

Original Research

The impact of the COVID-19 pandemic on first-episode psychosis presentations in two early intervention in psychosis services

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Abstract

Objectives: To assess the impact of the COVID-19 pandemic on first-episode psychosis (FEP) presentations across two Early Intervention in Psychosis (EIP) services in Ireland, by comparing pre-pandemic and post-pandemic cohorts.

Methods: A cross-sectional observational design with retrospective medical record review was employed. The study population comprised 187 FEP patients (77 in pre-pandemic and 110 in post-pandemic cohort). Outcomes measured included duration of untreated psychosis (DUP), FEP presentation numbers, referral sources, global assessment of functioning scores, inpatient admissions, substance misuse and service delivery methods. Statistical analyses utilised chi-square tests to assess categorical variables, Mann–Whitney U tests to compare non-normally distributed continuous variables and Kruskal–Wallis tests to examine interactions between categorical and continuous variables.

Results: A significant increase in FEP presentations was observed in the post-pandemic cohort (p = 0.003), with an increase in all urban areas and a decrease in the study's only rural area. The difference in DUP between cohorts was not significant. However, significant interaction between gender, cohort and DUP was shown (p = 0.008), with women in the post-pandemic cohort experiencing longer DUP (p = 0.01). A significant rise in telephone (p = 0.05) and video consultations (p = 0.001) offered was observed, in the post-pandemic cohort. A similar number of in-person appointments were attended across both cohorts.

Conclusions: This study highlights the impact of the pandemic on FEP presentations, particularly rurally and regarding increased DUP among women. These findings underscore the need for flexible EIP services to respond to public health crises. Despite increased presentations, services adapted, maintaining service continuity through telehealth and modified in-person contact.

Keywords: COVID-19; duration of untreated psychosis; early intervention in psychosis; first-episode psychosis; Ireland; mental health services; telehealth

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Introduction

The COVID-19 pandemic and early intervention in psychosis (EIP) services

The Early Intervention in Psychosis (EIP) model has been in place internationally for the last three decades (McGorry et al., 1996, McGorry 2015). The Irish National Clinical Programme for EIP published its model of care in 2019, providing a framework to establish EIP services across the country. The central tenets of EIP services are early detection, ready access to evidence-based interventions and assertive follow-up; during the critical 3-5 years, following a first episode of psychosis (FEP) (HSE National Working

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Group and Clinical Advisory Group of College of Psychiatrists of Ireland, 2019). The efficacy of EIP services in improving patient outcomes is well documented (O'Connell et al., 2021; Csillag et al., 2016).

The COVID-19 pandemic has had a profound and multifaceted impact on both the mental health of the population, and the delivery of mental health services (Lewis et al., 2022; Bodini et al., 2023). It had been posited that disruptions in service access associated with the COVID-19 pandemic, were likely to present significant challenges for mental health services (O'Donoghue et al., 2020; Kelly 2020; Cullen et al., 2020). EIP services were highlighted as particularly vulnerable to disruption, given their focus on early detection and rapid access (O'Donoghue et al., 2020). As the pandemic progressed, empirical evidence to support these concerns were reported, including disruption to EIP service provision (Roberts et al., 2022; Tan et al., 2022) and a pivot towards

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greater provision of virtual care in EIP (Tempelaar et al., 2021; Tempelaar et al., 2023).

Risk factors and psychosis presentations during COVID-19 pandemic

Internationally, government mandated restrictions on travel, work and leisure activities led to an increase in known risk factors for developing psychosis: e.g. isolation, lack of employment and additional psychosocial stressors (Tibber et al., 2019, Ajnakina et al., 2021). This had been predicted by Brown et al. (2020), in an early review of the potential impact of the pandemic on psychosis. It had been hypothesised that infection with COVID-19, may itself be associated with an increased risk for developing psychosis (Puiu et al., 2023; Moccia et al., 2023), although empirical data for this remains lacking.

Research has shown mixed findings on FEP presentations during the pandemic internationally. Some studies (e.g. Kelbrick 2023) demonstrated an increase in acute psychiatric admissions for first-episode psychosis, in the first year of the pandemic; while others (e.g. Casanovas et al., 2022) did not. Studies have variously demonstrated an increase in the age of those presenting (Kelbrick 2023; Esposito et al., 2021), lower rates of substance misuse (Esposito et al., 2021) and increased female presentation (Kelbrick 2023; Casanovas et al., 2022).

Study rationale and aim

Despite concerns about the impact of the COVID-19 pandemic on FEP presentations, and the potential vulnerability of the model to public health related restrictions, there has been no empiric report in an Irish context to date.

The aim of this study was to assess the impact of the COVID-19 pandemic on FEP presentations across two diverse EIP sites in Ireland, by comparing presentations pre and post the COVID-19 pandemic.

Methods

Study design

This study employed a cross-sectional observational design. A retrospective medical record review of all participants was conducted, to examine the impact of COVID-19 across the study sites.

Participants

All individuals presenting to either service with FEP, within the study timeframe, were included. Those who did not present with FEP were excluded. The study population was divided into two cohorts, based on the timing of the first confirmed COVID-19 case in Ireland, on February 29, 2020. The pre-COVID-19 cohort comprised of all individuals who presented to either site from 1/3/2019 to 28/2/2020, henceforth referred to as 'Cohort 1'. The post-COVID-19 cohort comprised of those presenting to the study sites between 1/3/20 and 28/2/2021, henceforth referred to as 'Cohort 2'.

Study sites

There were two study sites – the DETECT EIP service in the east of the country in a mixed urban rural setting (Dublin/Wicklow) and the RISE EIP service in the south of the country. Both services

provided care for individuals presenting with FEP from 18 to 65 years of age.

DETECT was established in 2005, and the current population served is approximately 455,000. DETECT covers three service catchment areas, two urban ('Dublin A' and 'Dublin B') and one predominantly rural.

RISE was established in 2019 and serves a population of 200,000. However, only the urban area within the service (population of approximately 105,000) was included in this research. This part of the service was longer established and had data available for the full pre-pandemic year.

While both study sites were tertiary services, routes of access to secondary mental health services, varied throughout the four service catchment areas. Only two service catchment areas, (Dublin B and Cork South Lee) contained hospital emergency departments. Individuals within the two remaining service catchment areas could access the emergency departments in neighbouring areas. However, for the rural service catchment area, this was up to a 75 km distance. Direct general practitioner referral to secondary mental health services was possible in all catchment areas.

Outcomes

The primary outcome was duration of untreated psychosis (DUP) in individuals presenting with a FEP.

The secondary outcomes were:

- Number of FEP presentations
- Referral source
- Global assessment of functioning (GAF) score
- Number of inpatient admissions and legal status
- Substance misuse
- · Methods of service delivery

Data collection

Data was collected by three of the authors (AD and SB at RISE and EF at DETECT). A standard data template was employed across all sites. Data were collected on a number of variables, including: age, gender, psychiatric disorder, alcohol and drug use, patient contact with EIP service, as well as data pertaining to the outcomes outlined above.

Data analysis

Descriptive and comparative statistics were conducted to compare cohorts and study sites.

Chi-square tests were utilised to evaluate categorical variables. In instances where expected contingency table cell counts were below the recommended threshold for chi square tests, Fisher's exact test was used. T-tests were used to compare normally distributed variables. A significance value of p < 0.05 was assumed.

Continuous variables which were not normally distributed were logarithmically transformed to satisfy criteria for analysis and to reduce the impact of extreme values. Duration of untreated psychosis (DUP) was positively skewed and a logarithmic transformation of DUP (logDUP) was employed. The Mann-Whitney U test and Kruskal-Wallis test was used to compare DUP, due to its non-parametric distribution. Univariate ANOVA was utilised to examine interactions between categorical and continuous variables with additional post hoc pairwise testing with the

Table 1. Comparison of cohort demographics here

	Cohort 1 (pre-COVID-19) ($n = 77$) n	Cohort 2 (post–COVID–19) ($n = 110$) n	Chi square test cohort comparisor
Gender			$X^2(1) = 0.04, p = 0.95$
Male	41 (57%)	62 (57%)	
Female	31 (43%)	46 (43%)	
Age			$(X^2(4) = 0.95, p = 0.92)$
18-24	26 (34%)	39 (36%)	
25-34	25 (32%)	39 (36%)	
35-44	12 (16%)	15 (14%)	
45-54	9 (12%)	9 (8%)	
55-64	4 (5%)	7 (6%)	
65+	0	0	
Diagnostic classification			$X^2(6) = 1.33, p = 0.97$
Schizophrenia spectrum	17 (24%)	23 (25%)	
Affective disorder	20 (29%)	29 (31%)	
Substance or medication Induced	16 (23%)	24 (26%)	
Brief psychotic disorder	6 (9%)	6 (6%)	
Delusional disorder	7 (10%)	8 (9%)	
Psychoticdisorder (NOS)	2 (3%)	1 (1%)	
Organic	2 (3%)	2 (2%)	
Total FEP presentations	77	110	$X^2(3) = 13.82, p = 0.003$

Bonferroni correction, to further examine interactions between variables.

