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Evaluation of the “Champion” pilot project to standardize workflow for patients with diabetes and/or hypertension at the Palo Alto Medical Foundation

Submission date
15/03/2017

Recruitment status
No longer recruiting

Registration date
27/03/2017

Overall study status
Completed

Last Edited
20/04/2017

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Many people suffer from long-term medical conditions, such as hypertension (high blood pressure), diabetes (disorder of blood sugar control) or depression (low mood). These conditions require monitoring and effective management on the part of health providers, especially in primary care (GP). New models of primary care to manage long-term conditions have shown promising results; however, these models are not widely adopted in community practice for several reasons. These include concerns about reimbursement and uncertainty regarding fees. The Palo Alto Medical Foundation designed and implemented a program called “Champion,” a new model of care that includes new standard work (such as proactive patient outreach, pre-visit schedule grooming, depression screening, care planning) to support patients’ self-management of hypertension and diabetes. The aim of this study is to collect data from providers, patients, and other staff to evaluate the various effect of the Champion program on patient outcomes, provider satisfaction, service utilization, and organisational costs.

Who can participate?
Adults who have been diagnosed with high blood pressure, diabetes or depression in any combination.

What does the study involve?
The study is looking at two health clinics, one which is following the Champion program and one which is not. At the start of the study and then six and twelve months later, a selection of patients complete interviews and surveys about their experiences with the care they are being offered, and have their scheduled appointments with their primary care physician observed by members of the research team. At the same timepoints, health providers and other members of the health care team, such as the medical assistants and health coaches, also complete interviews in order to allow the research team to evaluate the success of the program.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
1. Mountain View Clinic- Palo Alto Medical Foundation (USA)
2. Fremont Clinic- Palo Alto Medical Foundation (USA)

When is the study starting and how long is it expected to run for?
December 2010 to June 2015

Who is funding the study?
Gordon and Betty Moore Foundation (USA)

Who is the main contact?
1. Dr Ming Tai-Seale (scientific)
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2. Dr Ellis Dillon (public)
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Contact information

Type(s)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
769702

Study information

Scientific Title
A quasi-experimental prospective evaluation of the CHAMPION chronic care model in a pilot clinic at PAMF

Study objectives
The aim of this study is to evaluate to what degree Champion helps patients who suffer from diabetes and/or hypertension meet clinical targets more quickly, provide more effective coordination of their care, and improve both patient and provider satisfaction with the experience.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sutter Health Institutional Review Board (SHIRB), 09/12/2013, ref: 769702

Study design
Multi-centre epidemiological study

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Hypertension and diabetes

Interventions
This mixed-methods study incorporate direct observation of patient appointments, patient and health care team interviews, patient and physician surveys, and EHR data at baseline and then 6 months and 12 months after implementation.

Physician surveys: A 5-10 minute survey delivered to all primary care physicians in both the clinic implementing Champion and the control clinic at baseline, 6 months and 12 months.

Physician interviews: A 30-60 minute interview with a member of the research team completed by the enough physicians to reach saturation at baseline, 6 months and 12 months. Some physicians were interviewed at each of the 3 stages, while others were interviewed only once or twice.

Appointment observations: A member of the research team recorded and physically observed enough regularly scheduled Champion appointments to reach saturation at baseline, 6 months and 12 months. Some primary care physicians, health coaches, medical assistants and patients had their appointments observed at all 3 stages, while others were only observed once or twice. Champion patients with upcoming appointments were identified and approached in the waiting room prior to their appointment to ask if they would like to participate by having their appointment observed.

Health care team interviews: A 30-60 minute interview with a member of the research team completed by the enough members of the health care team, such as medical assistants and health coaches, to reach saturation at baseline, 6 months and 12 months. Some members of the health care team were interviewed at each of the 3 stages, while others were interviewed only once or twice.

Patient surveys: A 5-10 minutes delivered to all Champion patients in both the clinic implementing Champion and the control clinic at baseline, 6 months and 12 months.

Patients interviews: A 30-60 minute interview with a member of the research team completed by the enough patients to reach saturation at baseline, 6 months and 12 months. Some patients were interviewed at each of the 3 stages, while others were interviewed only once or twice.

Intervention Type
Other

Primary outcome measure
PCP experience with providing chronic care management using appointment observations, interviews, surveys and EHR data at baseline, 6 months and 12 months.

Secondary outcome measures
Patient experience with receiving chronic care management using appointment observations, interviews, surveys and EHR data at baseline, 6 months and 12 months.

Overall study start date
01/12/2010

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Age 18 years or older
2. Male and female
3. Diagnoses: hypertension only; diabetes only; hypertension & diabetes; hypertension & depression; diabetes & depression; hypertension & diabetes & depression

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Accounting for the multiple types of interviewees there are plans to recruit, 30-35 participants (patients, physicians, and clinic staff) may be required per site, per wave (interviews are repeated at intervention sites at baseline, 6 months, and 12 months; at comparison site only once). However, saturation may be reached before conducting 30 interviews, in which case data collection for that wave would cease. The study team intends to interview the same participants in each wave, resulting in a tentative maximum of 70 (30-35 at intervention site; 30-35 at comparison site) participants in the qualitative component of this study. In 2016, there will be 15-20 interviews conducted at Dublin and Danville. For the quantitative portion of this research, the estimated total number of subjects we planned to include is 1,008 (that is, 504 per arm).

Key exclusion criteria
1. Terminal illness
2. Residence in a long-term care facility
3. Severe hearing loss
4. Ongoing psychiatric care for bipolar or schizophrenia, or dementia

Date of first enrolment
13/09/2013

Date of final enrolment
23/12/2014

Locations

Countries of recruitment
United States of America

Study participating centre
Mountain View Clinic- Palo Alto Medical Foundation
701 E El Camino Real
Mountain View
United States of America
94040

Study participating centre
Fremont Clinic- Palo Alto Medical Foundation
3200 Kearney Street
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94538

Sponsor information

Organisation
Palo Alto Medical Foundation Research Institute

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795 El Camino Real
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94301

Sponsor type
Research organisation

Website
http://www.pamf.org/research/

Funder(s)

Funder type
Charity

Funder Name

Gordon and Betty Moore Foundation

Alternative Name(s)
Moore Foundation, GORDON E. & BETTY I. MOORE FOUNDATION, GORDON E. AND BETTY I. MOORE FOUNDATION, Gordon & Betty Moore Foundation, GBMF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
A manuscript titled “Workflow Standardization of a Novel Team Care Model to Improve Chronic Care: a Quasi-Experimental Study” is currently under review by BMC Health Services Research.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to the protocol that was approved by the Institutional Review Board.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2016		Yes	No
Results article	results	19/04/2017		Yes	No