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Assessing options to increased screening for diabetic retinopathy using education, incentives, or education and incentives in a community health plan

Submission date
28/05/2019

Recruitment status
No longer recruiting

Registration date
18/06/2019

Overall study status
Completed

Last Edited
07/04/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Diabetic retinopathy is a leading cause of blindness worldwide. National bodies in the United Kingdom and Australia provide guidelines on screening for diabetic retinopathy; however, no such national level screening guidelines exist in the United States. The National Committee on Quality Assurance assessed and reports on the quality of services offered by health plans in the United States, including screening for diabetic retinopathy. The purpose of this study was to increase diabetic member uptake of the retinal eye examination in compliance with NCQA HEDIS quality measures.

Who can participate?
People insured by Sendero Health Plans who were making a claim to treat type 2 diabetes mellitus between 01/01/2017 and 31/06/2017, and who were the only household member with type 2 diabetes.

What does the study involve?
Individuals with type 2 diabetes were assigned to one of four arms (three intervention arms and one control group) to determine if being assigned to one of these groups was associated with the individuals obtaining a medical eye exam.

What are the possible benefits and risks of participating?
To identify what interventions are associated with obtaining a medical eye exam. In this case, we sought to determine the association
between an incentive (US$25 gift card), education, or education plus incentive (US$25 gift card) and obtaining the medical eye exam.
This study presented a minimal risk to the patient as this outcome of interest (medical eye exam) is a well-recognized procedure with evidence
to support its use in medical practice to identify diabetic retinopathy.

Where is the study run from?
Sendero Health Plans, Inc., Austin TX, USA.

When is the study starting and how long is it expected to run for?
September to October 2017

Who is funding the study?
Sendero Health Plans, Inc.

Who is the main contact?
Dr John Litaker,
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Contact information

Type(s)
Scientific

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Protocol serial number
2016F-09-05

Study information

Scientific Title
A multi-armed intervention trial to increase diabetic retinopathy screening by a community-based health insurance plan in Central Texas

Study objectives
H1: A person's decision to obtain a retinal eye exam is dependent of whether or not they receive any cue to action (education only or incentive only, or both education and incentive) or no cue to action (control)
H2: A person's decision to obtain a retinal eye exam is dependent of the type of cue to action received, including no cue to action, education only, incentive only, or both education and incentive

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/07/2017, Aspire Institutional Review Board (11491 Woodside Avenue, Santee, California 9207, USA; 619-469-0108; email@aspire-irb.com), ref: 2016F-09-05.

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Diabetic Retinopathy

Interventions
The purpose of this study was to increase diabetic member uptake of the retinal eye examination in compliance with NCQA HEDIS quality measures. Specifically, we conducted a multi-armed intervention trial designed to assess member uptake of the annual retinal eye examination in one of four groups: (1) a control group with no intervention; (2) a monetary incentive group that received a $25 gift card after completion of the examination; (3) a patient education material only group; and (4) a group that received both patient education material and a $25 gift card after completion of the examination.

Sendero members were eligible to participate in this trial if they had a medical claim for type 2 diabetes or a medication claim used to treat
type 2 diabetes from January 1 through June 30, 2017. Excluding individuals who had already obtained a retinal eye exam through June 30, 2017 and excluding members who had ongoing, active management for ocular complications associated with diabetes mellitus, 1,648 individuals with medical claims for type 2 diabetes were identified. Of these members, 1,459 lived in a household with only one person diagnosed with diabetes. Single member households were chosen as the unit of analysis to prevent cross-contamination among additional household members who may have type 2 diabetes, but who may have been assigned to a different intervention group or to the control group.

Incentive group:
a. Outreach letter to members with diabetes offering a US$25 gift card for completing the medical eye examination by a specific date
b. A list of Sendero providers who can perform these exams.
Education group:
a. Outreach letter to members with diabetes to encourage them to obtain a medical eye exam by a specific date
b. Educational material related to diabetes with a checklist of preventive care related to diabetes
c. A list of Sendero providers who can perform these exams
Education and Incentive:
a. Outreach letter to members with diabetes offering a US$25 gift card for completing the

medical eye examination by a specific date
b. Educational material related to diabetes with a checklist of preventive related to diabetes
c. A list of Sendero providers who can perform these exams.
Control group: No contact or information related to this clinical trial was provided to these individuals.

Randomization Process:
- Power analysis indicated that the control group should be twice the size of the individual intervention groups[2]
- Each individual was randomly assigned (using a random number generator) a number 1 through 5.
- The numbers 1 through 5 were randomly selected and assigned to the groups as follows:
o Control Group: Assigned groups 1 and 4 (to account for the power analysis calculation that advised the control group should have twice as many cases as the intervention groups
o Incentive Only Group: Assigned group 5
o Education Only Group: Assigned group 3
o Incentive + Education Group: Assigned group 2

Intervention Type
Behavioural

Primary outcome(s)
Members who obtained a retinal eye exam from either an ophthalmologist or optometrist were deemed to have completed a retinal eye
exam based solely on CPT codes 92004, 92012, and 92014, in accordance with US Centers for Medicare and Medicaid Services Quality Rating System technical specifications. Non-eye care providers must have also provided either a category two CPT code or a HCPCS code to indicate retinal examination occurred (2022F, 2024F, 2026F, and 3072F).
Method of Measurement: CPT codes were obtained by SQL query of medical claims processed by Sendero Health Plans, Inc. based on member identification number
Timepoint: CPT claims status was obtained based on a date of claim that occurred from September 19, 2017 October 31, 2017 (the study
period). Providers have up to 90 days to submit a claim after the date of service. In accordance with end of year activities, we ran the SQL query after March 31, 2018 to account for any claims that occurred during the September 19, 2017 - October 31, 2017 time period.

Key secondary outcome(s))
none

Completion date
31/10/2017

Eligibility

Key inclusion criteria
1. Insured by Sendero Health Plans in the IdealCare line of business during the calendar year 2017
2. Medical claim for type 2 diabetes or a medication claim used to treat type 2 diabetes mellitus from January 1 through June 30, 2017
3. Live in a household that only had one person diagnosed with type 2 diabetes mellitus

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
1454

Key exclusion criteria
1. Individuals who had already obtained a retinal eye exam through June 30, 2017 and excluding members who had ongoing, active management for ocular complications associated with type 2 diabetes mellitus.

Date of first enrolment
19/09/2017

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
United States of America

Study participating centre
Sendero Health Plans, Inc.
2028 E Ben White Blvd #400
Austin
United States of America
78741

Sponsor information

Organisation
Sendero Health Plans

ROR
https://ror.org/02syt4h28

Funder(s)

Funder type
Charity

Funder Name
Sendero Health Plans, Inc.

Results and Publications

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:
a. This data, will de-identified, is considered personal health information
b. At this time, we do not know if we are able to release the final data set due to federal privacy regulations regarding personal health information (i.e., the US Health Insurance Portability and Accountability Act of 1996)
c. Individual requests for the data set are welcomed (and encouraged) and will be considered on a case by case basis
d. At a minimum, any agreement to release data would be by Sendero Health Plans, Inc. and would require a signed business associate agreement outlining data protection steps, confidentiality, and how data will be used
e. All decisions relating to the release of data are at the discretion of Sendero Health Plans and in compliance with applicable rules, regulations, and statute

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2020	07/04/2020	Yes	No