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Computerised decision support for poorly-controlled type 2 diabetes mellitus in Irish General Practice

Submission date
25/05/2017

Recruitment status
No longer recruiting

Registration date
26/07/2017

Overall study status
Completed

Last Edited
05/03/2021

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a lifelong condition that causes a person's blood sugar level to become too high. Poor control of sugar levels and blood pressure in people with type 2 diabetes is linked to poorer health outcomes and increased costs for patients and healthcare systems. A computerised decision support system allows specific information relating to a patient to be matched with an expert computer system, to deliver recommendations to the doctor or nurse and support decision making relating to a diagnosis, prognosis, investigation or treatment. A computerised decision support tool has been developed for GPs managing patients with type 2 diabetes. The DECIDE tool identifies patients with poor control of sugar (i.e. high HbA1c levels) and blood pressure based on data in their electronic GP record. The GP is presented with a list of patients within his/her own practice who may need additional treatment to improve their treatment. The GP is then provided with a DECIDE web-based treatment algorithm to support them, escalating treatment where appropriate for these patients. The aim of this study is to test the DECIDE tool in two general practices.

Who can participate?
Patients aged 18 to 75 with poorly controlled type 2 diabetes

What does the study involve?
Participating GPs are randomly allocated to either use the DECIDE system or to continue to provide care as usual. At the start of the study and after six months the patients' HbA1c, blood pressure and lipid levels are collected by the practice GP (or practice nurse) using existing search tools within GP software systems.

What are the possible benefits and risks of participating?
If this study indicates that the DECIDE tool is acceptable, easy to use and cost effective in terms of improving diabetes risk factors, a larger national study will be carried out to test the DECIDE tools. This type of intervention has the potential to improve diabetes outcomes for patients and reduce the health system burden associated with poorly controlled risk factors in type 2 diabetes. As a GP, the benefits of participating in the study include accessing continuous

professional development points, improving the quality of care for patients through ensuring the application of up-to-date guidelines, promoting evidence-based practice in general practice, and adding to the current research investigating clinical inertia. There are no risks of participation. For patients, there are no observable negative effects, as the study ensures that the latest evidence and guidelines are provided to their GP.

Where is the study run from?
Royal College of Surgeons (Ireland)

When is the study starting and how long is it expected to run for?
June 2017 to April 2019 (updated 03/07/2019, previously: June 2018)

Who is funding the study?
1. HRB Centre for Primary Care Research (Ireland)
2. HRB Clinical Trials Network (Ireland)
3. HRB-funded SPHeRE Programme (Ireland)
4. Irish College of General Practitioners (Ireland)
5. WestREN Network, National University of Ireland, Galway (Ireland)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HRBDECIDE

Study information

Scientific Title
Supporting General Practitioners intensify medications for patients with poorly-controlled type 2 diabetes mellitus with computerised decision support: a cluster randomised controlled trial in Irish General Practice (the DECIDE study)

Acronym
DECIDE

Study objectives
The primary aim of this study is to evaluate a complex intervention that will identify type 2 diabetes mellitus (T2DM) patients with poor glycaemic and blood pressure control and support GP treatment escalation where appropriate. This will be called the DECIDE intervention and will be tested through a cluster randomised control trial. Secondary objectives include a process evaluation to record GP decision-making processes and a cost effectiveness analysis of the DECIDE intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Irish College of General Practitioners Research Ethics Committee, approval on the 16/06/2016 for the DECIDE study to pilot the study. An extension ethics approval to perform the study as an exploratory trial will be issued on completion of the pilot.

Study design
Pilot study and cluster randomised control trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Poorly controlled type 2 diabetes mellitus (T2DM)

Interventions

A theory-based complex intervention to target GPs' prescribing behaviour in the treatment of patients with poorly controlled T2DM was developed using the first stage of the UK Medical Research Council (MRC) framework. The study utilised the Behaviour Change Wheel (BCW) to provide a theoretical guide to intervention development. The DECIDE study has three components:

1. Finding poorly controlled type 2 diabetes mellitus (T2DM) patients: Though GPs could use existing electronic health record search functions to find target patients (e.g. with a HbA1c > 70mmol/mol), the research team has worked with the Irish Primary Care Research Network (IPCRN) and Irish College of General Practitioners (ICGP) to develop an automated finder function, permitting the rapid retrieval of all target patients in each practice. These patients can then be logged and recorded securely on a local database in each practice.
2. The DECIDE clinical decision support system (CDSS). A web-based decision CDSS was created which delivers patient-specific recommendations to the GP on what medication intensifications could be recommended, if any. The algorithms in the CDSS are based on ICGP guidance for management of hypertension and T2DM.
3. A training module was developed for intervention group GPs to explain all the steps in the intervention. A practice-based training session on the use of IPCRN DECIDE finder tool and web-based DECIDE treatment algorithms was created. The training session explains that either the practice nurse or GP can insert the patient specific information into the DECIDE website, either at a chart review or with the patient during the Diabetes Cycle of Care visit. In the second step of the CDSS, the GP is offered with intensification suggestions, linking the patient-specific information with ICGP guidelines, regarding anti-diabetic, anti-hypertensive and lipid-lowering agent medications. Intervention GPs are typically offered three choices in relation to the patient' s medications; a) to intensify medications through increase doses; b) to intensify medications through the addition or switching of medications; or c) will choose not to intensify medications. After the GP makes the changes, the decision of sharing this decision with the patient is at the discretion of the GP.