Results

Study demographics

A total of 254 patients were referred to both EIP services during the two-year study period. Of these, 187 participants were considered to be FEP and were included. Cohort 1 (pre-COVID-19 cohort) contained 77 participants and Cohort 2 (post-COVID-19 cohort) contained 110 participants.

The cohorts did not differ with respect to gender ($X^2(1) = 0.04$, p = 0.95), age ($X^2(4) = 0.95$, p = 0.92) or diagnostic classification ($X^2(6) = 1.33$, p = 0.97). There was a significant difference between the cohorts in the number of FEP presentations, across the service catchment areas ($X^2(3) = 13.82$, P = 0.003) (Table 1).

Duration of untreated psychosis (DUP)

Mean DUP was 10.28 months in Cohort 1 (SD = 21.73) and 14.97 months in Cohort 2 (SD = 35.17), with a notable positive skew. The median DUP was one month in Cohort 1, compared to two months in Cohort 2. When DUP was logarithmically transformed, a Mann–Whitney U test showed that there was no significant difference in logDUP between Cohort 1 (Mean Rank = 76.14) and Cohort 2 (Mean Rank = 86.82), U = 2722.00, Z = -1.403, p = 0.161.

However, a Kruskal–Wallis test examining the interaction between cohort, gender and logDUP showed a significant interaction (H(3) = 11.75, p = 0.008). To further investigate this interaction, pairwise comparisons were performed using Mann–Whitney U tests for the subgroups: 1: (Male/Cohort 1), 2: (Female/Cohort 1), 3: (Male/Cohort 2) and 4: (Female/Cohort 2).

The results indicated a significant difference in logDUP between men and women in Cohort 1, with male patients experiencing a longer DUP (U=220.5, Z=-2.898, p=0.004). Furthermore, there was a significant difference in logDUP between women in Cohorts 1 and 2 (U=290, Z=-3.229, p=0.01), with women experiencing a longer DUP in Cohort 2. No significant differences were observed in logDUP between men in Cohorts 1 and 2 (U=863, Z=-0.914, p=0.361), men in Cohort 1 and women in Cohort 2 (U=720, Z=-0.233, p=0.816) or men and women in Cohort 2 (U=1200, Z=-0.855, D=0.393). This is illustrated in Figure 1.

FEP presentations and service catchment areas

There was a significant difference in FEP presentations between the two cohorts, across each service catchment area ($\chi^2(3) = 13.82$, p = 0.003). The effect size, measured by Cramer's V, was 0.272, indicating a moderate effect.

All service catchment areas saw an increase in FEP cases in Cohort 2, with the exception of the only rural catchment area, where there was a 50% decrease in presentations in Cohort 2. Dublin A showed a 39% increase in presentations in Cohort 2. Dublin B showed a 93% increase in presentations. Cork South Lee showed a 143% increase in presentations in Cohort 2 (Table 2). Given this clear disparity between presentation trends in the rural area (Wicklow) compared to the other service catchment areas, further subgroup analysis of the rural service catchment area was conducted. There was no significant difference in the rural area between Cohorts 1 and 2 regarding gender $(X^2(1) = 0.34, p = 0.55)$ with Bonferroni continuity correction) age (Fisher's exact test, p = 0.63) or referral pathway $(X^2(2) = 0.92, p = 0.63)$.

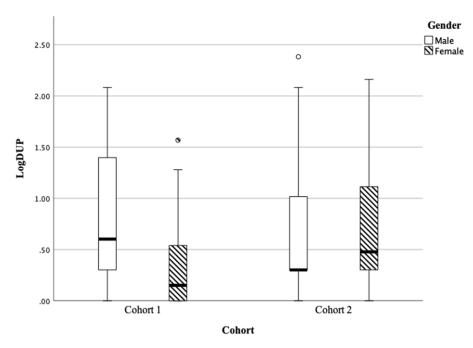


Figure 1. Boxplot of logDUP by gender and cohort.

Table 2. FEP presentations by service catchment areas

	Cohort 1 (pre-COVID -19) (n = 77)	Cohort 2 (post- COVID-19) (n = 110)	
	n	n	% change
DETECT			
Dublin A (urban)	23	32	39% increase
Wicklow (rural)	24	12	50% decrease
Dublin B (urban)	14	27	93% increase
RISE Cork South Lee (urban)	16	39	143% increase

Referral pathways

There was a trend of increased presentations through three of the referral pathways for Cohort 2 (Figure 2). There was an overall threefold increase in referrals from emergency departments, and a 75% increase in referrals received from psychiatric inpatient units, in Cohort 2. However, these changes did not reach statistical significance ($X^2(3) = 2.193$, p = 0.55). Neither was there any significant difference between referral pathways regarding gender ($X^2(3) = 4.75$, p = 0.19) or age (F = 10.30, p = 0.52).

Changes in service delivery

The cohorts were compared regarding in-person, telephone and video appointments offered and attended over 12 months. There was a significant difference in telephone calls offered ($X^2(1) = 7.72$, p = 0.05) or attended ($X^2(1) = 5.95$, p = 0.01), in Cohort 2, with an increase across age groups and gender. Similarly, there was a significant increase in video appointments offered in Cohort 2 ($X^2(1) = 10.92$, p = 0.001). However, there was no significant difference in video appointments attended, between the cohorts ($X^2(1) = 2.63$, p = 0.1). This effect was seen across age groups and

gender. There was no significant difference between the cohorts, in in-person appointments offered ($X^2(1) = 1.02$, p = 0.31), or attended ($X^2(1) = 2.75$, p = 0.9).

Global assessment of functioning (GAF)

The GAF scale was used to measure patients' functioning, at the time of their first contact with the EIP services. Data were normally distributed. An independent samples t-test indicated no significant difference in the means of the cohorts (Cohort 1: M = 37.29, SD = 15.7; Cohort 2: M = 36.42, SD = 16.11), t (162) = 0.34, p = 0.73 (two-tailed). A univariate ANOVA indicated no significant interaction between GAF and cohort, gender or age group (F(18,139) = 1.01, p = 0.44).

Substance use

There was no significant difference between cohorts in drug misuse within the previous month $(X^2(1) = 0.02, p = 0.96)$ or lifetime drug misuse $(X^2(1) = 0.27, p = 0.6)$. This was also the case for both recent $(X^2(1) = 0.01, p = 0.97)$ and lifetime alcohol misuse $(X^2(1) = 2.24, p = 0.13)$. Neither did alcohol or drug misuse have a significant impact on logDUP across the cohorts (Kruskal–Wallis H(3) = 0.31, p = 0.95). A univariate ANOVA indicated no significant interaction between gender, age, catchment area and substance misuse on logDUP (F(43,11) = 1.41, p = 0.076).

Hospital admissions

There was an observed trend level increase in the number of voluntary admissions to an acute mental health unit, in Cohort 2 (Cohort 1 (n = 9), Cohort, 2, (n = 20); p = 0.82). This was also the case with involuntary hospital admissions, (Cohort 1 (n = 12), Cohort 2 (n = 20); p = 0.10). Fisher's exact test showed that neither of these results were statistically significant.

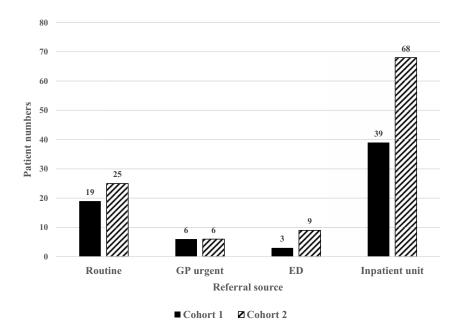


Figure 2. Referral sources across cohorts.

Discussion

Summary of findings

This study demonstrated that there was a significant increase in FEP presentations, in the first year of the pandemic, across both study sites. Further subgroup analysis showed a clear rural/urban divide. Notably, there was a 50% decrease in FEP presentations in the study's only rural catchment area. In contrast, all urban sites showed an increase in FEP presentations. There was no significant difference between the cohorts, across catchment areas, in age, gender or referral pathways. Subgroup analysis within the rural catchment area also indicated no significant difference between the cohorts, in age, gender or referral pathways.

While there was a trend level increase in DUP in the first year of the pandemic, this was not statistically significant. There was however, a significant association between DUP, gender and cohort. This indicated that that the effect of gender on DUP differed, depending on cohort.

Although not statistically significant, differences in referral pathways were seen between the cohorts. There was an increase in referrals from emergency departments and from psychiatric inpatient units, in Cohort 2. Similarly, a trend towards higher rates of hospital admissions in Cohort 2 was seen. Despite relatively modest absolute figures, the data reveals a non-significant trend of escalation in both voluntary and involuntary hospital admissions. There was no significant difference between either referral pathways or hospital admissions, regarding gender or age.

A key consideration is the change to EIP service provision, that occurred in the first year of the pandemic. This involved a restructuring and shift towards new means of engagement, such as digital communication. This is evidenced by the format of appointments offered and availed of by patients during the pandemic. In Cohort 2, there was an overall increase in telephone and video communication, when compared to Cohort 1. It is noteworthy that there was no significant difference between cohorts, in in-person appointments offered or attended.

Results in context

Increase in FEP presentations

The increase in FEP presentations following the pandemic has been echoed by other international research in this area. Esposito et al. (2021), found a 29.6% increase in FEP presentations during the first three months of the pandemic in Italy, compared to the same period in 2019. Segev et al. (2021), also found an increased ratio of new-onset psychosis among patients who presented to psychiatric emergency departments in Israel during this time.

In contrast, in Spain, Casanovas et al. (2022) found an overall decrease in FEP presentations in the first nine months of the pandemic. However, they also noted a significant increase in female presentations during this time. A Melbourne study (O'Donoghue et al., 2022) found an overall trend level rise in incidence rate during the pandemic. This was aligned with phases of public health restrictions, with a trend level decrease in the treated incidence following the introduction of restrictions, and a significant increase in the later stages of the pandemic, including both voluntary and involuntary admissions.

Gruber et al. (2021), observed that the COVID-19 pandemic was a multifaceted stressor, affecting individuals, family, educational, occupational and medical systems. They also noted that COVID-19 preventative measures obstructed access to important protective factors, such as interpersonal contact, social, work and volunteering activities. It is well documented that stress itself constitutes an independent risk factor for the development of psychosis (Shah & Malla, 2015). Although we did not systematically evaluate all known aetiological factors apart from substance use, it is reasonable to surmise that the increase in FEP presentations shown in our study, may at least in part be associated with psychological reaction to stress, and COVID-19 preventative measures.

Duration of untreated psychosis

Delays in seeking and receiving care during the pandemic, were seen across mental health and medical services. For example,

Driscoll et al. (2023) found disruption to treatment continuity for individuals with eating disorders. They found an increase in patients experiencing worsening symptoms. Crowley et al., (2021) reported that Irish cancer diagnostic and treatment pathways were severely affected, with an overall reduction in diagnostic activity and treatment. Given the scale of the COVID-19 pandemic and sequelae for health service access, one might have expected a significant increase in DUP. However, the difference in DUP between the cohorts was not significant. This finding is in line with other reports, with Casanovas et al. (2022), reporting a non-significant increase in DUP, in FEP patients in the first nine months of the pandemic, compared to the previous year.

Indeed against this backdrop of severe disruption across health services, it demonstrates the agility of EIP services in responding to changing needs, amidst a public health crisis.

Impact of gender on DUP

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There was a significant difference in DUP between men and women in Cohort 1, with men experiencing a longer DUP. This was not repeated in Cohort 2, where there was no significant difference in DUP between men and women. There was however, a significant difference in DUP between women in Cohorts 1 and 2. This indicates an increase in DUP for women in the second cohort. This suggests a disproportionate impact of the pandemic, on DUP in women. While a wide body of literature has examined the factors that influence DUP, findings regarding the association of gender and DUP are equivocal. For example, the large Danish OPUS study (Thorup et al., 2007) suggested a longer DUP for male patients. However, later studies including a meta-analysis examining the interaction of gender and DUP, showed no significant difference (Catalan et al., 2021). This increase in DUP for women in Cohort 2, is likely to reflect a delay in help-seeking amongst this group, specifically influenced by the pandemic. As already mentioned, a number of studies have reported an increase in female FEP presentations during the pandemic (Kelbrick 2023; Casanovas et al., 2022). However, to our knowledge, a specific increase in DUP in women during the pandemic, has not been reported elsewhere. We can reason that social isolation, caring responsibilities, access issues and reluctance to seek help due to infection risk, may all have contributed to the longer DUP for women in Cohort 2.

For men in Cohort 2, DUP did not differ significantly from Cohort 1. However, it is important to note that DUP for men was longer in Cohort 1 at baseline. There is a body of literature that suggests that men may face additional barriers in seeking help for mental health issues, due to gender role conformity and subconscious reluctance to subvert hegemonic ideas of masculinity (see e.g. Powell et al., 2017). However, it appears that pandemic specific factors did not have a significant impact on male DUP.

Rural/urban divide

The only rural catchment site in this study, showed a decrease in FEP presentations, while all urban sites showed an increase, in Cohort 2. It is reasonable to assume that the logistics of gaining access to dispersed rural services were more difficult during the pandemic, particularly when travel restrictions were at their most rigid. It is also likely that digital poverty and access to reliable internet and mobile phone connections, may have further compromised opportunities to engage with health services. In a study of mental health providers in the U.S. during the pandemic, Bornheimer et al. (2022), also reported particular challenges for rural populations in accessing mental health services. This raises an

important issue regarding facilitating access to care in rural areas and utilising alternative engagement methods.

Referral pathways and hospital admissions

Although a trend level increase in emergency referral pathways and hospital admissions was found in Cohort 2, this was not statistically significant. This may suggest that reconfigured EIP services, which continued to facilitate access to care through all referral routes, prevented a larger increase. In contrast, much of the international research reported findings indicating patients presenting later and in crisis, necessitating Emergency Department attendance or hospital admission. Szmulewicz et al. (2021) examined electronic health records from patients receiving care at an FEP clinic and found a higher proportion of involuntary admissions. Similarly, Fasshauer et al. (2021) found an increase in involuntary admissions in the year post COVID, across psychiatric diagnoses. O'Donoghue et al. (2022) found a twofold increase in voluntary admissions and a threefold increase in involuntary admissions, for FEP patients, during the pandemic.

Clinical implications of findings

It is clear from this study that the COVID-19 pandemic has had a significant impact on the diagnosis and treatment of FEP. The findings described above demonstrate higher FEP presentations, with lower numbers of presentations in rural areas, and a disproportionate impact of the pandemic on DUP in women. Evidence suggests that outcomes are best for those who receive early diagnosis and treatment of FEP (O'Keeffe et al., 2022). Thus, any treatment delays may have a substantial effect on these particular groups. However, it is very encouraging that overall, there was no significant increase in total DUP, hospital admissions and emergency referral pathways in Cohort 2.

This attests to the manner in which mental health services, both secondary and tertiary, adapted and continued to provide services for an increased number of presentations, during the pandemic. Jauhar et al., (2021) recommended that 'E-health' technology be embedded in the assessment and treatment of those treated by EIP teams, during the COVID-19 pandemic. Tempelaar et al. (2021), & Tempelaar et al. (2023), have also reported on the adaptation of EIP service provision for virtual delivery. This practice was adopted by the EIP services in this study. Despite contact restrictions, the services rapidly adapted and made use of alternative engagement means. Telephone and video contacts were used to good effect, to carry out assessments and maintain service delivery. Additionally, in-person contact was maintained, utilising alternative socially distanced settings. It is key that these adaptations and innovations are carried forward and embedded in services.

Strengths and limitations

This study presents a epidemiologically complete cohort study, with a combined catchment area population of over 500,000. Each case in the study was seen by a specialist key worker and psychiatrist, to ascertain diagnosis. The study sites (and service catchment areas within), allowed examination of trends in urban and rural settings, with varying local arrangements.

The research methodology did not include the recording of socio-economic domains such as employment status and symptomatology. This data could have further elucidated the impact of such variables on FEP presentation. Our data was not

categorised by time increments, beyond belonging to Cohort 1 or 2. This limited our ability to track changing patterns in presentation and help seeking, during the pandemic. The increased incidence of FEP presentations during the first year of the COVID-19 pandemic was shown across both EIP sites. While DETECT had been established for nineteen years, RISE was in its second year of operation in February 2020. Thus, one could argue that the increased incidence at the RISE site, was partly due to the service becoming embedded locally. However, this does not explain the increased incidence of presentations at the more established site.

Conclusion

This study highlights the impact of the COVID-19 pandemic on FEP presentations, particularly in rural areas and regarding increased DUP in women. This emphasises the importance of continuous planning and adaptive care strategies in EIP, to respond to these groups, particularly in crisis situations. The services described here demonstrated the ability to adapt and to incorporate new means of engaging with patients where routine healthcare delivery was disrupted. This reflects the overall innovation and flexibility of such services, in their response to a rapidly changing public health environment.

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Competing interests. None.

Ethical standards. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. The authors assert that ethical approval for publication of this study has been provided by the local Ethics Committee.

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