

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

☐ Prospectively registered

☒ Protocol

Registration date

26/07/2011

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

28/11/2018

Condition category

Mental and Behavioural Disorders

☐ 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

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Contact details

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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 diagnostic 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 behaviour 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

Canynges 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