ISRCTN84692657 https://doi.org/10.1186/ISRCTN84692657

Screening for health problems and emotional distress in GP clinics

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
13/05/2015

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
GPs are encouraged to screen people for health and emotional problems. However, we know little of how people feel about being screened and the impact of screening on their health and well-being.
In order to find this out, we would like to conduct two short interviews with people over the telephone.

Who can participate?
Patients aged 18 and over at the participating 30 GP practices.

What does the study involve?
All participants will be randomly allocated to one of two groups. The participants in one group will be asked screening questions related to health and emotional problems whilst those in the other group will be asked similar questions at the follow-up interview in 7-10 days. The order in which people will be asked questions will be determined in advance at random (by chance). Selecting the order in which people are asked questions at random provides the best possible way for us to find out what, if any, effect this has.

What are the possible benefits and risks of participating?
There is no intended benefit for those people who agree to take part in the study. The main disadvantage of taking part would be the inconvenience of two telephone interviews. These interviews would last no more than 15 minutes and would be held at a time of your choosing. We do not have any evidence that the screening questions you will be asked would cause you any discomfort or distress. However, if the questions cause distress then let us know. A support mechanism is in place.

Where is the study run from?
Imperial College London (UK).

When is the study starting and how long is it expected to run for?
From July 2006 to February 2009.

Who is funding the study?
Brent Primary Care Trust (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0179192264

Study information

Scientific Title
Screening for suicidal ideation: a randomised trial

Study objectives
What are the views of GPs, other primary care workers and patients to screening for suicidal ideation and behaviour?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

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
Mental and Behavioural Disorders: Distress

Interventions
The study involves a multi-method evaluation incorporating three linked components:
A. A survey of 100 GP and other primary care workers working in North and West London
B. A randomised trial examining the impact of screening for suicidal ideation on the subsequent incidence of suicidal ideation
C. A survey of the first 100 patients who participate in the trial

A. Survey of GPs and Primary Care workers
The lead GP in all GP surgeries in Brent and Westminster will be contacted and invited to help with the study. All GPs and primary care nurses working in selected GP surgeries will be invited to complete a short questionnaire in which they are asked their views about screening for suicidal ideation and behaviour among their patients. Arrangements will then be made to recruit up to 15 patients attending each of these surgeries

B. Randomised controlled trial
Patients attending the surgery with non-urgent medical problems will be approached by the GP during the consultation and be given written and verbal information about the study. Patients who agree to be contacted by a member of the research team will be provided with a copy of the Patient Information Sheet, and asked to sign a consent form and a short screening questionnaire to identify whether they have signs of depression (using the screening tool devised by Arroll et al 2003) and provide the researcher with details of how and when they can be contacted. They will also be given a sealed envelope in which they can place the completed questionnaire and the consent form. The sealed envelopes will be collected from the surgeries. Among them, all patients who describe feeling down, depressed or hopeless during the last four weeks or state that they have been bothered by little interest or pleasure in doing things, will be contacted by telephone within one week and asked to consider participating in the study.

Patients who answer no to both screening questions will be contacted to thank them for their help with the study and told that we do not need to ask them any further questions because they do not appear to have symptoms of mental distress. Patients who answered yes to one or both screening questions will be reminded about the aims of the study and asked to confirm their willingness to participate in the study.

Those willing to participate will be asked to complete a short interview over the telephone. The interview will comprise a measure of mental health - the twelve-item General Health Questionnaire (GHQ-12, Goldberg, 1992) followed by either six questions screening either suicidal ideation and behavior (early screening group), or diet and lifestyle (delayed screening group).

Randomisation
Each time a patient agrees to have a baseline interview the researcher will open a pre-prepared sealed opaque envelope that will contain either:
1. Early screening: Six questions on suicidal ideation and behaviour which have been widely used in previous studies of suicidal behaviour among the general public (Meltzer, et al, 2002; Department of Health, 2002; Jenkins et al, 2003). The questions asked are:
1.1 In the last few weeks, have you felt that life was not worth living?
1.2 Have you wished that you were dead - for instance, that you would go to sleep and not wake up?
1.3 Have you thought of taking your life even if you would not really do it?
1.4 Have you seriously considered taking your life?
1.5 Have you attempted to take your life?
1.6 Has any member of your family or someone else you are close to attempted to harm themselves or committed suicide in the past?

2. Delayed screening: Six questions regarding diet and lifestyle (taken from the Preventive Nutrition Project, 2004).

Allocation to questions on suicidal ideation and behaviour at baseline (early screening) and diet and lifestyle at baseline (delayed screening) will be made by simple randomisation using randomisation lists derived from random number tables which are stored on a secure computer. The randomisation ratio for early and delayed screening arms of the trial will be 1 to 1.

Follow-up procedures
Seven to 10 days after completion of the baseline interviews all patients will be contacted by telephone and asked to complete a short (15 minute) interview. The interview will comprise:
1. Screening questions for depression (Arroll et al 2003)
2. Screening questions for suicidal ideation and behaviour
3. An 8-item screening tool to assess personality (SAP-AS, Moran et al, 2003)
4. Questions on level of social support (Stansfeld & Marmot, 1992)

C. Survey of the first 100 patients who participate in the trial
The first 100 patients to be included in the study will also be asked a short series of open-ended questions regarding their feelings and attitudes to being screened for suicidal ideation and behaviour.

References
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2. Department of Health (2002) Ethnic Minority Psychiatric Illness Rates in the Community

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4. Jenkins R, Bebbington P, Brugha T, Farrell M, Gill B, Lewis G, Meltzer H & Petticrew M (2003) The National Psychiatric Morbidity Surveys of Great Britain-strategy and methods. International Review of Psychiatry, 15 (1-2), February-May 2003, 5-13
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7. Preventive Nutrition Project (2004) Department of Family and Preventive Medicine, University of Arkansas For Medical Sciences, 4301 W. Markham St., Little Rock, AR 72205
8. Stansfeld, S.A. & Marmot, M.G. (1992) Deriving a survey measure of social support: the reliability and validity of the Close Persons Questionnaire. Social Science and Medicine 35, 1027-1035.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Level of thinking life is not worth living

Secondary outcome measures
1. Attitudes of GPs and other primary care workers to screening for suicidal ideation and factors that promote and hinder screening in primary care
2. Patients' attitudes about screening for suicidal ideation and behaviour
3. Impact of screening for depression and suicidal ideation on the incidence of feelings that life is not worth living

Overall study start date
01/07/2006

Completion date
01/02/2009

Eligibility

Key inclusion criteria
A. Inclusion criteria (for the randomised trial and patient survey)
1. Aged 18 years and above
2. Willingness to provide written informed consent to participate in the study
3. Have a contact telephone number where they can be contacted for a baseline and follow-up interview 7–10 days after the baseline interview

B. Inclusion Criteria (for the survey among GP and primary care workers): all GP and primary care workers in primary care clinics in north and west London.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
429 patients from 30 GP practices

Key exclusion criteria
Exclusion criteria (for the randomised trial and patient survey):
1. Those who decline to provide consent to participate in the study
2. All those presenting to the surgery for emergency medical problems
3. All those who have insufficient command of English to complete the baseline interview. As one of the researchers is fluent in Hindi, Urdu, Punjabi and Marathi, all patients who can only speak these languages will also be included.

B. Exclusion criteria (for the survey among GP and primary care workers): all those who decline to participate

Date of first enrolment
01/07/2006

Date of final enrolment
01/02/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Claybrook Centre
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W6 8LN

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
Brent Primary Care Trust (UK)

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	01/05/2011		Yes	No