

# Pharmacy based screening of high risk individuals using stepwise methods

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/02/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 31/10/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The prevalence of diabetes has risen dramatically in recent years. It is estimated that there are up to half a million people in the UK who have undiagnosed diabetes and this figure is expected to rise. People with undiagnosed diabetes are at a higher risk of problems with the eyes, feet and kidneys as well as serious problems with the cardiovascular system such as strokes and heart attacks.

Because of the increasing numbers of people with undiagnosed diabetes in the UK the government introduced a large-scale screening programme called NHS health checks. As part of this programme all people aged 40-75 are offered screening tests for diabetes, kidney disease and cardiovascular disease risk. These tests are usually carried out by a GP (doctor).

We know that not all people eligible for these checks have taken up the invitation to have them. There is a significant proportion of the population who do not access healthcare through established routes and may be less likely to visit a GP or may not be registered with a GP at all. It is important that screening tests are made available to everyone.

Community pharmacists are often seen as a first port of call for people seeking medical advice. They provide high street access to the majority of the population who will visit a pharmacy at least once a year. By offering screening tests for diabetes in pharmacies it is hoped that it may make it easier for people who have not had a diabetes test to have one done.

We want to test whether community pharmacies are feasible sites for carrying out diabetes screening. We also want to find out whether having a fingerpick blood test with the result immediately available means people are more likely to follow up a pharmacist's advice to see a GP compared to filling out a questionnaire which assesses diabetes risk without needing to have a blood test.

The aim of this study is to evaluate the level of uptake to further testing in participants who have a positive screening test result at their local pharmacy. Response rates will be compared between the two study groups. Other objectives are to compare the yield (numbers) diagnosed with either diabetes or impaired glucose regulation following a confirmatory test by a GP.

### Who can participate?

Participants must be aged 40-75 (35-75 if south Asian due to the increased risk of diabetes), not diabetic, and should not have had a fasting test to screen for diabetes in the previous 12 months.

What does the study involve?

Participants are randomly allocated to one of two groups:

1. Near patient test arm

Once consent has been given, participants will be asked to fill out a questionnaire to assess diabetes risk. Should the participant score 16 points or above they will be immediately be offered a fingerprick test for HbA1c at the pharmacy. If their HbA1c result is greater or equal to 6% (42mmol/l) they will be given a print out of their results and asked to visit their GP for a follow-up test. Regardless of the participants diabetes risk status the results will be sent to their GP with a recommendation on the appropriate course of follow up.

2. Risk score only arm

Once consent has been given, participants will be asked to fill out a questionnaire to assess diabetes risk. Should the participant score 16 points or above they will be given a print out of their results and asked to visit their GP for a follow-up test. Regardless of the participants diabetes risk status the results will again be sent to their GP with a recommendation on the appropriate course of follow up.

What are the possible benefits and risks of participating?

Participants will be able to get screened for diabetes without having to make an appointment with their GP. Some patients may not want their GP to know if they have been diagnosed with diabetes due to implications it may have on employment. This will be made clear to participants before they are asked to give consent.

Where is the study run from?

The study will be run within Leicester, UK.

When is the study starting and how long is it expected to run for?

The study started in March 2011. It is expected that recruitment will be completed in March 2014.

Who is funding the study?

Merck Sharp & Dohme Limited, NHS Leicester City and the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care - Leicestershire, Northamptonshire and Rutland (UK).

Who is the main contact?

Andrew Willis, study coordinator  
aw187@le.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Prof Kamlesh Khunti

### Contact details

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Leicester

United Kingdom  
LE5 4PW

## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers  
N/A

## **Study information**

### **Scientific Title**

Pharmacy based screening of high Risk Individuals using Stepwise Methods: the PRISM study

### **Acronym**

PRISM

### **Study objectives**

The hypothesis to be tested is that screening using a self assessed risk score followed by near patient HbA1c testing in pharmacies will increase uptake of a confirmatory test conducted at the GP surgery compared to screening with a risk score alone.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Northamptonshire and Rutland Research Ethics Committee 2, 27/07/10

### **Study design**

Two arm individually randomised study with no control (single site)

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

GP practice

### **Study type(s)**

Screening

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

Early detection of type 2 diabetes

### **Interventions**

Participants will be individually block randomised to one of two screening arms

#### **Trial arm 1. Near patient test**

A paper based version of the Leicester Self-Assessment (LSA) diabetes risk score questionnaire will be given to all individuals who meet the inclusion criteria for the study who are approached at the pharmacy over the recruitment period. Participants with a high LSA risk score (>16 points) randomised to the near patient HbA1c test arm of the study will be immediately offered an appointment with the pharmacist to discuss modifiable risk factors. Following this appointment the participant will immediately be offered a finger prick NPT HbA1c test in the pharmacy. If the individual presents with a HbA1c above 6% they will be referred to their GP for a confirmatory test.

#### **Trial Arm 2. GP Test method**

High risk participants identified by the LSA diabetes risk score questionnaire randomised to the GP test arm will be immediately offered an appointment with the pharmacist to discuss modifiable risk factors. Following this consultation they will be given a letter of referral asking for an HbA1c or fasting plasma glucose (FPG) test to be performed at their general practice. If the individual presents with a HbA1c above 6% or a FPG of 6mmol/l or above they will be asked to re-attend their general practice for a confirmatory test.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Percentage uptake of high risk individuals by a pharmacy test to a confirmatory test at the GP surgery

Primary and secondary outcome data will be extracted via a query of participants medical records by a member of the study team. This will be completed at 3 months post screening appointment.

### **Secondary outcome measures**

Number of participants diagnosed with type 2 diabetes and impaired glucose regulation according to the final confirmatory test at the GP surgery

### **Overall study start date**

01/03/2011

### **Completion date**

01/03/2014

# Eligibility

## Key inclusion criteria

40-75 years old (35 to 75 if South Asian due to the increased diabetes risk)

## Participant type(s)

Patient

## Age group

Adult

## Sex

Both

## Target number of participants

2406

## Key exclusion criteria

1. Already diagnosed with diabetes
2. Have had a fasting test for diabetes in the previous 12 months performed elsewhere
3. Have a mental impairment, learning difficulty or chronic disease which may impair ability to give informed consent

## Date of first enrolment

01/03/2011

## Date of final enrolment

01/03/2014

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

Leicester Diabetes Centre

Leicester

United Kingdom

LE5 4PW

# Sponsor information

## Organisation

University of Leicester (UK)

**Sponsor details**

Research and Development Office  
Leicester General Hospital  
Leicester  
England  
United Kingdom  
LE5 4PW

**Sponsor type**

University/education

**ROR**

<https://ror.org/04h699437>

**Funder(s)**

**Funder type**

Industry

**Funder Name**

Merck Sharp and Dohme

**Alternative Name(s)**

MSD United Kingdom, Merck Sharp & Dohme, Merck Sharp & Dohme Corp., MSD

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United Kingdom

**Funder Name**

NHS Leicester City (UK)

**Funder Name**

The National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care - Leicestershire, Northamptonshire and Rutland (UK)

# Results and Publications

## Publication and dissemination plan

2015 results published in thesis <http://hdl.handle.net/2381/37251>

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration