ISRCTN58561170 https://doi.org/10.1186/ISRCTN58561170

Psychological Advocacy Towards Healing (PATH): To determine if a psychological intervention delivered by domestic violence advocates is effective and cost-effective

Submission date
26/07/2011

Recruitment status
No longer recruiting

Registration date
26/07/2011

Overall study status
Completed

Last Edited
28/11/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.provide.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Gwen Brierley

Contact details
Academic Unit of Primary Health Care
School of Social and Community Medicine
Canynge Hall
39 Whatley Road
Bristol
United Kingdom
BS8 2PS
-
gwen.brierley@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10429

Study information

Scientific Title
An individually randomised, parallel group controlled trial to determine if a psychological intervention delivered by domestic violence advocates is effective and cost-effective: Psychological Advocacy Towards Healing (PATH)

Acronym
PATH

Study objectives
The Psychological Advocacy Towards Healing (PATH) Study is an individually randomised two-arm controlled trial of a psychological intervention delivered by domestic violence advocates to women entering specialist domestic violence and abuse (DVA) services in Bristol and Cardiff respectively. Participants in the intervention arm will receive weekly specialist psychological advocacy sessions for 8 weeks and 2 reinforcement sessions over the subsequent 3 months. They will be followed up with questionnaires measuring violence, quality of life and mental health measures up to one year after recruitment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West 4 approved on 08/03/2011 ref: REC 10/H0102/86

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: Mental Health

Interventions
Control Intervention: Routine care from domestic violence agency

Experimental Intervention: Routine care from domestic violence agency plus additional psychological support (8 one-to-one session with specialist psychological advocate plus two 'booster' sessions).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Clinical Outcomes in Routine Evaluation - Outcome Measure (CORE-OM); Timepoint(s): 4, 8 & 12 Months

Secondary outcome measures
1. Composite Abuse Scale (CAS); Timepoint(s): 4, 8, & 12 Months
2. EuroQoL EQ5D; Timepoint(s): 4, 8 & 12 Months
3. Generalised Anxiety Disorder (GAD-7); Timepoint(s): 4, 8 & 12 months
4. Patient Health Questionnaire (PHQ9); Timepoint(s): 4, 8 & 12 Months
5. Post-traumatic diagnositc scale (PDS); Timepoint(s): 4, 8 & 12 Months
6. Short form 12 (SF12); Timepoint(s): 4, 8 & 12 Months

Overall study start date
28/03/2011

Completion date
28/09/2012

Eligibility

Key inclusion criteria
Female, aged 16 years or older. Target Gender: Female ; Lower Age Limit 16 years

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 250; UK Sample Size: 250

Key exclusion criteria
1. Psychotic illness
2. Unable to read English
3. Severe current drug or alcohol abuse
4. Currently attending counselling, cognitive beahviour therapy (CBT) or other psychological treatments either in primary care or specialist psychiatric services

Date of first enrolment
28/03/2011

Date of final enrolment
28/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Unit of Primary Health Care
Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
University of Bristol (uk)

Sponsor details
School of Social and Community Medicine
Canynge Hall
39 Whatley Road
Bristol
England
United Kingdom
BS8 2PS

Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (Grant Codes: RP-PG-0108-10084)

Results and Publications

Publication and dissemination plan
2015 results presented at Oxford 2015 - Evidence and innovation in primary care https://sapc.ac.uk/conference/2015/abstract/womens-experience-of-meaningful-change-following-domestic-abuse-qualitative

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	17/07/2013		Yes	No
Results article	results	27/11/2018		Yes	No