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Results of a multicentre study to assess feasibility, acceptability, and effectiveness of TRIumPH (Treatment and Recovery In PsycHosis): Integrated Care Pathway for Psychosis

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Abstract

Objectives: We evaluated TRIumPH (Treatment and Recovery In PsycHosis), a co-produced integrated care pathway that prescribes standards for access and interventions in first episode psychosis. This was a pragmatic, non-randomised, mixed methods study comparing an intervention (pathway) and comparator site to assess feasibility, acceptability and effectiveness of an integrated care pathway for psychosis

Setting: NHS Early Intervention in Psychosis (EIP) teams, one pathway implementation site and one comparator organisation.

Participants: All patients accepted into EIP services between 1 June 2014 – 31 May 2017 were followed up for one year.

Outcome measures:. The controlled trial has evaluated the effect of TRIumPH (Intervention) with Care As Usual (Comparator). Quantitative data collection consisted of treatment, process and symptom measures to assess adherence to the features of the pathway and change against the comparator group. Qualitative measures consisted of questionnaires, interviews and focus groups to assess acceptability and satisfaction.

Results: Outcome measures were assessed at baseline, 12 and 24 months to measure if there was an effect and if so, whether this was sustained over time. Improvements in achievement of access and quality standards and time frames occurred in the pathway area from a generally low baseline.

Conclusions:

Improvements in achievement of access and quality standards and time frames occurred in the pathway area from a generally low baseline.

Strengths and Limitations

- Robust methodology used for development of the pathway
- This is the first and only evaluation of a psychosis care pathway
- Baseline differences between the areas affected interpretation of the results
- Results will be generalizable to NHS and managed care organisations
- Financial and human resource limitations may have impact on results

Study registration: UK Clinical Research Network Portfolio: 19187

Keywords: Integrated Care Pathway, psychosis, access, early intervention, co-production

Word count: 3572

Background

Schizophrenia is listed as the 8th leading cause of DALYs worldwide in the age group 15 - 44 years in the World Health Report[1]. In addition to the direct cost, there is a considerable burden on the relatives[2]. Life expectancy is reduced by approximately 15-20 years, mostly because of physical health problems[3].

The longer the duration of psychosis prior to the start of treatment (DUP), the worse the outlook especially for social functioning and recovery[4,5]. DUP is the strongest predictor of symptom severity and prognosis[6]. Evidence from trans-cultural and international research suggests that DUP ranges between 364 and 721 days[5,6] and so reducing DUP is of individual, national and international importance[1].

The UK government strategy 'No Health Without Mental Health' acknowledged that more must be done to address the disparity in care for people experiencing psychosis. It highlighted the importance of prevention, early detection, and support for evidence-based models such as Early Intervention in Psychosis (EIP) services. The National Access and Waiting Time (AWTS) standard for psychosis[7] announced in the UK from 1 April 2016 required that more than 50% of people experiencing a first episode psychosis should commence a NICE (National Institute of Health and Care Excellence) recommended package of care within two weeks of referral to secondary care services. The Five Year Forward View (NHS England)[8] recommended development of standardized care pathways for every major mental health condition.

Evidenced-based integrated pathways provide a standardized framework for good clinical practice, reduce variation in care and have improved outcomes for patients

through providing timely access and intervention. Standardized pathways improve quality by improving multidisciplinary communication with different care agencies using care planning, and improve patient satisfaction[9]. NICE has formulated quality standards for treatment of schizophrenia and psychosis[10], but does not prescribe timeframes.

TRIumPH (Treatment and Recovery In PsycHosis) is an integrated care pathway for psychosis that prescribes time frames around access and clinical interventions as developed in the UK[11]. The work has used a similar approach to that taken to improve care in other health areas like stroke care, where there has been a demonstrable improvement in outcomes for patients and carers. This new psychosis pathway aims to reduce the impact of disease and promote recovery by ensuring that every individual gets the best evidence-based care at the right time and in the right place.

In developing the pathway, a multi-pronged approach has been used, using i) intelligence from information, ii) co-production with individuals with lived experience of mental illness and their carers, and iii) engagement with clinicians and other stakeholders including commissioners, primary care and third sector organisations. The approach has used a robust methodology which can be adapted and adopted nationally and internationally[12].

Therefore, the pathway goals are to treat the symptoms as early as possible, provide skills to patients and their families, maintain the improvement over a period, prevent relapses and reintegrate the individuals into the community so that they can lead as normal a life as possible.

Study objectives

The objective of this study was to assess the feasibility, acceptability and effectiveness of the TRIumPH psychosis care pathway.

Methods

Study design

This is a mixed method pragmatic and non-randomised study comparing the intervention (pathway) and comparison area (that had treatment as usual) to evaluate feasibility, acceptability and effectiveness of an integrated care pathway, TRIumPH for psychosis. Both qualitative and quantitative data were collected and analysed. Ethics approval was obtained from East of Scotland Research Ethics Service (REC Ref no: LR/15/ES/0091).

Setting

The study originally had Early Intervention in Psychosis (EIP) teams from two pathway implementation and two comparator organisations. However, one pathway and one comparator site withdrew in the early stages due to an inability to provide necessary data.

The NHS Trust implementing the pathway covers a population of 1.3 million and has four EIP services. The comparator trust covers a population of 780 000 and had two EIP teams initially which were amalgamated during the study period. The areas were predicted to have an incidence of psychosis, respectively, of 110 and 54 patients (Psymaptic.org). The EIP teams were working to principles originally set out in the NHS Plan (2000).

The intervention

TRIumPH is an integrated care pathway for psychosis that emphasises the importance of timely access and interventions (see Diagram 1). The development, design and details of this pathway have been described in detail in the protocol paper[12].

Comparator area

Participants in the comparator area received treatment as usual (TAU). TAU had been variable in different organisations as some had EIP teams and some did not. It usually consisted of care coordination and out patient appointments when needed. Access to psychological treatments and physical health interventions had been variable. The Access and Waiting Time target was launched in April 2016 after the study started and will have influenced treatment as usual in each area.

Patient and Public Involvement

Co-production workshops were held with patients, carers and clinicians to develop the pathway and key outcomes areas and a service user researcher sat on the study team. For further details see the previously published protocol[12].

Outcome measures

Feasibility and acceptability were assessed through both qualitative and quantitative data collection regarding recruitment, retention and adherence to the process. This included timeliness of access and intervention, type of intervention offered including medication, physical health assessment (within 3 months in accordance with NICE

quality standard), psychological intervention (within 6 months), and others. The reasons for deviation from the pathway were recorded. Additionally, satisfaction and acceptability were assessed using questionnaires, interviews and focus groups. This consisted of the following qualitative methods; patient experience (using specifically designed patient experience focus groups/interviews), staff experience (staff questionnaires and focus groups designed to measure the impact of the pathway on staff experience), and carer experience (using carer focus groups/interviews).

Effectiveness was assessed through data collection in the following areas; process outcomes, physical health measures, acute care usage, interventions offered, clinical, functional and recovery outcomes. Impact of pathway on functioning and recovery outcomes (e.g. physical health), clinical outcomes (Health of Nation Outcome Scores - HoNOS), change in service use (e.g. routinely collected data on crisis, admissions, detentions, Emergency Department attendances) was collected.

All outcome measures were assessed at baseline and after 12 and 24 months (except patient and carer experience which was at 12 and 24 months).

Sample size

As this is a prospective, feasibility study, no a priori power and sample size calculations were performed or required as data for all available patients and staff during the study period was used.

Data Collection

Baseline data was collected for the period 1 June 2014 – 31 May 2015. The pathway was launched on 1 June 2015 and disseminated to four EIP teams in the intervention organisation. Data was collected over the subsequent two-year period on every patient that was referred to and accepted by the EIP teams in participant organisations.

Qualitative methods

Staff, patients and carers were approached via the mental health teams they were currently involved in. Patients and carers showed a preference to semi-structured interviews rather than attending offered focus groups. All focus groups and interviews were audio recorded, transcribed and then coded and analysed using thematic analysis[13]. Thematic analysis was inductive using themes developed from the data produced by the structured scripts and remained at a semantic level to allow for a description of the views reported. Staff were also invited to complete a questionnaire to explore the impact of the pathway on staff experience and enable comparisons across the three time points.

Statistical Analysis

Continuous normal data was summarised by mean and standard deviation, with comparisons to baseline made using t-tests. Continuous data that is non-normal as tested by Kolmogorov-Smirnov or Shapiro-Wilk tests, was presented by median and interquartile range (IQR) and compared using Mann-Whitney U test. Categorical variables were presented as n (%) and compared using Chi-Square or Fisher's Exact test as appropriate. However, no statistical comparisons were undertaken when the

event rates in most groups were <5. p<0.05 was assumed to indicate statistical significance. Missing data was excluded on a case-by-case basis. Statistical analyses were undertaken using IBM SPSS Statistics 19 and R 3.4.2.

Safety Assessments

The development of the pathway was tailored to the needs of people with psychosis as a service improvement based on evidence-based practice. No adverse events were therefore expected to be identified as a direct result of implementation of the pathway although analysis of results would show where success or failure had occurred.

Results

The participant information and demographic data is presented in Table 1. The demographic characteristics of individuals in both comparator and pathway arm was broadly similar throughout the study period, with around 3 in 5 of subjects being male, and the majority being of White Caucasian ethnicity, unemployed and residing in mainstream housing.

In both arms, the most common source of referral to EIP services was primary care, making up between 55 to 63% of referrals, followed by other mental health services and then Emergency Departments.

Table 1 here

Waiting times

Table 2 here

In the pathway site, waiting times for EIP assessment from both EIP referral and central triage points (most commonly a community mental health team) reduced significantly compared with baseline, from median 11 to 7 days, and from 20 to 11 days respectively ($p<0.0001$ for both). Conversely, in the comparator arm waiting time from EIP referral to assessment increased significantly from 7 to 12 days ($p<0.0001$) and was unchanged from central triage to assessment at 33 days ($p=0.56$). This suggests an improvement in assessment speed following referral to services in the intervention site.

The pathway site also saw significantly reduced waiting times for allocation to and engagement by care co-ordinator, Multidisciplinary team (MDT) discussions, risk assessment completion and discharge of service users found unsuitable for the service on assessment ($p<0.0001$ for all). There was no statistically significant difference in the time to medical formulation or CPA (Care Programme Approach). In the comparator arm, time to allocation and engagement by care co-ordinator

remained unchanged at median 0 days throughout the study. Although not significantly different from baseline in year 1, by year 2 time to MDT discussion and to risk assessment completion had both increased significantly ($p<0.0001$ for both).

The numbers of patients accepted onto the EIP case load were much higher than expected in the comparator site, but this reduced to nearer the expected levels during the course of the project. The pathway site started below but rose to just above expected levels.

Reasons for discharge from EIP services remained similar in the comparator arm throughout the study. However, in the pathway site there was a significant change, seemingly led by an increase in the number of unsuitable referrals to the service, which increased from 55% to 81%. Non-acceptance was also broadly similar as it was agreed with sites that 'did not meet EIP criteria' and 'discharged on professional advice' effectively meant the same thing.

Physical health assessments

Table 3 here

Both arms of the study saw significant improvements in the proportion of individuals receiving assessments of their general physical health, substance use, alcohol use and weight, having their bloods taken and given ECGs, but at much higher levels in the pathways area. Assessment of smoking status only increased significantly in the intervention arm. While measurements of pulse and blood pressure assessments increased in both arms, they were significant in the comparator arm. Assessment of

waist measurement increased significantly in the pathway site whilst decreasing significantly in the comparator arm. Finally, neither arm significantly increased the number of individuals receiving a full 8-pt NICE recommended health check within 8 weeks of EIP assessment.

Interventions

The proportion of individuals being offered CBT (Cognitive Behaviour Therapy) increased significantly in the comparator arm from 1% to 22% ($p<0.0001$ and was matched with a significant increase in taking up CBT intervention from 0% to 7% ($p=0.010$). The pathway site did not see any significant change in either of these factors however throughout the period, CBT for psychosis and family work for psychosis were much more likely to be offered.

Prevalence of individuals receiving any of the listed interventions increased in both the pathway (83% to 94%, $p=0.0071$) and comparator arms (57% to 81%, $p<0.0001$), as did engagement (75% to 90%, $p=0.039$ and 57% to 79%, $p<0.0001$ respectively) from baseline to year 2.

The pathway site saw increases in the proportion of participants receiving carer support (35% to 68%, $p<0.0001$) and medication (54% to 73%, $p=0.027$), although neither of these changed significantly in the comparator arm. Receipt of collaborative care planning increased significantly in the pathway site (32% to 69%, $p<0.0001$) whilst the comparator site saw a decrease (31% to 1%, $p<0.0001$). Prevalence of physical health interventions also decreased in the comparator arm (26% to 15%,

p<0.0001) but did not change significantly in the pathway site, remaining low (3% to 6%, p=0.58). Receipt of vocational support increased substantially in the pathway site (20% to 72%, p<0.0001) and somewhat in the comparator arm (20% to 39%, p=0.0023). However subsequently, after six months, there was a much higher take-up rate with over 80% in the pathway and over 70% in the comparator site.

Acute care

Table 4 here

There was a substantial contrast in the numbers of patients who had been admitted to hospital at the point of referral, much higher in the pathway area compared to comparator but reducing over time. Further admissions were low in both with neither arm seeing a significant change in the prevalence of acute mental health admissions, in the time to being admitted or in the time to discharge. Similarly, the number of EIP participants subject to MHA section did not change significantly, although there was a tendency towards a decrease in the intervention arm (36% to 33% to 27%, p=0.58). In both arms, the number of EIP service users attending Emergency Department (ED) or general hospital within a year was low. There were no significant changes over time.

Crisis planning

In the pathway site, the proportion of participants having a crisis plan completed reduced significantly (51% to 35%, p=0.032), occurring alongside a decrease in the time to crisis plan completion (50.0 to 12.5 weeks, p<0.0001). Conversely, in the comparator arm the proportion of participants having a crisis plan completed

increased significantly (49% to 67%, p=0.00023), while the time to crisis plan completion increased but non-significantly (8.0 to 12.0 weeks, p=0.10).

Clinical and social outcomes

Table 5 here

These were assessed by extracting the data routinely collected using the Health of the Nation Outcome Scales (HoNOS). There were significant reductions over the two-year period in 'problems with relationships' (p=0.013) and 'problems with occupation and activities' (p=037) in the pathways group and in 'problems with activities of daily living' (p=0.04) in the comparator site. The latter site however had substantial amounts of missing data. There was no significant difference in reductions in 'problems with delusions and hallucinations' between sites.

Criminal justice system contact

The number of participants having contact with the criminal justice system decreased significantly in the pathway site (22% to 3%, p<0.0001) whilst increasing significantly in the comparator site (14% to 21%, p<0.0001). Criminal convictions were rare in both study arms, and were observed to decrease very slightly, (from 1% to 0% and 3% to 1% in the pathway and comparator sites respectively) however statistical testing was not performed due to very low event numbers.

Discharge and death

Discharge from services once accepted by EIP teams within a year was relatively low although disengagement remained a concern. It reduced in pathways site (18 to 11%) and remained stable in comparator (10% to 12%). There was one death occurring to a participant within a year of EIP assessment.

Results from staff and patient interviews and focus groups

Across the two years, 64 staff in intervention site reported that the psychosis pathway appeared to be beneficial, well embedded and a positive change with good team working within the teams and with other services. However, they found workload to be high and had some difficulties getting the right staff skills mix in teams to deliver all the needed interventions. They also noted that often interventions were offered but were not always completed due to patient's ability to engage with them. Additionally, they worried about future changes being implemented in addition to their current workload. They felt by year 2 that they were more able to adapt the pathway to individuals' needs which they saw as important rather than a prescriptive measure.

Patients (14 participants) in intervention site reported that they were generally satisfied with being seen quickly and developed good relationships with the staff members. They found appointments helpful and felt they gained useful skills. However, they also reported that at times there was inconsistencies in the staff they saw and out of hours services could be improved. Carers views (7) in intervention site appears to improve from year 1 to year 2 with more positive reports about the team and services than at year 1 however at both time points the sample was small.

Results from staff questionnaires

In total 1,680 questionnaires were completed by staff members in the intervention and control arm across the three time points. As can be seen from Supplementary Table 1 there was no significant change in staff experience across the time points or between the sites. This may be due to all staff members with adult mental health services being eligible to complete this questionnaire. This was done to capture the experience of staff referring into services and caring for services users with psychosis in services such as hospital settings. The lack of change seen in either site may have therefore been a result of the impact of the pathway being less apparent across all staff in adult mental health services. Overall staff members were reporting that they felt they were able to adequately support people experiencing psychosis in their services.

Discussion

This comparison study provides evidence that the introduction of an integrated psychosis care pathway led to improvements in access to EIP and implementation of quality standards, especially for physical health care in comparison with an area which did not implement the pathway with generally positive staff, service user and carer responses. However, there were pre-existing differences between the sites which influenced the comparison. Prior to the project, the intervention area had dismantled three out of four EIP teams and integrated them into community mental health teams. At the beginning of the project, the area reintroduced EIP teams in contrast to the comparator area which had maintained specialist teams. A marked

difference in referrals occurred in each area with movement in both towards predicted levels of patients accepted by EIP teams.

Time to assessment improved in the pathway area and remained within the target in comparator site. Referral from Central Triage Point though was relatively high especially in comparator area, as found by Birchwood and colleagues[14] and this remains a very important area for attention. Meeting of quality standards increased substantially in the intervention area, but was more variable and reached lower levels in the comparator area. This was especially noticeable for physical health standards, although the full set of NICE recommendations was only met in under 10% within 3 months of acceptance. In the pathway group, offering of CBT for psychosis was relatively high throughout although take up within 6 months was low. However, by 2 years, this was considerably higher. There was an increase in offering of CBT and family work in comparator area from a very low base which had been due to a lack of fully trained therapists. This seems an area where implementation of the quality standards through a pathway process be especially effective. Family intervention, carer and employment support were all offered to a greater extent in pathway area and take up increased over the period.

The changes in teams were reflected in the results as patients accepted onto case load were much higher than expected in the latter but reduced to nearer expected levels during the project. Referrals also increased substantially in intervention but then plateaued after introduction of specialist teams.

The introduction of the access and waiting standard target brought increased funding for FEP nationally. In the pathway area the commissioners remained well engaged with the pathway outcomes and this enabled positive contract discussions. A formal cost effectiveness analysis was therefore not conducted but the reduction in patients referred as in-patients and the subsequent reduction in relapses to hospital suggest that the re-introduction of the EIP teams and the pathway may have had a positive impact on cost in the pathway area.

Study Limitations

This is an observational retrospective study based on manual audit of patients' medical records. Therefore, causality cannot be assumed. We took steps to maintain data consistency by having one dedicated member of staff involved in the data audit throughout, and by performing post-hoc data checks for consistency and outliers; however, data accuracy is naturally limited by the quality of mental health care providers' original record keeping. Additionally, missing data was common, for example only 237 (33%) of participants had a HoNoS score recorded at both referral and one year later allowing us to analyse the impact of their care on this endpoint; we cannot rule out the possibility of statistical bias caused by this.

Conclusion

This comparison of the implementation of a quality standard based psychosis pathway with a comparator area which followed established guidelines for Early Intervention for Psychosis teams suggests that the former was more effective at improving the level of evidence-based practice offered to patients and their carers. The findings also compare with the National Clinical Audit of Psychosis[15]. Integrated

care pathways can offer a platform to inform gaps in services, implement good clinical practice and measure the impact.

Competing interests

The production of the pathway has been supported by the Wessex Academic Health Sciences Network (AHSN) and evaluation has also been supported by the Wessex Clinical Research Network (CRN). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of funders, NIHR, NHS or the RCPsych, AHSN or CRN. The study is sponsored by Southern Health NHS Foundation Trust.

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Study Status

The study is complete.

Authors' contributions

SR, DK are grant holders and contributed to the concept and design of the study. SR is the CI and led the development of the study protocol and study documentation and made a significant contribution to the manuscript. All authors contributed to elaboration and refinement of the study protocol and approved the final manuscript.

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Tables

Table 1: Demographic information for all individuals referred to EIP service. Numbers represent either median (IQR) for continuous variables or proportions for categorical variables. Excludes EIP to EIP transfers.

		Intervention arm			Control Arm		
		Baseline (n=123)	Year 1 (n=416)	Year 2 (n=463)	Baseline (n=237)	Year 1 (n=271)	Year 2 (n=252)
Age (Years)		22.4 (19.3 to 28.2)	21.4 (19.0 to 26.1)	21.6 (19.0 to 25.9)	19.4 (16.7 to 24.9)	19.7 (17.1 to 24.8)	21.8 (17.9 to 30.3)
Gender:	*Female*	35%	40%	39%	43%	40%	38%
	Male	65%	60%	61%	57%	60%	62%
Ethnicity:	*White*	88%	89%	93%	92%	93%	92%
	Black or Black British	5%	3%	3%	1%	3%	1%
	Asian or Asian British	0%	2%	0%	1%	1%	1%
	Mixed race	3%	3%	2%	3%	1%	4%
	Other	5%	2%	1%	3%	3%	2%
Accommodation Status:							
Accommodation with MH care support		3%	1%	0%	0%	2%	0%
Accommodation with other support		3%	4%	7%	4%	5%	2%
Acute/long stay healthcare residential facility/hospital		0%	0%	1%	3%	8%	13%
Homeless		7%	9%	13%	10%	8%	7%
Mainstream housing		88%	86%	80%	79%	76%	76%
Bail/probation hostel		0%	0%	0%	2%	0%	0%
Other		0%	0%	0%	2%	1%	3%
Employment status:							
Employed		38%	20%	29%	24%	26%	20%
Unemployed		26%	38%	40%	48%	40%	54%
Homemaker		1%	2%	1%	4%	3%	1%
Student		16%	15%	14%	11%	12%	11%
Long term sickness/disability benefit		15%	16%	12%	9%	5%	5%
Statutory sick pay		0%	3%	0%	5%	9%	3%
Retired		0%	0%	0%	0%	0%	1%
Other		3%	6%	4%	0%	4%	4%
Change in employment status during EIP:							
No reported change		58 (84%)	107 (91%)	124 (100%)	128 (88%)	163 (97%)	88 (86%)
Became employed		0 (0%)	4 (3%)	0 (0%)	13 (9%)	2 (1%)	5 (5%)
Left employment/became unemployed		10 (14%)	4 (3%)	0 (0%)	4 (3%)	2 (1%)	3 (3%)
Other		1 (1%)	3 (3%)	0 (0%)	0 (0%)	1 (1%)	6 (6%)
Referral source:							
Primary care		75 (62%)	256 (63%)	283 (62%)	143 (60%)	172 (63%)	139 (55%)
Community mental health service		19 (16%)	66 (16%)	104 (23%)	14 (6%)	26 (10%)	14 (6%)
Inpatient mental health service		1 (1%)	21 (5%)	15 (3%)	12 (5%)	16 (6%)	4 (2%)
A&E department		11 (9%)	20 (5%)	21 (5%)	5 (2%)	13 (5%)	23 (9%)
Physical healthcare service		0 (0%)	13 (3%)	8 (2%)	4 (2%)	8 (3%)	2 (1%)
Caring and social services		0 (0%)	0 (0%)	5 (1%)	10 (4%)	5 (2%)	11 (4%)
Education service		0 (0%)	6 (1%)	4 (1%)	12 (5%)	7 (3%)	8 (3%)
Police/prison/probation		9 (7%)	8 (2%)	11 (2%)	14 (6%)	11 (4%)	25 (10%)
Self-referral		1 (1%)	2 (0%)	2 (0%)	12 (5%)	6 (2%)	17 (7%)
Other		5 (4%)	16 (4%)	4 (1%)	11 (5%)	8 (3%)	9 (4%)
Central triage point (CTP):							
EIP		22 (18%)	107 (26%)	120 (26%)	33 (14%)	24 (9%)	27 (11%)
Community mental health service		98 (80%)	281 (69%)	325 (71%)	183 (78%)	217 (81%)	184 (73%)
Inpatient mental health service		2 (2%)	21 (5%)	14 (3%)	17 (7%)	26 (10%)	27 (11%)
Physical healthcare service		0 (0%)	1 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Police/prison/probation		0 (0%)	0 (0%)	0 (0%)	3 (1%)	2 (1%)	14 (6%)

Table 2: Process outcomes for all individuals referred to EIP service. Numbers represent either N (%) for categorical variables or median (IQR) for continuous variables. Excludes EIP to EIP transfers. P values for categorical comparisons from chi-squared test or Fisher's exact test as appropriate. P values for continuous data from Mann-Whitney U tests.

	Intervention arm					Control arm				
	Baseline (n=123)	Year One (n=416)	Year Two (n=463)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=237)	Year One (n=271)	Year Two (n=252)	P value Y1 vs baseline	P value Y2 vs baseline
Accepted onto EIP pathway	69 (56%)	118 (28%)	124 (27%)	< 0.0001	< 0.0001	145 (61%)	168 (62%)	102 (40%)	0.89	< 0.0001
Time from EIP referral to EIP assessment (in days)	11.0 (6.0 to 20.5)	6.0 (3.0 to 12.0)	7.0 (4.0 to 14.0)	< 0.0001	< 0.0001	7.0 (3.0 to 12.0)	7.0 (4.0 to 12.8)	12.0 (7.0 to 21.0)	0.24	< 0.0001
Time from CTP referral to EIP assessment (in days)	20.0 (11.8 to 55.3)	15.0 (6.0 to 40.0)	11.0 (6.0 to 23.0)	0.0053	< 0.0001	33.0 (11.0 to 142.5)	24.0 (9.3 to 130.5)	33.0 (13.0 to 98.0)	0.45	0.96
DNAs prior to assessment										
0	113 (92%)	378 (91%)	434 (94%)	0.37		211 (89%)	247 (91%)	232 (92%)	0.59	
1	7 (6%)	28 (7%)	17 (4%)			17 (7%)	19 (7%)	12 (5%)		
2 or more	3 (2%)	10 (2%)	12 (3%)			9 (4%)	6 (2%)	9 (4%)		
Time to allocation and engagement by care coordinator (in weeks)	4.0 (0.0 to 11.0)	1.0 (0.0 to 5.0)	0.0 (0.0 to 3.0)	0.0033	< 0.0001	0.0 (0.0 to 7.3)	0.0 (0.0 to 7.0)	0.0 (0.0 to 14.8)	0.054	0.48
Time to multidisciplinary team (MDT) discussion (in weeks)	6.2 (1.7 to 20.0)	1.9 (1.0 to 4.6)	1.9 (0.9 to 3.0)	< 0.0001	< 0.0001	1.8 (0.7 to 3.0)	1.7 (1.0 to 2.7)	4.9 (1.8 to 28.0)	0.74	< 0.0001
Time to medical formulation (in weeks)	4.7 (2.3 to 8.4)	3.9 (1.9 to 8.4)	3.3 (1.9 to 6.0)	0.45	0.11	6.5 (2.3 to 10.3)	6.7 (2.4 to 11.0)	8.3 (3.8 to 11.9)	0.99	0.14
Time to CPA (care plan approach) /care plan (in weeks)	2.4 (0.0 to 6.9)	2.7 (0.8 to 5.4)	2.0 (0.4 to 5.8)	0.62	0.87	2.0 (0.7 to 5.6)	3.0 (1.0 to 14.5)	13.0 (4.3 to 34.0)	0.080	< 0.0001
Time to risk assessment completion (in weeks)	50.3 (2.6 to 91.1)	6.4 (1.0 to 15.3)	4.7 (1.4 to 8.1)	< 0.0001	< 0.0001	5.3 (1.4 to 15.0)	3.6 (1.0 to 15.1)	4.6 (1.1 to 13.4)	0.38	0.60
Reason for non-acceptance to EIP:										
Does not fulfil EIP criteria	29 (71%)	202 (79%)	280 (85%)	0.0010		18 (20%)	20 (19%)	28 (19%)	0.76	
Discharged on professional advice	4 (10%)	14 (5%)	2 (1%)			62 (67%)	65 (63%)	100 (66%)		
DNA/did not engage/declined treatment	6 (15%)	27 (11%)	35 (11%)			5 (5%)	8 (8%)	13 (9%)		
Moved out of area	0 (0%)	11 (4%)	10 (3%)			6 (7%)	7 (7%)	9 (6%)		

	Intervention arm					Control arm				
	Baseline (n=123)	Year One (n=416)	Year Two (n=463)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=237)	Year One (n=271)	Year Two (n=252)	P value Y1 vs baseline	P value Y2 vs baseline
Other	2 (5%)	3 (1%)	4 (1%)			1 (1%)	4 (4%)	1 (1%)		
Reason for discharge from EIP after acceptance:										
Care completed	4 (15%)	4 (9%)	0 (0%)	0.076		0 (0%)	0 (0%)	0 (0%)	0.40	
Does not fulfil EIP criteria	8 (31%)	22 (48%)	22 (50%)			7 (6%)	6 (5%)	4 (9%)		
Discharged on professional advice	0 (0%)	1 (2%)	3 (7%)			80 (72%)	72 (61%)	25 (54%)		
DNA/did not engage/declined treatment	6 (23%)	8 (17%)	8 (18%)			16 (14%)	25 (21%)	11 (24%)		
Moved out of area	5 (19%)	11 (24%)	9 (20%)			7 (6%)	12 (10%)	5 (11%)		
Other	3 (12%)	0 (0%)	2 (5%)			1 (1%)	4 (3%)	1 (2%)		
Change in accommodation status during EIP:										
No reported change	63 (91%)	118 (100%)	124 (100%)	<0.0001		136 (94%)	157 (93%)	78 (76%)	<0.0001	
Moved to mainstream housing	0 (0%)	0 (0%)	0 (0%)			2 (1%)	3 (2%)	10 (10%)		
Moved from acute/long stay/ hospital to supported accommodation	0 (0%)	0 (0%)	0 (0%)			1 (1%)	3 (2%)	2 (2%)		
Moved to acute/long stay/ hospital	1 (1%)	0 (0%)	0 (0%)			0 (0%)	1 (1%)	4 (4%)		
Committed to bail/probation hostel/prison	0 (0%)	0 (0%)	0 (0%)			0 (0%)	0 (0%)	1 (1%)		
No longer homeless	1 (1%)	0 (0%)	0 (0%)			3 (2%)	2 (1%)	1 (1%)		
Became homeless	1 (1%)	0 (0%)	0 (0%)			1 (1%)	2 (1%)	1 (1%)		
Other	3 (4%)	0 (0%)	0 (0%)			2 (1%)	0 (0%)	5 (5%)		

Table 3: Physical health assessments and interventions. N (%) individuals accepted onto the EIP pathway at each site who received listed physical health checks within 12 weeks, were offered interventions or took up interventions within 6 months of EIP referral. Excludes EIP to EIP transfers. P values from chi-squared test or Fisher's exact test as appropriate.

	Intervention arm				Control Arm			
	Baseline (n=69)	Year One (n=118)	Year Two (n=124)	P value	Baseline (n=145)	Year One (n=168)	Year Two (n=102)	P value
Physical health assessments received within 12 weeks:								
Physical Health (general)	33 (48%)	81 (69%)	86 (69%)	0.0038	38 (26%)	40 (24%)	44 (43%)	0.0019
Smoking	23 (33%)	72 (61%)	76 (61%)	0.00033	38 (26%)	42 (25%)	34 (33%)	0.30
Substance Use	35 (51%)	93 (79%)	98 (79%)	<0.0001	71 (49%)	63 (38%)	66 (65%)	<0.0001
Alcohol	35 (51%)	89 (75%)	102 (82%)	<0.0001	60 (41%)	60 (36%)	61 (60%)	0.00045
Weight	17 (25%)	46 (39%)	60 (48%)	0.0065	46 (32%)	39 (23%)	39 (38%)	0.027
Waist	4 (6%)	16 (14%)	27 (22%)	0.011	18 (12%)	9 (5%)	2 (2%)	0.0037
Pulse	20 (29%)	48 (41%)	47 (38%)	0.30	25 (17%)	32 (19%)	33 (32%)	0.010
Blood Pressure	22 (32%)	50 (42%)	55 (44%)	0.25	32 (22%)	38 (23%)	40 (39%)	0.0036
Bloods Taken	18 (26%)	58 (49%)	50 (40%)	0.010	15 (10%)	25 (15%)	36 (35%)	<0.0001
ECG	10 (14%)	49 (42%)	27 (22%)	<0.0001	17 (12%)	10 (6%)	30 (29%)	<0.0001
NICE health check in 12 weeks	2 (3%)	9 (8%)	11 (9%)	0.30	1 (1%)	1 (1%)	1 (1%)	0.94
Interventions offered at any time:								
Cognitive behaviour therapy	43 (62%)	68 (58%)	84 (68%)	0.26	1 (1%)	23 (14%)	22 (22%)	<0.0001
Family intervention	36 (52%)	64 (54%)	80 (65%)	0.17	7 (5%)	7 (4%)	10 (10%)	0.13
Carer support	50 (72%)	82 (69%)	90 (73%)	0.86	34 (23%)	29 (17%)	25 (25%)	0.26
Employment support	41 (59%)	47 (40%)	57 (46%)	0.043	37 (26%)	47 (28%)	18 (18%)	0.15
Interventions taken up within 6 months:								
Engagement	52 (75%)	103 (87%)	111 (90%)	0.039	82 (57%)	74 (44%)	80 (79%)	<0.0001
CBT for psychosis	3 (4%)	10 (8%)	8 (6%)	0.56	0 (0%)	7 (4%)	7 (7%)	0.010
Carer support	24 (35%)	63 (53%)	84 (68%)	<0.0001	17 (12%)	22 (13%)	16 (16%)	0.66
Medication	37 (54%)	80 (68%)	91 (73%)	0.027	25 (17%)	37 (22%)	28 (28%)	0.16
Collaborative care planning	22 (32%)	85 (72%)	86 (69%)	<0.0001	45 (31%)	38 (23%)	1 (1%)	<0.0001
Physical Health	2 (3%)	4 (3%)	7 (6%)	0.58	37 (26%)	9 (5%)	15 (15%)	<0.0001
Vocational	14 (20%)	79 (67%)	89 (72%)	<0.0001	29 (20%)	37 (22%)	39 (39%)	0.0023
Family work for psychosis	2 (3%)	11 (9%)	8 (6%)	0.25	2 (1%)	6 (4%)	1 (1%)	0.26
Any of these	57 (83%)	113 (96%)	117 (94%)	0.0071	83 (57%)	74 (44%)	82 (81%)	<0.0001

Table 4: Acute care & clinical outcomes. Proportion of individuals accepted onto the EIP pathway at each trust experiencing acute care outcomes [n (%)] within 1 year of trust referral, and time to reach those outcomes where applicable [median (IQR)]. Excludes EIP to EIP transfers. P values for categorical comparisons from chi-squared test or Fisher's exact test as appropriate. P values for continuous data from Mann-Whitney U tests.

	Intervention arm					Control arm				
	Baseline (n=69)	Year One (n=118)	Year Two (n=124)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=145)	Year One (n=168)	Year Two (n=102)	P value Y1 vs baseline	P value Y2 vs baseline
Acute MH admission within 1 year of EIP referral	27 (39%)	47 (40%)	36 (29%)	0.16		16 (11%)	21 (13%)	19 (19%)	0.20	
Time to acute admission (where applicable) (weeks)	0.0 (0.0 to 10.0)	1.0 (0.0 to 7.0)	0.0 (0.0 to 3.5)	0.88	0.11	15.0 (3.0 to 41.0)	11.0 (2.0 to 41.0)	13.5 (3.0 to 34.0)	0.82	0.92
Time to acute MH/inpatient screening (hours)										
0 - 4	21 (91%)	1 (100%)	14 (67%)	-		11 (73%)	11 (58%)	8 (53%)	0.49	
4 - 6	0 (0%)	0 (0%)	6 (29%)			3 (20%)	4 (21%)	3 (20%)		
6 - 8	1 (4%)	0 (0%)	0 (0%)			0 (0%)	2 (11%)	1 (7%)		
8 - 10	1 (4%)	0 (0%)	1 (5%)			1 (7%)	2 (11%)	3 (20%)		
Time from acute admission to discharge (where applicable) (weeks)	4.5 (2.0 to 10.3)	4.0 (2.0 to 6.8)	3.0 (1.0 to 5.3)	0.42	0.56	3.0 (2.0 to 13.5)	3.0 (2.0 to 5.0)	3.0 (2.3 to 3.8)	0.56	0.95
Number of subsequent acute admissions										
None	18 (64%)	41 (85%)	25 (71%)	0.091		14 (67%)	15 (65%)	13 (62%)	0.95	
1	6 (21%)	4 (8%)	9 (26%)			5 (24%)	2 (9%)	8 (38%)		
More than 1	4 (14%)	3 (6%)	1 (3%)			2 (10%)	6 (26%)	0 (0%)		
MHA section within 1 year of EIP referral	25 (36%)	39 (33%)	34 (27%)	0.58		16 (11%)	21 (13%)	18 (18%)	0.18	
Contact acute MH services (post EIP)	32 (46%)	41 (35%)	37 (30%)	< 0.0001		25 (17%)	30 (18%)	22 (22%)	< 0.0001	
Crisis plan completed	35 (51%)	59 (50%)	44 (35%)	0.032		71 (49%)	69 (41%)	68 (67%)	0.00023	
Time to crisis plan completed (weeks)	50.0 (15.0 to 79.0)	22.5 (10.0 to 37.8)	12.5 (6.0 to 22.8)	0.0010	< 0.0001	8.0 (1.0 to 23.0)	11.0 (1.0 to 39.0)	12.0 (2.0 to 34.3)	0.36	0.10
A&E attendance within 1 year of EIP referral	7 (10%)	10 (8%)	11 (9%)	0.91		11 (8%)	12 (7%)	10 (10%)	0.72	
Time to A&E attendance (weeks)	21.0 (2.5 to 68.3)	8.5 (0.0 to 17.0)	13.0 (8.0 to 43.0)	0.15	0.88	30.0 (25.0 to 41.0)	44.0 (11.0 to 76.0)	14.5 (7.3 to 31.5)	0.87	0.11
Reason for A&E attendance:										

	Intervention arm					Control arm				
	Baseline (n=69)	Year One (n=118)	Year Two (n=124)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=145)	Year One (n=168)	Year Two (n=102)	P value Y1 vs baseline	P value Y2 vs baseline
Deterioration in mental state	7 (41%)	7 (50%)	5 (42%)	-		2 (15%)	4 (24%)	2 (20%)	-	
Self harm/suicidal ideation/suicide attempt/overdose	6 (35%)	5 (36%)	4 (33%)			10 (77%)	6 (35%)	4 (40%)		
Alcohol/substance abuse	1 (6%)	1 (7%)	2 (17%)			0 (0%)	1 (6%)	0 (0%)		
Medication side effects	0 (0%)	0 (0%)	0 (0%)			0 (0%)	1 (6%)	1 (10%)		
Physical injury/illness (not apparently psychosis related)	3 (18%)	1 (7%)	1 (8%)			1 (8%)	5 (29%)	3 (30%)		
General hospital admission within 1 year of EIP referral	1 (1%)	4 (3%)	3 (2%)	-		2 (1%)	0 (0%)	4 (4%)	-	
Contact with criminal justice system whilst in EIP pathway	15 (22%)	34 (29%)	4 (3%)	< 0.0001		20 (14%)	20 (12%)	21 (21%)	< 0.0001	
Criminal conviction within 1 year of EIP referral	1 (1%)	0 (0%)	0 (0%)	-		4 (3%)	4 (2%)	1 (1%)	-	
Deaths within 1 year of EIP referral	0 (0%)	0 (0%)	0 (0%)	-		0 (0%)	0 (0%)	1 (1%)	-	

Table 5: Clinical outcomes (HoNoS). Mean (SD) change in HoNoS scores from referral to one year at each trust for patients accepted onto EIP pathway. Excludes EIP to EIP transfers. P values from paired t-tests.

	Intervention Arm					Control Arm				
	Baseline (n=52)	Year One (n=77)	Year Two (n=53)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=28)	Year One (n=16)	Year Two (n=11)	P value Y1 vs baseline	P value Y2 vs baseline
Change in HoNoS scores (from referral to 1 year)										
1. Overactive, aggressive, disruptive or agitated behaviour	-0.56 (1.73)	-0.43 (1.72)	-0.69 (1.45)	0.59	0.78	-0.43 (1.55)	-1.06 (1.65)	-0.09 (1.14)	0.21	0.52
2. Non-accidental self injury	-0.50 (1.38)	-0.22 (1.26)	-0.22 (1.15)	0.18	0.21	-0.25 (0.84)	-0.06 (1.29)	-0.36 (1.43)	0.56	0.76
3. Problem drinking or drug taking	-0.40 (1.48)	-0.15 (1.87)	0.04 (1.71)	0.30	0.12	0.14 (1.04)	-0.31 (1.20)	-0.10 (1.52)	0.19	0.58
4. Cognitive problems	-0.27 (1.34)	-0.15 (1.32)	-0.06 (1.32)	0.48	0.33	-0.29 (1.18)	-0.38 (0.96)	-0.50 (1.51)	0.80	0.65
5. Physical illness or disability problems	-0.23 (1.10)	0.03 (1.35)	0.02 (1.08)	0.19	0.17	0.11 (0.50)	-0.38 (1.02)	0.45 (1.44)	0.041	0.26
6. Problems associated with hallucinations and delusions	-0.56 (1.62)	-0.71 (1.70)	-0.11 (1.51)	0.74	0.14	-0.86 (1.46)	-1.81 (1.42)	-0.91 (1.76)	0.041	0.93
7. Problems with depressed mood	-0.50 (1.59)	-0.19 (1.49)	-0.55 (1.12)	0.24	0.94	-0.46 (1.29)	-0.88 (1.41)	-0.55 (1.21)	0.33	0.86
8. Other mental and behavioural problems	-0.45 (1.53)	-0.73 (1.81)	-0.27 (1.49)	0.58	0.68	-0.61 (1.26)	-0.75 (1.98)	-0.36 (1.69)	0.77	0.62
9. Problems with relationships	-0.83 (1.32)	-0.41 (1.51)	-0.20 (1.25)	0.07	0.013	-0.21 (1.26)	-1.00 (1.41)	-0.10 (0.57)	0.064	0.78
10. Problems with activities of daily living	-0.33 (1.57)	-0.32 (1.55)	-0.46 (1.47)	0.85	0.68	-0.64 (1.16)	-1.00 (1.55)	0.18 (0.75)	0.39	0.04
11. Problems with living conditions	-0.20 (1.51)	-0.33 (1.44)	0.08 (1.21)	0.69	0.28	-0.36 (1.31)	-0.69 (1.20)	0.45 (1.13)	0.41	0.079
12. Problems with occupation and activities	-0.33 (1.64)	-0.19 (1.47)	0.30 (1.45)	0.54	0.037	-0.25 (1.58)	-1.06 (1.57)	-0.09 (1.45)	0.11	0.77

Table 6: Staff survey results

Section A: Demographics

	Intervention arm			Control arm		
	Baseline (n=438)	**Year 1 (n=412)**	**Year 2 (n=418)**	**Baseline (n=122)**	**Year 1 (n=155)**	**Year 2 (n=135)**
Type of team						
CMHT	39%	32%	30%	51%	46%	49%
EIP	7%	10%	8%	7%	5%	9%
Psychology	5%	6%	8%	2%	1%	2%
Inpatient	35%	42%	42%	30%	35%	27%
Hospital at home	8%	6%	8%	4%	8%	7%
Other (inc. AAT/AOT)	13%	7%	8%	10%	8%	9%
Job role						
Psychiatrist/SpR/SHO	15%	7%	10%	5%	6%	10%
Psychologist/Psychotherapist	7%	6%	8%	6%	1%	2%
Nurse practitioner	42%	41%	39%	39%	43%	34%
Occupational therapist	4%	6%	5%	7%	8%	7%
Social worker	7%	5%	5%	8%	5%	8%
Mental health care support worker	19%	25%	23%	20%	22%	16%
Other	8%	10%	10%	16%	15%	22%
Geographical area of living						
North Hampshire	7%	6%	11%	22%	35%	24%
West Hampshire	24%	23%	18%	20%	11%	27%
East Hampshire	32%	23%	21%	48%	54%	47%
Southampton	36%	43%	50%	8%	0%	1%
Unknown/other	1%	5%	0%	2%	0%	0%
Gender						
Male	32%	33%	32%	31%	39%	36%
Female	67%	66%	67%	68%	61%	64%
Other	0%	0%	<1%	0%	0%	0%
Not answered	1%	2%	1%	1%	0%	0%
Age group						
Under 24	5%	5%	6%	6%	5%	3%
25-34	26%	23%	25%	17%	21%	24%
35-44	30%	28%	30%	29%	21%	25%
45-54	28%	28%	27%	39%	34%	36%
55-64	9%	14%	11%	8%	17%	11%
65 or over	1%	1%	1%	0%	1%	1%
Not answered	1%	1%	<1%	1%	1%	0%
Ethnicity						
White	82%	80%	83%	92%	94%	90%

	Intervention arm			Control arm		
	Baseline (n=438)	Year 1 (n=412)	Year 2 (n=418)	Baseline (n=122)	Year 1 (n=155)	Year 2 (n=135)
Mixed race	4%	5%	5%	2%	3%	3%
Asian	6%	5%	5%	1%	1%	3%
Black	5%	9%	6%	3%	1%	1%
Other	1%	1%	1%	0%	1%	1%
Not stated	<1%	1%	1%	1%	0%	1%

Section B: Experience

	Intervention arm			Control arm		
	Baseline (n=438)	Year 1 (n=412)	Year 2 (n=418)	Baseline (n=122)	Year 1 (n=155)	Year 2 (n=135)
I have been able to support people with FEP to have more control in their lives:						
Always	16%	15%	18%	24%	15%	16%
Sometimes	62%	50%	54%	60%	55%	55%
Rarely	13%	14%	13%	8%	12%	10%
Never	5%	9%	6%	3%	9%	6%
Don't know	3%	7%	6%	2%	6%	11%
Not answered	2%	5%	3%	3%	2%	2%
I have been able to support people with FEP to manage their physical, mental and social needs holistically:						
Always	24%	27%	27%	25%	22%	22%
Sometimes	58%	47%	49%	63%	57%	54%
Rarely	9%	8%	10%	3%	6%	7%
Never	3%	7%	5%	3%	8%	5%
Don't know	2%	8%	6%	0%	6%	9%
Not answered	3%	5%	3%	5%	2%	3%
I have been able to support people with FEP to involve carers:						
Always	29%	25%	27%	30%	31%	31%
Sometimes	52%	43%	43%	60%	48%	47%
Rarely	9%	11%	12%	4%	8%	8%
Never	4%	8%	6%	2%	7%	4%
Don't know	2%	8%	9%	1%	5%	7%
Not answered	3%	5%	4%	4%	1%	3%
I feel appropriately trained and supervised to deliver psychological informed interventions:						
Always	22%	21%	21%	16%	12%	19%
Sometimes	47%	40%	38%	52%	42%	45%
Rarely	15%	14%	11%	11%	19%	11%
Never	7%	10%	8%	13%	7%	6%
Don't know	5%	11%	10%	4%	8%	10%
Not answered	4%	5%	13%	3%	1%	9%
I feel appropriately trained and supervised to deliver physical health assessment and intervention:						

	Intervention arm			Control arm		
	Baseline (n=438)	**Year 1 (n=412)**	**Year 2 (n=418)**	**Baseline (n=122)**	**Year 1 (n=155)**	**Year 2 (n=135)**
Always	34%	34%	29%	27%	34%	37%
Sometimes	41%	34%	39%	42%	41%	33%
Rarely	12%	10%	9%	14%	10%	12%
Never	10%	9%	8%	14%	9%	7%
Don't know	3%	8%	9%	2%	3%	8%
Not answered	2%	5%	6%	1%	4%	3%
I feel appropriately trained and supervised to deliver vocational support:						
Always	16%	20%	15%	17%	13%	19%
Sometimes	49%	42%	44%	55%	54%	51%
Rarely	23%	16%	17%	19%	21%	10%
Never	6%	9%	9%	5%	3%	7%
Don't know	4%	10%	9%	3%	5%	10%
Not answered	2%	4%	6%	1%	5%	3%
I feel appropriately trained and supervised to deliver alcohol, smoking and substance misuse support:						
Always	22%	22%	23%	30%	22%	29%
Sometimes	58%	46%	49%	50%	58%	48%
Rarely	12%	14%	11%	14%	10%	10%
Never	5%	5%	5%	5%	4%	4%
Don't know	2%	9%	9%	1%	1%	7%
Not answered	1%	4%	4%	1%	5%	3%
I believe service users and carers are involved in planning their care:						
Always	46%	47%	45%	48%	38%	47%
Sometimes	47%	46%	47%	52%	41%	52%
Rarely	4%	2%	3%	1%	4%	1%
Never	0%	0%	1%	0%	0%	0%
Don't know	1%	3%	2%	0%	2%	0%
Not answered	2%	2%	2%	0%	15%	1%
I feel supported to carry out holistic assessment and care plans:						
Always	44%	42%	43%	46%	47%	40%
Sometimes	39%	36%	34%	43%	34%	44%
Rarely	5%	6%	4%	3%	8%	5%
Never	3%	5%	5%	4%	2%	1%
Don't know	3%	6%	8%	2%	5%	5%
Not answered	6%	5%	6%	2%	5%	4%

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	7/8
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*NA*+
Bias	9	Describe any efforts to address potential sources of bias	17-19
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9
		(*b*) Describe any methods used to examine subgroups and interactions	9
		(*c*) Explain how missing data were addressed	9
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	9
		(*e*) Describe any sensitivity analyses	

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Table 1
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Table 1
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*Tables*
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Tables
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Tables Pg 10
Discussion			
Key results	18	Summarise key results with reference to study objectives	19
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	19
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	17
Generalisability	21	Discuss the generalisability (external validity) of the study results	19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

[+] Not possible as data collected from various sources across intervention and comparator site (depending on how information collected by services in real world setting). Data dictionary produced for researchers to allow for this.

BMJ Open

Results of a prospective, mixed methods study to assess feasibility, acceptability, and effectiveness of TRIumPH (Treatment and Recovery In PsycHosis), an Integrated Care Pathway for Psychosis, compared to usual treatment.

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Keywords:	Adult psychiatry < PSYCHIATRY, Early Intervention, Integrated Care Pathways, Schizophrenia & psychotic disorders < PSYCHIATRY

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Results of a prospective, mixed methods study to assess feasibility, acceptability, and effectiveness of TRIumPH (Treatment and Recovery In PsycHosis), an Integrated Care Pathway for Psychosis, compared to usual treatment.

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Abstract

Objectives: To evaluate whether a newly developed care pathway, TRIumPH (Treatment and Recovery In PsycHosis) is feasible, acceptable and effective in meeting NICE quality standards in a timely manner.

Methods: This was a pragmatic, non-randomised, prospective, mixed methods study comparing an implementation (TRIumPH) and comparator site (not implementing TRIumPH) across three cohorts to assess feasibility, acceptability and effectiveness of the integrated pathway.

Setting: NHS Early Intervention in Psychosis (EIP) services at two NHS. .

Participants: All patients accepted into EIP services between 1 June 2014 and 31 May 2017 were each followed up for one year within their respective cohorts.

Methodology: Quantitative data consisted of routinely collected clinical data retrieved from patient records to asses whether the implementation of TRIumPH achieved better concordance to NICE standards. These included: time to access services, physical health assessments, clinical outcomes based timeliness of delivery, acute data. The controlled trial has evaluated the effect of TRIumPH (Intervention) with Care As Usual (Comparator). Qualitative measures consisted of questionnaires, interviews and focus groups to assess acceptability and satisfaction. Outcome measures were compared within the baseline, year 1 and year 2 cohorts and between the two sites.

Results: Quantitative data was statistically analysed by comparing means and proportions. Time to assessment improved in the implementation site and remained within the target in comparator site. Meeting of quality standards increased substantially in the implementation site but was more variable and reached lower

levels in the comparator site especially for physical health standards. Cognitive therapy for psychosis, family intervention, carer and employment support were all offered to a greater extent in the implementation site and uptake increased over the period.

Conclusions: Pathway implementation generally led to greater improvements in achievement of access and quality standards compared to comparator site.

Strengths and Limitations

- This is the first and only evaluation of a psychosis care pathway, especially since the access and waiting time standard
- Results will be generalizable to NHS and managed care organisations as this study was delivered in real world setting
- Pragmatic nature of the study meant that baseline differences between the sites could potentially affect interpretation of the results. The exploratory nature of this study meant that power or sample size calculations were not performed. The conclusions need to be interpreted in light of this methodology
- Two sites initially planned to participate and expand this research withdrew during the course of the study due to inability to provide required data. The sites were from implementation and comparator groups each
- Routine data was used to evaluate implementation which had the disadvantage of significant amounts of missing data in some areas.
- Financial and human resource limitations may have impact on results

Study registration: UK Clinical Research Network Portfolio: 19187

Keywords: Integrated Care Pathway, psychosis, access, early intervention

Word count: **3965**

Background

Schizophrenia is listed as the 8th leading cause of DALYs worldwide in the age group 15 - 44 years in the World Health Report[1]. In addition to the direct cost, there is a considerable burden on the relatives[2] and life expectancy is reduced by approximately 15-20 years, mostly because of physical health problems[3].

A primary factor contributing to the impact of schizophrenia is that the longer the duration of untreated psychosis (DUP) the worse the outlook especially for social functioning and recovery[4,5]. DUP has been found to be the strongest predictor of symptom severity and prognosis[6]. A meta-analysis showed a mean DUP of 61.3 weeks[7] and further evidence from trans-cultural and international research suggests that DUP ranges between 364 and 721 days[5,6] and so reducing DUP is of individual, national and international importance[7].

In order to address both the impact of schizophrenia and the length of DUP the UK government strategy 'No Health Without Mental Health'[8] acknowledged that more must be done to address the disparity in care for people experiencing psychosis. It highlighted the importance of prevention, early detection, and support for evidence-based models such as Early Intervention in Psychosis (EIP) services. The National Access and Waiting Time (AWTS) standard for psychosis[9] announced in England from 1 April 2016 required that more than 50% of people experiencing a first episode psychosis should commence a National Institute of Health and Care Excellence (NICE) recommended package of care[10] within two weeks of referral to secondary care services. This action was specifically introduced to reduce DUP and ensure people access services and start treatment in a timely manner.

In addition to the introduction of care standards the Five Year Forward View (NHS England)[11] recommended development of standardized care pathways for every major mental health condition. Evidenced-based integrated pathways provide a standardised framework for good clinical practice, reduce variation in care and improving outcomes for patients through providing timely access and intervention[12]. Standardised pathways improve quality by improving multidisciplinary communication with different care agencies using care planning and improve patient satisfaction[13]. NICE has formulated quality standards for treatment of schizophrenia and psychosis[10] but does not prescribe timeframes.

TRIumPH (Treatment and Recovery In PsycHosis) is a co-developed, integrated care pathway for psychosis that prescribes time frames around access and clinical interventions as developed in England[14,15,16]. The work has used a similar approach to that taken to improve care in other health areas like acute stroke care[13] and has produced a demonstrable improvement in outcomes for patients and carers. This new psychosis pathway aims to reduce the impact of disease and promote recovery by ensuring that every individual gets the best evidence-based care at the right time and in the right place.

In developing the pathway, a multi-pronged approach has been used, using i) intelligence from information, ii) co-production with individuals with lived experience of mental illness and their carers, and iii) engagement with clinicians and other stakeholders including commissioners, primary care and third sector organisations. The development of TRIumPH used a robust methodology, outlined in previous publications by this group, which can be adapted and adopted nationally and internationally[14,15,16].

Therefore, the pathway goals are to treat the symptoms as early as possible, provide skills to patients and their families, maintain the improvement over a period, prevent relapses and reintegrate the individuals into the community so that they can lead as normal a life as possible.

Study objectives

The objective of this study was to assess the feasibility, acceptability and effectiveness of the TRIumPH psychosis care pathway.

- Does implementation of TRIumPH improve standards in line with the NICE quality standards as measured by: time taken to access services and waiting times, lengths of hospital stay, clinical outcomes based on HoNOS scores, treatment options offered and how timely the delivery of these were?
- How did staff members, service users and carers experience the implementation of the pathway? Was it feasibile and acceptable?

Methods

Study design

This is a prospective, mixed methods, pragmatic[17] and non-randomised study comparing the intervention implementation (TRIumPH pathway) and comparison site that had treatment as usual to evaluate feasibility, acceptability and effectiveness of an integrated care pathway, TRIumPH. Both qualitative and quantitative data were collected and analysed.

Setting

The study originally had four NHS sites: Early Intervention in Psychosis (EIP) teams from two pathway implementation and two comparator organisations. However, one pathway and one comparator site withdrew in the early stages due to an inability to provide necessary data. The remaining two NHS sites had pre-existing EIP teams who were working to principles originally set out in the NHS Plan (2000).

Implementation site

The implementation site was an NHS Trust in the south of England implementing the pathway and covers a population of 1.3 million. This site had four EIP service teams. The Trust was predicted to have an incidence of psychosis of 100 patients (Psymaptic.org).

Comparator site

The comparator was an NHS Trust in the south of England and covers a population of 780 000. This site had two EIP teams at the start of the study. Due to the needs of the service these two teams were amalgamated into one team during the study period. This Trust was predicted to have an incidence of psychosis of 54 patients (Psymaptic.org).

Intervention

TRIumPH is an integrated care pathway for psychosis that emphasises the importance of timely access and interventions (see Figure 1). The development, design and details of this pathway have been described in detail in the protocol paper[15] and in other publications[14,16].

Treatment as Usual

Participants in the comparator site received treatment as usual (TAU). This usually consisted of care coordination and outpatient appointments when needed. Access to psychological treatments and physical health interventions had been variable. The AWTS target was launched in April 2016, one year after the study started and will have influenced access to treatment in both the implementation and comparator site as a national standard for seeing referrals within two weeks was established. Other requirements for the standard included physical health assessments and availability of treatments.

Research Ethics Approval and Safety Assessments

Ethics approval was obtained from East of Scotland Research Ethics Service (REC Ref no: LR/15/ES/0091). Written consent was taken for all those providing data for the questionnaires, focus groups and interviews. Quantitative data used for the study was limited to that routine collected as part of clinical care and consent to access for research purposes was not sought by individual but approved via NHS Ethics Service. No adverse events were identified as a direct result of implementation of the pathway.

Patient and Public Involvement

Co-production workshops were held with patients, carers and clinicians to develop the pathway and key outcomes areas and a service user researcher sat on the study team. For further details see the previously published protocol[15].

Outcome measures

Feasibility and acceptability were assessed through both qualitative and quantitative data collection regarding recruitment, retention and adherence to the process. These measures were defined based on TRIumPH pathway[15,16] and NICE recommendations[10].

Quantitative measures:

- Timeliness of access: Waiting times from EIP referral and central triage points, time to allocation and engagement with a care coordinator, time to multidisciplinary team discussion, time to medical formulation, time to care planning approach (CPA meeting), time to risk assessment completion (See figure 1)
- NICE recommended interventions offered: medication, physical health assessment (within three months in accordance with NICE quality standard), psychological intervention (offered within six months), carers support, family intervention, employment support
- Clinical outcomes: Severity of symptoms (HoNoS scores), number of acute admissions during referral, length of hospital stay, mental health act (MHA) sections during referral, A&E attendance and contact with acute mental health services post EIP referral.
- Reason for discharge to assess appropriateness of referrals

These measures were collected for each cohort of participants from the time of their referral for one year. The Health of the Nation Outcome Scales (HoNOS)[18] were the source of clinical outcome data collected routinely in the NHS including

in EIP. It comprises twelve scales covering health and social care using a severity measure from 0-4 with 2-4 signifying clinically significant disorder.

Qualitative measures

Satisfaction and acceptability were assessed using questionnaires, interviews and focus groups. This consisted of the following: patient experience (using specifically designed patient experience focus groups/interviews), staff experience (staff questionnaires and focus groups designed to measure the impact of the pathway on staff experience), and carer experience (using carer focus groups/interviews). Staff experience was assessed at baseline and after 12 and 24 months, carer and service user experience was assessed at 12 and 24 months.

Sample size

As this was a prospective and pragmatic study, no a priori power and sample size calculations were performed or required as routinely collected and available data for all patients and staff during the study period was used.

Data Collection

Baseline data was collected for the period 1 June 2014 – 31 May 2015. The pathway was launched on 1 June 2015 and disseminated to four EIP teams in the implementation site. Data was collected over the subsequent two-year period on every patient that was referred to and accepted by the EIP teams in participant organisations. This led to the following cohorts who were all followed up for one year:

Baseline (referral received 1 June 2014 – 31 May 2015)

Year 1 (referral received 1 June 2015 – 31 May 2016)

Year 2 (referral received 1 June 2016 – 31 May 2017)

Qualitative methods

Staff, patients and carers were approached via the mental health teams they were currently engaged with. Patients and carers showed a preference to semi-structured interviews rather than attending offered focus groups. All focus groups and interviews were audio recorded, transcribed and then coded and analysed using thematic analysis[19]. Thematic analysis was inductive using themes developed from the data produced by the structured scripts and remained at a semantic level to allow for a description of the views reported. Staff was also invited to complete a questionnaire to explore the impact of the pathway on staff experience and enable comparisons across the three time points (baseline, 12 & 24 months).

Statistical Analysis

Continuous normal data was summarised by mean and standard deviation, with comparisons to baseline made using t-tests. Continuous data that is non-normal as tested by Kolmogorov-Smirnov or Shapiro-Wilk tests, was presented by median and interquartile range (IQR) and compared using Mann-Whitney U test. Categorical variables were presented as n (%) and compared using Chi-Square or Fisher's Exact test as appropriate. However, no statistical comparisons were undertaken when the event rates in most groups were <5. $p<0.05$ was assumed to indicate statistical significance. Missing data was excluded on a case-by-case basis. Statistical analyses were undertaken using IBM SPSS Statistics 19 and R 3.4.2.

Results

The participant information and demographic data is presented in Table 1. The demographic characteristics of individuals in both comparator and pathway site was broadly similar throughout the study period, with around 3 in 5 of subjects being male, and the majority being of White Caucasian ethnicity (88-93%), unemployed (26-54%) and residing in mainstream housing (76-88%).

In both sites, the most common source of referral to EIP services was primary care, making up between 55 to 63% of referrals, followed by other mental health services (6-23%) and then Emergency Departments (2-9%).

Table 1 here

Quantitative Results

Timeliness of access

Table 2 here

Waiting times (shown in table 2) for EIP assessment from both EIP referral and central triage points (teams where referrals received) reduced significantly compared with baseline, from median 11 to 7 days, and from 20 to 11 days respectively ($p<0.0001$ for both) in the implementation site. Conversely, in the comparator site the median waiting time from EIP referral to assessment increased significantly from 7 to 12 days ($p<0.0001$) and was unchanged from central triage to assessment at 33 days ($p=0.56$).

This suggests an improvement in assessment speed following referral to services in the implementation site.

The pathway implementation site also saw significantly reduced waiting times for allocation to and engagement by care co-ordinator, Multidisciplinary team (MDT) discussions, risk assessment completion and discharge of service users found unsuitable for the service on assessment ($p<0.0001$ for all). There was no statistically significant difference in the time to medical formulation or Care Programme Approach development (CPA). In the comparator site, time to allocation and engagement by care co-ordinator remained unchanged at median 0 days throughout the study. Although not significantly different from baseline in year 1, by year 2 time to MDT discussion and to risk assessment completion had both increased significantly ($p<0.0001$ for both).

The numbers of patients accepted onto the EIP case load were much higher than expected in the comparator site, but this reduced to nearer the expected levels during the course of the project. The implementation site started below but rose to just above expected levels.

Reasons for discharge from EIP services remained similar in the comparator site throughout the study. However, in the implementation site there was a significant change, seemingly led by an increase in the number of unsuitable referrals to the service, which increased from 55% to 81%. Non-acceptance was also broadly similar as it was agreed with sites that 'did not meet EIP criteria' and 'discharged on professional advice' effectively meant the same thing.

NICE recommended interventions offered

Physical Health Assessments

Table 3 here

Both sites of the study saw significant improvements in the proportion of individuals receiving assessments of their general physical health, substance use, alcohol use and weight, having their bloods taken and given ECGs, but at much higher levels in the implementation site as seen in Table 3. Assessment of smoking status increased significantly at the implementation site (p=0.00033). Measurements of pulse and blood pressure assessments increased significantly in the comparator site (p=0.010, p=0.0036). Assessment of waist measurement increased significantly in the pathway implementation site (p=0.011) whilst decreasing significantly in the comparator site (p=0.0037). Finally, neither site significantly increased the number of individuals receiving a full 8-point NICE recommended health check within 8 weeks of EIP assessment.

Other Interventions

The proportion of individuals being offered CBT (Cognitive Behaviour Therapy) increased significantly in the comparator site from 1% to 22% (p<0.0001) and was matched with a significant increase in taking up CBT intervention from 0% to 7% (p=0.010). The implementation site did not see any significant change in either of these

factors. However throughout the period, CBT for psychosis and family work for psychosis were much more likely to be offered (Table 3).

Prevalence of individuals receiving any of the listed interventions increased in both the pathway (83% to 94%, p=0.0071) and comparator sites (57% to 81%, p<0.0001), as did engagement (75% to 90%, p=0.039 and 57% to 79%, p<0.0001 respectively) from baseline to year 2.

The implementation site saw increases in the proportion of participants receiving carer support (35% to 68%, p<0.0001) and medication (54% to 73%, p=0.027), although neither of these changed significantly in the comparator site. Receipt of collaborative care planning increased significantly in the implementation site (32% to 69%, p<0.0001) whilst the comparator site saw a decrease (31% to 1%, p<0.0001). Prevalence of physical health interventions also decreased in the comparator site (26% to 15%, p<0.0001) but did not change significantly in the implementation site, remaining low (3% to 6%, p=0.58). Receipt of vocational support increased significantly in both the implementation site (20% to 72%, p<0.0001) and the comparator site (20% to 39%, p=0.0023). However subsequently, after six months, there was a much higher take-up rate with over 80% in the implementation and over 70% in the comparator site.

Table 4 here

Clinical Outcomes

Acute care

There was a substantial contrast in the numbers of patients who had been admitted to hospital at the point of referral, much higher in the implementation site compared to comparator but reducing over time (table 4). Further admissions were low across both sites with neither site seeing a significant change in the prevalence of acute mental health admissions, in the time to being admitted or in the time to discharge. Similarly, the number of EIP participants subject to MHA section did not change significantly, although there was a tendency towards a decrease in the implementation site (36% to 33% to 27%, p=0.58). In both sites, the number of EIP service users attending Emergency Department (ED) or general hospital within a year was low (7-10%) and there were no significant changes over time.

Crisis planning

In the implementation site, the proportion of participants having a crisis plan completed reduced significantly (51% to 35%, p=0.032), occurring alongside a decrease in the time to crisis plan completion (50.0 to 12.5 weeks, p<0.0001) as seen in table 4. Conversely, in the comparator site the proportion of participants having a crisis plan completed increased significantly (49% to 67%, p=0.00023).

Table 5 here

Clinical and social outcomes

These were assessed by extracting the data routinely collected using the Health of the Nation Outcome Scales (HoNOS) as seen in table 5. At the implementation site there were significant reductions over the two-year period in 'problems with relationships' (p=0.013) and 'problems with occupation and activities' (p=037). At the comparator site there were significant reductions in 'problems with activities of daily living' (p=0.04). The comparator site however had substantial amounts of missing data. There was no significant difference in reductions in 'problems with delusions and hallucinations' between sites.

Criminal justice system contact

The number of participants having contact with the criminal justice system decreased significantly in the implementation site (22% to 3%, p<0.0001) whilst increasing significantly in the comparator site (14% to 21%, p<0.0001). Criminal convictions were rare in both sites (table 4).

Discharge and death

Discharge from services within a year of patients accepted by EIP teams (Table 2), was relatively low although disengagement remained a concern. It reduced in the implementation site (18% to 11%) and remained stable in comparator (10% to 12%). There was one death of a participant within a year of EIP assessment in the comparator site, Year 2 cohort (Table 4).

Qualitative Results

Staff and patient interviews and focus groups

Across the two years, 64 staff in the implementation site took part in focus groups and reported that the psychosis pathway appeared to be beneficial, well embedded and a positive change with good team working within the teams and with other services. However, they found workload to be high and had some difficulties getting the right staff skills mix in teams to deliver all the needed interventions. They also noted that often interventions were offered but were not always completed due to patient's ability to engage with them. Additionally, they worried about future changes being implemented in addition to their current workload. They felt by year 2 that they were more able to adapt the pathway to individuals' needs which they saw as important rather than a prescriptive measure.

Patients (14 participants) in the implementation site reported that they were generally satisfied with being seen quickly and developed good relationships with the staff members. They found appointments helpful and felt they gained useful skills. However, they also reported that at times there was inconsistencies in the staff they saw and out of hours services could be improved. Carers views (7) in the implementation site appeared to improve from year 1 to year 2 with more positive reports about the team and services than at year 1, however at both time points the sample was small.

Results from staff questionnaires

In total 1,680 questionnaires were completed by staff members in the implementation and comparator site across the three time points. There was no significant change in staff experience across the time points or between the sites (Supplementary Table 1). All staff members with adult mental health services were eligible to complete this

questionnaire to capture the experience of staff referring into services and caring for services users with psychosis in services such as hospital settings.

Discussion

This comparison study provides evidence that the introduction of an integrated psychosis care pathway led to improvements in access to EIP and implementation of quality standards, especially for physical health care in comparison with a site which did not implement the pathway. In terms of acceptability and feasibility, staff, service user and carer attitudes to TRIumPH were found to be generally positive. However, there were pre-existing differences between the sites which influenced the comparison as seen by access and waiting times, and level of interventions offered during the baseline period. Prior to the project, the implementation site had dismantled three out of four EIP teams and integrated them into community mental health teams, in contrast to the comparator site which had maintained specialist teams. At the beginning of the project the implementation site reintroduced the four EIP teams. A marked difference in referrals occurred in each site with movement in both towards predicted levels of patients accepted by EIP teams.

Time to assessment improved in the implementation site and remained within the AWTS in the comparator site. Referral from the Central Triage Point was relatively high especially in the comparator site, as was found by Birchwood and colleagues[20] and this remains a very important area for attention.

Meeting of quality standards increased substantially in the implementation site but was more variable and reached lower levels in the comparator site. This was especially noticeable for physical health standards, although the full set of NICE recommendations was still only met in under 10% patients within 3 months of acceptance. In the implementation site, offering of CBT for psychosis was relatively high throughout, although uptake within 6 months was low. However, by 2 years, this was considerably higher. There was an increase in offering of CBT and family work in the comparator site from a very low base which had been due to a lack of fully trained therapists. This seems an area where implementation of the quality standards through a pathway process could be especially effective. Family intervention, carer and employment support were all offered to a greater extent in implementation site and uptake increased over the period. The findings also compare favourably with those of the National Clinical Audit of Psychosis[21].

The changes in teams were reflected in the results as numbers of patients accepted onto case load were much higher than expected in the comparator site but reduced to nearer expected levels during the project. Referrals increased substantially in implementation site but then plateaued after introduction of the pathway.

The introduction of the AWTS target brought increased funding for EIP nationally. In the implementation site the local service commissioners remained well engaged with the pathway implementation and resulting outcomes and this enabled positive contract discussions for future investment. A formal cost effectiveness analysis was not conducted due to limitations in data availability but the reduction in patients admitted to in-patients and the subsequent reduction in relapses to hospital suggest that the re-

introduction of the EIP teams and the implementation of the pathway could be expected to have had a positive impact on cost in the implementation site.

Study Limitations

This is an observational retrospective study based on manual audit of patients' medical records. Therefore, causality cannot be assumed. We took steps to maintain data consistency by having one dedicated member of staff involved in the data audit throughout, and by performing post-hoc data checks for consistency and outliers; however, data accuracy is naturally limited by the quality of mental health care providers' original record keeping. Additionally, missing data was common, for example only 237 (33%) of participants had a HoNoS score recorded at both referral and one year later allowing us to analyse the impact of their care on this endpoint; we cannot rule out the possibility of statistical bias caused by this.

Conclusion

This comparison of the implementation of a quality standard based psychosis pathway with a comparator site which followed established guidelines for Early Intervention for Psychosis teams suggests that the former was more effective at improving the level of evidence-based practice offered to patients and their carers. Integrated care pathways can offer a platform to inform gaps in services, implement good clinical practice and measure the impact.

Competing interests

The production of the pathway has been supported by the Wessex Academic Health Sciences Network (AHSN) and evaluation has also been supported by the Wessex Clinical Research Network (CRN). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of funders, NIHR, NHS or the RCPsych, AHSN or CRN. The study is sponsored by Southern Health NHS Foundation Trust.

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Study Status

The study is complete.

Authors' contributions

SR and DK are grant holders and contributed to the concept and design of the study. SR is the CI and led the development of the study protocol and study documentation and made a significant contribution to the manuscript. KT provided statistical expertise throughout the protocol development, data collection and analysis. CA provided PPI expertise throughout the protocol development and study delivery. AG supported the implementation of the TRIumPH development and delivery. EG, PP and TR supported the delivery of the study at their respective sites. All authors contributed to elaboration and refinement of the study protocol and approved the final manuscript.

Data Availability

All data relevant to the study are included in the article or uploaded as supplementary information.

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Figure 1 Caption

TRIumPH Pathway

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Tables

Table 1: Demographic information for all individuals referred to EIP service. Numbers represent either median (IQR) for continuous variables or proportions for categorical variables. Excludes EIP to EIP transfers.

		Implementation site			Comparator Site		
		Baseline (n=123)	Year 1 (n=416)	Year 2 (n=463)	Baseline (n=237)	Year 1 (n=271)	Year 2 (n=252)
Age (Years)		22.4 (19.3 to 28.2)	21.4 (19.0 to 26.1)	21.6 (19.0 to 25.9)	19.4 (16.7 to 24.9)	19.7 (17.1 to 24.8)	21.8 (17.9 to 30.3)
Gender:	*Female*	35%	40%	39%	43%	40%	38%
	Male	65%	60%	61%	57%	60%	62%
Ethnicity:	*White*	88%	89%	93%	92%	93%	92%
	Black or Black British	5%	3%	3%	1%	3%	1%
	Asian or Asian British	0%	2%	0%	1%	1%	1%
	Mixed race	3%	3%	2%	3%	1%	4%
	Other	5%	2%	1%	3%	3%	2%
Accommodation Status:							
Accommodation with MH care support		3%	1%	0%	0%	2%	0%
Accommodation with other support		3%	4%	7%	4%	5%	2%
Acute/long stay healthcare residential facility/hospital		0%	0%	1%	3%	8%	13%
Homeless		7%	9%	13%	10%	8%	7%
Mainstream housing		88%	86%	80%	79%	76%	76%
Bail/probation hostel		0%	0%	0%	2%	0%	0%
Other		0%	0%	0%	2%	1%	3%
Employment status:							
Employed		38%	20%	29%	24%	26%	20%
Unemployed		26%	38%	40%	48%	40%	54%
Homemaker		1%	2%	1%	4%	3%	1%
Student		16%	15%	14%	11%	12%	11%
Long term sickness/disability benefit		15%	16%	12%	9%	5%	5%
Statutory sick pay		0%	3%	0%	5%	9%	3%
Retired		0%	0%	0%	0%	0%	1%
Other		3%	6%	4%	0%	4%	4%
Change in employment status during EIP:							
No reported change		58 (84%)	107 (91%)	124 (100%)	128 (88%)	163 (97%)	88 (86%)
Became employed		0 (0%)	4 (3%)	0 (0%)	13 (9%)	2 (1%)	5 (5%)
Left employment/became unemployed		10 (14%)	4 (3%)	0 (0%)	4 (3%)	2 (1%)	3 (3%)
Other		1 (1%)	3 (3%)	0 (0%)	0 (0%)	1 (1%)	6 (6%)
Referral source:							
Primary care		75 (62%)	256 (63%)	283 (62%)	143 (60%)	172 (63%)	139 (55%)
Community mental health service		19 (16%)	66 (16%)	104 (23%)	14 (6%)	26 (10%)	14 (6%)
Inpatient mental health service		1 (1%)	21 (5%)	15 (3%)	12 (5%)	16 (6%)	4 (2%)
A&E department		11 (9%)	20 (5%)	21 (5%)	5 (2%)	13 (5%)	23 (9%)
Physical healthcare service		0 (0%)	13 (3%)	8 (2%)	4 (2%)	8 (3%)	2 (1%)
Caring and social services		0 (0%)	0 (0%)	5 (1%)	10 (4%)	5 (2%)	11 (4%)
Education service		0 (0%)	6 (1%)	4 (1%)	12 (5%)	7 (3%)	8 (3%)
Police/prison/probation		9 (7%)	8 (2%)	11 (2%)	14 (6%)	11 (4%)	25 (10%)
Self-referral		1 (1%)	2 (0%)	2 (0%)	12 (5%)	6 (2%)	17 (7%)
Other		5 (4%)	16 (4%)	4 (1%)	11 (5%)	8 (3%)	9 (4%)
Central triage point (CTP):							
EIP		22 (18%)	107 (26%)	120 (26%)	33 (14%)	24 (9%)	27 (11%)

Community mental health service	98 (80%)	281 (69%)	325 (71%)	183 (78%)	217 (81%)	184 (73%)
Inpatient mental health service	2 (2%)	21 (5%)	14 (3%)	17 (7%)	26 (10%)	27 (11%)
Physical healthcare service	0 (0%)	1 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Police/prison/probation	0 (0%)	0 (0%)	0 (0%)	3 (1%)	2 (1%)	14 (6%)

Table 2: Process outcomes for all individuals referred to EIP service. Numbers represent either N (%) for categorical variables or median (IQR) for continuous variables. Excludes EIP to EIP transfers. P values for categorical comparisons from chi-squared test or Fisher's exact test as appropriate. P values for continuous data from Mann-Whitney U tests.

	Implementation site					Comparator site				
	Baseline (n=123)	Year One (n=416)	Year Two (n=463)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=237)	Year One (n=271)	Year Two (n=252)	P value Y1 vs baseline	P value Y2 vs baseline
Accepted onto EIP pathway	69 (56%)	118 (28%)	124 (27%)	< 0.0001	< 0.0001	145 (61%)	168 (62%)	102 (40%)	0.89	< 0.0001
Time from EIP referral to EIP assessment (in days)	11.0 (6.0 to 20.5)	6.0 (3.0 to 12.0)	7.0 (4.0 to 14.0)	< 0.0001	< 0.0001	7.0 (3.0 to 12.0)	7.0 (4.0 to 12.8)	12.0 (7.0 to 21.0)	0.24	< 0.0001
Time from CTP referral to EIP assessment (in days)	20.0 (11.8 to 55.3)	15.0 (6.0 to 40.0)	11.0 (6.0 to 23.0)	0.0053	< 0.0001	33.0 (11.0 to 142.5)	24.0 (9.3 to 130.5)	33.0 (13.0 to 98.0)	0.45	0.96
DNAs prior to assessment										
0	113 (92%)	378 (91%)	434 (94%)	0.37		211 (89%)	247 (91%)	232 (92%)	0.59	
1	7 (6%)	28 (7%)	17 (4%)			17 (7%)	19 (7%)	12 (5%)		
2 or more	3 (2%)	10 (2%)	12 (3%)			9 (4%)	6 (2%)	9 (4%)		
Time to allocation and engagement by care coordinator (in weeks)	4.0 (0.0 to 11.0)	1.0 (0.0 to 5.0)	0.0 (0.0 to 3.0)	0.0033	< 0.0001	0.0 (0.0 to 7.3)	0.0 (0.0 to 7.0)	0.0 (0.0 to 14.8)	0.054	0.48
Time to multidisciplinary team (MDT) discussion (in weeks)	6.2 (1.7 to 20.0)	1.9 (1.0 to 4.6)	1.9 (0.9 to 3.0)	< 0.0001	< 0.0001	1.8 (0.7 to 3.0)	1.7 (1.0 to 2.7)	4.9 (1.8 to 28.0)	0.74	< 0.0001
Time to medical formulation (in weeks)	4.7 (2.3 to 8.4)	3.9 (1.9 to 8.4)	3.3 (1.9 to 6.0)	0.45	0.11	6.5 (2.3 to 10.3)	6.7 (2.4 to 11.0)	8.3 (3.8 to 11.9)	0.99	0.14
Time to CPA (care plan approach) /care plan (in weeks)	2.4 (0.0 to 6.9)	2.7 (0.8 to 5.4)	2.0 (0.4 to 5.8)	0.62	0.87	2.0 (0.7 to 5.6)	3.0 (1.0 to 14.5)	13.0 (4.3 to 34.0)	0.080	< 0.0001
Time to risk assessment completion (in weeks)	50.3 (2.6 to 91.1)	6.4 (1.0 to 15.3)	4.7 (1.4 to 8.1)	< 0.0001	< 0.0001	5.3 (1.4 to 15.0)	3.6 (1.0 to 15.1)	4.6 (1.1 to 13.4)	0.38	0.60
Reason for non-acceptance to EIP:										
Does not fulfil EIP criteria	29 (71%)	202 (79%)	280 (85%)	0.0010		18 (20%)	20 (19%)	28 (19%)	0.76	
Discharged on professional advice	4 (10%)	14 (5%)	2 (1%)			62 (67%)	65 (63%)	100 (66%)		
DNA/did not engage/declined treatment	6 (15%)	27 (11%)	35 (11%)			5 (5%)	8 (8%)	13 (9%)		
Moved out of area	0 (0%)	11 (4%)	10 (3%)			6 (7%)	7 (7%)	9 (6%)		

	Implementation site					Comparator site				
	Baseline (n=123)	Year One (n=416)	Year Two (n=463)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=237)	Year One (n=271)	Year Two (n=252)	P value Y1 vs baseline	P value Y2 vs baseline
Other	2 (5%)	3 (1%)	4 (1%)			1 (1%)	4 (4%)	1 (1%)		
Reason for discharge from EIP after acceptance:										
Care completed	4 (15%)	4 (9%)	0 (0%)	0.076		0 (0%)	0 (0%)	0 (0%)	0.40	
Does not fulfil EIP criteria	8 (31%)	22 (48%)	22 (50%)			7 (6%)	6 (5%)	4 (9%)		
Discharged on professional advice	0 (0%)	1 (2%)	3 (7%)			80 (72%)	72 (61%)	25 (54%)		
DNA/did not engage/declined treatment	6 (23%)	8 (17%)	8 (18%)			16 (14%)	25 (21%)	11 (24%)		
Moved out of area	5 (19%)	11 (24%)	9 (20%)			7 (6%)	12 (10%)	5 (11%)		
Other	3 (12%)	0 (0%)	2 (5%)			1 (1%)	4 (3%)	1 (2%)		
Change in accommodation status during EIP:										
No reported change	63 (91%)	118 (100%)	124 (100%)	<0.0001		136 (94%)	157 (93%)	78 (76%)	<0.0001	
Moved to mainstream housing	0 (0%)	0 (0%)	0 (0%)			2 (1%)	3 (2%)	10 (10%)		
Moved from acute/long stay/ hospital to supported accommodation	0 (0%)	0 (0%)	0 (0%)			1 (1%)	3 (2%)	2 (2%)		
Moved to acute/long stay/ hospital	1 (1%)	0 (0%)	0 (0%)			0 (0%)	1 (1%)	4 (4%)		
Committed to bail/probation hostel/prison	0 (0%)	0 (0%)	0 (0%)			0 (0%)	0 (0%)	1 (1%)		
No longer homeless	1 (1%)	0 (0%)	0 (0%)			3 (2%)	2 (1%)	1 (1%)		
Became homeless	1 (1%)	0 (0%)	0 (0%)			1 (1%)	2 (1%)	1 (1%)		
Other	3 (4%)	0 (0%)	0 (0%)			2 (1%)	0 (0%)	5 (5%)		

Table 3: Physical health assessments and interventions

N (%) individuals accepted onto the EIP pathway at each site who received listed physical health checks within 12 weeks, were offered interventions or took up interventions within 6 months of EIP referral. Excludes EIP to EIP transfers. P values from chi-squared test or Fisher's exact test as appropriate.

	Implementation site				Comparator Site			
	Baseline (n=69)	Year One (n=118)	Year Two (n=124)	P value	Baseline (n=145)	Year One (n=168)	Year Two (n=102)	P value
Physical health assessments received within 12 weeks:								
Physical Health (general)	33 (48%)	81 (69%)	86 (69%)	0.0038	38 (26%)	40 (24%)	44 (43%)	0.0019
Smoking	23 (33%)	72 (61%)	76 (61%)	0.00033	38 (26%)	42 (25%)	34 (33%)	0.30
Substance Use	35 (51%)	93 (79%)	98 (79%)	<0.0001	71 (49%)	63 (38%)	66 (65%)	<0.0001
Alcohol	35 (51%)	89 (75%)	102 (82%)	<0.0001	60 (41%)	60 (36%)	61 (60%)	0.00045
Weight	17 (25%)	46 (39%)	60 (48%)	0.0065	46 (32%)	39 (23%)	39 (38%)	0.027
Waist	4 (6%)	16 (14%)	27 (22%)	0.011	18 (12%)	9 (5%)	2 (2%)	0.0037
Pulse	20 (29%)	48 (41%)	47 (38%)	0.30	25 (17%)	32 (19%)	33 (32%)	0.010
Blood Pressure	22 (32%)	50 (42%)	55 (44%)	0.25	32 (22%)	38 (23%)	40 (39%)	0.0036
Bloods Taken	18 (26%)	58 (49%)	50 (40%)	0.010	15 (10%)	25 (15%)	36 (35%)	<0.0001
ECG	10 (14%)	49 (42%)	27 (22%)	<0.0001	17 (12%)	10 (6%)	30 (29%)	<0.0001
NICE health check in 12 weeks	2 (3%)	9 (8%)	11 (9%)	0.30	1 (1%)	1 (1%)	1 (1%)	0.94
Interventions offered at any time:								
Cognitive behaviour therapy	43 (62%)	68 (58%)	84 (68%)	0.26	1 (1%)	23 (14%)	22 (22%)	<0.0001
Family intervention	36 (52%)	64 (54%)	80 (65%)	0.17	7 (5%)	7 (4%)	10 (10%)	0.13
Carer support	50 (72%)	82 (69%)	90 (73%)	0.86	34 (23%)	29 (17%)	25 (25%)	0.26
Employment support	41 (59%)	47 (40%)	57 (46%)	0.043	37 (26%)	47 (28%)	18 (18%)	0.15
Interventions taken up within 6 months:								
Engagement	52 (75%)	103 (87%)	111 (90%)	0.039	82 (57%)	74 (44%)	80 (79%)	<0.0001
CBT for psychosis	3 (4%)	10 (8%)	8 (6%)	0.56	0 (0%)	7 (4%)	7 (7%)	0.010
Carer support	24 (35%)	63 (53%)	84 (68%)	<0.0001	17 (12%)	22 (13%)	16 (16%)	0.66
Medication	37 (54%)	80 (68%)	91 (73%)	0.027	25 (17%)	37 (22%)	28 (28%)	0.16
Collaborative care planning	22 (32%)	85 (72%)	86 (69%)	<0.0001	45 (31%)	38 (23%)	1 (1%)	<0.0001
Physical Health	2 (3%)	4 (3%)	7 (6%)	0.58	37 (26%)	9 (5%)	15 (15%)	<0.0001
Vocational	14 (20%)	79 (67%)	89 (72%)	<0.0001	29 (20%)	37 (22%)	39 (39%)	0.0023
Family work for psychosis	2 (3%)	11 (9%)	8 (6%)	0.25	2 (1%)	6 (4%)	1 (1%)	0.26
Any of these	57 (83%)	113 (96%)	117 (94%)	0.0071	83 (57%)	74 (44%)	82 (81%)	<0.0001

Table 4: Acute care & clinical outcomes. Proportion of individuals accepted onto the EIP pathway at each trust experiencing acute care outcomes [n (%)] within 1 year of trust referral, and time to reach those outcomes where applicable [median (IQR)]. Excludes EIP to EIP transfers. P values for categorical comparisons from chi-squared test or Fisher's exact test as appropriate. P values for continuous data from Mann-Whitney U tests.

	Implementation site					Comparator site				
	Baseline (n=69)	Year One (n=118)	Year Two (n=124)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=145)	Year One (n=168)	Year Two (n=102)	P value Y1 vs baseline	P value Y2 vs baseline
Acute MH admission within 1 year of EIP referral	27 (39%)	47 (40%)	36 (29%)	0.16		16 (11%)	21 (13%)	19 (19%)	0.20	
Time to acute admission (where applicable) (weeks)	0.0 (0.0 to 10.0)	1.0 (0.0 to 7.0)	0.0 (0.0 to 3.5)	0.88	0.11	15.0 (3.0 to 41.0)	11.0 (2.0 to 41.0)	13.5 (3.0 to 34.0)	0.82	0.92
Time to acute MH/inpatient screening (hours)										
0 - 4	21 (91%)	1 (100%)	14 (67%)	-		11 (73%)	11 (58%)	8 (53%)	0.49	
4 - 6	0 (0%)	0 (0%)	6 (29%)			3 (20%)	4 (21%)	3 (20%)		
6 - 8	1 (4%)	0 (0%)	0 (0%)			0 (0%)	2 (11%)	1 (7%)		
8 - 10	1 (4%)	0 (0%)	1 (5%)			1 (7%)	2 (11%)	3 (20%)		
Time from acute admission to discharge (where applicable) (weeks)	4.5 (2.0 to 10.3)	4.0 (2.0 to 6.8)	3.0 (1.0 to 5.3)	0.42	0.56	3.0 (2.0 to 13.5)	3.0 (2.0 to 5.0)	3.0 (2.3 to 3.8)	0.56	0.95
Number of subsequent acute admissions										
None	18 (64%)	41 (85%)	25 (71%)	0.091		14 (67%)	15 (65%)	13 (62%)	0.95	
1	6 (21%)	4 (8%)	9 (26%)			5 (24%)	2 (9%)	8 (38%)		
More than 1	4 (14%)	3 (6%)	1 (3%)			2 (10%)	6 (26%)	0 (0%)		
MHA section within 1 year of EIP referral	25 (36%)	39 (33%)	34 (27%)	0.58		16 (11%)	21 (13%)	18 (18%)	0.18	
Contact acute MH services (post EIP)	32 (46%)	41 (35%)	37 (30%)	< 0.0001		25 (17%)	30 (18%)	22 (22%)	< 0.0001	
Crisis plan completed	35 (51%)	59 (50%)	44 (35%)	0.032		71 (49%)	69 (41%)	68 (67%)	0.00023	
Time to crisis plan completed (weeks)	50.0 (15.0 to 79.0)	22.5 (10.0 to 37.8)	12.5 (6.0 to 22.8)	0.0010	< 0.0001	8.0 (1.0 to 23.0)	11.0 (1.0 to 39.0)	12.0 (2.0 to 34.3)	0.36	0.10
A&E attendance within 1 year of EIP referral	7 (10%)	10 (8%)	11 (9%)	0.91		11 (8%)	12 (7%)	10 (10%)	0.72	
Time to A&E attendance (weeks)	21.0 (2.5 to 68.3)	8.5 (0.0 to 17.0)	13.0 (8.0 to 43.0)	0.15	0.88	30.0 (25.0 to 41.0)	44.0 (11.0 to 76.0)	14.5 (7.3 to 31.5)	0.87	0.11
Reason for A&E attendance:										

	Implementation site					Comparator site				
	Baseline (n=69)	Year One (n=118)	Year Two (n=124)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=145)	Year One (n=168)	Year Two (n=102)	P value Y1 vs baseline	P value Y2 vs baseline
Deterioration in mental state	7 (41%)	7 (50%)	5 (42%)	-		2 (15%)	4 (24%)	2 (20%)	-	
Self harm/suicidal ideation/suicide attempt/overdose	6 (35%)	5 (36%)	4 (33%)			10 (77%)	6 (35%)	4 (40%)		
Alcohol/substance abuse	1 (6%)	1 (7%)	2 (17%)			0 (0%)	1 (6%)	0 (0%)		
Medication side effects	0 (0%)	0 (0%)	0 (0%)			0 (0%)	1 (6%)	1 (10%)		
Physical injury/illness (not apparently psychosis related)	3 (18%)	1 (7%)	1 (8%)			1 (8%)	5 (29%)	3 (30%)		
General hospital admission within 1 year of EIP referral	1 (1%)	4 (3%)	3 (2%)	-		2 (1%)	0 (0%)	4 (4%)	-	
Contact with criminal justice system whilst in EIP pathway	15 (22%)	34 (29%)	4 (3%)	< 0.0001		20 (14%)	20 (12%)	21 (21%)	< 0.0001	
Criminal conviction within 1 year of EIP referral	1 (1%)	0 (0%)	0 (0%)	-		4 (3%)	4 (2%)	1 (1%)	-	
Deaths within 1 year of EIP referral	0 (0%)	0 (0%)	0 (0%)	-		0 (0%)	0 (0%)	1 (1%)	-	

Table 5: Clinical outcomes (HoNoS). Mean (SD) change in HoNoS scores from referral to one year at each trust for patients accepted onto EIP pathway. Excludes EIP to EIP transfers. P values from paired t-tests.

	Implementation Site					Comparator Site				
	Baseline (n=52)	Year One (n=77)	Year Two (n=53)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=28)	Year One (n=16)	Year Two (n=11)	P value Y1 vs baseline	P value Y2 vs baseline
Change in HoNoS scores (from referral to 1 year)										
1. Overactive, aggressive, disruptive or agitated behaviour	-0.56 (1.73)	-0.43 (1.72)	-0.69 (1.45)	0.59	0.78	-0.43 (1.55)	-1.06 (1.65)	-0.09 (1.14)	0.21	0.52
2. Non-accidental self injury	-0.50 (1.38)	-0.22 (1.26)	-0.22 (1.15)	0.18	0.21	-0.25 (0.84)	-0.06 (1.29)	-0.36 (1.43)	0.56	0.76
3. Problem drinking or drug taking	-0.40 (1.48)	-0.15 (1.87)	0.04 (1.71)	0.30	0.12	0.14 (1.04)	-0.31 (1.20)	-0.10 (1.52)	0.19	0.58
4. Cognitive problems	-0.27 (1.34)	-0.15 (1.32)	-0.06 (1.32)	0.48	0.33	-0.29 (1.18)	-0.38 (0.96)	-0.50 (1.51)	0.80	0.65
5. Physical illness or disability problems	-0.23 (1.10)	0.03 (1.35)	0.02 (1.08)	0.19	0.17	0.11 (0.50)	-0.38 (1.02)	0.45 (1.44)	0.041	0.26
6. Problems associated with hallucinations and delusions	-0.56 (1.62)	-0.71 (1.70)	-0.11 (1.51)	0.74	0.14	-0.86 (1.46)	-1.81 (1.42)	-0.91 (1.76)	0.041	0.93
7. Problems with depressed mood	-0.50 (1.59)	-0.19 (1.49)	-0.55 (1.12)	0.24	0.94	-0.46 (1.29)	-0.88 (1.41)	-0.55 (1.21)	0.33	0.86
8. Other mental and behavioural problems	-0.45 (1.53)	-0.73 (1.81)	-0.27 (1.49)	0.58	0.68	-0.61 (1.26)	-0.75 (1.98)	-0.36 (1.69)	0.77	0.62
9. Problems with relationships	-0.83 (1.32)	-0.41 (1.51)	-0.20 (1.25)	0.07	0.013	-0.21 (1.26)	-1.00 (1.41)	-0.10 (0.57)	0.064	0.78
10. Problems with activities of daily living	-0.33 (1.57)	-0.32 (1.55)	-0.46 (1.47)	0.85	0.68	-0.64 (1.16)	-1.00 (1.55)	0.18 (0.75)	0.39	0.04
11. Problems with living conditions	-0.20 (1.51)	-0.33 (1.44)	0.08 (1.21)	0.69	0.28	-0.36 (1.31)	-0.69 (1.20)	0.45 (1.13)	0.41	0.079
12. Problems with occupation and activities	-0.33 (1.64)	-0.19 (1.47)	0.30 (1.45)	0.54	0.037	-0.25 (1.58)	-1.06 (1.57)	-0.09 (1.45)	0.11	0.77

TRIumPH: Treatment and Recovery In PsycHosis

Routine Referral

RIumPH
Treatment and Recovery In PsycHosis

Southern Health NHS
NHS Foundation Trust

Prevention and Early Detection

Screen

Referral received

Tel. triage using screening checklist to:

- determine urgency
- consider medication, social, psychological and physical health needs

Holistic Assessment

'At risk of psychosis' assessment:

- engagement
- medication, social, psychological and physical health needs
- patient and carer views
- outcome measures incl. PROM

MDT Discussion

Involving medical, nursing and social care staff as minimum to agree:

- provisional **formulation**/ diagnosis
- priorities for **care planning**

Care Plan/CPA

Collaborative planning from first contact:

- Safety and **crisis plan**
- Safeguarding (adult/child)
- **Social care** (incl. education, **vocation**/IPS, accommodation)
- **Medication management** (incl. Clozapine)
- **Psychological interventions** (see stepped pathway)
- **Physical health** (Lester tool and NICE); perinatal
- **Substance misuse** needs
- **Carers support**

Delivery of Care

Engagement from first contact (incl. assertive):

As indicated:

- **Social care**
- **Medication**
- **Psychological interventions**
- **Physical health**
- **Substance misuse**
- **Carers support**

Review of Care Plan

If deterioration in mental health/crisis/relapse:

- identify any deterioration early and fast track
- consider acute care pathway
- **MDT discussion** (CPA if criteria met) to review medication, social, psychological and physical health needs; update care plan
- consider advance statements
- patient and carer views
- communication with GP
- **WRAP**/Recovery College
- review outcome measures incl. PROM

Discharge

Plan with patient/service user, carers and GP if over 6-12 months:

- stable and functioning well
- no medication or stable medication
- not detained
- acute care pathway not needed

Complete **crisis** and contingency plans

Comprehensive communication with primary care, patient and carer

Screen

Within **24 hours**

Assessment

First face to face contact within **7 days**

Medication screen within **3 days** of referral if on prescribed medication

MDT Discussion

Within **7 days** of assessment

Earlier medical review if concerns

Discharge/ signpost if psychosis pathway not appropriate

Care Plan/CPA

Allocation of a care coordinator and care plan within **14 days** of referral

Formulation by medic within **21 days** of assessment

Delivery of Care

Commence within **14 days** of referral

Review as Required by Personal Plan

Weekly face to face: if first episode

Weekly: if medication changes, changing mental state, current risks, carer concerns, specific interventions

Weekly/biweekly: if difficulties engaging in services

Every 4 weeks: consider Clozapine if no response to antipsychotic medication. If mental state is settled, consider increasing review to 3 monthly then 6 monthly

Annual review: (if not indicated sooner) of Care Plan/CPA (incl. items listed in Care Plan / CPA box above). Completion of outcome measures

WESSEX ACADEMIC HEALTH SCIENCE NETWORK
IMPROVING HEALTH THROUGH INNOVATION

Table 1: Staff survey results

Section A: Demographics

	Intervention arm			Control arm		
	Baseline (n=438)	**Year 1 (n=412)**	**Year 2 (n=418)**	**Baseline (n=122)**	**Year 1 (n=155)**	**Year 2 (n=135)**
Type of team						
CMHT	39%	32%	30%	51%	46%	49%
EIP	7%	10%	8%	7%	5%	9%
Psychology	5%	6%	8%	2%	1%	2%
Inpatient	35%	42%	42%	30%	35%	27%
Hospital at home	8%	6%	8%	4%	8%	7%
Other (inc. AAT/AOT)	13%	7%	8%	10%	8%	9%
Job role						
Psychiatrist/SpR/SHO	15%	7%	10%	5%	6%	10%
Psychologist/Psychotherapist	7%	6%	8%	6%	1%	2%
Nurse practitioner	42%	41%	39%	39%	43%	34%
Occupational therapist	4%	6%	5%	7%	8%	7%
Social worker	7%	5%	5%	8%	5%	8%
Mental health care support worker	19%	25%	23%	20%	22%	16%
Other	8%	10%	10%	16%	15%	22%
Geographical area of living						
North Hampshire	7%	6%	11%	22%	35%	24%
West Hampshire	24%	23%	18%	20%	11%	27%
East Hampshire	32%	23%	21%	48%	54%	47%
Southampton	36%	43%	50%	8%	0%	1%
Unknown/other	1%	5%	0%	2%	0%	0%
Gender						
Male	32%	33%	32%	31%	39%	36%
Female	67%	66%	67%	68%	61%	64%
Other	0%	0%	<1%	0%	0%	0%
Not answered	1%	2%	1%	1%	0%	0%
Age group						
Under 24	5%	5%	6%	6%	5%	3%
25-34	26%	23%	25%	17%	21%	24%
35-44	30%	28%	30%	29%	21%	25%
45-54	28%	28%	27%	39%	34%	36%
55-64	9%	14%	11%	8%	17%	11%
65 or over	1%	1%	1%	0%	1%	1%
Not answered	1%	1%	<1%	1%	1%	0%
Ethnicity						
White	82%	80%	83%	92%	94%	90%

	Intervention arm			Control arm		
	Baseline (n=438)	Year 1 (n=412)	Year 2 (n=418)	Baseline (n=122)	Year 1 (n=155)	Year 2 (n=135)
Mixed race	4%	5%	5%	2%	3%	3%
Asian	6%	5%	5%	1%	1%	3%
Black	5%	9%	6%	3%	1%	1%
Other	1%	1%	1%	0%	1%	1%
Not stated	<1%	1%	1%	1%	0%	1%

Section B: Experience

	Intervention arm			Control arm		
	Baseline (n=438)	Year 1 (n=412)	Year 2 (n=418)	Baseline (n=122)	Year 1 (n=155)	Year 2 (n=135)
I have been able to support people with FEP to have more control in their lives:						
Always	16%	15%	18%	24%	15%	16%
Sometimes	62%	50%	54%	60%	55%	55%
Rarely	13%	14%	13%	8%	12%	10%
Never	5%	9%	6%	3%	9%	6%
Don't know	3%	7%	6%	2%	6%	11%
Not answered	2%	5%	3%	3%	2%	2%
I have been able to support people with FEP to manage their physical, mental and social needs holistically:						
Always	24%	27%	27%	25%	22%	22%
Sometimes	58%	47%	49%	63%	57%	54%
Rarely	9%	8%	10%	3%	6%	7%
Never	3%	7%	5%	3%	8%	5%
Don't know	2%	8%	6%	0%	6%	9%
Not answered	3%	5%	3%	5%	2%	3%
I have been able to support people with FEP to involve carers:						
Always	29%	25%	27%	30%	31%	31%
Sometimes	52%	43%	43%	60%	48%	47%
Rarely	9%	11%	12%	4%	8%	8%
Never	4%	8%	6%	2%	7%	4%
Don't know	2%	8%	9%	1%	5%	7%
Not answered	3%	5%	4%	4%	1%	3%
I feel appropriately trained and supervised to deliver psychological informed interventions:						
Always	22%	21%	21%	16%	12%	19%
Sometimes	47%	40%	38%	52%	42%	45%
Rarely	15%	14%	11%	11%	19%	11%
Never	7%	10%	8%	13%	7%	6%
Don't know	5%	11%	10%	4%	8%	10%
Not answered	4%	5%	13%	3%	1%	9%
I feel appropriately trained and supervised to deliver physical health assessment and intervention:						

	Intervention arm			Control arm		
	Baseline (n=438)	**Year 1 (n=412)**	**Year 2 (n=418)**	**Baseline (n=122)**	**Year 1 (n=155)**	**Year 2 (n=135)**
Always	34%	34%	29%	27%	34%	37%
Sometimes	41%	34%	39%	42%	41%	33%
Rarely	12%	10%	9%	14%	10%	12%
Never	10%	9%	8%	14%	9%	7%
Don't know	3%	8%	9%	2%	3%	8%
Not answered	2%	5%	6%	1%	4%	3%
I feel appropriately trained and supervised to deliver vocational support:						
Always	16%	20%	15%	17%	13%	19%
Sometimes	49%	42%	44%	55%	54%	51%
Rarely	23%	16%	17%	19%	21%	10%
Never	6%	9%	9%	5%	3%	7%
Don't know	4%	10%	9%	3%	5%	10%
Not answered	2%	4%	6%	1%	5%	3%
I feel appropriately trained and supervised to deliver alcohol, smoking and substance misuse support:						
Always	22%	22%	23%	30%	22%	29%
Sometimes	58%	46%	49%	50%	58%	48%
Rarely	12%	14%	11%	14%	10%	10%
Never	5%	5%	5%	5%	4%	4%
Don't know	2%	9%	9%	1%	1%	7%
Not answered	1%	4%	4%	1%	5%	3%
I believe service users and carers are involved in planning their care:						
Always	46%	47%	45%	48%	38%	47%
Sometimes	47%	46%	47%	52%	41%	52%
Rarely	4%	2%	3%	1%	4%	1%
Never	0%	0%	1%	0%	0%	0%
Don't know	1%	3%	2%	0%	2%	0%
Not answered	2%	2%	2%	0%	15%	1%
I feel supported to carry out holistic assessment and care plans:						
Always	44%	42%	43%	46%	47%	40%
Sometimes	39%	36%	34%	43%	34%	44%
Rarely	5%	6%	4%	3%	8%	5%
Never	3%	5%	5%	4%	2%	1%
Don't know	3%	6%	8%	2%	5%	5%
Not answered	6%	5%	6%	2%	5%	4%

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	7/8
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*NA*+
Bias	9	Describe any efforts to address potential sources of bias	17-19
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9
		(*b*) Describe any methods used to examine subgroups and interactions	9
		(*c*) Explain how missing data were addressed	9
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	9
		(*e*) Describe any sensitivity analyses	

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Table 1
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Table 1
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*Tables*
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Tables
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Tables Pg 10
Discussion			
Key results	18	Summarise key results with reference to study objectives	19
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	19
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	17
Generalisability	21	Discuss the generalisability (external validity) of the study results	19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

[+] Not possible as data collected from various sources across intervention and comparator site (depending on how information collected by services in real world setting). Data dictionary produced for researchers to allow for this.

BMJ Open

Results of a prospective, mixed methods study to assess feasibility, acceptability, and effectiveness of TRIumPH (Treatment and Recovery In PsycHosis), an Integrated Care Pathway for Psychosis, compared to usual treatment.

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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Evidence based practice, Medical management, Health services research
Keywords:	Adult psychiatry < PSYCHIATRY, Early Intervention, Integrated Care Pathways, Schizophrenia & psychotic disorders < PSYCHIATRY

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Results of a prospective, mixed methods study to assess feasibility, acceptability, and effectiveness of TRIumPH (Treatment and Recovery In PsycHosis), an Integrated Care Pathway for Psychosis, compared to usual treatment.

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Abstract

Objectives: To evaluate whether a newly developed care pathway, TRIumPH (Treatment and Recovery In PsycHosis) is feasible, acceptable and effective in meeting NICE quality standards in a timely manner.

Methods: This was a pragmatic, non-randomised, prospective, mixed methods study comparing an implementation (TRIumPH) and comparator site (not implementing TRIumPH) across three cohorts to assess feasibility, acceptability and effectiveness of the integrated pathway.

Setting: NHS Early Intervention in Psychosis (EIP) services at two NHS. .

Participants: All patients accepted into EIP services between 1 June 2014 and 31 May 2017 were each followed up for one year within their respective cohorts.

Methodology: Quantitative data consisted of routinely collected clinical data retrieved from patient records to asses whether the implementation of TRIumPH achieved better concordance to NICE standards. These included: time to access services, physical health assessments, clinical outcomes based timeliness of delivery, acute data. The controlled trial has evaluated the effect of TRIumPH (Intervention) with Care As Usual (Comparator). Qualitative measures consisted of questionnaires, interviews and focus groups to assess acceptability and satisfaction. Outcome measures were compared within the baseline, year 1 and year 2 cohorts and between the two sites. Quantitative data was statistically analysed by comparing means and proportions.

Results: Time to assessment improved in the implementation site and remained within the target in comparator site. Meeting of quality standards increased

substantially in the implementation site but was more variable and reached lower levels in the comparator site especially for physical health standards. Cognitive therapy for psychosis, family intervention, carer and employment support were all offered to a greater extent in the implementation site and uptake increased over the period.

Conclusions: Pathway implementation generally led to greater improvements in achievement of access and quality standards compared to comparator site.

Strengths and Limitations

• This is the only evaluation of a psychosis care pathway and results will be generalizable to NHS and managed care organisations

• Baseline differences between the sites could potentially affect interpretation of the results and conclusions need to be interpreted in this light

• Two additional sites initially planned to participate but withdrew during the course of the study due to inability to provide required data.

• Routine data was used to evaluate implementation which had the disadvantage of leading to significant amounts of missing data in some areas.

• Financial and human resource limitations may have had an impact on results

Study registration: UK Clinical Research Network Portfolio: 19187

Keywords: Integrated Care Pathway, psychosis, access, early intervention

Word count: **3965**

Background

Schizophrenia is listed as the 8th leading cause of DALYs worldwide in the age group 15 - 44 years in the World Health Report[1]. In addition to the direct cost, there is a considerable burden on the relatives[2] and life expectancy is reduced by approximately 15-20 years, mostly because of physical health problems[3].

A primary factor contributing to the impact of schizophrenia is that the longer the duration of untreated psychosis (DUP) the worse the outlook especially for social functioning and recovery[4,5]. DUP has been found to be the strongest predictor of symptom severity and prognosis[6]. A meta-analysis showed a mean DUP of 61.3 weeks[7] and further evidence from trans-cultural and international research suggests that DUP ranges between 364 and 721 days[5,6] and so reducing DUP is of individual, national and international importance[7].

In order to address both the impact of schizophrenia and the length of DUP the UK government strategy 'No Health Without Mental Health'[8] acknowledged that more must be done to address the disparity in care for people experiencing psychosis. It highlighted the importance of prevention, early detection, and support for evidence-based models such as Early Intervention in Psychosis (EIP) services. The National Access and Waiting Time (AWTS) standard for psychosis[9] announced in England from 1 April 2016 required that more than 50% of people experiencing a first episode psychosis should commence a National Institute of Health and Care Excellence (NICE) recommended package of care[10] within two weeks of referral to secondary care services. This action was specifically introduced to reduce DUP and ensure people access services and start treatment in a timely manner.

In addition to the introduction of care standards the Five Year Forward View (NHS England)[11] recommended development of standardized care pathways for every major mental health condition. Evidenced-based integrated pathways provide a standardised framework for good clinical practice, reduce variation in care and improving outcomes for patients through providing timely access and intervention[12]. Standardised pathways improve quality by improving multidisciplinary communication with different care agencies using care planning and improve patient satisfaction[13]. NICE has formulated quality standards for treatment of schizophrenia and psychosis[10] but does not prescribe timeframes.

TRIumPH (Treatment and Recovery In PsycHosis) is a co-developed, integrated care pathway for psychosis that prescribes time frames around access and clinical interventions as developed in England[14,15,16]. The work has used a similar approach to that taken to improve care in other health areas like acute stroke care[13] and has produced a demonstrable improvement in outcomes for patients and carers. This new psychosis pathway aims to reduce the impact of disease and promote recovery by ensuring that every individual gets the best evidence-based care at the right time and in the right place.

In developing the pathway, a multi-pronged approach has been used, using i) intelligence from information, ii) co-production with individuals with lived experience of mental illness and their carers, and iii) engagement with clinicians and other stakeholders including commissioners, primary care and third sector organisations. The development of TRIumPH used a robust methodology, outlined in previous publications by this group, which can be adapted and adopted nationally and internationally[14,15,16].

Therefore, the pathway goals are to treat the symptoms as early as possible, provide skills to patients and their families, maintain the improvement over a period, prevent relapses and reintegrate the individuals into the community so that they can lead as normal a life as possible.

Study objectives

The objective of this study was to assess the feasibility, acceptability and effectiveness of the TRIumPH psychosis care pathway.

- Does implementation of TRIumPH improve standards in line with the NICE quality standards as measured by: time taken to access services and waiting times, lengths of hospital stay, clinical outcomes based on Health of the Nation Outcome Scales (HoNOS scores)[17], treatment options offered and how timely the delivery of these were?
- How did staff members, service users and carers experience the implementation of the pathway? Was it feasibile and acceptable?

Methods

Study design

This is a prospective, mixed methods, pragmatic[18] and non-randomised study comparing the intervention implementation (TRIumPH pathway) and comparison site that had treatment as usual to evaluate feasibility, acceptability and effectiveness of an integrated care pathway, TRIumPH. Both qualitative and quantitative data were collected and analysed.

Setting

The study originally had four NHS sites: Early Intervention in Psychosis (EIP) teams from two pathway implementation and two comparator organisations. However, one pathway and one comparator site withdrew in the early stages due to an inability to provide necessary data. The remaining two NHS sites had pre-existing EIP teams who were working according to principles originally set out in the NHS Plan (2000).

Implementation site

The implementation site was an NHS Trust in the south of England implementing the pathway and covers a population of 1.3 million. This site had four EIP service teams. The Trust was predicted to have an incidence of psychosis of 100 patients (Psymaptic.org).

Comparator site

The comparator was an NHS Trust in the south of England and covers a population of 780 000. This site had two EIP teams at the start of the study. Due to the needs of the service these two teams were amalgamated into one team during the study period. This Trust was predicted to have an incidence of psychosis of 54 patients (Psymaptic.org).

Intervention

TRIumPH is an integrated care pathway for psychosis that emphasises the importance of timely access and interventions (see Figure 1). The development, design and details of this pathway have been described in detail in the protocol paper[15] and in other publications[14,16].

Treatment as Usual

Participants in the comparator site received treatment as usual (TAU). This usually consisted of care coordination and outpatient appointments when needed. Access to psychological treatments and physical health interventions had been variable. The AWTS target was launched in April 2016, one year after the study started and will have influenced access to treatment in both the implementation and comparator site as a national standard for seeing referrals within two weeks was established. Other requirements for the standard included physical health assessments and availability of treatments.

Research Ethics Approval and Safety Assessments

Ethics approval was obtained from East of Scotland Research Ethics Service (REC Ref no: LR/15/ES/0091). Written consent was taken for all those providing data for the questionnaires, focus groups and interviews. Quantitative data used for the study was limited to that routinely collected as part of clinical care and consent to access for research purposes was not sought by individual but approved via NHS Ethics Service. No adverse events were identified as a direct result of implementation of the pathway.

Patient and Public Involvement

Co-production workshops were held with patients, carers and clinicians to develop the pathway and key outcomes areas and a service user researcher sat on the study team. For further details see the previously published protocol[15].

Outcome measures

Feasibility and acceptability were assessed through both qualitative and quantitative data collection regarding recruitment, retention and adherence to the process. These measures were defined based on TRIumPH pathway[15,16] and NICE recommendations[10].

Quantitative measures:

- Timeliness of access: Waiting times from EIP referral and central triage points, time to allocation and engagement with a care coordinator, time to multidisciplinary team discussion, time to medical formulation, time to care planning approach (CPA meeting), time to risk assessment completion (See figure 1)
- NICE recommended interventions offered: medication, physical health assessment (within three months in accordance with NICE quality standard), psychological intervention (offered within six months), carers support, family intervention, employment support
- Clinical outcomes: Severity of symptoms (HoNoS scores[17]), number of acute admissions during referral, length of hospital stay, mental health act (MHA) sections during referral, A&E attendance and contact with acute mental health services post EIP referral.
- Reason for discharge to assess appropriateness of referrals

These measures were collected for each cohort of participants from the time of their referral for one year. The HoNOS[17] were the source of clinical outcome

data collected routinely in the NHS including in EIP. It comprises twelve scales covering health and social care using a severity measure from 0-4 with 2-4 signifying clinically significant disorder.

Qualitative measures

Satisfaction and acceptability were assessed using questionnaires, interviews and focus groups. The later two were only conducted at the intervention site to enable a process evaluation of the implementation of the pathway at this site. Measures consisted of the following: patient experience (using specifically designed patient experience focus groups/interviews), staff experience (staff questionnaires and focus groups designed to measure the impact of the pathway on staff experience), and carer experience (using carer focus groups/interviews). Staff experience was assessed at baseline and after 12 and 24 months, carer and service user experience was assessed at 12 and 24 months.

Sample size

As this was a prospective and pragmatic study, no a priori power and sample size calculations were performed or required as routinely collected and available data for all patients and staff during the study period was used.

Data Collection

Baseline data was collected for the period 1 June 2014 – 31 May 2015. The pathway was launched on 1 June 2015 and disseminated to four EIP teams in the implementation site. Data was collected over the subsequent two-year period on

every patient that was referred to and accepted by the EIP teams in participant organisations. This led to the following cohorts who were all followed up for one year:

Baseline (referral received 1 June 2014 – 31 May 2015)

Year 1 (referral received 1 June 2015 – 31 May 2016)

Year 2 (referral received 1 June 2016 – 31 May 2017)

Qualitative methods

Staff, patients and carers were approached via the mental health teams they were currently engaged with. Patients and carers showed a preference to semi-structured interviews rather than attending offered focus groups. All focus groups and interviews were audio recorded, transcribed and then coded and analysed using thematic analysis[19]. Thematic analysis was inductive using themes developed from the data produced by the structured scripts and remained at a semantic level to allow for a description of the views reported. Staff was also invited to complete a questionnaire to explore the impact of the pathway on staff experience and enable comparisons across the three time points (baseline, 12 & 24 months).

Statistical Analysis

Continuous normal data was summarised by mean and standard deviation, with comparisons to baseline made using t-tests. Continuous data that is non-normal as tested by Kolmogorov-Smirnov or Shapiro-Wilk tests, was presented by median and interquartile range (IQR) and compared using Mann-Whitney U test. Categorical variables were presented as n (%) and compared using Chi-Square or Fisher's Exact test as appropriate. However, no statistical comparisons were undertaken when the event rates in most groups were <5. $p<0.05$ was assumed to indicate statistical

significance. Missing data was excluded on a case-by-case basis. Statistical analyses were undertaken using IBM SPSS Statistics 19 and R 3.4.2. It was planned that in addition to analysing data by comparing means (or ranks) or proportions (depending on the data), regression analyses would be used to compare groups (for effect sizes and predictive models). However the extent of the missing data for many outcome variables meant that the validity and reliability would have been compromised. Thus, analysis was restricted to exploratory analysis rather than measuring effects and developing models using regression approach.

Results

The participant information and demographic data is presented in Table 1. The demographic characteristics of individuals in both comparator and pathway site was broadly similar throughout the study period, with around 3 in 5 of subjects being male, and the majority being of White Caucasian ethnicity (88-93%), unemployed (26-54%) and residing in mainstream housing (76-88%).

In both sites, the most common source of referral to EIP services was primary care, making up between 55 to 63% of referrals, followed by other mental health services (6-23%) and then Emergency Departments (2-9%).

Table 1 here

Quantitative Results

Timeliness of access

Table 2 here

Waiting times (shown in table 2) for EIP assessment from both EIP referral and central triage points (teams where referrals received) reduced significantly compared with baseline, from median 11 to 7 days, and from 20 to 11 days respectively ($p<0.0001$ for both) in the implementation site. Conversely, in the comparator site the median waiting time from EIP referral to assessment increased significantly from 7 to 12 days ($p<0.0001$) and was unchanged from central triage to assessment at 33 days ($p=0.56$). This suggests an improvement in assessment speed following referral to services in the implementation site.

The pathway implementation site also saw significantly reduced waiting times for allocation to and engagement by care co-ordinator, Multidisciplinary team (MDT) discussions, risk assessment completion and discharge of service users found unsuitable for the service on assessment ($p<0.0001$ for all). There was no statistically significant difference in the time to medical formulation or Care Programme Approach development (CPA). In the comparator site, time to allocation and engagement by care co-ordinator remained unchanged at median 0 days throughout the study. Although not significantly different from baseline in year 1, by year 2 time to MDT discussion and to risk assessment completion had both increased significantly ($p<0.0001$ for both).

The numbers of patients accepted onto the EIP case load were much higher than expected in the comparator site, but this reduced to nearer the expected levels during the course of the project. The implementation site started below but rose to just above expected levels.

Reasons for discharge from EIP services remained similar in the comparator site throughout the study. However, in the implementation site there was a significant change, seemingly led by an increase in the number of unsuitable referrals to the service, which increased from 55% to 81%. Non-acceptance was also broadly similar as it was agreed with sites that 'did not meet EIP criteria' and 'discharged on professional advice' effectively meant the same thing.

NICE recommended interventions offered

Physical Health Assessments

Table 3 here

Both sites of the study saw significant improvements in the proportion of individuals receiving assessments of their general physical health, substance use, alcohol use and weight, having their bloods taken and given ECGs, but at much higher levels in the implementation site as seen in Table 3. Assessment of smoking status increased significantly at the implementation site (p=0.00033). Measurements of pulse and blood pressure assessments increased significantly in the comparator site (p=0.010, p=0.0036). Assessment of waist measurement increased significantly in

the pathway implementation site (p=0.011) whilst decreasing significantly in the comparator site (p=0.0037). Finally, neither site significantly increased the number of individuals receiving a full 8-point NICE recommended health check within 8 weeks of EIP assessment.

Other Interventions

The proportion of individuals being offered CBT (Cognitive Behaviour Therapy) increased significantly in the comparator site from 1% to 22% (p<0.0001) and was matched with a significant increase in taking up CBT intervention from 0% to 7% (p=0.010). The implementation site did not see any significant change in either of these factors. However throughout the period, CBT for psychosis and family work for psychosis were much more likely to be offered (Table 3).

Prevalence of individuals receiving any of the listed interventions increased in both the pathway (83% to 94%, p=0.0071) and comparator sites (57% to 81%, p<0.0001), as did engagement (75% to 90%, p=0.039 and 57% to 79%, p<0.0001 respectively) from baseline to year 2.

The implementation site saw increases in the proportion of participants receiving carer support (35% to 68%, p<0.0001) and medication (54% to 73%, p=0.027), although neither of these changed significantly in the comparator site. Receipt of collaborative care planning increased significantly in the implementation site (32% to 69%, p<0.0001) whilst the comparator site saw a decrease (31% to 1%, p<0.0001). Prevalence of physical health interventions also decreased in the comparator site (26% to 15%, p<0.0001) but did not change significantly in the implementation site,

remaining low (3% to 6%, p=0.58). Receipt of vocational support increased significantly in both the implementation site (20% to 72%, p<0.0001) and the comparator site (20% to 39%, p=0.0023). However subsequently, after six months, there was a much higher take-up rate with over 80% in the implementation and over 70% in the comparator site.

