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DEPression in Visual Impairment Trial

Submission date
12/10/2011

Recruitment status
No longer recruiting

Registration date
21/12/2011

Overall study status
Completed

Last Edited
24/02/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The National Institute for Health and Clinical Excellence (NICE) recommends screening high-risk groups for depression. Although there are good reasons for believing that people with a visual impairment are a high-risk group, screening for depression and referral for treatment is not currently part of the service that people receive at a low vision assessment. Therefore, this study aims to establish depression screening and referral for treatment at several optometrists practices across south-east Wales and at St Thomas's Hospital in London. We aim to estimate the prevalence of depressive symptoms in people with a visual impairment and to compare two types of treatment.

Who can participate?
All patients aged 18 and over who attend these optometrists practices during the recruitment period will be asked to complete a depression screening questionnaire and will be asked to take part if they meet certain criteria for the study.

What does the study involve?
Participants are randomly allocated to one of three groups. For one group a letter is sent to the patient's GP informing them that their patient may have a depressive disorder and inviting them to offer the patient assessment and treatment. The second group receive Problem Solving Treatment (PST). This involves a trained psychological therapist working with the patient in their own home or at one of the research centres. The third group are put on a waiting list and referred to their GP after the end of the study (6 months). All participants attend a follow-up appointment with their optician after 6 weeks, and complete a telephone interview before treatment, and 3 and 6 months later.

What are the possible benefits and risks of participating?
There are no known risks to taking part, but some of the interview questions may be emotionally uncomfortable.

Where is the study run from?
Cardiff University (UK).

When is study starting and how long is it expected to run for?
November 2011 to April 2014.

Who is funding the study?
Guide Dogs for the Blind (UK).

Who is the main contact?
Claire Bartlett (née Nollett)
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Study website
http://www.cardiff.ac.uk/optom/depvit

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
DEPression in Visual Impairment Trial

Acronym
DEPVIT

Study objectives

The National Institute for Health and Clinical Excellence (NICE) recommends screening high risk groups for depression and providing treatment according to the 'stepped care' framework. However, although there are good reasons for believing that the prevalence of depression is high in people who access low vision rehabilitation services, screening and referral for treatment is not currently part of the service.

This study aims to establish depression screening and referral for treatment in two centres to:
1. Estimate the prevalence of depressive symptoms in consecutive attendees of low vision services in England and Wales
2. Compare three interventions for newly-diagnosed low vision patients with depressive symptoms in an exploratory randomised controlled trial

We also aim to obtain preliminary information about the cost effectiveness of our interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. South East Wales Research Ethics Committee, 04/05/2011, ref: 11/WA/0014
2. Substantial Amendment No.1, 20/09/2011

Study design
Exploratory multi-centre two-arm and waiting list control randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
http://www.cardiff.ac.uk/optom/research/researchprojects/depvit/depvit.html

Health condition(s) or problem(s) studied
Visual Impairment and depression

Interventions
This trial includes three interventions:
1. Waiting list control
The control arm of this trial will be a follow up low vision assessment 6 weeks after the initial visit (follow up appointments of this type are typical for people who appear depressed or are obviously struggling at the initial low vision assessment) and, referral to the GP stating that the patient has symptoms of depression after the 6 month outcome measure i.e. this is a 'waiting list control'.

2. Referral letter
A follow up low vision assessment visit at 6 weeks plus a letter to the patient's GP , within 2 weeks of randomisation, informing them that their patient has screened positive for a possible depressive disorder and inviting them to offer the patient an assessment and treatment as per the NICE Guidelines for the management of depression. This is a pragmatic intervention and we acknowledge that GPs may or may not adhere to NICE guidelines i.e. we propose to evaluate the impact of the referral, not 'best practice' as described by NICE.

3. Problem Solving Treatment (PST)
A follow up low vision assessment visit 6 weeks plus a 'problem-solving psychological treatment' based on that described by Rovner, Casten et al, (2007). Briefly, this involves a trained psychological therapist working with the patient in their own home or at one of the research centres. Over a 6-8 week period, patients are taught a 7-step method for approaching and solving their problems. The steps are:
3.1. Defining the problem
3.2. Establishing realistic goals
3.3. Brainstorming possible solutions and evaluating the pros and cons of each
3.4. Implementing decision making guidelines
3.5. Choosing a preferred solution
3.6. Implementing the solution
3.7. Evaluating the outcome

The first PST session will take place within 2 weeks of randomisation. The PST intervention will also include additional self-help materials for patients e.g. materials concerning an explanation of depression, a discussion on the importance of treating depression, and a description of the various treatment options as well as vision related sign posting materials.

The follow up period is 6 months.

We are also estimating the prevalence of depression in people attending Low Vision Clinics.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Trial outcomes will be assessed by telephone at the baseline interview, immediately before randomisation, and then again at 3 and 6 months after randomisation.

1. At 3 months, participants in all arms of the study will be interviewed using five outcome measures:
1.1. The Beck Depression Inventory (BDI-II)
1.2. The 7 item Visual Function Questionnaire (7 item NEI-VFQ)
1.3. Near vision subscale of the VFQ-48
1.4. The EQ-5D
1.5. ICECAP capability measures

2. At 6 months the same outcome measures will be used again along with:
2.1. GDS-15

2.2. Client Services Receipt Inventory (CSRI)
In order to minimise 'loss to follow up', interviews will be based on a standard script and will remind participants of their valuable contribution and the need to complete the study.

3. In the exploratory randomised trial the primary outcome measure will be the change in depressive symptoms at 3 and 6 months (before randomisation - 3 & 6 months after randomisation) as measured by the BDI-II. These time intervals were chosen to:
3.1. Examine the short and longer term effects of the interventions
3.2. Coincide with those used in previous studies (Rovner, Casten et al, 2007)
3.3. Minimise the chance that a subsequent depressive episode might impact on outcomes

Secondary outcome measures
1. Change in visual disability between baseline telephone interview and, 3 and 6 months as measured with the 7 item NEI VFQ (Ryan et al, 2008). We have recently used the 7 item NEI VFQ to evaluate functional ability outcomes in hospital and community based low vision services and it has shown itself to be a sensitive outcome measure (Court et al, 2010). Change in visual disability will also be evaluated using the near vision subscale of the VFQ-48 as used by Stelmack et al, (2008) in the LOVIT trial.
2. Change in 'generic health related quality-of-life' at 3 and 6 months as measured by the EQ-5D which assesses 5 health related dimensions i.e. mobility, self-care, usual activities, pain /discomfort and anxiety/depression. NICE recommend the use of the EQ-5D, which can be used to calculate 'utility', as a standardised outcome measure.
3. The proportion of people still screening positive for depression as measured with the GDS-15 at 6 months.

At the end of the trial (6 months):
1. Participants will be asked about any treatments for depression they have received during the trial period (specifically, whether they received regular review and support by their GP, referral to a community mental health team, supportive psychotherapy, counselling, problem-solving therapy, cognitive-behavioural therapy or antidepressant therapy). They will also be asked about the acceptability of this intervention.
2. Participants in the PST arm will be asked about the acceptability of this intervention.
3. Participants in the waiting list control group who still screen positive for depression (GDS-15, 6+) will be referred to their GP. And, 3 months later asked about any treatment for depression received as a result of the referral (as per 1 above).

Overall study start date
01/11/2011

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. Adults (aged at least 18 years)
2. Score of at least 6 on the GDS-15 (administered as part of the routine pre assessment questionnaire)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000 attendees will be screened, anticipated 1/3 will be eligible, of those, about 100 will consent to take part (recruitment will be capped at 150)

Key exclusion criteria
1. Those who have already had a low vision assessment within the previous 12 months
2. Those who are referred to the clinic in error (i.e. so visually impaired that low vision care and follow up are inappropriate or, so visually able (e.g. following refraction) that there are no low vision needs)
3. Those already being treated for depression including psychotherapeutic and psychopharmacological treatments
4. Inability to understand English
5. Inability to use the telephone e.g. caused by very poor hearing
6. Severe medical illness that would preclude participation in a 6 month study
7. A score of 2 or 3 on the BDI-II question about suicidal ideation. All people in this group will be urgently referred to their GP (See Appendix N for referral protocol)
8. Those screening positive for significant cognitive / memory problems will be excluded (see Appendix I for cognitive screening instrument / scoring key)

Date of first enrolment
01/11/2011

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
Guide Dogs for the Blind (UK) ref: OR2009-07b

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?
Protocol article	protocol	06/06/2012		Yes	No
Results article	results	01/02/2016		Yes	No
Results article	results	17/01/2019		Yes	No