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Evaluating Self -Management in Diabetes

Submission date	Recruitment status	[ ] Prospectively registered
28/10/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/08/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/01/2018	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes is a long-term condition suffered by an increasing number of people around the world. It is a major challenge for healthcare services, being the single biggest cause of stroke, blindness, amputation and end stage kidney failure. Its cost will be severely challenging for the National Health Service (NHS) in the UK (already 10% of the budget).
Self-management of diabetes is an essential factor in achieving target blood glucose levels and avoiding future complications. The aim of this study is to understand the attributes that are deemed most important by patients and members of the general public in the self-management of diabetes. Knowing this will help healthcare providers design future treatments in a better way.

Who can participate?
Adults diagnosed with type 1 or type 2 diabetes mellitus.

What does the study involve?
Sheffield-based adult diabetes patients are invited to take part in individual semi-structured qualitative interviews. After consenting, participants will answer a series of questions to help the research team identify the attributes of self-management that they see as essential. Information on the significance of each attribute and possible trade-offs in self-management will also be explored.
Information from the interviews will inform the design of an online survey, presented to two invited groups, one of individuals with diabetes and another of members of the general public.

What are the possible benefits and risks of participating?
This survey will present a series of comparison questions explaining the key features of two health states and asking which is preferred. Information from this survey will be used to quantify preferences in self-management of diabetes and assign a quality adjusted life years (QALY) value and a monetary value for use in willingness to pay analysis.
There are no risks to participants.

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
May 2014 to December 2015.

Who is funding the study?
The Health Foundation (UK)

Who is the main contact?
Martin Fox, study coordinator
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
Sponsor ref.: STH 18354 Funder ref.: 7265

Study information

Scientific Title
Evaluating Self -Management in Diabetes: an observational cohort study

Acronym
ESMiD

Study objectives
Self-management is key in achieving and maintaining blood glucose control in diabetes, but research centred on clinical outcomes has largely ignored how individuals with diabetes value self-management. Quantified values for self-management can be used to inform health technology assessment of self-management interventions, such as DAFNE, DESMOND and their derivatives. This study will seek to:
1. Derive up to 3 multilevel attributes for each type of diabetes that reflects self-management in type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) patients using: existing evidence in the literature on self-management in T1DM and T2DM, and qualitative work with patients

2. Estimate the value of self-management in T1DM and in T2DM in comparison to standard care both in QALY terms and monetary terms
3. Estimate the relative value of each of the attributes of self-management identified for T1DM and T2DM patients in comparison to health-related quality of life (HRQOL)
4. Recommend how these results can inform health technology assessment of self-management in T1DM patients and T2DM patients and the implementation of self-management both in T1DM, T2DM and other conditions

17/08/2015:
Recruitment end date extended to 31st October 2015 (previously 31st July 2015).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Health Research Authority, NRES Committee London - Bromley, 17/07/2014, REC ref.: 14/LO/1334

Study design
An observational cohort study: 1. development 2. management 3. analysis of a Discrete Choice Experiment with diabetes patients. Duration is 14 months

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Type 1 and Type 2 Diabetes Mellitus

Interventions
Stage 1: Deriving the attributes and levels for the DCE:
• A literature review will examine attributes related to self-management valued by individuals with diabetes
• Semi-structured interviews with diabetes patients will explore the severity levels of the proposed self-management attributes and determine whether these attributes are appropriate and sufficient (20-40 participants)

Stage 2: Online DCE survey:
This stage will value the attributes derived in stage 1 using two approaches: valuation of self-management in Quality of Life Year (QALY) terms and valuation of self-management in monetary terms. The DCE survey will use two different formats:
• combining the attributes derived in stage 1 with a duration attribute
• combining the attributes derived in stage 2 with a cost attribute
Each respondent will complete a survey online in only one format.
Sample size for the DCE:
• Up to 350 individuals with T1DM
• Up to 350 individuals with T2DM
• Up to 2000 members of the general public who do not have diabetes

Stage 3: Analysis:
Results from the DCE survey will be analysed using regression analysis to produce QALY and monetary values for the attributes of self-management. Findings will be circulated to internal and external experts, The Health Foundation and other stakeholders for comments before final reporting.

Intervention Type
Behavioural

Primary outcome(s)
To estimate the value of self-management for patients with T1DM and with T2DM in comparison to standard care in both QALY and monetary terms, by discrete choice experiment (DCE) questionnaire survey during May/June 2015

Key secondary outcome(s))
1. To derive up to 3 multilevel attributes for each type of diabetes that reflects self-management in T1DM and T2DM patients using: existing evidence in the literature on self-management in T1DM and T2DM, and the qualitative work with patients
2. To estimate the relative value of each of the attributes of self-management identified for T1DM and T2DM patients in comparison to health-related quality of life (HRQOL)
3. To recommend how these results can inform health technology assessment of self-management in T1DM patients and T2DM patients and the implementation of self-management both in T1DM, T2DM and other conditions.

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Patients diagnosed with type 1 or type 2 diabetes mellitus
2. Patients who are aged 18+ years when taking part in this study
3. Patients who are fluent in English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

To ensure informed consent potential participants must have a good understanding of the English language

Date of first enrolment
01/09/2014

Date of final enrolment
31/10/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Sheffield
Sheffield
United Kingdom
S1 4ED

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes