Collaborative care intervention for individuals with severe mental illness: the PARTNERS2 programme including complex intervention development and cluster RCT

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Scientific summary

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Scientific summary

Background

People with a diagnosis of schizophrenia, bipolar or other psychoses have a significantly reduced life expectancy; two-thirds of this mortality gap can be explained by physical health disparities. For many people with severe mental illness, about 1% of the population, their primary and secondary mental health care is delivered by separate teams, causing a negative impact on continuity of care. The PARTNERS1 study found that nearly one-third of people with severe mental illness in the UK were seen only in primary care, and other studies show that more than a half of individuals receive no specialist input. A significant policy shift in the UK prioritises the better integration of place-based mental health systems involving primary and secondary care, the voluntary sector and local authorities.

Collaborative care is a system of care that includes clinicians from primary and secondary care working together, proactive review and psychological support. Previous studies have mostly included populations with depression and anxiety, who have different challenges from individuals with serious mental illness. Most of the work on collaborative care for serious mental illness has been in the USA, where the nature of service user populations and of service use differ from the way we fund, structure and use the NHS. Research into effectiveness is, so far, equivocal.

Aims, objectives and summary of approach

The aim of the PARTNERS2 research programme was to co-develop and evaluate a model of collaborative care for people diagnosed with schizophrenia, bipolar and other forms of psychosis in addition to usual care, in comparison with usual care alone. The programme was carried out between 2014 and 2021, adapting according to circumstances, and included:

Phase 1: development work (2014–7) –

- describing the context of current care delivery by assessment of support provided to people with SMI in three areas of England, including investigation of collaborative care evidence (workstream 1)
- developing a theoretical model of the intervention (workstream 3)
- developing trial methodology (workstreams 2, 4 and 5).

Phase 2: full trial and process evaluation (2017–21) (workstream 6) –

- a randomised controlled trial
- a health economics analysis
- a parallel process evaluation to examine fidelity, evaluate process of delivery and further develop the programme theory for implementation.

The programme was co-produced with our patient and public involvement team, including the Lived Experience Advisory Panel. The originally planned external pilot trial was replaced with an internal pilot trial feeding into a fully powered randomised controlled trial.

Phase 1

Understanding context

Method

- An observational retrospective cohort study of primary and secondary care medical notes (2012–4). A total of 297 participants with serious mental illness under a specialist were selected from three participating mental health services (West Midlands, Lancashire and Devon).
- An update of our original Cochrane review 'Collaborative care approaches for people with severe mental illness'.

Results

From the notes review activity, we found that for individuals with serious mental illness who are in contact with secondary mental health services, these services are centrally involved in their care. On average, three-quarters of all direct contacts were from secondary care, and individuals were seen on average every 2 weeks. These individuals were also seen on average every 6 weeks in primary care. However, a significant minority (12%) did not receive any specialist care.

The Cochrane update comprised 8 randomised controlled trials, with a total of 1165 participants for review. The trials provided data for comparison between collaborative care and standard care. Collaborative care interventions varied a lot. There was no evidence that they are more effective than standard care; however, confidence in these findings is limited.

Development of the intervention

Method

A realist informed approach was taken to identify underlying mechanisms and to integrate findings as an initial model from:

- a review of the literature on collaborative care for mental health (from workstream 1) and personal recovery literature
- interviews with key leaders in collaborative care and personal recovery to explore their perceptions about best practice (n = 11)
- focus groups with service users about their experiences of care (n = 33).

The intervention was delivered by care partners at the three sites to those recruited for pilot work. A formative evaluation of this initial model used semistructured interviews with practitioners, service users, carers, general practitioners and secondary care practitioners along with recordings of interactions to adapt the intervention.

Results

Researchers extracted 'explanatory statements' representing candidate mechanisms that could make collaborative care effective. These were consolidated to 106 statements and used to develop the programme theory for the initial model. This was represented graphically and in a manual for practitioners and in guides for service users and carers.

The PARTNERS intervention involves change at three levels: institutional level (secondary care trusts/ Community Mental Health Teams and primary care), practitioner level (care partners, supervisors, other primary and secondary care staff, third-sector and community organisational staff) and service user level (service users and friends and family, where there was consent). The manual details how practitioners should work flexibly to provide person-centred care through a coaching approach.

The formative evaluation found that some aspects of implementation were not always delivered as expected, particularly interaction with primary care teams, the use of coaching and the supervision of practitioners. The model was further refined based on these results, with added training and support for the care partners in the main trial.

