

# The Ambulance-Hypo Study

<b>Submission date</b> 05/01/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/02/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/08/2022	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Hypoglycaemia is a condition usually experienced by people with diabetes when the level of sugar in the blood falls to a very low level. Hypoglycaemia is often caused by the medication people with diabetes take but it can also be caused by exercise, diet and having other conditions as well as diabetes. Hypoglycaemia causes symptoms such as tiredness and dizziness but can also cause very serious symptoms such as loss of consciousness and can even be fatal if it is not treated. In some parts of the UK, ambulance staff who attend patients with hypoglycaemia can refer them to a new care pathway aimed at preventing further episodes of hypoglycaemia. As part of this care pathway, ambulance staff give the patient's details to a nurse who is specially trained in helping people with diabetes. This nurse then contacts the patient by phone to talk about why the person had hypoglycaemia and how they can avoid it in the future. If necessary, the nurse may arrange an out-patient appointment or request that the patients' medication is changed. There have been small studies of this care pathway to see whether it is effective at preventing further episodes of hypoglycaemia. Although the results have been promising we need to collect more data to see if the care pathway can be set up in new areas and prevent future episodes of hypoglycaemia and improve overall outcomes for patients.

### Who can participate?

Patients aged 18 or older living in Northamptonshire or Lincolnshire, assessed by a paramedic as hypoglycaemic.

### What does the study involve?

Ambulance staff either refer patients to the new care pathway or send the patient's details to their GP. This is determined randomly. Patients allocated to the new care pathway receive help and advice from a diabetes specialist nurse who may discuss the cause of the hypoglycaemia and how it can be prevented in the future, in addition to an advice leaflet. The nurse also conducts a review of the patients' current medications to establish if any changes are required to help prevent future episodes. The other patients still receive an advice leaflet but are asked to visit their GP to discuss their hypoglycaemia. Referred patients are followed-up four weeks later. This involves sending them an invitation letter and information leaflet along with a consent form and a questionnaire to complete. Patients who consent to take part are followed up 12 months later. This involves contacting the patient's general practice to obtain relevant information about the patient, which is agreed to when the patient consents to join the study.

What are the possible benefits and risks of participating?

Participants in both groups will receive help and advice about hypoglycaemia. As the intervention does not include changes to the way in which patients with hypoglycaemia are treated there are no anticipated risks from the intervention per se. However, if participants consent to the study their GP will be made aware that they have been treated by a paramedic for a hypoglycaemic event. This may have implications for their ability to drive as the DVLA would normally be informed of the episode of hypoglycaemia.

Where is the study run from?

The study is taking place in Northamptonshire, where the ambulance service and the diabetes care service are both involved.

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

January 2015 to April 2018.

Who is funding the study?

National Institute for Health Research Collaborations for Leadership in Applied Health Research and Care East Midlands (UK).

Who is the main contact?

Dr Andy Willis

## Contact information

### Type(s)

Scientific

### Contact name

Dr Andy Willis

### ORCID ID

<https://orcid.org/0000-0002-9671-2162>

### Contact details

Leicester Diabetes Centre  
Gwendolen Road  
Leicester  
United Kingdom  
LE5 4PW

## Additional identifiers

### Protocol serial number

UNOLE 0550

## Study information

### Scientific Title

Innovative hypoglycaemia pathway for self-care at home and admission avoidance: a partnership approach with a regional ambulance trust

**Acronym**

Ambulance-Hypo

**Study objectives**

Patients randomised to the intervention arm of the study (intervention from a diabetes nurse) will have a higher rate of evidence of discussion of the hypo and/or change in medication documented in the participants' medical notes when compared to participants randomised to the control arm (GP referral).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

East Midlands - Nottingham 1 committee, 19/01/2016, REC ref: 15/EM/0538

**Study design**

Multicentre randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Prevention of hypoglycaemia in people with diabetes

**Interventions**

Patients are randomised to the intervention arm (intervention from a diabetes nurse) or the control arm (GP referral).

The intervention involves ambulance staff from East Midlands Ambulance Service attending the call-out and Diabetes Specialist Nurses working for the Integrated Care Diabetes Service in Leicester. The ambulance staff gives the patient a "Hypos can Strike Twice" information booklet. The booklet includes information on what a 'hypo' is, their prevention and treatment as well as advice on driving. The booklet explains that the patient will be contacted by phone within two working days, by a DSN who will discuss the episode of hypoglycaemia, offer advice and suggest treatment changes (if required) in an attempt to prevent future hypoglycaemic episodes. If the DSN is unable to contact the patient by telephone a letter is sent offering them a face-to-face appointment. The general practitioner (GP) is informed following all telephone calls and consultations or if the patient refuses an appointment.

**Intervention Type**

Other

**Primary outcome(s)**

Documented evidence in the patient's notes (practice notes or those maintained by DSNs) that the hypoglycaemic episode was discussed (within 4 weeks of the call-out) during a telephone consultation or a face-to-face consultation with a Health Care Professional (HCP), and that advice was given and/or changes made to their medication

### **Key secondary outcome(s)**

1. Patient's satisfaction with the treatment they have received (Diabetes Treatment Satisfaction Questionnaire (Bradley, 1994)) 4 weeks after consent
2. Patient's knowledge of DVLA driving regulations relating to hypoglycaemia (unvalidated questionnaire) 4 weeks after consent
3. Patient's fear of hypoglycaemia, Fear of Hypoglycaemia Scale (Cox et al., 1987) 4 weeks after consent
4. Patient's quality of life EQ5D (The EuroQol Group, 1990) 4 weeks after consent
5. Rates of CVD and CVD-related mortality (rates of all-cause mortality) extracted from patients medical notes at 12 months after consent
6. Rate of hypoglycaemic episodes requiring repeat ambulance attendance (recorded by ambulance service) collected at 12 months after consent
7. Rate of hypoglycaemic episodes requiring repeat ambulance attendance and conveyance to hospital (including information on whether or not admitted) (recorded by ambulance service) collected at 12 months after consent

### **Completion date**

20/06/2019

## **Eligibility**

### **Key inclusion criteria**

1. Willing and able to give informed consent
2. Age 18 years and older
3. Able to speak and read English
4. Paramedic assessment of a hypoglycaemic event on the basis of blood glucose reading of <4.0 mmol/l
5. Lives in Northamptonshire or Lincolnshire
6. Responsible for their own care and/or medication

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

81

### **Key exclusion criteria**

1. Unwilling or not able to give informed consent
2. Aged under 18 years
3. Not able to speak and read English
4. Lives outside Northamptonshire and Lincolnshire
5. Not responsible for their own care and/or their medication
6. Previously referred to the present study
7. Admitted to hospital for more than 2 days
8. Registered with a GP outside of the Northamptonshire or Lincolnshire CCGs (i.e., Nene and Corby, West Lincolnshire, East Lincolnshire, South West Lincolnshire and South Lincolnshire, respectively)

**Date of first enrolment**

01/03/2016

**Date of final enrolment**

20/06/2018

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Leicester Diabetes Centre**  
Leicester General Hospital  
Gwendolen Road  
Leicester  
United Kingdom  
LE5 4PW

**Study participating centre**

**East Midlands Ambulance Service NHS Trust**  
East Division HQ  
Cross O'Cliff Court  
Bracebridge Heath  
Lincoln  
United Kingdom  
LN4 2HL

## Sponsor information

## Organisation

University of Leicester (UK)

## ROR

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

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health Research Collaborations for Leadership in Applied Health Research and Care East Midlands (UK)

## Results and Publications

### Individual participant data (IPD) sharing plan

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### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/03/2022	11/08/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes