risk of developing type 2 diabetes. The aim of this project is to explore these issues with diverse BME groups with view to informing a social marketing campaign to raise awareness of diabetes risk and prevention.

A scoping literature review identified existing evidence of contributory factors to the higher prevalence of type 2 diabetes in BME communities. Seven focus groups were then convened which discussed levels of awareness of diabetes and the cultural influences on lifestyle choices and behaviours. Indicative findings strongly suggest that a 'one size fits all' social marketing campaign or intervention would not work due to diverse cultural beliefs and traditions. This study is demonstrating the complex inter-related factors which can influence development of type 2 diabetes both across and within BME communities and how, by working in partnership with community members, strategies can be developed to support healthier lifestyle choices. This work will illustrate an efficient, cost effective methodology which would be applicable in all communities, for multiple conditions and situations resulting in the co-production of culturally appropriate interventions and services.

http://www.clahrc-em.nihr.ac.uk/clahrc-em-nihr/east-midlands-centre-for-black-and-minority-ethnic-health.aspx

#### STUDY 9 (ONGOING)

# NIHR CLAHRC Greater Manchester: Evaluating lifestyle interventions

Due to publish 2017

As part of the national Diabetes Prevention Programme, Public Health England has commissioned seven demonstrator sites to explore the local implementation of lifestyle interventions to prevent diabetes among people at risk of developing the disease. The Salford demonstrator site includes a telephone support service (Care Call), an exercise programme and a new community-based service to improve the identification and referral of people at risk of diabetes from hard to reach groups. This builds on previous research which included an uncontrolled before-after study showing promising results for health coaching, and an ongoing trial looking at the role of web-based coaching. They will conduct a mixed-methods evaluation, using qualitative interviews with professionals, observation analysis and quantitative process-related data collection, focussing on three objectives:

- Identify what role a community referral service can play in supporting people at risk of diabetes to access and use lifestyle support services
- Identify what role an enhanced GP referral service can play in supporting people at risk of diabetes to access and use lifestyle support services
- Describe the Care Call service model, present the evidence that underlies it, and look at the extent to which Salford's telephone-based intervention approach aligns with the service model and evidence diabetes prevention programmes.

http://clahrc-gm.nihr.ac.uk/our-work/exploiting-technologies/catfish/

#### STUDY 10 (ONGOING)

#### Pilot interventions with children from ethnic minority groups

The aims of this project are (1) to develop and pilot interventions based on changes in diet and behaviour to prevent insulin resistance in children from ethnic groups at high risk for type 2 diabetes and (2) to develop and pilot interventions to improve the identification of overweight-obesity in children, particularly those from high risk ethnic groups.

http://www.clahrc-southlondon.nihr.ac.uk/diabetes/working-children-help-prevent-development-diabetes-type-2

#### STUDY 11 (ONGOING)

NIHR CLAHRC North Thames: A participatory female healthvolunteer led intervention to promote healthy nutrition in children of Bangladeshi origin in East London.

Due to publish 2019

NEON (Nurture Early for Optimal Nutrition) is a partnership between the department of Population, Policy and Practice, University College London, Barts and the London NHS trust and the Bangladeshi community of Tower Hamlets. The project explores the socio-ecological influences of feeding practices of infants in the Bangladeshi community. Tower Hamlets experiences the highest prevalence of low birth weight babies born at term, and approximately one third of residents are of Bangladeshi origin. Prevalence of obesity in British Bangladeshi children aged 4-5 years is 12.5%, growing to 23.7% by age 10-11 years, and the South Asian community are 2-4 times more likely to develop Type 2 diabetes in adulthood. The project involves literature reviews, focus groups, creative initiatives and active engagement with both the community and health professionals. Collated information will be used to inform the design and implementation of a participatory health intervention to improve infant feeding practices in the Bangladeshi community.

http://www.clahrc-norththames.nihr.ac.uk/nutrition-obesity-bangladeshi-community/

#### STUDY 12 (ONGOING)

NIHR CLAHRC North Thames: Co-designing community-based diabetes services responsive to the needs of children and young people.

Due to publish 2017

This project was designed to inform and influence the re-design of children and young people's diabetic services and improve peer education. The focus of the project was initially on Newham, and has widened to other parts of East and North London. The project is half way through its 30 month programme, and has already recruited fourteen young people living with Type 1 or 2 diabetes or who care for a relative with diabetes. The young people joined the project as cultural advisors, co-inquirers, diabetes champions and Youth Commissioners. A mixed methodology and participatory approach has been adopted, and activities include a literature review, qualitative interviews, and community workshops, all of which are to ensure active engagement with young people and commissioners. To date, outputs include Service Commissioning Guidance for Children and Young People Diabetes Services (2016-17) and Newham CCG Youth Diabetes Project Business Case (2016-17). This project has also led to work on designing educational materials to encourage Youth Forums in the NHS.

http://www.clahrc-norththames.nihr.ac.uk/co-designing-young-peoples-diabetic-services/

#### STUDY 13 (PUBLISHED)

Anglo-Danish-Dutch study of Intensive Treatment of people with Newly diagnosed diabetes in primary care (ADDITION) - effects on cardiovascular events at five years.

This study explored whether earlier detection and intensive treatment of diabetes are worthwhile. It has produced a range of outputs on different aspects of diabetes screening and management, which are described below.

