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Spotlight tools to improve routine clinical care

Submission date
08/10/2021

Recruitment status
No longer recruiting

Registration date
11/10/2021

Overall study status
Completed

Last Edited
31/01/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Routine patient care visits currently leave both patients and healthcare professionals feeling frustrated both in primary and specialist care settings. The lack of understanding of the psychological and social burden of diabetes and the evolving consequences results in a negative impact on clinical practice with negative outcomes for patients and increasing frustration for healthcare professionals. The aim of this study is to determine the clinical and cost-effectiveness of the Spotlight Consultations tools in routine primary or secondary care clinic appointments between healthcare professionals and adults with type 1 diabetes, type 2 diabetes or pre-diabetes.

Who can participate?
Patients aged 18 and over with type 1 diabetes, type 2 diabetes or pre-diabetes treated in primary or secondary care

What does the study involve?
The researchers are testing the usefulness of a new digital health tool called: 'Spotlight' in helping healthcare professionals better understand their patients' priority concerns during routine diabetes clinic visits. Despite the therapies available, people with type 1 diabetes, type 2 diabetes and pre-diabetes often are unable to reach blood glucose targets for optimal health. Improving routine consultations could help.
Participants will be randomly assigned to the intervention group or the control group. Those in the intervention group will be asked to complete study questionnaires and the Spotlight Consultations online pre-clinic assessment before their routine outpatient consultation. Results of this assessment will form the basis of discussion during the consultation. Those in the control group will be asked to complete stud questionnaires only. At the end of the intervention period, all participants in the control group will be offered the use of the Spotlight Consultations pre-clinic assessment.

What are the possible benefits and risks of participating?
Participants may learn more about the factors in their everyday life that impact their diabetes and the way they manage it. Participants may learn more about how diabetes affects their life and contribute to research that may benefit others.

The risks associated with taking part are very small. Taking part may make participants think more about their own mood, how they feel about their diabetes, and the impact of their diabetes management on their quality of life.

Where is the study run from?
Southern Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2020 to December 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Prof. Katharine Barnard-Kelly, katharinebarnard@bhrltd.com
2. Dr Peter Phiri

Contact information

Type(s)
Scientific

Contact name
Prof Katharine Barnard-Kelly

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
289964

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 289964, CPMS 47856

Study information

Scientific Title
Multi-centre randomised controlled trial to determine the clinical and cost-effectiveness of Spotlight-AQ

Acronym
Spotlight-AQ

Study objectives
The hypothesis is that it is feasible and acceptable using the Spotlight Consultations tool, to improve outpatient visits, ensuring patient-driven healthcare to match the most relevant and appropriate care pathways to the personalized needs of the individual, thus optimizing outcomes and reducing the burden on both the person with diabetes and the healthcare professionals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/02/2021, Wales REC7 (Health and Care Research Wales, Health and Care Research Wales Support Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0) 2920 230457, +44 (0)7920 565664; Wales.REC7@wales.nhs.uk), REC ref: 21/WA/0020

Study design
Multi-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Type 1 diabetes, type 2 diabetes, pre-diabetes

Interventions
Following recruitment and consent, each participant will complete baseline questionnaires. Participants will then be randomized into either the intervention arm or the control arm of the study at each centre for a period of 12 months (i.e. baseline and follow-up visits). The researchers will randomise on a 1:1 basis using computerised randomisation software. Those in

the intervention group will be asked to complete study questionnaires and the Spotlight Consultations online pre-clinic assessment prior to their routine outpatient consultation. Results of this assessment will form the basis of discussion during the consultation. Those in the control group will be asked to complete study questionnaires only. At the end of the intervention period, all participants in the control group will be offered the use of the Spotlight Consultations pre-clinic assessment.

Clinic visits will occur every 6 months i.e. baseline, 6 and 12 months within the intervention period. Haemoglobin A1c will be assessed, together with psychosocial outcomes throughout the trial, i.e. reflecting routine clinical care. The 12-month duration of the intervention is determined by the goal to observe meaningful A1c changes AND reduced consultations times, alongside improvements on PROs; reduced burden/distress of HCPs and is sufficient for this purpose. The researchers have considered alternative designs, such as a cluster randomised controlled trial, however, it was decided that this approach would be more appropriate in order to minimize the number of participants needed for recruitment, and optimizes the total time and effort. Following the study, the participating centres may keep the tools and offer them to those in the control group.

Intervention Type
Behavioural

Primary outcome measure
Consultation duration time measured by timing each consultation at baseline, 3, 6, 9 and 12 months follow-up

Secondary outcome measures
Measured at baseline, 3, 6, 9 and 12 months follow-up:
1. Diabetes distress measured using the Diabetes Distress Scale (DDS)
2. Depression measured using Patient Health Questionnaire (PHQ)-9
3. Anxiety measured using Generalised Anxiety Disorder (GAD)-7
4. Social functioning measured using 12-Item Short Form Survey (SF-12)
5. Engagement measured using the Self-Care Inventory (SCI)
6. Treatment satisfaction/utility measured using the Diabetes Treatment Satisfaction Questionnaire
7. Health resource utility measured using EQ-5D (EuroQol five dimension)
8. Well-being measured using World Health Organisation- Five Well-Being Index (WHO-5)
9. HCP burnout measured using the Maslach Burnout Inventory

Overall study start date
01/06/2020

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Aged ≥18 years. There is no upper age limit
2. Diagnosed with type 1 diabetes or at risk of or diagnosed with type 2 diabetes (including pre-diabetes) for at least 6 months
3. Any diabetes treatment

4. Willing/able to use the Spotlight Consultations tool
5. Ability to give informed consent
6. Ability to speak and read English fluently

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
98

Key exclusion criteria
1. Aged <18 years
2. Mental illness that could seriously reduce their ability to participate in the study
3. Lack of capacity

Date of first enrolment
01/10/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Moorgreen Hospital
Southern Health NHS Foundation Trust
Tom Rudd Unit
Botley Road
Southampton
United Kingdom
SO30 3BJ

Sponsor information

Organisation
Southern Health NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.southernhealth.nhs.uk/research/cris

ROR
https://ror.org/03qesm017

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Data from all centres will be analysed together and published as soon as possible. Individual investigators may not publish data concerning their patients that are directly relevant to questions posed by the trial until the Trial Management Group (TMG) has published its report. The TMG will form the basis of the Writing Committee and advise on the nature of publications. All publications shall include a list of investigators, and if there are named authors, these should include the Chief Investigator, Co-Investigators, Trial Manager, and Statistician(s) involved in the

trial. Named authors will be agreed upon by the CI and Director of Southern Health. If there are no named authors then a 'writing committee' will be identified.

Intention to publish date
01/08/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to commercial sensitivity.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	HCP version 1.6	08/10/2021	11/10/2021	No	Yes
Participant information sheet	Participant version 1.9	08/10/2021	11/10/2021	No	Yes
Protocol file	version 1.10	03/02/2021	11/10/2021	No	No
Protocol article		20/06/2022	21/06/2022	Yes	No
HRA research summary			26/07/2023	No	No
Results article		23/06/2023	29/08/2023	Yes	No
Results article		30/01/2025	31/01/2025	Yes	No