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

| Submission date | Recruitment status | [X] Prospectively registered |
|-------------------|----------------------|------------------------------|
| 23/02/2015 | No longer recruiting | ☐ Protocol |
| Registration date | Overall study status | Statistical analysis plan |
| 05/03/2015 | Completed | Results |
| Last Edited | Condition category | Individual participant data |
| 11/06/2019 | Other | 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

EudraCT/CTIS number

2015-000810-23

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

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

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 measure

- 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.

Secondary outcome measures

- 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.

Overall study start date

01/02/2015

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

Age group

Adult

Lower age limit

Sex

Both

Target number of participants

7000

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

England

United Kingdom

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

Sponsor details

Sveavägen 63 Stockholm Sweden 11359

Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Health Navigator AB (Sweden)

Results and Publications

Publication and dissemination plan

Intention to publish date

01/04/2024

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?HRA research summary28/06/2023NoNo