The DECIDE tools have been developed over the past two years in the first phase of the study and will be piloted in two general practices. The interventions will then be tested in an exploratory randomised trial with the GPs being randomised into treatment (using the DECIDE system) or control (continuing to provide care as usual) groups. Each practice will be allocated into intervention or control group using minimisation due to the small number of clusters. Practices will be minimised by practice region (West of Ireland vs Dublin region). Sequence generation and practice allocation will be carried out remotely by a statistician independent of the trial management team using a computer-generated sequence.

The intervention period will take place over a 3-month run-in period. Intervention practices, through the existing T2DM Cycle of Care, will have an opportunity over this period to perform baseline investigations before applying the DECIDE intervention. After this intervention period has finished, follow up will be 6 months later - at which point both control and intervention practices will re-perform these investigations (as per the existing Cycle of Care) and the practices will provide this anonymised information to the DECIDE website. The outcomes - HbA1c, blood pressure and lipids - will be collected at practice level by the practice GP (or practice nurse) using existing search tools within GP software systems and no individual identifiable patient data will be collected for this feasibility and exploratory study. Due to the nature of the project and targeting of the intervention at cluster level, patient reported outcome measures will not be collected, as this would be beyond the scope of the proposed project and would require individual patient consent.

Intervention Type

Behavioural

Primary outcome measure
HbA1c, a measure of glycaemic control, collected from medical records at baseline and at 6 months follow up

Secondary outcome measures
Medications, blood pressure and lipids collected from medical records at baseline and at 6 months follow up

Overall study start date
01/06/2017

Completion date
30/04/2019

Eligibility

Key inclusion criteria
GPs will be the target of the intervention and will be unit of randomisation. All GPs who are part of the HRB Clinical Trials Network will be eligible for inclusion.

1. Only patients with poorly controlled T2DM will be targeted by the GP with the DECIDE intervention
2. Patients must have a diagnosis of T2DM
3. They must be aged over 18 years and less than 75, as there is less evidence about treatment intensification in patients aged above 75 years
4. There is no validated cut-off which defines poor control of T2DM for targeted interventions. For the purposes of this study, the trialists have selected HbA1C or BP levels for which there would be consensus on the importance of intervention and treatment and have clinical face validity in terms of intervention. In the DECIDE study only patients with a HbA1c reading of 8.5% (70 mmol/mol) or above and/or a blood pressure reading over 150/95mmHg will be included
5. Not all patients will be suitable for treatment intensification and individual decisions on treatment changes will be made by each patient's GP.

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The pilot study will take place in three General Practices. The trialists will then move on to an exploratory trial. A preliminary sample size, based upon HbA1c and BP has estimated that up to

20 GPs (10 in each arm) are needed, if there are 15 patients with poorly controlled T2DM in each practice.

Total final enrolment
134

Key exclusion criteria
1. All GPs will be included
2. Patients are excluded if they do not fulfill the inclusion criteria

Date of first enrolment
01/10/2018

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Ireland

Study participating centre
HRB Centre for Primary Care Research
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Sponsor type
University/education

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ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Research organisation

Funder Name
HRB Centre for Primary Care Research

Funder Name
HRB Clinical Trials Network, Ireland

Funder Name
HRB-funded SPHeRE Programme (structured PhD programme in Health Services Research)

Funder Name
Irish College of General Practitioners

Alternative Name(s)
Coláiste Dochtúirí Teaghlaigh Éireann, Irish GP, Irish College of GPs, ICGP

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Funder Name

Results and Publications

Publication and dissemination plan

1. The results will be disseminated to policy makers, service providers and the wider public, including general practitioners and primary healthcare professionals who deliver care to patients with T2DM, health policy groups within the HSE and service planners, patients with T2DM, the wider public and the academic community, especially with health services research networks
2. A paper will be submitted outlining the intervention development and protocol for the exploratory cluster RCT in an international peer review journal after the first 6 months of the study
3. The results of the exploratory trial will be reported in a main outcome paper to be submitted to a peer reviewed journal.
4. On study completion a lay summary report will be prepared on the feasibility and effectiveness of the proposed intervention and will be disseminated through lay media
5. A qualitative evaluation that explores the GP experience of delivering the DECIDE intervention: the evaluation of the study will incorporate a consideration of the feasibility of implementing the intervention and will be reported in the final academic paper, which will be delivered on study completion
6. An economic analysis of the exploratory cluster RCT: a separate economic analysis paper will be led by health economist Dr Paddy Gillespie and will be delivered on study completion
7. Results from this research will be reported at national and international conferences. Lay media will be disseminated through RCSI's media support office

Intention to publish date

01/09/2018

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/10/2018		Yes	No
Results article	results	12/02/2020	05/03/2021	Yes	No