Table 4 here

Clinical Outcomes

Acute care

There was a substantial contrast in the numbers of patients who had been admitted to hospital at the point of referral, much higher in the implementation site compared to comparator but reducing over time (table 4). Further admissions were low across both sites with neither site seeing a significant change in the prevalence of acute mental health admissions, in the time to being admitted or in the time to discharge. Similarly, the number of EIP participants subject to MHA section did not change significantly, although there was a tendency towards a decrease in the implementation site (36% to 33% to 27%, p=0.58). In both sites, the number of EIP service users attending Emergency Department (ED) or general hospital within a year was low (7-10%) and there were no significant changes over time.

Crisis planning

In the implementation site, the proportion of participants having a crisis plan completed reduced significantly (51% to 35%, p=0.032), occurring alongside a decrease in the time to crisis plan completion (50.0 to 12.5 weeks, p<0.0001) as seen in table 4. Conversely, in the comparator site the proportion of participants having a crisis plan completed increased significantly (49% to 67%, p=0.00023).

Table 5 here

Clinical and social outcomes

These were assessed by extracting the data routinely collected using the Health of the Nation Outcome Scales (HoNOS) as seen in table 5. At the implementation site there were significant reductions over the two-year period in 'problems with relationships' (p=0.013) and 'problems with occupation and activities' (p=0.037). At the comparator site there were significant reductions in 'problems with activities of daily living' (p=0.04). The comparator site however had substantial amounts of missing data. There was no significant difference in reductions in 'problems with delusions and hallucinations' between sites.

Criminal justice system contact

The number of participants having contact with the criminal justice system decreased significantly in the implementation site (22% to 3%, p<0.0001) whilst increasing significantly in the comparator site (14% to 21%, p<0.0001). Criminal convictions were rare in both sites (table 4).

Discharge and death

Discharge from services within a year of patients accepted by EIP teams (Table 2), was relatively low although disengagement remained a concern. It reduced in the implementation site (18% to 11%) and remained stable in comparator (10% to 12%). There was one death of a participant within a year of EIP assessment in the comparator site, Year 2 cohort (Table 4).

Qualitative Results

Staff and patient interviews and focus groups

Across the two years, 64 staff in the implementation site took part in focus groups and reported that the psychosis pathway appeared to be beneficial, well embedded and a positive change with good team working within the teams and with other services. However, they found workload to be high and had some difficulties getting the right staff skills mix in teams to deliver all the needed interventions. They also noted that often interventions were offered but were not always completed due to patient's ability to engage with them. Additionally, they worried about future changes being implemented in addition to their current workload. They felt by year 2 that they were more able to adapt the pathway to individuals' needs which they saw as important rather than a prescriptive measure.

Patients (14 participants) in the implementation site reported that they were generally satisfied with being seen quickly and developed good relationships with the staff members. They found appointments helpful and felt they gained useful skills. However, they also reported that at times there was inconsistencies in the staff they

saw and out of hours services could be improved. Carers views (7) in the implementation site appeared to improve from year 1 to year 2 with more positive reports about the team and services than at year 1, however at both time points the sample was small.

Results from staff questionnaires

In total 1,680 questionnaires were completed by staff members in the implementation and comparator site across the three time points. There was no notable change in staff experience across the time points or between the sites (Supplementary Table 1). All staff members with adult mental health services were eligible to complete this questionnaire to capture the experience of staff referring into services and caring for services users with psychosis in services such as hospital settings.

Discussion

This comparison study provides evidence that the introduction of an integrated psychosis care pathway led to improvements in access to EIP and implementation of quality standards, especially for physical health care in comparison with a site which did not implement the pathway. In terms of acceptability and feasibility, staff, service user and carer attitudes to TRIumPH were found to be generally positive. However, there were pre-existing differences during the baseline period between the sites, which influenced the comparison as seen by access and waiting times, and level of interventions offered. Prior to the project, the implementation site had dismantled three out of four EIP teams and integrated them into community mental health

teams, in contrast to the comparator site which had maintained specialist teams. At the beginning of the project the implementation site reintroduced the four EIP teams. There was a marked difference in referrals in each site with movement in both sites towards predicted levels of patients accepted by EIP teams. This reflects the variations in service commissioning and provision landscape in the UK which can be geographically determined and can potentially impact on outcomes. There are other factors like staff skillset, recruitment, data quality among others. Due to the pragmatic nature of the study, it was not designed to explore these differences and their potential impact.

Time to assessment improved in the implementation site and remained within the AWTS in the comparator site. From a patient and carer perspective, a reduction in waiting times and DUP even of a few days, especially when acutely unwell, could be meaningful for example the potential impact being unwell could cause on relationships and employment. Referral from the Central Triage Point was relatively high especially in the comparator site, as was found by Birchwood and colleagues[20] and this remains an important area for attention.

Compliance with quality standards increased substantially in the implementation site but was more variable and reached lower levels in the comparator site. This was especially noticeable for physical health standards, although the full set of NICE recommendations was only met in under 10% patients within 3 months of acceptance. In the implementation site, offering of CBT for psychosis was relatively high throughout, although uptake within 6 months was low. However, by 2 years, this was considerably higher. There was an increase in offering of CBT and family

work in the comparator site from a very low baseline, attributed to a lack of fully trained therapists. This seems an area where implementation of the quality standards through a pathway process could be especially effective. Family intervention, carer and employment support were all offered to a greater extent in implementation site and uptake increased over the period. The findings also compare favourably with those of the National Clinical Audit of Psychosis[21].

The changes in teams were reflected in the results as numbers of patients accepted onto case load were much higher than expected in the comparator site but reduced to nearer expected levels during the project. Referrals increased substantially in implementation site but then plateaued after introduction of the pathway.

The introduction of the AWTS target brought increased funding for EIP nationally. In the implementation site the local service commissioners remained well engaged with the pathway implementation and resulting outcomes and this enabled positive contract discussions for future investment. A formal cost effectiveness analysis was not conducted due to limitations in data availability but the reduction in patients admitted to inpatient wards and the subsequent reduction in relapses to hospital suggest that the implementation of the pathway could be expected to have had a positive impact on cost in the implementation site.

However, not all outcomes for the intervention site were positive, for example the decrease in the recording of crisis plans, paralleled by the significant increase in the comparator site are worth note.

Study Limitations

This is an observational prospective study based on manual audit of patients' medical records. Therefore, causality cannot be assumed. We took steps to maintain data consistency by having one dedicated member of staff involved in the data audit throughout, and by performing post-hoc data checks for consistency and outliers. However, data accuracy is naturally limited by the quality of mental health care providers' original record keeping. This was additionally limited by the amount of analyses performed on the data. Furthermore, missing data was common, for example only 237 (33%) of participants had a HoNoS score recorded at both referral and one year later. The HoNoS data was lower in the comparator site which meant it was not meaningful to test for changes among cohorts at the comparator sites due to the fact that 90% had missing data.

Conclusion

This comparison of the implementation of a quality standard based psychosis pathway with a comparator site which followed established guidelines for Early Intervention for Psychosis teams suggests that the former was more effective at improving the level of evidence-based practice offered to patients and their carers. Integrated care pathways can offer a platform to inform gaps in services, implement good clinical practice and measure the impact.

Competing interests

The production of the pathway has been supported by the Wessex Academic Health Sciences Network (AHSN) and evaluation has also been supported by the Wessex Clinical Research Network (CRN). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of funders, NIHR, NHS or the RCPsych, AHSN or CRN. The study is sponsored by Southern Health NHS Foundation Trust.

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Study Status

The study is complete.

Authors' contributions

SR and DK are grant holders and contributed to the concept and design of the study. SR is the CI and led the development of the study protocol and study documentation and made a significant contribution to the manuscript. KT provided statistical expertise throughout the protocol development, data collection and analysis. CA provided PPI expertise throughout the protocol development and study delivery. AG supported the implementation of the TRIumPH development and delivery. EG, PP and TR supported the delivery of the study at their respective sites. All authors

contributed to elaboration and refinement of the study protocol and approved the final manuscript.

Data Availability

All data relevant to the study are included in the article or uploaded as supplementary information.

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Figure 1 Caption

TRIumPH Pathway

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Tables

Table 1: Demographic information for all individuals referred to EIP service. Numbers represent either median (IQR) for continuous variables or proportions for categorical variables. Excludes EIP to EIP transfers.

		Implementation site			Comparator Site		
		Baseline (n=123)	Year 1 (n=416)	Year 2 (n=463)	Baseline (n=237)	Year 1 (n=271)	Year 2 (n=252)
Age (Years)		22.4 (19.3 to 28.2)	21.4 (19.0 to 26.1)	21.6 (19.0 to 25.9)	19.4 (16.7 to 24.9)	19.7 (17.1 to 24.8)	21.8 (17.9 to 30.3)
Gender:	*Female*	35%	40%	39%	43%	40%	38%
	Male	65%	60%	61%	57%	60%	62%
Ethnicity:	*White*	88%	89%	93%	92%	93%	92%
	Black or Black British	5%	3%	3%	1%	3%	1%
	Asian or Asian British	0%	2%	0%	1%	1%	1%
	Mixed race	3%	3%	2%	3%	1%	4%
	Other	5%	2%	1%	3%	3%	2%
Accommodation Status:							
Accommodation with MH care support		3%	1%	0%	0%	2%	0%
Accommodation with other support		3%	4%	7%	4%	5%	2%
Acute/long stay healthcare residential facility/hospital		0%	0%	1%	3%	8%	13%
Homeless		7%	9%	13%	10%	8%	7%
Mainstream housing		88%	86%	80%	79%	76%	76%
Bail/probation hostel		0%	0%	0%	2%	0%	0%
Other		0%	0%	0%	2%	1%	3%
Employment status:							
Employed		38%	20%	29%	24%	26%	20%
Unemployed		26%	38%	40%	48%	40%	54%
Homemaker		1%	2%	1%	4%	3%	1%
Student		16%	15%	14%	11%	12%	11%
Long term sickness/disability benefit		15%	16%	12%	9%	5%	5%
Statutory sick pay		0%	3%	0%	5%	9%	3%
Retired		0%	0%	0%	0%	0%	1%
Other		3%	6%	4%	0%	4%	4%
Change in employment status during EIP:							
No reported change		58 (84%)	107 (91%)	124 (100%)	128 (88%)	163 (97%)	88 (86%)
Became employed		0 (0%)	4 (3%)	0 (0%)	13 (9%)	2 (1%)	5 (5%)
Left employment/became unemployed		10 (14%)	4 (3%)	0 (0%)	4 (3%)	2 (1%)	3 (3%)
Other		1 (1%)	3 (3%)	0 (0%)	0 (0%)	1 (1%)	6 (6%)
Referral source:							
Primary care		75 (62%)	256 (63%)	283 (62%)	143 (60%)	172 (63%)	139 (55%)
Community mental health service		19 (16%)	66 (16%)	104 (23%)	14 (6%)	26 (10%)	14 (6%)
Inpatient mental health service		1 (1%)	21 (5%)	15 (3%)	12 (5%)	16 (6%)	4 (2%)
A&E department		11 (9%)	20 (5%)	21 (5%)	5 (2%)	13 (5%)	23 (9%)
Physical healthcare service		0 (0%)	13 (3%)	8 (2%)	4 (2%)	8 (3%)	2 (1%)
Caring and social services		0 (0%)	0 (0%)	5 (1%)	10 (4%)	5 (2%)	11 (4%)
Education service		0 (0%)	6 (1%)	4 (1%)	12 (5%)	7 (3%)	8 (3%)
Police/prison/probation		9 (7%)	8 (2%)	11 (2%)	14 (6%)	11 (4%)	25 (10%)
Self-referral		1 (1%)	2 (0%)	2 (0%)	12 (5%)	6 (2%)	17 (7%)
Other		5 (4%)	16 (4%)	4 (1%)	11 (5%)	8 (3%)	9 (4%)
Central triage point (CTP):							
EIP		22 (18%)	107 (26%)	120 (26%)	33 (14%)	24 (9%)	27 (11%)
Community mental health service		98 (80%)	281 (69%)	325 (71%)	183 (78%)	217 (81%)	184 (73%)

Inpatient mental health service	2 (2%)	21 (5%)	14 (3%)	17 (7%)	26 (10%)	27 (11%)
Physical healthcare service	0 (0%)	1 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Police/prison/probation	0 (0%)	0 (0%)	0 (0%)	3 (1%)	2 (1%)	14 (6%)

Table 2: Process outcomes for all individuals referred to EIP service. Numbers represent either N (%) for categorical variables or median (IQR) for continuous variables. Excludes EIP to EIP transfers. P values for categorical comparisons from chi-squared test or Fisher's exact test as appropriate. P values for continuous data from Mann-Whitney U tests.

	Implementation site					Comparator site				
	Baseline (n=123)	Year One (n=416)	Year Two (n=463)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=237)	Year One (n=271)	Year Two (n=252)	P value Y1 vs baseline	P value Y2 vs baseline
Accepted onto EIP pathway	69 (56%)	118 (28%)	124 (27%)	< 0.0001	< 0.0001	145 (61%)	168 (62%)	102 (40%)	0.89	< 0.0001
Time from EIP referral to EIP assessment (in days)	11.0 (6.0 to 20.5)	6.0 (3.0 to 12.0)	7.0 (4.0 to 14.0)	< 0.0001	< 0.0001	7.0 (3.0 to 12.0)	7.0 (4.0 to 12.8)	12.0 (7.0 to 21.0)	0.24	< 0.0001
Time from CTP referral to EIP assessment (in days)	20.0 (11.8 to 55.3)	15.0 (6.0 to 40.0)	11.0 (6.0 to 23.0)	0.0053	< 0.0001	33.0 (11.0 to 142.5)	24.0 (9.3 to 130.5)	33.0 (13.0 to 98.0)	0.45	0.96
DNAs prior to assessment										
0	113 (92%)	378 (91%)	434 (94%)	0.37		211 (89%)	247 (91%)	232 (92%)	0.59	
1	7 (6%)	28 (7%)	17 (4%)			17 (7%)	19 (7%)	12 (5%)		
2 or more	3 (2%)	10 (2%)	12 (3%)			9 (4%)	6 (2%)	9 (4%)		
Time to allocation and engagement by care coordinator (in weeks)	4.0 (0.0 to 11.0)	1.0 (0.0 to 5.0)	0.0 (0.0 to 3.0)	0.0033	< 0.0001	0.0 (0.0 to 7.3)	0.0 (0.0 to 7.0)	0.0 (0.0 to 14.8)	0.054	0.48
Time to multidisciplinary team (MDT) discussion (in weeks)	6.2 (1.7 to 20.0)	1.9 (1.0 to 4.6)	1.9 (0.9 to 3.0)	< 0.0001	< 0.0001	1.8 (0.7 to 3.0)	1.7 (1.0 to 2.7)	4.9 (1.8 to 28.0)	0.74	< 0.0001
Time to medical formulation (in weeks)	4.7 (2.3 to 8.4)	3.9 (1.9 to 8.4)	3.3 (1.9 to 6.0)	0.45	0.11	6.5 (2.3 to 10.3)	6.7 (2.4 to 11.0)	8.3 (3.8 to 11.9)	0.99	0.14
Time to CPA (care plan approach) /care plan (in weeks)	2.4 (0.0 to 6.9)	2.7 (0.8 to 5.4)	2.0 (0.4 to 5.8)	0.62	0.87	2.0 (0.7 to 5.6)	3.0 (1.0 to 14.5)	13.0 (4.3 to 34.0)	0.080	< 0.0001
Time to risk assessment completion (in weeks)	50.3 (2.6 to 91.1)	6.4 (1.0 to 15.3)	4.7 (1.4 to 8.1)	< 0.0001	< 0.0001	5.3 (1.4 to 15.0)	3.6 (1.0 to 15.1)	4.6 (1.1 to 13.4)	0.38	0.60
Reason for non-acceptance to EIP:										
Does not fulfil EIP criteria	29 (71%)	202 (79%)	280 (85%)	0.0010		18 (20%)	20 (19%)	28 (19%)	0.76	
Discharged on professional advice	4 (10%)	14 (5%)	2 (1%)			62 (67%)	65 (63%)	100 (66%)		
DNA/did not engage/declined treatment	6 (15%)	27 (11%)	35 (11%)			5 (5%)	8 (8%)	13 (9%)		
Moved out of area	0 (0%)	11 (4%)	10 (3%)			6 (7%)	7 (7%)	9 (6%)		

	Implementation site					Comparator site				
	Baseline (n=123)	Year One (n=416)	Year Two (n=463)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=237)	Year One (n=271)	Year Two (n=252)	P value Y1 vs baseline	P value Y2 vs baseline
Other	2 (5%)	3 (1%)	4 (1%)			1 (1%)	4 (4%)	1 (1%)		
Reason for discharge from EIP after acceptance:										
Care completed	4 (15%)	4 (9%)	0 (0%)	0.076		0 (0%)	0 (0%)	0 (0%)	0.40	
Does not fulfil EIP criteria	8 (31%)	22 (48%)	22 (50%)			7 (6%)	6 (5%)	4 (9%)		
Discharged on professional advice	0 (0%)	1 (2%)	3 (7%)			80 (72%)	72 (61%)	25 (54%)		
DNA/did not engage/declined treatment	6 (23%)	8 (17%)	8 (18%)			16 (14%)	25 (21%)	11 (24%)		
Moved out of area	5 (19%)	11 (24%)	9 (20%)			7 (6%)	12 (10%)	5 (11%)		
Other	3 (12%)	0 (0%)	2 (5%)			1 (1%)	4 (3%)	1 (2%)		
Change in accommodation status during EIP:										
No reported change	63 (91%)	118 (100%)	124 (100%)	<0.0001		136 (94%)	157 (93%)	78 (76%)	<0.0001	
Moved to mainstream housing	0 (0%)	0 (0%)	0 (0%)			2 (1%)	3 (2%)	10 (10%)		
Moved from acute/long stay/ hospital to supported accommodation	0 (0%)	0 (0%)	0 (0%)			1 (1%)	3 (2%)	2 (2%)		
Moved to acute/long stay/ hospital	1 (1%)	0 (0%)	0 (0%)			0 (0%)	1 (1%)	4 (4%)		
Committed to bail/probation hostel/prison	0 (0%)	0 (0%)	0 (0%)			0 (0%)	0 (0%)	1 (1%)		
No longer homeless	1 (1%)	0 (0%)	0 (0%)			3 (2%)	2 (1%)	1 (1%)		
Became homeless	1 (1%)	0 (0%)	0 (0%)			1 (1%)	2 (1%)	1 (1%)		
Other	3 (4%)	0 (0%)	0 (0%)			2 (1%)	0 (0%)	5 (5%)		

Table 3: Physical health assessments and interventions
N (%) individuals accepted onto the EIP pathway at each site who received listed physical health checks within 12 weeks, were offered interventions or took up interventions within 6 months of EIP referral. Excludes EIP to EIP transfers. P values from chi-squared test or Fisher's exact test as appropriate.