#### SCRFFNING:

a) Screening for type 2 diabetes and population mortality over 10 years (ADDITION-Cambridge): a cluster-randomised controlled trial

Published 2012, Simmons; 2011, van den Donk

This study was a cluster randomised trial conducted in 33 GP surgeries in eastern England in which practices were randomised to stepwise screening for undetected type 2 diabetes (27 practices) using random capillary blood glucose and HbA1c or fasting capillary blood glucose followed by an oral glucose tolerance test to confirm if positive. This was compared with no screening in 5 practices and the main outcome of interest was all-cause mortality over ten years (with secondary analyses including deaths from cardiovascular disease, cancers, other causes and diabetes-related death). They found that all-cause mortality was not reduced by undertaking this screening and concluded that screening for type 2 diabetes in patients at increased risk was not associated with a reduction in all-cause, cardiovascular, or diabetes-related mortality within 10 years.

Lancet 2012 doi:10.1016/S0140-6736(12)61422-6.

#### INTENSIVE TREATMENT:

b) Cardiovascular outcomes in the ADDITION-Europe study: a five-year cluster-randomised controlled trial of multifactorial therapy in individuals with screen-detected type 2 diabetes

Published 2011, Griffin

This study was a cluster randomised trial in 343 GP surgeries in Denmark, the Netherlands and the UK that aimed to investigate whether early intensive management of people with type 2 diabetes reduced the occurrence of cardiovascular events (myocardial infarction and stroke) and death. This study was conducted in people whose diabetes was detected early by screening. The intensive treatment consisted of structured education, aspirin 75mg daily (unless contra-indicated) and individualised, algorithm-driven treatment to optimise blood pressure, lipid and blood glucose control. This included blood pressure (BP) treatment for people with BP over 120/80mmHg (with angiotensin converting enzyme inhibitors) and statin for anyone with cholesterol of 3.5mmol/L or higher. This was compared with standard diabetes care. The incidence of new cardiovascular events was slightly lower in the intervention group (7.2% compared with 8.5% in the control group) but the difference was not statistically significant.

Lancet 2011 doi:10.1016/S0140-6736(11)60698-3

#### MODELLING EFFECTIVENESS AND COST EFFECTIVENESS:

c) Does early intensive multifactorial therapy reduce modelled cardiovascular risk in individuals with screendetected diabetes? Results from the ADDITION-Europe cluster randomised trial.

Published 2014, Black

This component of the ADDITION study used modelling to estimate the 10 year cardiovascular risk in 2101 people who had been randomised to receive intensive therapy compared to usual care. The study found that the 10 year modelled risk was lower in the intensive treatment group.

Diabetic Medicine 2014 doi: 10.1111/dme.12410

d) Cost effectiveness of early intensive multifactorial treatment for individuals with screen-detected type 2 diabetes: analysis of the ADDITION-UK cluster randomised controlled trial.

Published 2015, Tao

A further study explored the cost effectiveness of the intensive treatment offered in the ADDITION study in the UK study centres (69 GP surgeries) over five years. This was using the primary composite outcome of cardiovascular events or death. The researchers calculated short term cost effectiveness and modelled long-term cost-effectiveness using Quality Adjusted Life Years (QALYs). Even though there were some differences in control of blood sugar, blood pressure and cholesterol (favouring the intensive treatment), they found no statistically significant difference in short-term cost-effectiveness between intervention and control groups. From their long-term modelling they concluded that, while cost-effectiveness improved over time, it was still higher than commonly accepted thresholds after 20 or 30 years.

Diabetic Medicine 2015 doi: 10.1111/dme/12711

#### MICROVASCULAR COMPLICATIONS:

e) Effect of early multifactorial therapy compared to routine care on microvascular outcomes at 5 years in people with screen-detected diabetes: the ADDITION-Europe study.

Published 2014, Sandbaek

This aspect of the ADDITION study explored whether the intensive multifactorial therapy had any impact on microvascular outcomes in 343 practices in the UK, Denmark and the Netherlands after 5 years. The main outcomes of interest were albuminuria (to reflect kidney disease), retinopathy and neuropathy. The authors concluded that there were no differences in the frequency of these complications between the intervention and control groups. Albuminuria was present in 23% in the intervention group and 24% in the routine care group, retinopathy was present in 10 and 12% respectively and neuropathy in 5 and 6%. These differences were not statistically significant and they concluded that the intervention was not effective in reducing these outcomes at 5 years in people with screen-detected diabetes.

Diabetes Care2014 doi.org/10.2337/dc13-1544

# MODELLING SCREENING:

f) A comparison of cost per case detected of screening strategies for Type 2 diabetes and impaired glucose regulation.

Published 2012, Khunti

The aim of this study was to assess the cost of different screening strategies for type 2 diabetes, both alone and in combination with impaired glucose regulation. Data was used from the ADDITION-Leicester study to model 212 different screening strategies; including blood tests, a computer practice data score and a risk score, and cost per new case identified were estimated. Results showed the estimated costs per case identified for the 18 most sensitive strategies varied from £457 to £1639 for type 2 diabetes and £148 to £913 for both type 2 diabetes and impaired glucose regulation combined. The study concluded screening a population using a non-invasive risk stratification tool followed by a screening blood test was the most cost-effective method of screening for diabetes and abnormal glucose tolerance.

Diabetes Research and Clinical Practice. doi: 10.1016/j. diabres.2012.03.009.

#### STUDY 14 (PUBLISHED)

#### Screening for type 2 diabetes

Published 2013, Waugh

The aim of this review was to provide an update for the UK National Screening Committee (NSC) on screening for type 2 diabetes (from a previous review in 2007). It concluded that screening for type 2 diabetes does not meet the NSC criteria. For example Criterion 12, on optimisation of existing management, was not met, and Criterion 13 requires evidence from high-quality randomised controlled trials that screening is beneficial. This has not been met - the Ely trial of screening showed no benefit. The main factor identified was a lack of cardiovascular benefit demonstrated in the two trials published since the previous review. The review also concluded that no perfect screening test exists – HbA1c lacks sensitivity and would miss people with diabetes, and although the glucose tolerance test is more sensitive it would have lower uptake.

Health Technol Assess 2013: 10.3310/hta17350

#### STUDY 15 (PUBLISHED)

#### The cost-effectiveness of testing strategies for type 2 diabetes

Published 2015, Gillett

This study aimed to compare the cost-effectiveness of screening for type 2 diabetes using Haemoglobin A1c (HbA1c) versus fasting plasma glucose (FPG). It also looked at the use of a random capillary glucose (RCG) test versus a non-invasive risk score to prioritise individuals who should undertake a HbA1c or FPG test. The population of interest was people aged 40-74 (i.e. those eligible for an NHS health check) in the Leicester Ethnic Atherosclerosis and Diabetes Risk (LEADER) study, in order to analyse prevalence and screening outcomes for a multi-ethnic population. The results suggested that screening using a HbA1c test is more cost-effective than using FPG. However, in some places, diabetes prevalence and high diabetes risk may be higher for FPG relative to HbA1c than in the LEADER cohort. In such cases, whether or not it still holds that HbA1c is likely to be more costeffective than FPG depends on the relative uptake rates for HbA1c and FPG. Use of the risk score appears to be more cost-effective than a RCG test for pre-screening.

Health Technol Assess 2015 doi: 10.3310/hta19330

# STUDY 16 (PUBLISHED)

Assessment of response rates and yields for Two opportunistic Tools for Early detection of Non-diabetic hyperglycaemia and Diabetes (ATTEND). A randomised controlled trial and cost-effectiveness analysis

Published 2016, Khunti

The aim of this study was to assess the opportunistic use in primary care of a computer risk score versus a self-assessment risk score for type 2 diabetes. This was a randomised controlled trial carried out in 11 primary care practices in the UK. 577 patients aged 40-75 years with no current diagnosis of type 2 diabetes were recruited to a computer based risk score, the Leicester Practice Computer Risk Score (LPCRS), or a patient self-assessment score, the Leicester Self-Assessment Score (LSAS). The rate of self-referral blood tests was significantly higher for the LPCRS compared to the LSAS, 118.98 (95% CI: 102.85, 137.64) per 1000 high-risk patient years of follow-up compared to 92.14 (95% CI: 78.25, 108.49), p=0.022. Combined rate of diagnosis of type 2 diabetes and those at risk of developing the disease (i.e. impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) was similar between the two arms, 15.12 (95% CI: 9.11, 25.08) per 1000 high-risk patient years for LPCRS compared to 14.72 (95% CI: 9.59, 22.57) for the LSAS, p=0.699. For the base case scenario the cost per new case of type 2 diabetes diagnosed was lower for the LPCRS compared to the LSAS, £168 (95% Credible Interval (CrI): 76, 364), and £352 (95% CrI: 109, 1,148),

respectively. In conclusion compared to a self-assessment risk score, a computer based risk score resulted in greater attendance to an initial blood test and is potentially more cost-effective.

Diabetes Research and Clinical Practice doi:10.1016/j. diabres.2016.04.054

#### STUDY 17 (ONGOING/INTERIM FINDINGS PUBLISHED)

A clinical and economic evaluation of screening and diagnostic tests to identify and treat women with gestational diabetes: association between maternal risk factors, glucose levels, and adverse outcomes.

Interim findings published 2015, Farrar

Full findings due to publish 2016

This systematic review will identify all published studies that have compared strategies and tests to identify gestational diabetes or treat women with gestational diabetes or collected information on the associated costs of identifying or treating gestational diabetes. It will combine published evidence with population data from 12,000 women who took part in the Born in Bradford study who had an oral glucose tolerance test when they were 24 to 28 weeks pregnant. They plan to use modelling techniques and other approaches to find out what is the most cost- and clinicallyeffective method of identifying women with gestational diabetes and which is the most accurate, safe and cost- and clinicallyeffective way of treating women to improve outcomes. Interim findings from one part of the study – using the Born in Bradford cohort data - have been published (Farrar 2015). The findings indicate that, as in white British women, women of south Asian origin have graded linear associations of fasting and 2 h post-load glucose with adverse perinatal outcomes such as very large babies. The data suggest lower thresholds for diagnosing gestational diabetes in south Asian women than white European women.

http://www.nets.nihr.ac.uk/projects/hta/119902

# STUDY 18 (ONGOING)

Development of a structured screening and lifestyle intervention for prevention of Type 2 Diabetes Mellitus in a population with Learning Disabilities

Due to publish 2017

This programme of research developed and tested a structured screening programme for diabetes in people with learning disabilities and developed and piloted a tailored lifestyle intervention to reduce risk. People with learning difficulties tend to have poorer health status and are more likely to be overweight and inactive, and therefore may have a higher risk of developing diabetes. Overall the screening part of this programme of work found low levels of undiagnosed type 2 diabetes and non-diabetic hyperglycaemia (NDH). The investigators also want to find out the best way to give people with learning disabilities some education around healthy lifestyles (for example, eating and exercise) to help with prevention of diabetes and cardiovascular disease. Therefore, the investigators also aim to develop a lifestyle education programme that is suitable for use in this population and test whether it is feasible and acceptable.

http://www.nihr.ac.uk/funding/fundingdetails.htm?postid=2236

#### STUDY 19 (ONGOING)

**Diabetes Intervention for Agenda Trial (DIAT)** 

Due to publish 2016

People with diabetes need to be actively involved in managing their condition. They receive advice and support from health professionals but these appointments may be infrequent, and it may be difficult for a patient to bring up all the issues they would like to discuss. This study developed an intervention to help patients make the most of their appointments, by first seeing a healthcare assistant who guided them through a questionnaire, identifying the

most important issues they wished to discuss. The team have piloted this approach, to see if it is feasible and acceptable to patients. Preliminary findings suggest that the intervention 'magnified' the existing dynamic in the doctor-patient relationship, whether positive or negative. Full analysis of the data is still underway.

http://www.clahrcprojects.co.uk/impact/projects/diabetes-intervention-agenda-trial-diat

#### STUDY 20 (PUBLISHED)

Clinical effectiveness of a patient decision aid to improve decision quality and glycaemic control in people with diabetes making treatment choices: a cluster randomised controlled trial (PANDAs) in general practice

Published 2012, Mathers

Patient decision aids provide evidence-based information about treatment options, and thus help patients clarify their goals and preferences and make informed decisions about treatment. This study tested the use of a decision aid in 49 GP practices, randomly allocated to use the decision aid or to continue with treatment as usual. In practices that used the decision aid, patients demonstrated a better understanding of the implications of some treatment options, and more realistic expectations of the impact of treatments. These patients had a slightly greater improvement in glycaemic control, but this was not statistically significant.

BMJ Open 2012, doi: 10.1136/bmjopen-2012-001469

# STUDY 21 (PUBLISHED)

Newer agents for blood glucose control in type 2 diabetes: systematic review and economic evaluation.

Published 2010, Waugh

This study explored whether new agents (exenatide, the gliptins – and the 'not so new' detemir) were clinically and cost effective compared to existing treatments. The study found that the long-acting insulin analogues, glargine and detemir, have only slight clinical advantages over Neutral Protamine Hagedorn (NPH) insulin, but have much higher costs. They do not appear cost effective as first-line insulins compared with NPH insulin in type 2 diabetes. Exenatide, when used as third drug instead of progressing immediately to insulin therapy after failure of dual oral combination therapy, appears cost-effective relative to glargine. However, exenatide appears to be unlikely to be cost-effective compared with NPH. The gliptins are comparable to the glitazones in glycaemic control and costs, but, at present, appear to have fewer long-term side effects. The authors concluded that new drugs were all clinically effective.

Health Technol Assess 2010, doi: 10.3310/hta14360

#### STUDY 22 (PUBLISHED)

Development of a cost-effectiveness model for optimization of the screening interval in diabetic retinopathy screening.

Published 2015, Scanlon

Under the NHS Diabetic Eye Screening Programme, eligible people with diabetes are invited annually for digital retinal photography screening, to identify those at high risk and requiring intervention. This study set out to establish whether moving from a fixed annual screening interval, to an interval calculated based on individual risk factors, would be cost-effective. The study used a modelling approach based on data from four UK regions. This found that annual screening was not cost-effective. Screening those in low-risk groups every five years, and those in higher-risk groups every two years, was found to be most cost-effective.

Health Technol Assess 2015, doi: 10.3310/hta19740

#### STUDY 23 (ONGOING)

Introducing personalised risk based intervals in screening for diabetic retinopathy: development, implementation and assessment of safety, cost-effectiveness and patient experience.

Due to publish 2018

This programme grant aims to explore varying the diabetic eye disease (retinopathy) screening interval for people with diabetes according to their degree of risk, and whether longer screening intervals would be acceptable to people at lower risk. The programme of work will include use of a whole population cohort (about 18,000 people) to measure the risk of progression to treatment and visual impairment. Qualitative research methods will also be used to assess patient and professional experience.

http://www.nihr.ac.uk/funding/funded-research/funded-research.htm?postid=2249

#### STUDY 24 (PUBLISHED)

Colour vision testing for diabetic retinopathy: a systematic review of diagnostic accuracy and economic evaluation.

Published 2009, Rodgers

This systematic review examined the diagnostic performance and cost-effectiveness of colour vision testing to identify and monitor the progression of diabetic retinopathy. Twenty-five studies were identified, with quality being generally poor. It found insufficient evidence to support the use of colour vision testing, alone or in combination with retinal photography, as a screening mechanism.

Health Technol Assess 2009, doi: 10.3310/hta13600

#### STUDY 25 (ONGOING)

Can automated Diabetic Retinopathy Image Assessment softwares replace one or more steps of manual imaging grading and is this cost-effective for the NHS Diabetic Eye Screening Programme?

Due to publish 2016

This observational study will look at the use of software to assess images taken during diabetic retinopathy screening, instead of manual assessment. This approach could increase the efficiency of screening, help identify low risk patients and allow staff to focus on assessment of more serious cases. The study will also examine cost-effectiveness.

http://www.nets.nihr.ac.uk/projects/hta/112102

# STUDY 26 (PUBLISHED) – COCHRANE

Blood pressure control for diabetic retinopathy

Published 2015, Do

This review summarised the evidence regarding the effect of interventions to control blood pressure on the incidence and progression of diabetic retinopathy. The study found 15 trials involving almost 15,000 participants (the majority with type 2 diabetes). The evidence suggested that intervening to lower blood pressure in diabetics reduces the incidence of retinopathy but only by a modest amount, but it did not appear to slow progression of retinopathy. The evidence was of low to moderate quality. Intervening to lower blood pressure solely in order to reduce the incidence or progression of diabetic retinopathy is probably not justified.

Cochrane Database of Systematic Reviews 2015, doi: 10.1002/14651858.CD006127.pub2

#### STUDY 27 (ONGOING)

What Works to Increase Attendance for Diabetic Retinopathy Screening? An Evidence synthesis (WIDER-EyeS) An evidence synthesis of published and grey literature to identify the effectiveness and cost-effectiveness of quality improvement (QI) interventions for increasing uptake and ongoing attendance for diabetic retinopathy screening

Due to publish 2017

This study will review the evidence for the best ways of encouraging attendance at retinopathy screening and explore the reasons for people not attending. This will include interventions aimed at increasing both the initial uptake and ongoing attendance for diabetic retinopathy screening, whether targeted at the individual, healthcare professional or healthcare system. The exact nature of different interventions will be described as part of the review. It will then suggest ways of enhancing attendance in the future.

http://www.nets.nihr.ac.uk/projects/hta/1313705

#### STUDY 28 (PUBLISHED)

Improving the economic value of photographic screening for optical coherence tomography-detectable macular oedema: a prospective, multicentre, UK study.

Published 2013, Olson

This study aimed to assess the best of these surrogate markers for detecting potentially sight-threatening macular oedema. Macular oedema is the more common cause of vision loss in people with diabetes. At present, macular oedema is identified during screening using a number of surrogate photographic markers. The study also examined the use of optical coherence tomography, a form of ultrasound imaging. More than 3000 patients were recruited across seven centres, and underwent both retinal photography and optical coherence tomography. The resulting images were analysed to identify the most effective pathways for screening for macular oedema. It was found that compared with all current manual grading schemes, a fully automated annotation grading strategy – which uses an automated detection of patterns of surrogate markers – achieves a higher specificity for detecting macular oedema. This approach is more cost-effective than more sensitive strategies, which tend to increase the costs to the health service for only small gains in health outcomes. The addition of optical coherence tomography prior to referral resulted in cost savings without reducing health benefits.

Health Technol Assess 2013, doi: 10.3310/hta17510

#### STUDY 29 (ONGOING)

DIAbetic Macular Oedema aNd Diode Subthreshold micropulse laser (DIAMONDS).

Due to publish 2020

This multi-centre study aims to evaluate the clinical and costeffectiveness of Diode Subthreshold Micropulse Laser (DSML) compared with standard threshold laser to treat Diabetic Macular Oedema (DMO) with Central Retinal Thickness (CRT) of < 400 microns. It will be based in 10 Ophthalmic Units in the UK and will involve adults with Type 1 or Type 2 diabetes and who have DMO with a retinal thickness greater than 400 microns. The aim is to recruit 266 patients. Patients receiving these treatments and the people assessing the response to these treatments will not know which type of laser was used. The primary outcome will be the best corrected distance visual acuity (BCdVA) in the study eye at 2 years, with a range of secondary outcomes including binocular BCdVA, central retinal thickness by optical coherence tomography (OCT), mean deviation of the Humphrey 10-2 visual field, percentage of people meeting driving standards, general and visual related quality of life, side effects, number of laser treatments needed, and need for additional treatment. Cost effectiveness will also

be evaluated. The research team includes expert clinicians, methodologists, statisticians, health economists, and qualitative researchers, whilst patients have been involved in the study design.

http://www.nets.nihr.ac.uk/projects/hta/1314204

#### STUDY 30 (PUBLISHED)

Pan-retinal photocoagulation and other forms of laser treatment and drug therapies for non-proliferative diabetic retinopathy: systematic review and economic evaluation

Published 2015, Royle

This study undertook systematic reviews of the evidence in order to determine whether it would be worthwhile to intervene with pan-retinal photocoagulation (PRP) earlier in diabetic retinopathy, at the severe non-proliferative (pre-proliferative) diabetic retinopathy stage, rather than wait till the high-risk proliferative diabetic retinopathy stage. A second aim was to determine what form of laser treatment could be used and whether drug-PRP combinations are clinically effective and cost-effective. They concluded that, although there have been recent advances in laser technologies there is, as yet, no convincing evidence that modern lasers are more effective than existing argon lasers and therefore they could not recommend a policy of PRP at the severe NPDR stage. They also carried out systematic reviews of the efficacy and cost effectiveness of using of PRP, with or without anti-vascular endothelial growth factor (anti-VEGF) drugs or steroid. Overall, adjuvant (anti-VEGF) or steroid treatment (triamcinolone) reduced the adverse effects of PRP.

Health Technol Assess 2015, doi: 10.3310/hta19510

# STUDY 31 (PUBLISHED)

Optimal strategies for monitoring kidney disease in diabetes: properties of monitoring tests, progression of renal dysfunction and impact of treatment.

Published 2014, Farmer

The aim of this project was to determine the clinical value and cost-effectiveness of screening programmes for kidney disease in people with diabetes (type 1 and type 2), including assessing the current practice of annual screening. Current and alternative screening programmes with different screening intervals were evaluated using simulation models to determine whether current UK annual screening guidelines are cost-effective.

The investigators also aimed to determine whether the effectiveness of using angiotensin converting enzyme inhibitors (ACEi) or angiotensin 2 receptor blockers (A2RB) varied according to whether a patient already has kidney disease by conducting a review of previous studies. They found that annual screening with albumin to creatinine ratio (ACR) appeared to be cost-effective to minimise the risk of adverse kidney outcomes for patients with type 1 and patients with type 2 diabetes.

They also showed that, in patients with type 1 diabetes, the extent of reduction in renal albumin excretion with ACEi and A2RB treatment varies with presence or absence of microalbuminuria (treatment reduced albumin excretion by two-thirds in patients with microalbuminuria, but there was no benefit for patients without albuminuria). For people with type 2 diabetes, the relative benefit of treatment was approximately the same regardless of the presence or absence of microalbuminuria.

Health Technol Assess 2014, doi: 10.3310/hta18140

#### STUDY 32 (PUBLISHED)

A systematic review and individual patient data meta-analysis of prognostic factors for foot ulceration in people with diabetes: the international research collaboration for the prediction of diabetic foot ulcerations (PODUS)

Published 2015, Crawford

This study was a systematic review and analysis from studies that explored the best factors to consider in identifying people at risk of foot ulceration. They identified 16 studies and were able to analyse individual patient data from ten of those. They found that previous history of foot ulceration, inability to feel a 10-g monofilament test, at least one absent foot pulse, and longer duration with diagnosed diabetes were all predictive of increased risk of ulceration.

Health Technol Assess 2015, doi: 10.3310/hta19570

#### STUDY 33 (ONGOING)

Implementation of corneal confocal microscopy (CCM) in primary care optometry practices for screening and early assessment of diabetic neuropathy: a feasibility study

Due to publish 2016

This was the first feasibility and acceptability study of corneal confocal microscopy (CCM) in community optometry practices. It was conducted alongside routine diabetic eye (retinopathy) screening programme appointments. The most common complication in diabetes is damage to the nerves in the limbs, particularly the feet and legs; this is called diabetic neuropathy. Around one in five diabetic patients have diabetic neuropathy and it can lead to numbness, pain, loss of sensation, foot ulceration and in, some cases, amputation. CCM is a new, non-invasive eye test which can detect diabetic neuropathy in limbs in its earliest stages. Working with Heidelberg Engineering, CLAHRC Greater Manchester implemented CCM in four optometrist practices, recruiting 449 patients to have the screening test. Early results indicate CCM was acceptable to patients. To be implemented in routine practice it would be necessary to explore further the required resources and technological improvements, and the impact of earlier diagnosis on diabetic management (as no treatment for diabetic neuropathy is currently available).

http://clahrc-gm.nihr.ac.uk/our-work/exploiting-technologies/neuropathy/

#### STUDY 34 (PUBLISHED)

Does higher quality of primary healthcare reduce hospital admissions for diabetes complications? A national observational study.

Published 2015, Calderón-Larrañaga

The aim of this project was to determine if hospital admission rates for diabetes complications were associated with primary care diabetes management. An observational study was conducted during 2004-2009, involving 8140 general practices in England. Diabetes admissions decreased significantly during this period. In multivariate regression models, increasing deprivation and diabetes prevalence were risk factors for admission, while most healthcare covariates, i.e. a larger practice population, better patient-perceived urgent and non-urgent access to primary care and better HbA1c target achievement, were protective. The authors concluded that better scheduled primary care access and glycaemic control were associated with lower hospital admission rates across most complications. They further indicated that the risk of emergency hospital admission should be monitored routinely.

Diabetic Medicine 2014, doi: 10.1111/dme.12413

#### STUDY 35 (PUBLISHED)

Use of hospital admissions data to quantify the burden of emergency admissions in people with diabetes mellitus.

Published 2014, Gibbons

This study examined whether current approaches to identifying diabetes-related hospital admissions underestimated the true burden on hospital care. Hospital Episode Statistics data for England from 2006 to 2010 was reviewed, focusing on adults admitted to emergency departments citing diabetes, looking at primary and other diagnoses. During that period, 2,443,046 admissions were identified and diabetes was the primary diagnosis in 6.2% of cases, and as the third diagnosis in 23.1% of cases. Type 2 diabetes was the most common type (85%). The majority of diabetes citations were 'without complication' (89.6%). The most common primary diagnosis was 'chest pain, unspecified' (4.1%). The authors concluded that reliance on primary diagnosis to identify emergency admissions in people with diabetes largely underestimates the true burden placed on hospital care and leads to underestimates of effect sizes in studies utilizing admission rates as outcome measures. The authors therefore argued that an alternative strategy to identify admissions is required.

Diabetic Medicine 2014, doi: 10.1111/dme.12444

# STUDY 36 (PUBLISHED)

Non-pharmacological approaches to improving diabetes outcomes Published 2015 and 2016, Winkley

This small qualitative study involved interviews with people newly diagnosed with type 2 diabetes, who had not attended structured education, to establish why they had not. The first key theme was that patients felt that either structured education had not been mentioned at all by their healthcare professional, or that the benefits of it had not been clearly explained. Secondly, people mentioned practical barriers such as parking, access or timing; or preferences relating, for example, to the group nature of the session. Finally some participants expressed views relating to a perceived sense of shame or stigma relating to their diabetes. They had not attended the education session because they were worried about telling others of their diagnosis. A related study looked at the characteristics of both GP practices, and patients, to see whether these were correlated with uptake of education. It found that those at higher risk of diabetes complications, such as smokers, were less likely to attend, whilst GP practices with better records of achieving glycaemic control targets had more patients attending.

