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PARTNERS2: A cluster randomised control trial of a model of collaborative care for people with a diagnosis of bipolar, schizophrenia or other psychoses

Submission date
16/10/2017

Recruitment status
No longer recruiting

Registration date
26/10/2017

Overall study status
Completed

Last Edited
21/11/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Schizophrenia, bipolar and other psychosis are types of severe mental illness. Mental illness is the single largest cause of disability in the UK, contributing up to 22.8% of the total burden. These conditions lead to economic costs as a result of lost productivity and service costs. Furthermore, these conditions lead to poor physical health outcomes for those affected, as a result of increased prevalence of comorbid health conditions in these populations and a severely reduced life expectancy, believed to be up to 20 years shorter than the general population. Many people with a diagnosis of schizophrenia, bipolar and other types of psychosis have minimal and poorly coordinated primary and specialist care. PARTNERS2 aims to help primary care (GPs and Practices Nurses) and community mental health services (also called CMHTs) work more closely together by developing a system of collaborative care based in GP surgeries. Although primary care provides support to people with mental health problems, the coordination with secondary care is challenging in many areas of the country. Service user feedback states that some GPs do not contain sufficient specialist knowledge to support schizophrenia, bipolar and other psychosis; practitioners report the same knowledge and skills gap in primary care. It is hoped that by introducing someone who is trained in secondary mental health care, such as a psychiatric nurse, into general practice, will help improve care of people with these conditions. The mental health specialist, known as a 'Care Partner', will work with other health care providers, service users, their carers, friends and family as a team. The Care Partner will use methods such as coaching, motivational strategies and work with general practice staff to address individuals' emotional, social and physical needs in a co-ordinated way. The aim of this study is to examine if this programme will enhance primary mental and physical health care provision and deliver better outcomes for individuals and their families.

Who can participate?
Adults aged 18 and older with schizophrenia, bipolar or other types of psychosis.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive their usual care. Those in the second group work with a care partner who are based in their primary care centre. The Care Partner works to provide support for physical, mental and social health using a coaching goal-setting model. The Care Partner works with the participant for 12 months meeting on a regular basis. Both groups of participants will complete measures at month 0 and month 10, which seek to understand their state of wellbeing, quality of life, mental and physical health. Health economics measures will also be utilised to look at the costs of this new service. Results between the two groups will then be compared to see if the new service is beneficial and cost effective.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in the planning of their care. There are no direct risks with participating.

Where is the study run from?
This study is being run by the University of Birmingham and takes place in at GP sites filtering into Birmingham and Solihull Mental Health Foundation Trust, Livewell South West, Cornwall Partnership NHS Foundation Trust, or Somerset Partnership NHS Trust. They are part of CRN West Midlands and CRN South West Peninsula.

When is the study starting and how long is it expected to run for?
October 2016 to May 2021

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

Who is the main contact?
Dr Humera Plappert
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36484

Study information

Scientific Title
The PARTNERS2 Study: Trial of primary care based collaborative care for people with a diagnosis of schizophrenia, or bipolar or other types of psychosis

Acronym
PARTNERS2

Study objectives
The aim of this study is to determine the feasibility, effectiveness, safety and acceptability of a primary care based collaborative care model for adults in England with a clinical diagnosis of schizophrenia, bipolar, or other types of psychosis [diagnostic clusters 11 and 12] .

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands-Edgbaston REC, 29/06/2017, ref: 14/WM/0052

Study design
Randomised; Interventional; Design type: Treatment, Process of Care, Psychological & Behavioural, Management of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Schizophrenia, bipolar disorder or psychosis

Interventions

Current interventions as of 22/12/2020:
Cluster randomisation is done at GP Practice level. Participant numbers are across four localities: Birmingham and Solihull Mental Health NHS Foundation Trust, the South-West (Cornwall Partnership NHS Foundation Trust and Livewell South West) and Somerset Partnership NHS Trust. Recruitment is phased, each participant in the intervention arm receive up to 12 months of intervention, the entire intervention phase is expected to be 24 months. Participants are allocated to either the intervention or control group.

Intervention group:
Those in the intervention arm work with a Care Partner (a secondary care mental health worker) who are based in primary care with the participants' GP practice. The Care Partner work to provide collaborative physical, mental, and social health for the participant using a coaching goal-setting model. The Care Partner work with each participant for 12 months, meeting on a regular basis. As the model is individualised care, the frequency of meeting will vary. The collaborative care intervention works by structural change that supports care partners to be able to work across primary and secondary care. It also provides information and knowledge through a manual and protocols, training, supervision, structured monitoring and assessment and the context of primary care. It aims to improve the relationship between the care partner and the patient, involving ongoing development of shared understanding and coaching to help the patient be more confident and proactive about their health.

