ISRCTN12724749 https://doi.org/10.1186/ISRCTN12724749

A telephone-based case management intervention for patients at risk of high emergency department utilisation in the English NHS

Submission date
23/02/2015

Recruitment status
No longer recruiting

Registration date
05/03/2015

Overall study status
Completed

Last Edited
11/06/2019

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
There is a relatively large group of patients with repeated emergency visits and admissions who use a disproportionate amount of health care resources. Several studies have shown that programmes (interventions) that help people to develop the skills, knowledge and confidence to manage their own health (patient activation) can result in heath improvements, increased quality of life and fewer unplanned contacts with healthcare services without any increases in planned care. We want to test a proactive health coaching protocol designed for patients at high risk of being admitted to an emergency healthcare department. It involves regular and individualized contact with a trained nurse and includes care coordination efforts (where a number of healthcare professionals work together to deliver appropriate healthcare to a patient), advice and training. The overall goal of this study is to investigate whether this health coaching protocol can reduce avoidable use of the healthcare system by frequent visitors to emergency departments.

Who can participate?
Adults that are considered to be at high risk of hospital admissions in the next 6 months according to a risk prediction model.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are allocated a designated health coach. Following an initial assessment, the health coach regularly contacts the patient by telephone while also working with others, such as healthcare providers or social services, in order to improve and integrate care for that patient. Those in group 2 (control group) are not allocated a health coach. Participants in both the intervention and the control group are assessed in terms of how much they use healthcare services over a period of four years.

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

Where is the study run from?
The study is conducted in participation with the NHS Vale of York and NHS Harrow Clinical Commissioning Groups and Hospitals.

When is the study starting and how long is it expected to run for?
February 2015 to April 2023 (updated 11/06/2019, previously: April 2021)

Who is funding the study?
Health Navigator AB (Sweden)

Who is the main contact?
1. Joachim Werr (joachim.werr@healthnavigator.se)
2. Eleitha Medina (eleitha.medina@health-navigator.co.uk)

Contact information

Type(s)
Scientific

Contact name
Mr Joachim Werr

Contact details
Health Navigator AB
Sveavägen 63
Stockholm
Sweden
SE-113 59
+46 70 626 65 71
joachim.werr@healthnavigator.se

Type(s)
Scientific

Contact name
Ms Eleitha Medina

Contact details
One King Street
London
United Kingdom
W6 9HR
+44 79 9973 2622
eleitha.medina@health-navigator.co.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2015-000810-23

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Implementation of a telephone-based case management intervention for patients at risk of high emergency department utilisation in the English NHS

Study objectives
It is possible to reduce the rate of emergency admissions and emergency outpatient visits among patients with a predicted high healthcare utilisation

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London – Bromley, 07/07/2015, ref: 15/LO/0992

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
The study is based among patients deemed to have a high risk of emergency admission

Interventions
Each participant assigned to the intervention group will be allocated a designated health coach. Following an initial assessment, the health coach will be in regular contact with the patient by telephone while also engaging relevant other stakeholders (e.g. health care providers, or social services) with the objective of improving and integrating care for that patient.

Intervention Type
Behavioural

Primary outcome(s)
1. Emergency hospitalizations, ascertained using hospital electronic medical records
2. Emergency hospital outpatient visits, ascertained using hospital electronic medical records

These will be measured at the end of follow-up, i.e. after 2 years.

Key secondary outcome(s))
1. Non-elective bed days, ascertained using hospital electronic medical records
2. Total hospital admissions, ascertained using hospital electronic medical records
3. Total bed days, ascertained using hospital electronic medical records
4. A&E attendances, ascertained using hospital electronic medical records
5. Total health-care costs, ascertained using hospital electronic medical records
6. Patient activation, ascertained using PAM-13
7. Quality of life, ascertained using SF-12

These will be measured at the end of follow-up, i.e. after 2 years.

Completion date
01/04/2023

Eligibility

Key inclusion criteria
1. Patients residing in the studied region
2. Patients 18 years or older
3. Patients considered to be at high risk of non-elective admissions in the next 6 months according to a risk prediction model. The prediction model is based on patient administrative data, and makes an automated risk assessment based on the patient's sex, number of diagnoses (registered diagnoses in the past 2 years), planned and unplanned hospital contacts in the past 6 months and readmissions. The risk assessment is based on a logistic regression model which will be developed and validated specifically for the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients who have had contact with healthcare services within the past six months, and have one or more of the following diagnoses (not necessarily the diagnosis relating to their contacts):
1.1. Dementia
1.2. Psychotic disorders
1.3. Mental disorders caused by misuse
1.4. Terminal cancer

2. Estimated remaining life expectancy of < 1 year
3. Has undergone major surgery in the last six months or planned to undergo major surgery in the foreseeable future
4. Severe hearing loss
5. Language difficulties that require an interpreter
6. Level of cognitive ability which is not sufficient for receiving and responding to telephone counselling
7. Does not have access to a telephone connection

Date of first enrolment
04/05/2015

Date of final enrolment
05/05/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NHS Vale of York
York
United Kingdom
YO30 4GQ

Study participating centre
NHS Harrow
London
United Kingdom
HA1 3AW

Sponsor information

Organisation
Health Navigator AB

Funder(s)

Funder type

Industry

Funder Name
Health Navigator AB (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No