Development of trial methodology

Method

A core outcome set was developed for bipolar using three stages and with Lived Experience Advisory Panel input:

- A long list of outcomes was derived from focus groups with people with a bipolar diagnosis and their carers, interviews with healthcare professionals and a rapid review of outcomes used in trials.
- An expert panel with personal and/or professional experience of bipolar participated in a two-stage online Delphi survey, with 50 participants in round 1 and 33 in round 2.
- A consensus meeting was held to finalise the core outcome set.

Outcomes and associated measures for the randomised controlled trial were selected using a further consensus meeting, which took into account the wider population and nature of intervention.

The feasibility of trial processes was tested in the formative evaluation study. Different methods of approaching potentially suitable individuals using primary and secondary care databases, and involving practitioners, were tested. These took into account legal and research governance requirements while prioritising an ambition to include those individuals considered most likely to benefit from support.

Results

The Delphi survey included 66 outcomes, and participants were invited to add others. A consensus meeting generated the final core outcome set consisting of 11 outcome domains: personal recovery; connectedness; clinical recovery of bipolar symptoms; mental health; well-being; physical health; self-monitoring and management; medication effects; quality of life (QoL), service outcomes; service user experience of care; and use of coercion.

Quality of life was selected as the most important outcome domain for the proposed PARTNERS2 trial. The Manchester Short Assessment of Quality of Life (MANSA) was selected because it was clinically relevant to the target population and potentially amenable to change by the intervention.

To test approach procedures, we recruited 37 participants across three sites. Those eligible from secondary care were approached by a clinician known to them. Those seen in primary care received an invitation letter with an expression of interest from the general practitioner practice. Two strategies were tested to improve recruitment among those who did not respond to initial contacts:

1. a telephone call from a clinician or the research team to discuss the study
2. an 'appointment letter' inviting them to a short meeting at the practice to discuss the study.

Both approaches were acceptable to participants and added to recruitment.

Phase 2

Internal pilot and randomised controlled trial

Method

The cluster randomised trial recruited in four areas (Birmingham and Solihull, Cornwall, Plymouth and Somerset), involving 39 general practices. In total 198 participants were recruited, and practices

were randomised (1 : 1 allocation) so that individuals received either the PARTNERS intervention (20 practices, 116 participants) or usual care only (19 practices, 82 participants). The PARTNERS intervention involved a trained secondary mental healthcare worker in primary care (a 'care partner') working collaboratively with the participant, primary care, secondary care and other organisations, aiming to improve the participant's QoL, mental health and physical health care. Participants received the intervention for up to 12 months, including a 2-month transition period back to usual care only. During the COVID-19 pandemic, the intervention was moved online (using telephone calls and video conferencing). All participants allocated to the control arm of the trial continued to receive usual care, either within primary care only or also with secondary care.

At baseline, the following data were collected: QoL (MANSA), Time Use Survey (ONS TUS), general health status (EuroQol-5 Dimensions, five-level, Warwick–Edinburgh Mental Wellbeing Scale), capability measure (ICEpop CAPability) and experience of care (Brief-INSPIRE). All assessments were completed again at the follow-up visit (10 months from the point of unmasking), as was an extra questionnaire on the impact of COVID-19 for participants recruited during the pandemic.

Results

Primary outcome data were available for 99 (85.3%) intervention and 71 (86.6%) control participants. Mean change in overall MANSA score did not differ between the groups [0.25 (standard deviation 0.73) for intervention vs. 0.21 (standard deviation 0.86) for control]; the estimated fully adjusted between-group difference was 0.03 (95% confidence interval −0.25 to 0.31; $p = 0.819$). None of the secondary outcomes differed significantly between the groups. Acute mental health episodes (safety outcome) included three crises among those who received the intervention and four among those who did not.

Cost effectiveness analysis

Methods

The economic evaluation aimed to estimate the cost-effectiveness of PARTNERS2 compared with usual care. Quality-adjusted life-years measured health benefit. Patient-level service use data were costed using national unit costs for 2019–20. The primary outcome was the incremental cost-effectiveness ratio, which combines service use costs and health benefit. Participant-reported service use at follow-up was collected for a 3-month recall period. The planned audit of primary and secondary care notes was not feasible given the impact of the COVID-19 pandemic. Regression analysis estimated the net costs and quality-adjusted life-years of PARTNERS2, adjusting for key covariates.

Results

Using the multiple imputed data, the average quality-adjusted life-years (usual care: mean 0.55, 95% confidence interval 0.48 to 0.61; PARTNERS2: mean 0.51, 95% confidence interval 0.45 to 0.57) and costs (usual care: mean £2689, 95% confidence interval £999 to £4378; PARTNERS2: mean £1743, 95% confidence interval £1149 to £2338) were similar for the two groups. Overall, the 95% confidence intervals are wide and overlap, indicating a high level of variance and uncertainty. The net, bootstrapped quality-adjusted life-years (−0.007, 95% confidence interval −0.086 to 0.071) and costs (−£213, 95% confidence interval −£1030 to £603) were similarly inconclusive, with wide 95% confidence interval that overlapped zero. At the prespecified willingness-to-pay threshold of £15,000 to gain one additional quality-adjusted life-year, the probability that the PARTNERS2 intervention is cost-effective is <50%.

Process evaluation

A mixed-methods realist process evaluation aimed to assess fidelity, evaluate the processes that may impact on the understanding of care partners' behaviour over time, and further develop the programme theory for implementation.

Method

- An analysis of records to quantify intervention delivery.
- A fidelity analysis of a structured questionnaire on the components of care received.

A multiperspective, realist-informed, qualitative analysis of the following data was undertaken:

- semistructured interviews with 8 care partners, 13 service users, 4 supervisors, 9 health-care professionals, 4 PARTNERS2 researchers and 1 carer
- recordings of 10 intervention sessions between care partners and service users, followed by tape-assisted recall interviews with 4 care partners and 10 service users
- audio-recorded supervision sessions with care partners and supervisors.

Eight in-depth case-studies with care partners and 15 in-depth case studies with service users were constructed. A substudy was conducted to explore delivery during the COVID-19 lockdown.

Results

Intervention delivery was suboptimal. While 91% of participants in the intervention group received at least one contact and 87% had goals assessed, in five practices care partners were present for < 70% of the intervention period. During delivery in COVID-19 pandemic conditions, contact rates were maintained.

Fidelity to the PARTNERS model was more likely to have occurred with interpersonal practices [e.g. 70 out of 79 (89%) participants said that their care partner really listened to and understood them] than with liaison activities [e.g. 17 out of 32 (53%) participants said that their care partner linked them up to the general practitioner].

Practitioners delivering collaborative care coaching needed time to understand the model and make changes to their practice. Practitioner previous experience could act as a barrier to working collaboratively with service users but as a facilitator of collaborating with other professionals. Service users valued having a 'professional friend'. Some described improved confidence in themselves, particularly where coaching was tailored to their preferences, including how far they were 'pushed'. However, it was not possible to track QoL improvements.

Discussion

Study strengths and limitations

This study encountered several significant challenges over the course of 7 years, which impacted on the delivery of the PARTNERS2 cluster randomised controlled trial. We lost sites; care partners left or went on sick leave, leaving gaps in delivery; and, finally, COVID-19 affected the final phase of intervention delivery and follow-up data collection. We did have a substantial PPI programme, and our LEAP involvement was consistent throughout, including in developing the model we tested. Key successes were the iterative development of theory, methodological innovations for complex intervention evaluation, an in-depth quantitative description of standard care, the development of a COS for bipolar and adaptions for online delivery during the COVID-19 pandemic.

Recruitment to the trial was initially inconsistent and lacked racial and ethnic diversity. Follow-up under COVID-19 conditions was good. Although the intervention was designed to be flexible according to need, this level of flexibility was greater than intended, and this in part was due to significant periods when care partners were unwell or not in post, as well as individuals not engaging with the intervention offer.

Conclusions

The PARTNERS2 trial produced a neutral result. People with serious mental illness did not experience better outcomes (including QoL) from working with a care partner using standard outcome measures during delivery of the PARTNERS intervention between 2018 and 2020. Although the trial was not powered to assess non-inferiority, participants did not receive worse outcomes and safety concerns did not arise. The process evaluation helped us to understand the weaknesses in our delivery model, including suboptimal supervision arrangements. It showed that some participants did make changes to their thinking and actions in response to support; however, the lack of evidence of lasting changes in QoL is in keeping with the randomised controlled trial results. It is unclear whether a more flexible or more prolonged PARTNERS intervention would lead to modest changes over time. Training and ongoing support to deliver the important but difficult aspects of shifting to a person-centred approach and liaising with other services was appreciated, but this needs further development in the context of ongoing community mental health transformation.

Trial registration

This trial is registered as ISRCTN95702682.

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