Control group:
Participants in the control arm of the trial continue with their usual care are managed solely by their own GP and primary care practice staff and with secondary care specialist mental health services (if required). Crucially, they do not receive any contact with the PARTNERS care partner.

Follow up of participants in both arms of the trial takes place at month 10. Some participants are invited to take part in the process evaluation.

The primary outcome for the randomised control trial is the change in quality of life. The secondary outcome measures are personal recovery, time use, experience of care, physical health and capability, health economics, mental wellbeing and safety variables (Admissions: number of admissions and total days in patient, Crisis care: number of episodes under home treatment team and total days under home treatment team). There is also an process evaluation.

Previous interventions from 28/10/2020 to 22/12/2020:
Cluster randomisation is done at GP Practice level. Participant numbers are across three sites: Birmingham and Solihull Mental Health NHS Foundation Trust, the South-West (Cornwall Partnership NHS Foundation Trust and Livewell South West) and Somerset Partnership NHS Trust. Recruitment is phased, each participant in the intervention arm receive up to 12 months of intervention, the entire intervention phase is expected to be 24 months. Participants are allocated to either the intervention or control group.

Intervention group:
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across primary and secondary care. It also provides information and knowledge through a manual and protocols, training, supervision, structured monitoring and assessment and the context of primary care. It aims to improve the relationship between the care partner and the patient, involving ongoing development of shared understanding and coaching to help the patient be more confident and proactive about their health.

Control group:
Participants in the control arm of the trial continue with their usual care are managed solely by their own GP and primary care practice staff and with secondary care specialist mental health services (if required). Crucially, they do not receive any contact with the PARTNERS care partner.

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Previous interventions:
Cluster randomisation is done at GP Practice level. Participant numbers are across three sites: Birmingham and Solihull Mental Health NHS Foundation Trust, Blackburn with Darwin (Lancashire Care NHS Foundation Trust) and the South-West (Cornwall Partnership NHS Foundation Trust and Livewell South West). Recruitment is phased, each participant in the intervention arm receive up to 12 months of intervention, the entire intervention phase is expected to be 24 months. Participants are allocated to either the intervention or control group.

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number of admissions and total days in patient, Crisis care: number of episodes under home treatment team and total days under home treatment team). There is also an process evaluation.

Intervention Type
Behavioural

Primary outcome measure
1. Feasibility of the study is measured using practice recruitment rates, patient eligibility rates (via screening logs), patient recruitment rates, patient retention rates
2. Quality of life will be measured at baseline and 10 months using Manchester Short Assessment of Quality of Life (MANSA)

Secondary outcome measures
1. Time Use is measured using modified ONS Time Use Survey (TUS) at baseline and 10 months
2. Recovery is measured using Questionnaire about the Process of Recovery (QPR15) at baseline and 10 months
3. General health status is measured using EuroQol (EQ-5D-5L) at baseline and 10 months
4. Mental wellbeing is measured using Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline and 10 months
5. Capability measured are measured using ICEpop CAPability measure (ICECAP) at baseline and 10 months
6. NHS resource use is measured using the Mental Health Trust records at 10 months
7. Experience of care is measured using BriefINSPIRE at baseline and 10 months
8. Costs of NHS and social care service use is measure using using review of medical records at 10 months

Overall study start date
01/10/2016

Completion date
01/05/2021

Eligibility

Key inclusion criteria
1. Registered with a participating GP practice
2. Aged 18 years and over
3. A clinical diagnosis of schizophrenia, bipolar, or other types of psychosis schizoaffective disorder (including lifetime and current) or has evidence of chronic psychoses [care clusters 11 and 12]

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 204; UK Sample Size: 204

Total final enrolment
198

Key exclusion criteria
1. Inability to understand and complete questionnaires
2. Inability to understand English (or access to translation services)
3. Inability to give informed consent
4. Currently receiving crisis care or care in a secure setting

Date of first enrolment
07/11/2017

Date of final enrolment
28/02/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
Birmingham and Solihull Mental Health Foundation Trust

Sponsor details
National Centre for Mental Health,
The Barberry Centre,
Research and Innovation Department
25 Vincent Drive
Birmingham

England
United Kingdom
B15 2FG
+44 121 301 4343
emma.patterson@bsmhft.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00cjeg736

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
Future publication and dissemination is to be finalised but will include planned publication in a high-impact peer-reviewed journal around one year after the overall trial end date. We will be publishing the protocol once the trial registration number is available.

Intention to publish date
07/05/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Richard Byng (Richard.byng@plymouth.ac.uk). Details about the data and access criteria will be made available later.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	qualitative formative evaluation	07/01/2019	20/11/2019	Yes	No
Protocol article		30/06/2021	27/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article	epidemiological medical records review	15/02/2021	21/11/2023	Yes	No
Results article	outcome measures	20/04/2023	21/11/2023	Yes	No