Diabetic Medicine 2014, doi: 10.1111/dme.12556, and Patient Education and Counseling 2016, doi: 10.1016/j.pec.2015.08.015

# STUDY 37 (ONGOING)

Increasing uptake of effective self-management education programmes for type 2 diabetes in multi-ethnic primary care settings.

Due to publish 2020

This project aims to identify why some people are not offered education and why some of those who are, do not attend. The investigators will develop and try out a package of practical solutions for GPs to support more people with type 2 diabetes having structured education. This will include offering a choice in how people get education, for example through group sessions or home study.

https://kclpure.kcl.ac.uk/portal/en/projects/increasing-uptake-of-effective-selfmanagement-education-programmes-for-type-2-diabetes-in-multiethnic-primary-care-settings(9cd9cbe1-d9d9-4619-92c0-c2c1972765a8).html

#### STUDY 38 (ONGOING/INTERIM FINDINGS PUBLISHED)

Development, evaluation and implementation of a computerbased self-management programme for people with type 2 diabetes.

Interim findings published 2014, Murray

This study aims to research, develop, test and implement a computer-based self-management programme for people with type 2 diabetes. An initial systematic review (see reference below) formed the basis of the first stages of the research. The review considered the results from 16 randomised controlled trials with over 3,500 participants in total. These trials included a range of interventions delivered via clinics, the internet and mobile phones. Overall, computer-based diabetes self-management interventions had a small effect on glycaemic control, but no effect on other measures such as depression, quality of life, blood pressure, serum lipids, or weight. Interventions delivered via mobile phone, which were studied in three trials, achieved a slightly greater effect.

Diabetes Care 2014, doi: 10.2337/dc13-1386

## STUDY 39 (PUBLISHED)

The clinical effectiveness of diabetes education models for Type 2 diabetes: a systematic review.

Published 2008, Loveman

This review identified 13 studies on educational interventions in diabetes, with variable quality of reporting and methodology. The findings of these studies were mixed, with some reporting significant improvements in diabetic control as a result of educational interventions, and others not. Overall, the review found that education delivered by a team, with learning reinforced through additional points of contact, may offer the best opportunity for improving patient outcomes. Time, resources and a clear programme from the outset may also be factors in success. It was not clear what resources would need to be directed at the educators themselves to ensure that they can deliver programmes successfully. Good quality and long-term studies would be beneficial and future research should consider patient education within the context of overall diabetes.

Health Technol Assess 2008, doi: 10.3310/hta12090

#### STUDY 40 (PUBLISHED)

### Qualitative review of self-management

Published 2014, Frost; and 2016, Frost

This review of qualitative studies on type 2 diabetes patients' views of self-managing their condition found that having a sense of ownership of their management was very important. Ownership can be reinforced by the provision of personalised, relevant advice, but undermined if professionals do not take account of individual beliefs and preferences. Too great an emphasis on clinical markers such as blood glucose was seen as potentially unhelpful by some, who preferred a focus on goals tailored to their needs – for example, weight-loss or portion control.

BMC Health Services Research 2014, doi: 10.1186/1472-6963-14-348

#### STUDY 41 (PUBLISHED)

A systematic review and meta-ethnography to identify how effective, cost-effective, accessible and acceptable self management support interventions are for men with long-term conditions (SELF-MAN).

Published 2015, Galdas

This study reviewed quantitative and qualitative research on the effectiveness, cost-effectiveness, accessibility and acceptability of self-management support interventions for men with long-term conditions. The study looked at all types of long-term condition, not just diabetes, and does not present findings specifically relating to diabetes. Evidence on effectiveness is limited, although there

was some evidence that multicomponent interventions that include physical activity, education or peer support may have a positive impact on quality of life in men. There was not enough evidence to assess cost-effectiveness. More generally the review found that self-management support is more likely to be accessible and acceptable to men when it is tailored to individual preferences and lifestyles, including those relevant to male identities.

Health Serv Deliv Res 2015, doi: 10.3310/hsdr03340

#### STUDY 42 (PUBLISHED)

Non-pharmacological approaches to improving diabetes outcomes.

Published 2016, Graves

This qualitative study used semi structured interviews with nurses to explore their experiences of training in psychological skills in order to support people's self-management of diabetes. The study identified positive aspects such as empowering patients and negative aspects such as concerns about over-stepping their nursing role and potential degree of support from fellow clinicians.

Primary Care Diabetes 2016, doi: 10.1016/j.pcd.2016.03.001

#### STUDY 43 (ONGOING)

A systematic review of psychological interventions to improve motivation for self-management in people with type 1 and type 2 diabetes.

Due to publish 2018

This systematic review will look at studies that have examined the effectiveness of psychological interventions – such as talking therapies – in helping motivate people to manage their diabetes. Successful management of diabetes requires commitment and motivation from patients, including changing diet, taking exercise, checking blood sugar regularly and taking medication. Even having attended education programmes, many patients struggle to manage their diabetes successfully, and may experience negative feelings and depression. Talking therapies have been used to try and help people work out why they are not managing their diabetes well, then to support them in challenging negative feelings and to become more motivated and confident. This review will look at the existing evidence to see if these types of therapies are helpful, as well as considering cost-effectiveness.

http://www.nets.nihr.ac.uk/projects/hta/1421310

#### STUDY 44 (ONGOING)

Managing with Learning Disability and Diabetes.