	Implementation site				Comparator Site			
	Baseline (n=69)	Year One (n=118)	Year Two (n=124)	P value	Baseline (n=145)	Year One (n=168)	Year Two (n=102)	P value
Physical health assessments received within 12 weeks:								
Physical Health (general)	33 (48%)	81 (69%)	86 (69%)	0.0038	38 (26%)	40 (24%)	44 (43%)	0.0019
Smoking	23 (33%)	72 (61%)	76 (61%)	0.00033	38 (26%)	42 (25%)	34 (33%)	0.30
Substance Use	35 (51%)	93 (79%)	98 (79%)	<0.0001	71 (49%)	63 (38%)	66 (65%)	<0.0001
Alcohol	35 (51%)	89 (75%)	102 (82%)	<0.0001	60 (41%)	60 (36%)	61 (60%)	0.00045
Weight	17 (25%)	46 (39%)	60 (48%)	0.0065	46 (32%)	39 (23%)	39 (38%)	0.027
Waist	4 (6%)	16 (14%)	27 (22%)	0.011	18 (12%)	9 (5%)	2 (2%)	0.0037
Pulse	20 (29%)	48 (41%)	47 (38%)	0.30	25 (17%)	32 (19%)	33 (32%)	0.010
Blood Pressure	22 (32%)	50 (42%)	55 (44%)	0.25	32 (22%)	38 (23%)	40 (39%)	0.0036
Bloods Taken	18 (26%)	58 (49%)	50 (40%)	0.010	15 (10%)	25 (15%)	36 (35%)	<0.0001
ECG	10 (14%)	49 (42%)	27 (22%)	<0.0001	17 (12%)	10 (6%)	30 (29%)	<0.0001
NICE health check in 12 weeks	2 (3%)	9 (8%)	11 (9%)	0.30	1 (1%)	1 (1%)	1 (1%)	0.94
Interventions offered at any time:								
Cognitive behaviour therapy	43 (62%)	68 (58%)	84 (68%)	0.26	1 (1%)	23 (14%)	22 (22%)	<0.0001
Family intervention	36 (52%)	64 (54%)	80 (65%)	0.17	7 (5%)	7 (4%)	10 (10%)	0.13
Carer support	50 (72%)	82 (69%)	90 (73%)	0.86	34 (23%)	29 (17%)	25 (25%)	0.26
Employment support	41 (59%)	47 (40%)	57 (46%)	0.043	37 (26%)	47 (28%)	18 (18%)	0.15
Interventions taken up within 6 months:								
Engagement	52 (75%)	103 (87%)	111 (90%)	0.039	82 (57%)	74 (44%)	80 (79%)	<0.0001
CBT for psychosis	3 (4%)	10 (8%)	8 (6%)	0.56	0 (0%)	7 (4%)	7 (7%)	0.010
Carer support	24 (35%)	63 (53%)	84 (68%)	<0.0001	17 (12%)	22 (13%)	16 (16%)	0.66
Medication	37 (54%)	80 (68%)	91 (73%)	0.027	25 (17%)	37 (22%)	28 (28%)	0.16
Collaborative care planning	22 (32%)	85 (72%)	86 (69%)	<0.0001	45 (31%)	38 (23%)	1 (1%)	<0.0001
Physical Health	2 (3%)	4 (3%)	7 (6%)	0.58	37 (26%)	9 (5%)	15 (15%)	<0.0001
Vocational	14 (20%)	79 (67%)	89 (72%)	<0.0001	29 (20%)	37 (22%)	39 (39%)	0.0023
Family work for psychosis	2 (3%)	11 (9%)	8 (6%)	0.25	2 (1%)	6 (4%)	1 (1%)	0.26
Any of these	57 (83%)	113 (96%)	117 (94%)	0.0071	83 (57%)	74 (44%)	82 (81%)	<0.0001

Table 4: Acute care & clinical outcomes. Proportion of individuals accepted onto the EIP pathway at each trust experiencing acute care outcomes [n (%)] within 1 year of trust referral, and time to reach those outcomes where applicable [median (IQR)]. Excludes EIP to EIP transfers. P values for categorical comparisons from chi-squared test or Fisher's exact test as appropriate. P values for continuous data from Mann-Whitney U tests.

	Implementation site					Comparator site				
	Baseline (n=69)	Year One (n=118)	Year Two (n=124)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=145)	Year One (n=168)	Year Two (n=102)	P value Y1 vs baseline	P value Y2 vs baseline
Acute MH admission within 1 year of EIP referral	27 (39%)	47 (40%)	36 (29%)	0.16		16 (11%)	21 (13%)	19 (19%)	0.20	
Time to acute admission (where applicable) (weeks)	0.0 (0.0 to 10.0)	1.0 (0.0 to 7.0)	0.0 (0.0 to 3.5)	0.88	0.11	15.0 (3.0 to 41.0)	11.0 (2.0 to 41.0)	13.5 (3.0 to 34.0)	0.82	0.92
Time to acute MH/inpatient screening (hours)										
0 - 4	21 (91%)	1 (100%)	14 (67%)	-		11 (73%)	11 (58%)	8 (53%)	0.49	
4 - 6	0 (0%)	0 (0%)	6 (29%)			3 (20%)	4 (21%)	3 (20%)		
6 - 8	1 (4%)	0 (0%)	0 (0%)			0 (0%)	2 (11%)	1 (7%)		
8 - 10	1 (4%)	0 (0%)	1 (5%)			1 (7%)	2 (11%)	3 (20%)		
Time from acute admission to discharge (where applicable) (weeks)	4.5 (2.0 to 10.3)	4.0 (2.0 to 6.8)	3.0 (1.0 to 5.3)	0.42	0.56	3.0 (2.0 to 13.5)	3.0 (2.0 to 5.0)	3.0 (2.3 to 3.8)	0.56	0.95
Number of subsequent acute admissions										
None	18 (64%)	41 (85%)	25 (71%)	0.091		14 (67%)	15 (65%)	13 (62%)	0.95	
1	6 (21%)	4 (8%)	9 (26%)			5 (24%)	2 (9%)	8 (38%)		
More than 1	4 (14%)	3 (6%)	1 (3%)			2 (10%)	6 (26%)	0 (0%)		
MHA section within 1 year of EIP referral	25 (36%)	39 (33%)	34 (27%)	0.58		16 (11%)	21 (13%)	18 (18%)	0.18	
Contact acute MH services (post EIP)	32 (46%)	41 (35%)	37 (30%)	< 0.0001		25 (17%)	30 (18%)	22 (22%)	< 0.0001	
Crisis plan completed	35 (51%)	59 (50%)	44 (35%)	0.032		71 (49%)	69 (41%)	68 (67%)	0.00023	
Time to crisis plan completed (weeks)	50.0 (15.0 to 79.0)	22.5 (10.0 to 37.8)	12.5 (6.0 to 22.8)	0.0010	< 0.0001	8.0 (1.0 to 23.0)	11.0 (1.0 to 39.0)	12.0 (2.0 to 34.3)	0.36	0.10
A&E attendance within 1 year of EIP referral	7 (10%)	10 (8%)	11 (9%)	0.91		11 (8%)	12 (7%)	10 (10%)	0.72	
Time to A&E attendance (weeks)	21.0 (2.5 to 68.3)	8.5 (0.0 to 17.0)	13.0 (8.0 to 43.0)	0.15	0.88	30.0 (25.0 to 41.0)	44.0 (11.0 to 76.0)	14.5 (7.3 to 31.5)	0.87	0.11
Reason for A&E attendance:										

	Implementation site					Comparator site				
	Baseline (n=69)	Year One (n=118)	Year Two (n=124)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=145)	Year One (n=168)	Year Two (n=102)	P value Y1 vs baseline	P value Y2 vs baseline
Deterioration in mental state	7 (41%)	7 (50%)	5 (42%)	-		2 (15%)	4 (24%)	2 (20%)	-	
Self harm/suicidal ideation/suicide attempt/overdose	6 (35%)	5 (36%)	4 (33%)			10 (77%)	6 (35%)	4 (40%)		
Alcohol/substance abuse	1 (6%)	1 (7%)	2 (17%)			0 (0%)	1 (6%)	0 (0%)		
Medication side effects	0 (0%)	0 (0%)	0 (0%)			0 (0%)	1 (6%)	1 (10%)		
Physical injury/illness (not apparently psychosis related)	3 (18%)	1 (7%)	1 (8%)			1 (8%)	5 (29%)	3 (30%)		
General hospital admission within 1 year of EIP referral	1 (1%)	4 (3%)	3 (2%)	-		2 (1%)	0 (0%)	4 (4%)	-	
Contact with criminal justice system whilst in EIP pathway	15 (22%)	34 (29%)	4 (3%)	< 0.0001		20 (14%)	20 (12%)	21 (21%)	< 0.0001	
Criminal conviction within 1 year of EIP referral	1 (1%)	0 (0%)	0 (0%)	-		4 (3%)	4 (2%)	1 (1%)	-	
Deaths within 1 year of EIP referral	0 (0%)	0 (0%)	0 (0%)	-		0 (0%)	0 (0%)	1 (1%)	-	

Table 5: Clinical outcomes (HoNoS). Mean (SD) change in HoNoS scores from referral to one year at each trust for patients accepted onto EIP pathway. Excludes EIP to EIP transfers. P values from paired t-tests.

	Implementation Site					Comparator Site				
	Baseline (n=52)	Year One (n=77)	Year Two (n=53)	P value Y1 vs baseline	P value Y2 vs baseline	Baseline (n=28)	Year One (n=16)	Year Two (n=11)	P value Y1 vs baseline	P value Y2 vs baseline
Change in HoNoS scores (from referral to 1 year)										
1. Overactive, aggressive, disruptive or agitated behaviour	-0.56 (1.73)	-0.43 (1.72)	-0.69 (1.45)	0.59	0.78	-0.43 (1.55)	-1.06 (1.65)	-0.09 (1.14)	*	*
2. Non-accidental self injury	-0.50 (1.38)	-0.22 (1.26)	-0.22 (1.15)	0.18	0.21	-0.25 (0.84)	-0.06 (1.29)	-0.36 (1.43)	*	*
3. Problem drinking or drug taking	-0.40 (1.48)	-0.15 (1.87)	0.04 (1.71)	0.30	0.12	0.14 (1.04)	-0.31 (1.20)	-0.10 (1.52)	*	*
4. Cognitive problems	-0.27 (1.34)	-0.15 (1.32)	-0.06 (1.32)	0.48	0.33	-0.29 (1.18)	-0.38 (0.96)	-0.50 (1.51)	*	*
5. Physical illness or disability problems	-0.23 (1.10)	0.03 (1.35)	0.02 (1.08)	0.19	0.17	0.11 (0.50)	-0.38 (1.02)	0.45 (1.44)	*	*
6. Problems associated with hallucinations and delusions	-0.56 (1.62)	-0.71 (1.70)	-0.11 (1.51)	0.74	0.14	-0.86 (1.46)	-1.81 (1.42)	-0.91 (1.76)	*	*
7. Problems with depressed mood	-0.50 (1.59)	-0.19 (1.49)	-0.55 (1.12)	0.24	0.94	-0.46 (1.29)	-0.88 (1.41)	-0.55 (1.21)	*	*
8. Other mental and behavioural problems	-0.45 (1.53)	-0.73 (1.81)	-0.27 (1.49)	0.58	0.68	-0.61 (1.26)	-0.75 (1.98)	-0.36 (1.69)	*	*
9. Problems with relationships	-0.83 (1.32)	-0.41 (1.51)	-0.20 (1.25)	0.07	0.013	-0.21 (1.26)	-1.00 (1.41)	-0.10 (0.57)	*	*
10. Problems with activities of daily living	-0.33 (1.57)	-0.32 (1.55)	-0.46 (1.47)	0.85	0.68	-0.64 (1.16)	-1.00 (1.55)	0.18 (0.75)	*	*
11. Problems with living conditions	-0.20 (1.51)	-0.33 (1.44)	0.08 (1.21)	0.69	0.28	-0.36 (1.31)	-0.69 (1.20)	0.45 (1.13)	*	*
12. Problems with occupation and activities	-0.33 (1.64)	-0.19 (1.47)	0.30 (1.45)	0.54	0.037	-0.25 (1.58)	-1.06 (1.57)	-0.09 (1.45)	*	*

*p values not calculated due to amount of missing data

TRIumPH: Treatment and Recovery In PsycHosis

Routine Referral

RIumPH
Treatment and Recovery In PsycHosis

Southern Health NHS
NHS Foundation Trust

Prevention and Early Detection

Screen

Referral received

Tel. triage using screening checklist to:

- determine urgency
- consider medication, social, psychological and physical health needs

Holistic Assessment

'At risk of psychosis' assessment:

- engagement
- medication, social, psychological and physical health needs
- patient and carer views
- outcome measures incl. PROM

MDT Discussion

Involving medical, nursing and social care staff as minimum to agree:

- provisional **formulation**/ diagnosis
- priorities for **care planning**

Care Plan/CPA

Collaborative planning from first contact:

- Safety and **crisis plan**
- Safeguarding (adult/child)
- **Social care** (incl. education, **vocation**/IPS, accommodation)
- **Medication management** (incl. Clozapine)
- **Psychological interventions** (see stepped pathway)
- **Physical health** (Lester tool and NICE); perinatal
- **Substance misuse** needs
- **Carers support**

Delivery of Care

Engagement from first contact (incl. assertive):

As indicated:

- **Social care**
- **Medication**
- **Psychological interventions**
- **Physical health**
- **Substance misuse**
- **Carers support**

Review of Care Plan

If deterioration in mental health/crisis/relapse:

- identify any deterioration early and fast track
- consider acute care pathway
- **MDT discussion** (CPA if criteria met) to review medication, social, psychological and physical health needs; update care plan
- consider advance statements
- patient and carer views
- communication with GP
- **WRAP**/Recovery College
- review outcome measures incl. PROM

Discharge

Plan with patient/service user, carers and GP if over 6-12 months:

- stable and functioning well
- no medication or stable medication
- not detained
- acute care pathway not needed

Complete **crisis** and contingency plans

Comprehensive communication with primary care, patient and carer

Screen

Within **24 hours**

Assessment

First face to face contact within **7 days**

Medication screen within **3 days** of referral if on prescribed medication

MDT Discussion

Within **7 days** of assessment

Earlier medical review if concerns

Discharge/ signpost if psychosis pathway not appropriate

Care Plan/CPA

Allocation of a care coordinator and care plan within **14 days** of referral

Formulation by medic within **21 days** of assessment

Delivery of Care

Commence within **14 days** of referral

Review as Required by Personal Plan

Weekly face to face: if first episode

Weekly: if medication changes, changing mental state, current risks, carer concerns, specific interventions

Weekly/biweekly: if difficulties engaging in services

Every 4 weeks: consider Clozapine if no response to antipsychotic medication. If mental state is settled, consider increasing review to 3 monthly then 6 monthly

Annual review: (if not indicated sooner) of Care Plan/CPA (incl. items listed in Care Plan / CPA box above). Completion of outcome measures

WESSEX ACADEMIC HEALTH SCIENCE NETWORK
IMPROVING HEALTH THROUGH INNOVATION

Table 1: Staff survey results

Section A: Demographics

	Intervention arm			Control arm		
	Baseline (n=438)	**Year 1 (n=412)**	**Year 2 (n=418)**	**Baseline (n=122)**	**Year 1 (n=155)**	**Year 2 (n=135)**
Type of team						
CMHT	39%	32%	30%	51%	46%	49%
EIP	7%	10%	8%	7%	5%	9%
Psychology	5%	6%	8%	2%	1%	2%
Inpatient	35%	42%	42%	30%	35%	27%
Hospital at home	8%	6%	8%	4%	8%	7%
Other (inc. AAT/AOT)	13%	7%	8%	10%	8%	9%
Job role						
Psychiatrist/SpR/SHO	15%	7%	10%	5%	6%	10%
Psychologist/Psychotherapist	7%	6%	8%	6%	1%	2%
Nurse practitioner	42%	41%	39%	39%	43%	34%
Occupational therapist	4%	6%	5%	7%	8%	7%
Social worker	7%	5%	5%	8%	5%	8%
Mental health care support worker	19%	25%	23%	20%	22%	16%
Other	8%	10%	10%	16%	15%	22%
Geographical area of living						
North Hampshire	7%	6%	11%	22%	35%	24%
West Hampshire	24%	23%	18%	20%	11%	27%
East Hampshire	32%	23%	21%	48%	54%	47%
Southampton	36%	43%	50%	8%	0%	1%
Unknown/other	1%	5%	0%	2%	0%	0%
Gender						
Male	32%	33%	32%	31%	39%	36%
Female	67%	66%	67%	68%	61%	64%
Other	0%	0%	<1%	0%	0%	0%
Not answered	1%	2%	1%	1%	0%	0%
Age group						
Under 24	5%	5%	6%	6%	5%	3%
25-34	26%	23%	25%	17%	21%	24%
35-44	30%	28%	30%	29%	21%	25%
45-54	28%	28%	27%	39%	34%	36%
55-64	9%	14%	11%	8%	17%	11%
65 or over	1%	1%	1%	0%	1%	1%
Not answered	1%	1%	<1%	1%	1%	0%
Ethnicity						
White	82%	80%	83%	92%	94%	90%

	Intervention arm			Control arm		
	Baseline (n=438)	Year 1 (n=412)	Year 2 (n=418)	Baseline (n=122)	Year 1 (n=155)	Year 2 (n=135)
Mixed race	4%	5%	5%	2%	3%	3%
Asian	6%	5%	5%	1%	1%	3%
Black	5%	9%	6%	3%	1%	1%
Other	1%	1%	1%	0%	1%	1%
Not stated	<1%	1%	1%	1%	0%	1%

Section B: Experience

	Intervention arm			Control arm		
	Baseline (n=438)	Year 1 (n=412)	Year 2 (n=418)	Baseline (n=122)	Year 1 (n=155)	Year 2 (n=135)
I have been able to support people with FEP to have more control in their lives:						
Always	16%	15%	18%	24%	15%	16%
Sometimes	62%	50%	54%	60%	55%	55%
Rarely	13%	14%	13%	8%	12%	10%
Never	5%	9%	6%	3%	9%	6%
Don't know	3%	7%	6%	2%	6%	11%
Not answered	2%	5%	3%	3%	2%	2%
I have been able to support people with FEP to manage their physical, mental and social needs holistically:						
Always	24%	27%	27%	25%	22%	22%
Sometimes	58%	47%	49%	63%	57%	54%
Rarely	9%	8%	10%	3%	6%	7%
Never	3%	7%	5%	3%	8%	5%
Don't know	2%	8%	6%	0%	6%	9%
Not answered	3%	5%	3%	5%	2%	3%
I have been able to support people with FEP to involve carers:						
Always	29%	25%	27%	30%	31%	31%
Sometimes	52%	43%	43%	60%	48%	47%
Rarely	9%	11%	12%	4%	8%	8%
Never	4%	8%	6%	2%	7%	4%
Don't know	2%	8%	9%	1%	5%	7%
Not answered	3%	5%	4%	4%	1%	3%
I feel appropriately trained and supervised to deliver psychological informed interventions:						
Always	22%	21%	21%	16%	12%	19%
Sometimes	47%	40%	38%	52%	42%	45%
Rarely	15%	14%	11%	11%	19%	11%
Never	7%	10%	8%	13%	7%	6%
Don't know	5%	11%	10%	4%	8%	10%
Not answered	4%	5%	13%	3%	1%	9%
I feel appropriately trained and supervised to deliver physical health assessment and intervention:						

	Intervention arm			Control arm		
	Baseline (n=438)	**Year 1 (n=412)**	**Year 2 (n=418)**	**Baseline (n=122)**	**Year 1 (n=155)**	**Year 2 (n=135)**
Always	34%	34%	29%	27%	34%	37%
Sometimes	41%	34%	39%	42%	41%	33%
Rarely	12%	10%	9%	14%	10%	12%
Never	10%	9%	8%	14%	9%	7%
Don't know	3%	8%	9%	2%	3%	8%
Not answered	2%	5%	6%	1%	4%	3%
I feel appropriately trained and supervised to deliver vocational support:						
Always	16%	20%	15%	17%	13%	19%
Sometimes	49%	42%	44%	55%	54%	51%
Rarely	23%	16%	17%	19%	21%	10%
Never	6%	9%	9%	5%	3%	7%
Don't know	4%	10%	9%	3%	5%	10%
Not answered	2%	4%	6%	1%	5%	3%
I feel appropriately trained and supervised to deliver alcohol, smoking and substance misuse support:						
Always	22%	22%	23%	30%	22%	29%
Sometimes	58%	46%	49%	50%	58%	48%
Rarely	12%	14%	11%	14%	10%	10%
Never	5%	5%	5%	5%	4%	4%
Don't know	2%	9%	9%	1%	1%	7%
Not answered	1%	4%	4%	1%	5%	3%
I believe service users and carers are involved in planning their care:						
Always	46%	47%	45%	48%	38%	47%
Sometimes	47%	46%	47%	52%	41%	52%
Rarely	4%	2%	3%	1%	4%	1%
Never	0%	0%	1%	0%	0%	0%
Don't know	1%	3%	2%	0%	2%	0%
Not answered	2%	2%	2%	0%	15%	1%
I feel supported to carry out holistic assessment and care plans:						
Always	44%	42%	43%	46%	47%	40%
Sometimes	39%	36%	34%	43%	34%	44%
Rarely	5%	6%	4%	3%	8%	5%
Never	3%	5%	5%	4%	2%	1%
Don't know	3%	6%	8%	2%	5%	5%
Not answered	6%	5%	6%	2%	5%	4%

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	7/8
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*NA*+
Bias	9	Describe any efforts to address potential sources of bias	17-19
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9
		(*b*) Describe any methods used to examine subgroups and interactions	9
		(*c*) Explain how missing data were addressed	9
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	9
		(*e*) Describe any sensitivity analyses	

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Table 1
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Table 1
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*Tables*
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Tables
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Tables Pg 10
Discussion			
Key results	18	Summarise key results with reference to study objectives	19
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	19
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	17
Generalisability	21	Discuss the generalisability (external validity) of the study results	19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

[+] Not possible as data collected from various sources across intervention and comparator site (depending on how information collected by services in real world setting). Data dictionary produced for researchers to allow for this.