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Footprints in primary care

Submission date
24/06/2015

Recruitment status
No longer recruiting

Registration date
24/06/2015

Overall study status
Completed

Last Edited
09/04/2020

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
For some patients who attend primary care more significantly than the norm, although they experience persistent symptoms, a cause cannot readily be identified. Often, GPs may feel a pressure to do something and may prescribe medications or refer them for investigations and specialist appointments that they do not need. This may do patients more harm than good and incur unnecessary costs. One general practice has recently taken the initiative to change the way they look after this group of patients. The GPs have received expert training in a technique called BATHE that enhances the therapeutic relationship with their patients. When a patient seeks medical advice, either in a telephone or face-to-face consultation, after obtaining information about their complaint, the doctor applies the technique. The patients report high satisfaction with their care and consulting rates have dropped. We would like to take this model and observe whether it works in a wider range of patients in different types of practices. We also want to find out whether the intervention could be tested in a larger trial.

Who can participate?
Adult patients attending one of the GP practices taking place in the study,

What does the study involve?
Participating GP practices are randomly allocated into either the intervention group or control group. Eligible patients attending a control group GP practice receive normal care. Eligible patients attending a intervention group GP practice receive care via the BATHE technique. Data is collected from practice records and, using a questionnaire, from the patients themselves, about the service they receive over a period of 12 months, related personal costs, and any change in their health. We also record a sample of consultations to see how well the GPs are applying their training and we interview a group of patients and practice staff about their experiences. The results will be used to inform the design of a large study which will provide evidence about the effectiveness and cost-effectiveness of this method of caring for this patient group.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
NHS Bristol, North Somerset and South Gloucestershire Clinical Commissioning Groups (UK)

When is the study starting and how long is it expected to run for?
July 2015 to August 2015

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Rebecca Barnes

Contact information

Type(s)
Scientific

Contact name
Dr Rebecca K. Barnes

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18657

Study information

Scientific Title
Testing the feasibility of a consultation-level intervention for patients in primary care who attend more significantly than the norm with clinically inexplicable symptoms

Study objectives
Some patients attend primary care significantly more often than the norm, despite having no identifiable medical problem to account for this. These patients use considerable NHS resources without necessarily gaining benefit and may even be harmed by over-treatment. This feasibility study will assess whether GP training in BATHE, a rapid intervention for the assessment of psychosocial factors that might be contributing to patients' physical complaints, is an acceptable and potentially cost-effective model to reduce consulting rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West - Central Bristol, 30/05/2015, ref: 15/SW/0085

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care; Subtopic: Primary care; Disease: All Diseases

Interventions
1. Intervention: GP training in the BATHE technique and assignment of eligible patients to a 'usual' GP
2. Control: Treatment as usual

BATHE is an acronym (Background, Affect, Trouble, Handling and Empathy) for an established consultation technique designed to facilitate a more 'whole person' approach. This includes taking into account all aspects of patients' lives that might be having an impact on their health, and supporting self-management

Follow Up Length: 12 month(s); Practices are randomised and eligible patients invited to participate

Intervention Type
Behavioural

Primary outcome measure
The primary outcome measure will be difference in number of consultations (including consultation type), hospital admissions, tests/investigations, referrals and prescriptions extracted from the patient record between baseline and 12 months. items not available from this source will be obtained using a specially designed patient questions to be completed at 6 and 12 months.

Secondary outcome measures
Secondary outcomes to be measured at baseline and 12 months include patient health-related quality of life measured using the EQ-5D-5L; the SF-12 Health Survey; the Patient Health Questionnaire (PHQ-9); the Generalised Anxiety Disorder (GAD-7) scale; the PHQ-15 for monitoring somatic symptom severity; the PAM-13 Patient Activation Measure to measure knowledge, skills and confidence integral to managing one's own health and healthcare; and a patient satisfaction measure based on the GP Patient Survey.

At months 3 and 6 the questionnaire will include the EQ-5D-5L, PHQ-15 and PAM-13 only

At 6 and 12 months, questionnaires will also be used to obtain: information about the use of social services; personal out-of-pocket expenditure by patients and their carers due to their health such as over-the-counter medicine and remedies, travel costs, and expenditure on prescriptions; and wider costs to society such as the use of voluntary services and time off work.

Overall study start date
01/07/2015

Completion date
31/08/2015

Eligibility

Key inclusion criteria
1. Registered patient at one of the study practices
2. Patients aged ≥18 years
3. Within top 3% attenders in the 12 months prior to commencement of records search

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90; Description: 60 intervention, 30 control

Total final enrolment
96

Key exclusion criteria
1. Patients whose attendance can be accounted for by a diagnosed physical or mental illness
2. Patients with life-threatening illness such as cancer

3. Patients over 80 years with 4+medical problems
4. Patients at high risk of hospital admission
5. Patients undergoing distressing one-off events such as bereavement
6. Vulnerable adults and patients without capacity to provide informed consent

Date of first enrolment
01/07/2015

Date of final enrolment
31/08/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NHS Bristol, North Somerset and South Gloucestershire Clinical Commissioning Group
South Plaza, Marlborough Street
Bristol
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BS1 3NX

Sponsor information

Organisation
University of Bristol

Sponsor details
Department of Social Medicine, Canynge Hall , Whiteladies Road
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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/01/2019	21/02/2020	Yes	No
Results article	qualitative study results	03/09/2019	09/04/2020	Yes	No
HRA research summary			28/06/2023	No	No