Due to publish 2016

This study is exploring whether it is feasible to conduct a trial of a support intervention for people with learning disability and diabetes. The intervention consists of a manual and associated support to help people manage their condition, both by themselves and with the support of their main carer, relative or other supporter.

http://www.nets.nihr.ac.uk/projects/hta/1010203

# STUDY 45 (PUBLISHED)

Self-monitoring of blood glucose in type 2 diabetes.

Published 2010, Clar

This systematic review explored whether supporting patients with type 2 diabetes to monitor their own blood glucose is effective and cost-effective. The review included 30 trials, although few were of high quality. Comparing self-monitoring with usual care found a small reduction in blood glucose, though possibly not enough to be clinically significant. There was a similar small difference when comparing self-monitoring alone, with self-monitoring with education. Some patients found self-monitoring to be empowering and reassuring, but for others it led to adverse psychological effects including guilt and depression.

There was a lack of education for patients in how to interpret and use the data, and a lack of interest in the results from healthcare professionals. Overall the study found that self-monitoring is likely to be of limited clinical effectiveness in improving glycaemic control, and is therefore unlikely to be cost-effective. However there were signs that self-monitoring could be more effective if accompanied by appropriate education for patients and professionals on how to respond to data gleaned from self-monitoring; and if patients were able to self-adjust drug treatment. More research would be needed to establish the type of education and support that is most helpful.

Health Technol Assess 2010, doi: 10.3310/hta14120

#### STUDY 46 (PUBLISHED)

What is the evidence for the effectiveness, appropriateness, and feasibility of group clinics for patients with chronic conditions?: a systematic review.

Published 2015, Booth

Group clinics deliver care to small groups of patients with the same condition at the same time rather than each patient meeting a doctor on a one-to-one basis. This review aimed to find out whether or not group clinics worked better and were a better use of resources than one-to-one appointments. It also investigated what patients and health professionals thought about group clinics. Several studies looked at whether or not group clinics were cost effective but the results were unclear. Most studies took place in the USA.

The study found that most research focused on people with diabetes and that group clinics were better than individual appointments for improving some measures of diabetic control. Group clinics also improved the quality of life of patients. However, they did not find any other improvements for patients. Patients and health professionals tended to view group clinics positively, but the research did not include much on the views of people who disliked group clinics.

Health Serv Deliv Res 2015, doi: 10.3310/hsdr03460

## STUDY 47 (PUBLISHED)

The potential impact of displacing sedentary time in adults with type 2 diabetes.

Published 2015, Falconer

Sedentary time, in particular prolonged unbroken periods, is detrimental to health and reduces the time spent in any form of light physical activity. This study looked at the impact of reallocating time from sedentary behaviour to more active behaviour in people with type 2 diabetes. This involved undertaking measurement and modelling on data from over 500 patients enrolled in another diabetes trial. The study found that breaking up a period of 30 minutes of sedentary time into shorter sedentary bouts, interspersed with light activity, had a positive impact on body mass index and waist circumference. The effects were stronger if the 30 minutes of sedentary time was replaced with light physical activity. These findings suggest that simply breaking up inactive time into shorter bouts, or adding small amounts of light physical activity, can be beneficial for people with type 2 diabetes.

Medicine and Science in Sports and Exercise 2015, doi: 10.1249/ MSS.000000000000651

#### STUDY 48 (PUBLISHED)

Breaking Up Prolonged Sitting With Standing or Walking Attenuates the Postprandial Metabolic Response in Postmenopausal Women: A Randomized Acute Study

Published 2016, Henson

This study aimed to establish whether breaking up prolonged periods of sitting with regular short bouts of standing or walking would have a beneficial effect for women at risk of type 2 diabetes. Twenty-two women – all overweight or obese, postmenopausal and with raised blood glucose – each participated in two activities: prolonged, unbroken sitting or prolonged sitting broken up with 5 minutes of standing or walking every 30 minutes. Both standing and walking had significant, positive effects on blood glucose and other markers of metabolic health.

Diabetes Care 2016, doi: 10.2337/dc15-1240

#### STUDY 49 (PUBLISHED)

The effects of high-intensity interval training on glucose regulation and insulin resistance: a meta-analysis

Published 2015, Jelleyman

This review looked at the results of 50 studies exploring the impact of high-intensity interval training on markers of glucose regulation and insulin resistance. High-intensity interval training is an exercise regime which involves short but very vigorous bouts of exercise. The review found that this form of training was effective at improving measures of insulin resistance, compared with both not exercising, and continuous moderate exercise. For people with type 2 diabetes, there was also a reduction in blood glucose. However, study quality was poor and the interventions studied were diverse, suggesting that further research is needed to confirm these findings.

Obesity Reviews 2015, doi: 10.1111/obr.12317

#### STUDY 50 (PUBLISHED)

Diet or diet plus physical activity versus usual care in patients with newly diagnosed type 2 diabetes: the Early ACTID randomised controlled trial.

Published 2011, Andrews

This randomised controlled trial, involving over 500 participants, allocated patients to either usual care, a dietary intervention or dietary intervention plus exercise. The dietary intervention involved a consultation every 3 months with monthly nurse support. Glycaemic control improved in both the diet group, and the diet plus activity group, at 6 months and this was sustained at 12 months. Improvements were also seen in weight and insulin resistance. Adding activity to the dietary intervention did not seem to confer additional benefit.

Lancet 2011, doi: 10.1016/S0140-6736(11)60442-X

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